Human Research Program
Integrated Research Plan

January 2009

PREFACE

HUMAN RESEARCH PROGRAM INTEGRATED RESEARCH PLAN

The Integrated Research Plan (IRP) describes the portfolio of Human Research Program (HRP) research and technology tasks. The IRP is the HRP strategic and tactical plan for research necessary to meet HRP requirements. The need to produce an IRP is established in HRP-47052, Human Research Program - Program Plan, and is under configuration management control of the Human Research Program Control Board (HRPCB).

Approved By:

______________________________          __________________
Dennis Grounds                                      Date
Program Manager
Human Research Program
Human Research Program
Integrated Research Plan
January 2009

CONCURRENCE

Prepared By:

__________________________________          __________________
Paul R. Vargas                                      Date
Book Manager
Human Research Program

Concurred By:

__________________________________          __________________
Ned Penley                                            Date
Program Integration Office
Human Research Program

Concurred By:

__________________________________          __________________
John Charles                                      Date
Program Scientist
Human Research Program
## REVISION AND HISTORY PAGE

<table>
<thead>
<tr>
<th>REV.</th>
<th>DESCRIPTION</th>
<th>PUB. DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Baseline</td>
<td>Initial Release (Reference per SLSDCR-HRPCB-07-030, EFF. 12-20-07) approved by the HRPCB</td>
<td>12/20/07</td>
</tr>
<tr>
<td>Rev. A</td>
<td>Re-baseline (Reference per SLSDCR-HRPCB-08-025-R1, EFF. 01-23-09) approved by the HRPCB</td>
<td>01/23/09</td>
</tr>
</tbody>
</table>
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0</strong> INTRODUCTION AND BACKGROUND</td>
<td>1</td>
</tr>
<tr>
<td>1.1 CONTEXT OF THE INTEGRATED RESEARCH PLAN</td>
<td>1</td>
</tr>
<tr>
<td>1.2 PROGRAM REQUIREMENTS DOCUMENT</td>
<td>4</td>
</tr>
<tr>
<td>1.2.1 Standards</td>
<td>4</td>
</tr>
<tr>
<td>1.2.2 Risks</td>
<td>5</td>
</tr>
<tr>
<td>1.3 EVIDENCE BOOK</td>
<td>5</td>
</tr>
<tr>
<td>1.4 THE INTEGRATED RESEARCH PLAN</td>
<td>6</td>
</tr>
<tr>
<td>1.4.1 Priority to Missions</td>
<td>6</td>
</tr>
<tr>
<td>1.4.2 Tasks Required to Fill the Gaps (WHAT)</td>
<td>7</td>
</tr>
<tr>
<td>1.4.3 Schedule Drivers (WHEN)</td>
<td>8</td>
</tr>
<tr>
<td>1.4.4 Research platforms (WHERE)</td>
<td>8</td>
</tr>
<tr>
<td>1.4.5 Elements and Projects Responsible for the Research (WHO)</td>
<td>10</td>
</tr>
<tr>
<td>1.4.6 Products of the Research (PRODUCTS)</td>
<td>10</td>
</tr>
<tr>
<td><strong>2.0</strong> ORIENTATION SUMMARY OF THE RESEARCH PLAN</td>
<td>11</td>
</tr>
<tr>
<td>2.1 ENSURE THE CREW CAN ACCOMPLISH THE PHYSICAL TASKS OF THE MISSION</td>
<td>13</td>
</tr>
<tr>
<td>2.1.1 Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance</td>
<td>13</td>
</tr>
<tr>
<td>2.1.2 Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity</td>
<td>13</td>
</tr>
<tr>
<td>2.1.3 Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems</td>
<td>13</td>
</tr>
<tr>
<td>2.1.4 Risk of Reduced Safety and Efficiency Due to an Inadequately Designed Vehicle, the Environment, Tools, or Equipment</td>
<td>13</td>
</tr>
<tr>
<td>2.2 ENSURE THE CREW CAN ACCOMPLISH THE COGNITIVE, BEHAVIORAL, AND TEAM ASPECTS OF THE MISSION</td>
<td>14</td>
</tr>
<tr>
<td>2.2.1 Risk of Behavioral and Psychiatric Conditions</td>
<td>14</td>
</tr>
<tr>
<td>2.2.2 Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload</td>
<td>14</td>
</tr>
<tr>
<td>2.2.3 Risk of Performance Errors Due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation</td>
<td>14</td>
</tr>
<tr>
<td>2.2.4 Risk of Errors Due to Poor Task Design</td>
<td>14</td>
</tr>
<tr>
<td>2.2.5 Risk of Error Due to Inadequate Information</td>
<td>15</td>
</tr>
<tr>
<td>2.2.6 Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems</td>
<td>15</td>
</tr>
<tr>
<td>2.3 ENSURE THE CREW RECEIVES ADEQUATE NUTRITION</td>
<td>18</td>
</tr>
<tr>
<td>2.3.1 Risk Factor of Inadequate Nutrition</td>
<td>18</td>
</tr>
<tr>
<td>2.3.2 Risk of Inadequate Food System</td>
<td>18</td>
</tr>
<tr>
<td>2.4 PROTECT THE CREW FROM ENVIRONMENTAL HAZARDS</td>
<td>19</td>
</tr>
<tr>
<td>2.4.1 Risk of Carcinogenesis from Space Radiation</td>
<td>19</td>
</tr>
<tr>
<td>2.4.2 Risk of Acute Radiation Syndromes Due to Solar Particle Events</td>
<td>19</td>
</tr>
<tr>
<td>2.4.3 Risk of Accelerated Osteoporosis</td>
<td>19</td>
</tr>
<tr>
<td>2.4.4 Risk of Accelerated Osteoporosis</td>
<td>19</td>
</tr>
<tr>
<td>2.4.5 Risk of Accelerated Osteoporosis</td>
<td>19</td>
</tr>
<tr>
<td>2.4.6 Risk of Renal Stone Formation</td>
<td>19</td>
</tr>
<tr>
<td>2.4.7 Risk of Bone Fracture</td>
<td>19</td>
</tr>
<tr>
<td>2.4.8 Risk of Cardiac Rhythm Problems</td>
<td>19</td>
</tr>
<tr>
<td>2.4.9 Risk of Cardiac Rhythm Problems</td>
<td>19</td>
</tr>
<tr>
<td>2.4.10 Risk of Adverse Health Effects due to Alterations in Host-Microorganism Interactions</td>
<td>19</td>
</tr>
<tr>
<td>2.4.11 Risk of Crew Adverse Health Event due to Altered Immune Response</td>
<td>19</td>
</tr>
<tr>
<td>2.4.12 Risk of Intervertebral Disc Damage</td>
<td>19</td>
</tr>
<tr>
<td>2.4.13 Risk of Orthostatic Intolerance during Re-Exposure to Gravity</td>
<td>19</td>
</tr>
</tbody>
</table>
TABLE OF CONTENTS (Cont'd)

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 PROVIDE ADEQUATE MEDICAL CARE FOR THE CREW</td>
<td>25</td>
</tr>
<tr>
<td>2.5.1 Risk of Inability to Treat Adequately an Ill or Injured Crewmember</td>
<td>25</td>
</tr>
<tr>
<td>2.5.2 Risk of Therapeutic Failure Due to Ineffectiveness of Medication</td>
<td>25</td>
</tr>
<tr>
<td>3.0 ELEMENTS INPUT DESCRIPTION LOCATED IN APPENDIX A</td>
<td>27</td>
</tr>
<tr>
<td>3.1 RISKS</td>
<td>27</td>
</tr>
<tr>
<td>3.2 CONTEXT OF RISK FOR EXPLORATION</td>
<td>27</td>
</tr>
<tr>
<td>3.3 STRATEGY FOR MITIGATION</td>
<td>27</td>
</tr>
<tr>
<td>3.4 GAPS</td>
<td>27</td>
</tr>
<tr>
<td>3.5 TASKS</td>
<td>27</td>
</tr>
<tr>
<td>3.6 DELIVERABLES</td>
<td>28</td>
</tr>
<tr>
<td>3.7 REQUIRED DELIVERY MILESTONE</td>
<td>29</td>
</tr>
<tr>
<td>3.8 REQUIRED PLATFORMS</td>
<td>29</td>
</tr>
<tr>
<td>3.9 PROJECT OR ORGANIZATION RESPONSIBLE FOR THE IMPLEMENTATION OF ACTIVITY</td>
<td>30</td>
</tr>
<tr>
<td>3.10 GRAPHIC INPUT</td>
<td>30</td>
</tr>
<tr>
<td>3.11 DECISION POINTS</td>
<td>30</td>
</tr>
</tbody>
</table>

APPENDIX A RISKS

RISK OF IMPAIRED PERFORMANCE DUE TO REDUCED MUSCLE MASS, STRENGTH AND ENDURANCE – CRITICALITY: LUNAR OUTPOST – I, MARS – C .............................................. 36
RISK OF REDUCED PHYSICAL PERFORMANCE CAPABILITIES DUE TO REDUCED AEROBIC CAPACITY – CRITICALITY: LUNAR OUTPOST – I, MARS – C .............................................. 49
RISK OF COMPROMISED EVA PERFORMANCE AND CREW HEALTH DUE TO INADEQUATE EVA SUIT SYSTEMS – CRITICALITY: LUNAR OUTPOST – I, MARS – I ............................ 55
RISK OF REDUCED SAFETY AND EFFICIENCY DUE TO AN INADEQUATELY DESIGNED VEHICLE, ENVIRONMENT, TOOLS OR EQUIPMENT – CRITICALITY: LUNAR OUTPOST – D, MARS – I ............................ 87
RISK OF BEHAVIORAL AND PSYCHIATRIC CONDITIONS – CRITICALITY: LUNAR OUTPOST – D, MARS – C ........................................................................................................ 107
RISK OF PERFORMANCE ERRORS DUE TO SLEEP LOSS, CIRCADIAN DESYNCHRONIZATION, FATIGUE, AND WORK OVERLOAD – CRITICALITY: LUNAR OUTPOST – D, MARS – D .............................................. 124
RISK OF PERFORMANCE ERRORS DUE TO POOR TEAM COHESION AND PERFORMANCE, INADEQUATE SELECTION/TEAM COMPOSITION, INADEQUATE TRAINING, AND POOR PSYCHOSOCIAL ADAPTATION – CRITICALITY: LUNAR POST – D, MARS – I .............................................. 152
RISK OF ERRORS DUE TO POOR TASK DESIGN – CRITICALITY: LUNAR OUTPOST – D, MARS – I ............ 172
RISK OF ERROR DUE TO INADEQUATE INFORMATION – CRITICALITY: LUNAR OUTPOST – D, MARS – I ................................................................. 185
RISK OF IMPAIRED ABILITY TO MAINTAIN CONTROL OF VEHICLES AND OTHER COMPLEX SYSTEMS – CRITICALITY: LUNAR OUTPOST – D, MARS – I .............................................. 205
RISK FACTOR OF INADEQUATE NUTRITION – CRITICALITY: LUNAR OUTPOST – D, MARS – C ............ 214
RISK OF INADEQUATE FOOD SYSTEM – CRITICALITY: LUNAR OUTPOST – D, MARS – C ................... 220
RISK OF RADIATION CARCINOGENESIS FROM SPACE RADIATION – C X C .............................................. 238
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>RISK OF ACUTE RADIATION SYNDROMES DUE TO SOLAR PARTICLE EVENTS I X I</td>
<td>255</td>
</tr>
<tr>
<td>RISK OF ACUTE OR LATE CENTRAL NERVOUS SYSTEM EFFECTS FROM</td>
<td>264</td>
</tr>
<tr>
<td>RADIATION EXPOSURE I X C</td>
<td></td>
</tr>
<tr>
<td>RISK OF DEGENERATIVE TISSUE OR OTHER HEALTH EFFECTS FROM</td>
<td>272</td>
</tr>
<tr>
<td>RADIATION EXPOSURE I X C</td>
<td></td>
</tr>
<tr>
<td>RISK OF ADVERSE HEALTH EFFECTS FROM LUNAR DUST EXPOSURE -I X N/A</td>
<td>282</td>
</tr>
<tr>
<td>RISK OF BONE FRACTURE – CRITICALITY: LUNAR OUTPOST – D, MARS – D</td>
<td>303</td>
</tr>
<tr>
<td>RISK OF CARDIAC RHYTHM PROBLEMS – CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td>311</td>
</tr>
<tr>
<td>RISK OF ADVERSE HEALTH EFFECTS DUE TO ALTERATIONS IN HOST-MICROORGANISM</td>
<td>315</td>
</tr>
<tr>
<td>INTERACTIONS – CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td></td>
</tr>
<tr>
<td>RISK OF CREW ADVERSE HEALTH EVENT DUE TO ALTERED IMMUNE RESPONSE –</td>
<td>319</td>
</tr>
<tr>
<td>CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td></td>
</tr>
<tr>
<td>RISK OF INVERTEBRAL DISK DAMAGE – CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td>325</td>
</tr>
<tr>
<td>RISK OF ORTHOSTATIC INTOLERANCE DURING RE-EXPOSURE TO GRAVITY –</td>
<td>328</td>
</tr>
<tr>
<td>CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td></td>
</tr>
<tr>
<td>INABILITY TO ADEQUATELY TREAT AN ILL OR INJURED CREW MEMBER –</td>
<td>335</td>
</tr>
<tr>
<td>CRITICALITY: LUNAR OUTPOST – I, MARS – C</td>
<td></td>
</tr>
<tr>
<td>RISK OF THERAPEUTIC FAILURE DUE TO INEFFECTIVENESS OF MEDICATION –</td>
<td>373</td>
</tr>
<tr>
<td>CRITICALITY: LUNAR OUTPOST – D, MARS – I</td>
<td></td>
</tr>
<tr>
<td>HUMAN HEALTH COUNTERMEASURES INFRASTRUCTURE</td>
<td>379</td>
</tr>
<tr>
<td>APPENDIX B TECHNICAL READINESS LEVEL</td>
<td>382</td>
</tr>
</tbody>
</table>
1.0 INTRODUCTION AND BACKGROUND

Crew health and performance is critical to successful human exploration beyond low Earth orbit. The Human Research Program (HRP) is essential to enabling extended periods of space exploration because it provides knowledge and tools to mitigate risks to human health and performance. Risks include physiological and behavioral effects from radiation and hypogravity environments, as well as unique challenges in medical support, human factors, and behavioral or psychological factors. The Human Research Program (HRP) delivers human health and performance countermeasures, knowledge, technologies and tools to enable safe, reliable, and productive human space exploration. Without HRP results, NASA will face unknown and unacceptable risks for mission success and post-mission crew health.

This Integrated Research Plan (IRP) describes HRP’s approach and research activities that are intended to address the needs of human space exploration and serve HRP customers and how they are integrated to provide a risk mitigation tool. The scope of the IRP is limited to the activities that can be conducted with the resources available to the HRP; it does not contain activities that would be performed if additional resources were available. The timescale of human space exploration is envisioned to take many decades. The IRP illustrates the program’s research plan through the timescale of early lunar missions of extended duration.

The IRP serves several purposes for the Human Research Program. The IRP…

- provides a means to assure that the most significant risks to human space explorers are being adequately mitigated and/or addressed;
- shows the relationship of research activities to expected outcomes and need dates;
- shows the interrelationships among research activities that may interact to produce products that affect multiple HRP Element, Project or research disciplines;
- accommodates the uncertain outcomes of research and technology activities by including decision points that lead to potential follow-on activities;
- shows the assignments of responsibility within the program organization and, as practical, the proposed acquisition strategy;
- shows the intended use of research platforms such as the International Space Station (ISS), NASA Space Radiation Laboratory (NSRL), and various space flight analog environments; and
- shows the budgeted research activities of the Human Research Program, but does not show all budgeted activities, as some of these are enabling functions, such as management, facilities, and infrastructure.

1.1 CONTEXT OF THE INTEGRATED RESEARCH PLAN

There are three foundational documents to the HRP:

1. Program Requirements Document (PRD)
2. Evidence Book
3. Integrated Research Plan (IRP)
The PRD describes the high-level requirements that the program must meet. The Evidence Book provides the scientific basis for the risks that are contained in the PRD, and the IRP describes the approach to addressing the requirements in the PRD. The relationship of these HRP documents is illustrated in Figure 1.1.
Figure 1.1: HRP Requirements and Content Alignment
1.2 PROGRAM REQUIREMENTS DOCUMENT

The HRP’s top-level requirements are maintained in the Exploration Systems Mission Directorate (ESMD) Exploration Architecture Requirements Document (EARD), ESMD-EARD-08-07, Rev.-. The purpose of the EARD is to translate the expectations of stakeholders, both inside and outside NASA, for the next generation U.S. Space Exploration mission, into requirements that will flow down to the implementing organizations. The EARD allocates the following top requirements to the HRP.

- **[Ex-0061]** NASA’s Human Research Program (HRP) shall develop knowledge, capabilities, countermeasures, and technologies to mitigate the highest risks to crew health and performance and enable human space exploration.
- **[Ex-0062]** NASA’s HRP shall provide data and analysis to support the definition and improvement of human spaceflight medical, environmental and human factors standards.
- **[Ex-0063]** HRP shall develop technologies to reduce medical and environmental risks and to reduce human systems resource requirements (mass, volume, power, data, etc.).

The PRD decomposes those requirements into lower level requirements that are then allocated to the HRP Elements. The requirements in the PRD are divided into three categories: requirements related to human system standards, requirements related to human health and performance risks, and requirements related to provision of enabling capabilities. The HRP comprises the following major Program Elements: Behavioral Health and Performance (BHP), Exploration Medical Capability (ExMC), Human Health Countermeasures (HHC), ISS Medical Project (ISSMP), Space Human Factors and Habitability (SHFH), and Space Radiation (SR). Each element incorporates their respective PRD requirements into their specific element management plans. The research elements subsequently derive a research plan to address the requirements.

1.2.1 STANDARDS

The PRD requires that the HRP make recommendations for updates to the Space Flight Human System Standards (SFHSS). The SFHSS, Volume 1 (NASA-STD-3001, Vol. 1), describes Levels of Care required for human spaceflight missions, Permissible Exposure Limits, Permissible Outcomes, and Fitness for Duty Standards for crewmembers on exploration missions, among other things, and was first baselined on March 5, 2007, by the Office of the Chief Health and Medical Officer (OCHMO). Essentially, these are the definition of acceptable levels of risk for human health and performance associated with spaceflight. By comparing these standards with the existing evidence and knowledge base, the HRP can identify and quantify the risks associated with human exploration missions, and derive the research necessary to lower the risk.

SFHSS, Volume 2 (Spaceflight Habitability and Human Standards) provides the comprehensive set of requirements associated with Human Factors and Habitability. These standards must be met by the Constellation program in development of each vehicle and supporting equipment utilized in space exploration. Through comparison of these standards with the state of the art in engineering design, the HRP can identify areas where research is necessary to help the Constellation program meet these requirements.

The HRP has two main responsibilities concerning the standards. In some cases, the SFHSS has a wide band of uncertainty. The HRP must conduct research to help refine and narrow the uncertainty associated with the standard. In other cases, emerging evidence or knowledge may indicate that the
standards are not written in a way that captures a complete set of relevant considerations. The HRP is required to address the modification of such standards. Additional research may be required to facilitate this. The PRD decomposes the top-level requirement into the specific standards and allocates the requirement to inform these standards to the appropriate HRP Element.

1.2.2 RISKS
The HRP identifies risks relevant to the Chief Health and Medical Officer and to the health and human performance aspects of the Constellation Program. The HRP utilizes the Chief Medical Officer’s Human System Risk Board (HSRB) to identify risks requiring research. The PRD allocates requirements to quantify, mitigate, or monitor these human system risks to the appropriate Element within the HRP. The PRD, however, does not establish priority for the risks.

The risks in the PRD are arranged in two groups based on the level of available evidence. Risks for which substantial evidence exists are listed in Table 1 while those that cannot be supported or refuted by available information at this time are in Table 2. This IRP addresses each of the risks in the priority order described in Section 2.0 in the PRD.

1.3 EVIDENCE BOOK
The HRP Evidence Book documents WHY the risks are contained in the PRD. It is a record of the state of knowledge for each risk in the PRD and, therefore, provides bases for analyses of the likelihoods and consequences for each of the risks. As such, the Evidence Book, a compilation of all the evidence-based risk reports, makes important data accessible and available for periodic review. The Evidence Book is publicly available at the following internet address - http://humanresearch.jsc.nasa.gov/elements smo/hrp_evidence_book.asp

The documentation of evidence for each risk in the PRD is in the form of a review article that is aimed at a scientifically-educated, non-specialist reader. The documentation is broken into the following parts:

The body of each risk review contains a narrative discussion of the risk and its supporting evidence.

1. Declarative statements concerning the risk are supported by a description of the evidence, whether published or unpublished.
2. Relevant published references are listed at the end of the report.
3. Data that are significant or pivotal are summarized in text, tables, and charts in sufficient detail to allow the reader to critique and draw conclusions, especially when a published reference is not available.
4. In a similar fashion, the authors indicate, as appropriate, whether the data are from human, animal, or tissue/cell/molecular studies.
5. Evidence from space flight (including biomedical research, Medical Requirements Integration Document [MRID] data, and operational performance or clinical observations) is presented first, followed by ground-based evidence (including space analog research and non-space analog biomedical or clinical research).
6. When evidence is from ground-based studies, authors discuss why these results are likely to be applicable in the space environment, offering available validation information for the use of these ground-based systems.

Some Risk Reports will be published through refereed journals specific to the appropriate disciplines. In some cases, when the evidence reports are not published in a journal, the HRP will publish them in NASA Technical Reports. Further, all evidence reports will be made available on the HRP external website.

As new evidence is gathered, the Risk Reports will be updated. If new evidence indicates that a risk should be retired or that a new risk should be added, the HRP will, after thorough review with the HSRB, take the appropriate action to modify the PRD and update the Evidence Book accordingly.

1.4 THE INTEGRATED RESEARCH PLAN

The IRP documents the CRITICALITY of each risk:

- WHAT tasks are necessary to fill gaps,
- WHEN those tasks will be accomplished and their deliverables provided to the stakeholder,
- WHERE they will be accomplished (e.g., use the International Space Station, use a ground analog, etc.), WHO will accomplish them (which project or organization within the HRP), and
- what is being PRODUCED.

1.4.1 Criticality to Missions

Three categories of criticality have been developed for the mitigation of each of the risks: 1) Critical, 2) Important, and 3) Desirable.

Each of the three categories is applied to two different mission scenarios, the lunar mission(s) (including the lunar outpost missions) and the Mars mission.

The criticality of a risk for either a lunar or a Mars mission alone is not sufficient to determine the optimum level of activity (or budget) or timing for research investments. Other factors combine to determine the research approach, such as limited availability (of certain necessary resources like the Space Shuttle and the ISS), exceptionally long lead times (needed to improve understanding and mitigation of radiation risks), or the amount of risk reduction that can be obtained with a specific set of resources. All of the factors needed to determine the research approach are not explicitly represented in the IRP, only the resultant research plan.

For reference, each risk heading in this document is labeled with an abbreviated version of the Lunar and Mars criticalities.

Criteria for criticality of the risks applicable to the lunar outpost and Mars mission(s) are:

- **Critical** to Quantify and Reduce Prior to the Lunar Outpost or Mars Missions.
  Absence of additional data or risk mitigation countermeasures (beyond what is available at the approval date of this document) would likely delay Lunar Outpost or Mars Missions, even if all other elements of the mission were ready (e.g., if the launch systems, Extravehicular Activity (EVA) systems, landing and life support systems were ready). The lack of this data or an
adequate additional mitigation would leave NASA with unacceptable uncertainty in the residual risk, and/or with unacceptable absolute risk to human health and performance, thus precluding NASA’s ability to embark on the mission. Critical risks for lunar outpost are identified by the abbreviation LUNAR OUTPOST-C and for Mars by the abbreviation MARS-C.

- **Important to Quantify and Reduce Prior to the Lunar Outpost or Mars Missions.** Absence of additional data or risk mitigation countermeasures in this area (beyond what is available at the approval date of this document) would likely not delay lunar outpost or Mars missions, if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready). This would leave the mission with significant residual or unknown risk however. Mission loss or major impact to post-mission crew health could occur if this risk is not quantified and reduced. Important risks for lunar outpost are abbreviated LUNAR OUTPOST-I, and for Mars as MARS-I.

- **Desirable to Quantify and Reduce Prior to the Lunar Outpost or Mars Missions.** The absence of data or risk mitigation countermeasures in this area (beyond what is available at the approval date of this document) would not delay the lunar outpost or Mars missions if all other elements of the mission were ready (e.g., if the launch systems, EVA systems, landing and life support systems were ready). However, quantifying and reducing the risk would reduce the risk for that particular discipline. Engineering or operational workarounds/constraints could be avoided if this risk were quantified and/or reduced. Desirable risks for lunar outpost are abbreviated LUNAR OUTPOST-D, and Mars as MARS-D.

Ultimately, assessment of the criticality is based on the likelihood and consequence of the risks, the gaps, and the tasks, coupled with the uncertainty in risk projections. Assessment involves integration and comparison of risk factors and the impact each task may have on the reduction of the overall risk to the mission or the crew, given different mission scenarios, research approaches, and outcomes.

The HRP will use the Risk Management Analysis Tool (RMAT) to categorize and document the assessment of the risks and to document priority. At present, the RMAT is a two-dimensional tool. There is no integrated or validated assessment tool that will allow the use of the RMAT for cross-comparison or prioritization of risks or gaps now. Until the availability of such a tool, the HRP will rely on expert opinion, with consideration of the RMAT and existing evidence. The HRP’s Science Management Office has the responsibility of prioritizing the HRP’s research portfolio as described in the HRP Science Management Plan (HRP-47053 Rev. C), Paragraph 3.1.

### 1.4.2 TASKS REQUIRED TO FILL THE GAPS (WHAT)

For each risk, the appropriate HRP Elements identified gaps in the risk’s state of knowledge and NASA’s ability to mitigate the risk. Further, the HRP Elements identified specific research tasks required to fill each gap and the product(s) resulting from the tasks. This Integrated Research Plan lays out the risk, gaps, tasks, and resulting products in a notional schedule tied to the appropriate Exploration milestones for which the products will be needed. The rationale for the selected approach is documented in the text portions of the IRP.

This plan includes activities that are more than “Research or Technology Development.” In some cases, the activities reported in this document are not explicitly “research” or “technology development,” but are included to ensure logical completeness in describing those activities necessary to mitigate the risks. Examples are data mining activities, the results of which are pivotal
in defining further steps in the research path, and hardware evaluations that would further the engineering approach to risk mitigation.

Key Decision Points are built into the IRP, wherein the HRP will evaluate data with respect to closing the research gap, as well as the impact on the overall likelihood or consequence of the risk. The results of this analysis help formulate the next steps. In some cases, likelihood with existing countermeasures will not be high enough to warrant proceeding with more research. This risks-gaps-tasks-deliverables detail is required to ensure completeness in addressing the risks.

1.4.3 Schedule Drivers (WHEN)

The Integrated Research Plan describes a plan of knowledge production and technology development to address risks associated with human space flight. As new knowledge is gained, the required approach to research and development may change. The IRP attempts to describe a plan of research looking forward many years into the future. The fidelity of the IRP is quite high in the near term (2009-2010), but decreases with time. The IRP will be revised and updated annually based on available resources, Constellation mission development, other schedule constraints, achievement of key milestones, and consideration of new evidence gained from the previous year.

1.4.4 Research Platforms (WHERE)

The HRP uses various research platforms and data sources to address gaps in knowledge. Historical data derived from ground and spaceflight studies form the basis of the HRP Evidence Reports, with the intention of ensuring that the HRP does not duplicate effort already expended. Many of these activities appear in this IRP as “data mining,” although not explicitly “research.”

Data mining involves gathering and analyzing data from historical space flights via the Longitudinal Study of Astronaut Health and other sources, spaceflight operational data such as landing performance and simulator performance data to identify possible correlation with physiologic or psychological function, and relevant data from ground studies (NASA sponsored and otherwise).

The HRP utilizes the Space Shuttle and the International Space Station to conduct research requiring the unique environment of space. The spaceflight data primarily identify and/or quantify physiological and behavioral changes to the human system occurring in the microgravity environment. The ISS is utilized to both validate potential countermeasures and as an analog for long-duration Mars missions.

NASA has laid out specific schedule milestones/constraints for implementation of the Vision for Space Exploration (VSE). The Shuttle retirement in 2010, the Orion vehicle use in 2014, and the first lunar sortie by 2020 together create urgency for the acquisition of knowledge. The use of the Shuttle and ISS platforms, in several cases, is critical to obtaining the required knowledge to build products supporting longer, more challenging missions. The Shuttle retirement in 2010 and the uncertainty in the completion of ISS operations levies significant constraints on available flight resources, thus some research is accelerated to take advantage of these vehicles while available. Where possible, the HRP will utilize analog environments to perform the research required to fill gaps in knowledge, preserving the limited flight resources for only those that cannot be addressed elsewhere. These data are used as an analog to a long-duration Mars mission because the ISS is the only resource of its kind. The HRP will accelerate some of the research from this resource to facilitate future long-term stays in microgravity on exploration missions that could otherwise be delayed pending such a mission design.
There are several analog environments utilized by the HRP, some owned and operated by HRP, some by NASA, and others operated by other agencies. Each analog environment is assessed for its characteristics that mimic portions of the flight environment, the fidelity of the analog. No ground-based analog can serve to simulate the flight environment completely, thus each analog use is selected based on its important flight-like characteristics specific to the task objectives. Several analogs often will be required to fill a gap, and, in all cases, analog findings are validated in the space flight environment.

The Flight Analogs Project coordinates utilization of ground based research analogs to complement space research. Throughout the IRP, tasks requiring the use of specific analogs are identified. The bed rest analog mimics some of the physiological changes induced by weightlessness, using a bed rest model with a 6° head-down tilt. The NASA Extreme Environment Mission Operations (NEEMO) analog and Antarctic missions provide mission-like settings and interactions that incorporate the constraints of working in extreme environments. The Haughton-Mars and Devon Island analogs to provide rugged terrain and mission-like interactions to address specific lunar surface system concepts related to EVA and other factors related to behavioral health and performance. In some cases, the HRP also utilizes operational mission environments, such as the Phoenix Mars Scout Lander, to obtain data relevant to the behavioral health and performance of the ground crews supporting long duration spaceflight missions. Such data provide valuable lessons for future exploration missions. Isolation chambers also provide mission-like ground-to-crew and crew-to-crew interactions that facilitate behavioral studies of team cohesion, workload, fatigue, and sleep. The NASA Space Radiation Laboratory (NSRL) is a unique ground-based analog. This facility is owned and operated by the Department of Energy’s (DoE) Brookhaven National Laboratory, under a contract with the HRP. HRP utilization of the NSRL is managed by the Space Radiation Program Element.

As NASA prepares to send crewmembers back to explore the Moon for periods of up to six months, questions arise regarding the impacts of the lunar environment on the health, safety, and performance of the explorers. Among the environmental characteristics of concern is the relatively small force of gravity on the Moon, which is approximately one-sixth of that on Earth. “Space normal” is defined for this document as the normal human response to prolonged space flight. While the normal human response to prolonged microgravity exposure has been fairly well characterized during (and after) orbital space flight missions, little is known about the human physiological responses to prolonged fractional gravity exposure. Thresholds, non-linearities, and system-system interactions/dependencies are all likely to affect these responses. These things will certainly be studied in crewmembers participating in Lunar missions; however, it would be useful to know ahead of time whether any of the effects could be severe enough to cause functionally significant decrements in crew health, safety, or performance during these missions, so that appropriate countermeasures could be provided from the outset.

Various lunar gravity simulation techniques were developed during the Apollo era (e.g., parabolic flight, mechanical off-loading, vertical counter-weighting, underwater activities); these techniques can be used only for short-term simulations (seconds-to-hours). All are capable of simulating the musculoskeletal loading on the Moon, but only parabolic flight can provide a high-fidelity simulation of the physiological loading for the cardiovascular and sensory-motor systems. The long-term exposures (weeks-to-months) required to simulate lunar outpost missions have been attempted in humans only by using head-up-tilt (HUT) bed rest models. While such models can provide accurate static loading along the long body axis, they cannot eliminate the (nearly) orthogonal components of the gravity vector, nor can they allow for high-fidelity dynamic simulations. Nevertheless, within limits, they might provide insight into the expected adaptive responses of the
bone, muscle, and cardiovascular systems to prolonged lunar gravity exposure. The Flight Analogs Project is investigating the HUT model as a potential analog to physiological changes induced by the partial gravity environment of the lunar surface.

1.4.5 ELEMENTS AND PROJECTS RESPONSIBLE FOR THE RESEARCH (WHO)

Each risk is allocated to one of the five research elements within the HRP, and the IRP identifies which element is responsible for the identified risk. Three of the HRP Elements are single project elements: Behavioral Health and Performance (BHP), Exploration Medical Capability (ExMC) and Space Radiation, and the responsible Element is identified at the risk level, but they are responsible also for all gaps and tasks addressing the risks. Two HRP Elements, Human Health Countermeasures (HHC) and Space Human Factors and Habitability (SHFH) are multi-project Elements. Thus, the Element is identified at the risk level, and the responsible project within the Element is identified at the Gap level. The following HHC abbreviations are used throughout the IRP to designate the responsible project: EPSP (EVA Physiology and Systems Performance), ECP (Exercise Countermeasure Project), NxPCM (Non-Exercise Physiological Countermeasures), and FAP (Flight Analogs Project). The following abbreviations are used to designate the responsible SHFH project: AEH (Advanced Environmental Health), AFT (Advanced Food Technology), and SHFE (Space Human Factors Engineering).

The HRP’s intent is that each study is procured through competitive means, i.e., a NASA Research Announcement (NRA), Request for Proposal (RFP), etc. In some cases, due to timeliness of data, or close interconnectedness with operations or other NASA entities, the HRP will direct a specific study be done. Criteria for these decisions are given in the HRP Science Management Plan. The current and planned procurement method for each task in this research plan is identified. Identification of any investigation as a directed study within the IRP does not signify a commitment on the part of the HRP to implement that study as a directed study without further consideration by the Program Scientist as specified in the Science Management Plan.

It is the HRP’s policy that all investigations sponsored by the program will undergo independent scientific merit review. This includes proposals submitted in response to NASA Research Announcements, all directed study proposals, and all unsolicited proposals.

Each Element or Project within an HRP will be reviewed by an independent Standing Review Panel. The Panel’s primary responsibility is to review the Element Research Plan and provide recommendations on the scientific or technological approach and portfolio content. Those element research plans ultimately serve as the input to the IRP. Modifications to element research plans will result in modifications to the annual update of the IRP.

1.4.6 DELIVERABLES OF THE RESEARCH (DELIVERABLES)

The focus of this document is to identify deliverables necessary to complete the exploration (lunar and Mars) missions. This plan is NOT intended to mitigate risks associated with the ISS. The ISS is used as a platform to conduct research aimed at mitigating risks to the exploration missions. Some of the research may identify countermeasures, engineering, or operational solutions that would enhance the ISS and reduce risk in use (including to users) of that platform. In those cases, the HRP identifies the necessary deliverables and insertion points for the ISS.

Human health and performance risks can best be mitigated through the space system design. The HRP works closely with the Constellation program to communicate the areas of human health and performance risks, and to help inform engineering and development of the Constellation systems.
Mitigation of many human health and performance risks can be accomplished through engineering design and operational constraints, and do not need further research. Decision points in the research schedules are placed to evaluate the adequacy of the approach, research results, and deliverables to meet the intended application.

The first and most desirable approach to mitigating a human health and performance risk is to engineer the risk out of the system. HRP research is intended to reduce the uncertainty in the risk and free mission timelines and design from unnecessary conservatism. To facilitate risk avoidance, the HRP identifies requirements for crew selection, vehicle or mission design.

Some human health and performance risks can be mitigated through application of special space medicine operations procedures. The HRP works closely with the Space Medicine Division at JSC to evaluate the relative risks and to determine if the risks can be mitigated through known procedures. This coordination occurs through HRP participation on the HSRB, and interaction at the Human Systems Risk Forum (HSRF). This board and forum have been set up by the Chief Health and Medical Officer with chairmanship delegated to the JSC Chief Medical Officer. Members of this board consider the range of human health and performance risks, and identify those that can be mitigated through operational procedures vs. those that require further research. The risks addressed in this IRP are those identified by the HSRB as requiring research. The “inform medical operations” deliverables are the results of forum discussions, and research results are integrated into medical requirements or flight operations procedures. The HSRB is also used to evaluate the “deliver countermeasure” deliverable to ensure countermeasures can be adequately transitioned to medical practice.

The HSRB/HSRF is also used to evaluate data at various decision points in the research. The deliverables identified in the plan for “HSRB” utilize the board to concur with the next steps in the research plan.

Several other deliverables are identified throughout this IRP. Two designations are used for standards deliverables. The deliverable to “inform standards” represents the HRP’s intent to communicate information to the OCHMO and medical operations that may help interpret the existing standard. The “recommend update for standard” deliverable is used when the research results are expected to change the standard.

2.0 ORIENTATION SUMMARY OF THE RESEARCH PLAN

The IRP describes a plan of research that addresses both human physiology and the interconnected system of the human and spacecraft in a highly integrated manner. It is often not possible to address the risks simply as stand-alone units. The knowledge or mitigation gaps often appear in multiple risks. Many of the specific research tasks address multiple gaps. As such, it is instructive to rearrange the PRD risks into top-level themes characterizing the expected outcome. Sections 2.1 through 2.5 provide a high-level view of the research approach to the risks in these themes. Section 3.0 arranges the detailed research plans, including text and graphics, for each PRD risk (according to the themes with which the risks are most closely associated). The themes are:

1) Ensure the crew can accomplish the physical tasks of the mission.
2) Ensure the crew can accomplish the cognitive, behavioral, and team aspects of the mission.
3) Ensure the crew receives adequate nutrition.
4) Protect the crew from environmental hazards.
5) Provide adequate medical care for the crew.

Appendix A gives the risks for each theme, and shows which gaps address multiple risks.

The interactions between the risks, gaps, and tasks are not readily shown in a printed book. The HRP intends to include the IRP in a publicly accessible database (the Human Research Roadmap). In this database, the user will be able to identify quickly the gaps associated with a risk, the tasks associated with a given gap, the cross-integration of a task across multiple gaps or risks, deliverables associated with a gap or task, etc.
2.1 ENSURE THE CREW CAN ACCOMPLISH THE PHYSICAL TASKS OF THE MISSION

(Return to Table of Contents)

2.1.1 Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance

2.1.2 Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity

2.1.3 Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

2.1.4 Risk of Reduced Safety and Efficiency Due to an Inadequately Designed Vehicle, Environment, Tools, or Equipment

Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance and Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity

Sections 2.1.1 through 2.1.2 are highly interrelated. Occurrence or mitigation of a risk can be a contributing factor affecting another. Their research approaches are given together.

Human physiology’s “normal” response to spaceflight has not been determined for these risks. Several studies have been implemented to determine how muscle and aerobic capacity are affected by microgravity; these studies include the new ISS Exercise Prescription study, the Functional Task Test and the ISS VO₂max study.

The ISS Prescription study will apply principles learned from ground-based flight analogs to an in-flight platform in order to improve exercise countermeasures efficacy and efficiency by increasing exercise intensity and reducing exercise volume. Data will guide decision of whether current exercise countermeasures are protective or if improved countermeasures requiring flight validation studies are needed.

The Functional Task Test will be implemented as a flight study as well as a bed rest study. The goal of this study is to develop and evaluate an integrated set of functional and physiological tests and then use these tests to determine how postflight changes in sensorimotor, cardiovascular and muscle physiology impact postflight functional performance. These tests will be performed pre and postflight on astronauts exposed to short and long-duration space flight. The Functional Task Test will assess operational relevance of these changes by measuring the performance of specific exploration tasks (e.g., simulated seat egress, ladder climb, hatch opening, etc.). Additionally changes in functional performance will be mapped standard muscular, neurological, and cardiovascular measures. Data obtained from this study will facilitate the design of countermeasures that specifically target the physiological systems responsible for impaired functional performance.

The specific aims of the ISS VO₂max study are to measure VO₂max during and following long duration missions and to assess the validity of using submaximal measurements of heart rate (HR), oxygen consumption (VO₂) to track changes in aerobic capacity. In addition, non-invasive measurements of cardiac output (Qc) will be performed during exercise to determine if measurement of Qc will improve the accuracy of the submaximal estimations of VO₂max. Results from this study will determine if the current countermeasures are protective and need only optimization (e.g., reduced volume, time) or if improved countermeasures and flight validation studies are needed.
Due to scheduling constraints with the loss of the Mars transit analog in 2020, several concurrent studies are ongoing.

Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

To ensure completion of the physical tasks of the mission, the EVA suit system must allow safe and efficient performance of critical mission activities outside the habitat or vehicle. The Human Research Program has tasked the EVA Physiology, Systems and Performance (EPSP) Project to work with the Constellation EVA Systems Project Office to develop and execute an integrated human testing program across multiple environments to collect objective data needed to make informed design decisions in creating an EVA suit system that will optimize human health and performance. The research approach is to evaluate various parameters affecting human EVA performance, such as metabolic cost and biomechanics of different suit designs and operational concepts; impacts of suit weight, mass, pressure, center of gravity (cg), and the quantities of consumables required to support EVA. Other research tasks will determine biomedical monitoring requirements, methods to minimize suit-induced trauma, and operational concepts to improve work and task efficiency. This work will be done as a series of inter-related ground studies using multiple analog environments including, but not limited to, the Partial Gravity Simulator (Pogo) and Neutral Buoyancy Laboratory (NBL) at the Johnson Space Center, parabolic flight, Desert Research and Technology Studies (D-RATS), the Haughton Mars Project (HMP), and NEEMO.

Risk of Reduced Safety and Efficiency Due to Inadequately Designed Vehicles, Environments, Tools, or Equipment

This risk focuses on the overall environment in which the crew lives and works, which influences the development of hardware and interfaces, as well as how those interfaces will facilitate human performance and efficiency. Displays, controls, and procedures need to be appropriately designed and developed to allow for safe and efficient execution of tasks. Specific studies investigate the environment(s) surrounding the crew, namely the acoustic environment that can influence both health and performance. Other studies focus upon the vibration, acceleration, and microgravity environments, again all having potential to impact human health and performance. The approach to mitigating this risk is to develop a thorough understanding of the operational concepts, determine the methods, the metrics, and the verification strategies to ensure that both hardware and environment are designed for human safety and productivity.

2.2 ENSURE THE CREW CAN ACCOMPLISH THE COGNITIVE, BEHAVIORAL, AND TEAM ASPECTS OF THE MISSION

(Return to Table of Contents)

2.2.1 Risk of Behavioral and Psychiatric Conditions

2.2.2 Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload

2.2.3 Risk of Performance Errors Due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation

2.2.4 Risk of Errors Due to Poor Task Design
2.2.5 Risk of Error Due to Inadequate Information

2.2.6 Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems

Risk of Behavioral and Psychiatric Conditions,
Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload
Risk of Performance Errors Due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation

Sections 2.2.1 through 2.2.3 are highly interrelated. Occurrence or mitigation of a risk can be a contributing factor affecting another.

Risk of Behavioral and Psychiatric Conditions

Early detection of stress or other risk factors during spaceflight is imperative to deter development of behavioral or psychiatric conditions which could seriously harm and negatively impact the individual or the crew, and pose serious consequences for accomplishing mission objectives or jeopardizing the mission altogether. Toward this end, BHP is developing methods for monitoring behavioral health during a Lunar and Mars Mission, and adapting and refining various tools and technologies for use in the spaceflight environment. These measures and tools will be used to monitor, detect, and treat early risk factors. BHP will utilize analogs to test, further refine, and validate these measures for Exploration Missions. BHP also develops countermeasures for maintaining behavioral health and enhancing performance during long duration isolated, confined, and highly autonomous missions and provides updates for behavioral health and performance standards.

Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload

Ground evidence clearly demonstrates that performance impairments can occur when sleep is attained in quantities similar to that attained by astronauts in flight. A correlation between sleep quantity and performance during spaceflight however has not been documented. BHP research aims to accurately characterize and quantify this Risk by implementing studies on ISS that utilize validated measures for assessing performance relative to fatigue.

BHP research efforts further investigate contributors to sleep loss, fatigue, circadian desynchronization, and work overload, by evaluating environmental factors, individual vulnerabilities, and various aspects of mission operations. Such investigations help to inform the optimal countermeasure strategy for mitigating the health and performance effects of sleep loss and related issues in flight. As an example, preliminary studies indicate that light exposure can correct difficulties in sleep patterns that occur with shift work, jet lag and sleep disorders. Current efforts aim to investigate optimal lighting requirements for the space vehicle, as well as safe and efficacious methods for implementing lighting as a countermeasure. Other countermeasures that are currently being investigated include recommendations around sleep hygiene, optimal work-rest schedules, flight rules and requirements, and the effectiveness and safety of sleep-wake medication use in flight.
Risk of Performance Errors Due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation

While little empirical data have been collected regarding the impact of interpersonal and intrapersonal factors on spaceflight performance, it is possible that crew conflict could jeopardize long duration Exploration Missions. Reports from Mir reveal that several missions may have been terminated earlier than planned due to interpersonal frictions between crewmembers, and some veteran NASA astronauts have reported crew conflict during previous space travels. Understanding the potential negative impacts of interpersonal and intrapersonal issues from spaceflight and relevant, high fidelity analog environments is important for identifying countermeasures to aid crewmembers (ground and space) during exploration missions (e.g., moon and Mars) where operations will require more autonomy.

BHP will conduct literature reviews and interviews of crew and operations personnel to determine the most likely and most serious threats to crew cohesion, crew performance, and crew-ground interaction that might be expected for exploration missions.

The interviews will be used to formulate objective measures for monitoring crew cohesion and develop approaches to enhance current training and build upon the current highly successful in-flight support services and countermeasures. These measures will be tested for feasibility and acceptability in the appropriate analog environment(s). These tests will be followed by studies of ISS crew composition and crew cohesion/performance.

As crews begin operations for long duration missions beyond low Earth orbit, they will need to exercise increasing command and control of their daily activities. The distance for Mars Missions will result in loss of capability for real-time communication, downlink, and commanding. Likewise, the crew will have to augment and adapt their schedules based on real time changes in their schedules. The extreme distance and the duration of the planned Mars mission, are at the boundaries of our current knowledge. A better understanding of how to approach and address autonomous operations and its impact on crew dynamics and performance will help inform standards and countermeasures. BHP is collaborating with Space Medicine in a study of crew autonomy while we are still in low Earth orbit, to identify the impact (if any) of increased autonomy on crew dynamics and performance.

The BHP will test conflict management approaches in ground and analog environments, and subsequently on the ISS.

Risk of Error Due to Poor Task Design,
Risk of Error Due to Inadequate Information, and
Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems

Sections 2.2.4 through 2.2.6 are highly interrelated. Occurrence or mitigation of a risk can be a contributing factor affecting another.

The strategies for addressing these three risks are intertwined. The work described under the first risk (Task Design) focuses on planning how a given task or mission objective will be accomplished, as well as on how to decide what skills, tools, equipment, and information are needed to accomplish a task. It also provides tools and guidelines for determining optimal combinations of automation and human involvement. Work under the second risk (Inadequate Information) contributes to the crew having adequate knowledge, skills, and information at the time the task needs to be performed. The third risk, (Impaired Ability to Maintain Control) specifically addresses impairment in the
sensorimotor system due to changes in gravity, and searches for means to minimize the impact of these changes on performance.

Risk of Error Due to Poor Task Design

The risk associated with designing tasks focuses specifically on the process of assigning roles and responsibilities to individual crewmembers, a group of crewmembers, automation, ground support or various combinations of actors. SHFE specifically studies issues in designing tasks to be performed jointly by humans and automation, and deciding how much responsibility to assign to an automated system. The approach to mitigating this risk is to develop and specify “best practices” for human-automation function allocation, crew/automation interface design, incorporation considerations for crew workload and situational awareness in mixed-initiative operations concept design, and determination methods that ensure effective levels of trust between the crew and automation while avoiding unacceptable levels of crew complacency.

To mitigate this risk, it is necessary to develop an adequate understanding of human characteristics with respect to automation, determine optimal workload levels, and understand situational awareness. Mitigations to this risk will include requirements and guidelines for human interfaces to automation. This leads into the Risk of Error Due to Inadequate Information.

Risk of Error Due to Inadequate Information

The risk focuses on identifying the sources of crew performance errors. The lack of situational awareness that might be due to poorly designed interfaces or tasks is such an example. The subsequent development of information-presentation standards reduces operator errors in spaceflight through adequate understanding of the causes and mitigations of the errors. As the topic of inadequate information is comprehensive, the approach to mitigating this risk is to focus on the display of information, the types of controls that interface between the human and the displays, and the procedures to accomplish tasks.

It is not possible to separate the strategy for mitigating this risk from the strategy for dealing with the risk of Errors due to Poor Task Design. The information that is needed to perform a task at a given time depends substantially on the nature of the task and the crewmembers’ roles and responsibilities. The work described under this risk presumes the task is well designed, and focuses on the problems of ensuring the necessary information is presented so a timely, accurate performance is accomplished.

Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems

New evidence regarding landing performance indicates that research into these types of issues is not a high priority for Shuttle or ISS. However, since Mars operational scenarios are still TBD, it is agreed that the ISS should be utilized to gather the data required to define the research that might be needed to enable future Mars mission operations. It first must be determined what relevant spaceflight data exist and if it is accessible. If so, this data must be analyzed; if not, the data must be collected. In addition, performance related to neurosensory dysfunction should be used to determine the need for further research and countermeasure development.

Space normal must first be defined for this risk; data mining tasks are ongoing. Once the definition is in place, the data will be presented to the HSRF, and a determination made on whether
countermeasures need to be developed. In addition, the NRA solicitation process was utilized to obtain proposals to determine any manual and visual control deficits.

2.3 ENSURE THE CREW RECEIVES ADEQUATE NUTRITION

(Return to Table of Contents)

2.3.1 Risk Factor of Inadequate Nutrition

2.3.2 Risk of Inadequate Food System

Risk Factor of Inadequate Nutrition

As mission duration increases, the risk of nutrient deficiencies becomes greater. Nutrient requirements, delivery requirements, and the need to preserve the nutrient content in food will increase as the frequency and duration of EVAs increase and long Mars missions. Nutritional countermeasures can influence all systems.

Space normal must be defined for this risk; the Nutrition SMO is ongoing. Once space normal is defined, the data will be presented to the HSRF and it will be decided if countermeasures need to be developed. In addition, several studies are ongoing to determine the optimal dose of vitamin D.

Risk of Inadequate Food System

Studies of the stability of food nutrients will identify vitamins and amino acids at risk for degradation in space food supply; identify changes in fatty acids of foods flown on ISS, and characterize degradation profiles of the unstable nutrients. A ground study uses radiation exposure to test the stability of various food and pharmaceutical components; the results of the study will be compared to ongoing flight data being collected. The shelf life of the current thermostabilized food products have never been determined. Food items with varied formulations and bulk ingredients are now in accelerated shelf life testing. The approach will provide critical information about the susceptibility of vitamins in the space food system to adverse environmental factors and storage encountered during space missions.

The Advanced Food Technology Project is responsible for optimizing methods required to preserve, package, and ship, stow, and prepare the food while still preserving the nutritional value. The nutritional content of the flight food items is not currently measured. However the retort, irradiation, and freeze-drying processes used to produce shelf stable products, reduce the nutrient content. The nutrient levels in prepared foods will be measured to ensure that they meet the requirements of nutrition as specified by the nutrition standards and as determined through the Nutrition SMO mentioned above. If the nutrient levels are not adequate, other preservation methods that maintain the nutrient content of the foods will be investigated.

Reducing the flight resources required for the food system is a major goal due to the significant ratios of rocket size to mass per pound of cargo delivered on an exploration mission. Methods to reduce packaging mass and volume overhead will be studied. These studies must overcome challenges such as storing food for extended periods (i.e., 18 months for ISS, up to 5 years for a long duration mission having pre-positioned food). Food packaging materials must be developed that minimize the mass required, while providing an adequate oxygen and moisture barrier to maintain the required shelf lives.
2.4 PROTECT THE CREW FROM ENVIRONMENTAL HAZARDS

(Return to Table of Contents)

2.4.1 Risk of Carcinogenesis from Space Radiation

2.4.2 Risk of Acute Radiation Syndromes Due to Solar Particle Events

2.4.3 Risk of Acute or Late Central Nervous System Effects from Radiation Exposure

2.4.4 Risk of Degenerative Tissue or Other Health Effects from Radiation Exposure

2.4.5 Risk of Adverse Health Effects from Lunar Dust Exposure

2.4.6 Risk of Accelerated Osteoporosis

2.4.7 Risk of Bone Fracture

2.4.8 Risk of Renal Stone Formation

2.4.9 Risk of Cardiac Rhythm Problems

2.4.10 Risk of Adverse Health Effects Due to Alterations in Host-Microorganism Interactions

2.4.11 Risk of Crew Adverse Health Event Due to Altered Immune Response

2.4.12 Risk of Intervertebral Disc Damage

2.4.13 Risk of Orthostatic Intolerance during Re-Exposure to Gravity

Risk of Carcinogenesis from Space Radiation,
Risk of Acute Radiation Syndromes Due to Solar Particle Events,
Risk of Acute or Late Central Nervous System Effects from Radiation Exposure, and
Risk of Degenerative Tissue or Other Health Effects from Radiation Exposure

Sections 2.4.1 through 2.4.4 are highly interrelated. The occurrence or mitigation of one risk can be a contributing factor affecting another, so the research approaches are given together.

Radiation research does not follow the standard Risk-Gap-Task-Deliverable approach defined elsewhere in this document. The radiation element uses data from all funded studies and provides the integrating component through development of risks assessment tools and design tools. When critical deliverables are needed such as at mission or vehicle SRR/SDR, crew selection, or for key development of operational products, the radiation element will serve as an advisory function, using the output of the latest independently verified and validated tools. Thus, the many deliverables will not usually map to the end of a specific study, but rather are planned to occur at the key milestones when they are needed. However, tools utilized in the design and development of vehicles will be delivered prior to PDR and CDR to be utilized during the design and analysis cycles.

Near-term goals for cancer research focus on reducing the uncertainties in risk projections through the development of tissue specific models of cancer risks, the underlying mechanistic understanding of these models, and appropriate data collection at the NSRL. In the long-term, extensive validation
of these models with mixed radiation fields is envisioned and research on biological countermeasures and biomarkers will be pursued if needed. Research on improving cancer projections has two major emphases: 1) testing the correctness of the National Council on Radiation Protection (NCRP) model and 2) reducing the uncertainties in the coefficients that enter into the cancer projection model. Research on the validity of the NCRP model relies on studies at the NSRL observing qualitative differences in biological damage between HZE nuclei and gamma rays and the establishment of how these differences relate to cancer risk. There are distinct mechanisms of cancer induction across and within major tissue sites, and uncertainty reduction requires tissue specific risk estimates. NRA and NASA Specialized Center of Research (NSCOR) selections focus on these major sites: lung, breast, colon, stomach, esophagus, the blood system (leukemias), liver, bladder, skin, and brain. There are differences in radiation sensitivity based on genetic and epigenetic factors and research in these areas aids the development of tissue specific cancer models.

The approach to risk quantification and uncertainty reduction is based on modifying the current model for projecting cancer incidence and mortality risks for space missions. The cancer rate is the key quantity in the evaluation, representing the probability at a given age and years since exposure of observing a cancer. The life-span study of the Japanese survivors of the atomic bomb is the primary source for gamma ray data. More recently, however, meta-analysis data of patients exposed to radiation or reactor workers for several tissue types has become available. This newer data is being used to check or replace the Japanese data. Other assumptions in the model are made with regard to the transfer of risk across populations, the use of average rates for the U.S. population, age, and age-after exposure dependence of risk on radiation quality and dose-rate, etc.

Collaborative research with the DoE Low Dose Research Program is a key component of the strategy. The DoE program focus is on low Linear Energy Transfer (LET) irradiation; collaborative grants are also being selected from proposals that contain one or more Specific Aims addressing NASA interests using the NSRL. This research augments SR research with a large number of grants that use state-of-the art approaches, i.e., genetics, proteomics, and transgenic animal models, etc. The DoE research is an important part of the goal to identify biomarkers of cancer risk.

Determining the shape of the dose-response model for cancer induction is a near-term focus that is enumerated in biological terms through various cancer Gaps. In the NCRP model, the dose-response is linear and the slope coefficient is modulated by radiation shielding. Non-targeted models of cancer risk describe processes where cells traversed by HZE nuclei or protons produce cancer phenotypes in regions of tissue not limited to the traversed cells. Non-targeted effects are the major mechanism that has been identified that is in disagreement with the NCRP model, and leads to a sub-linear dose response. The implications of such a dose response for cancer risk are large since such a model predicts a reduced effectiveness for radiation shielding. The importance of mission length is also affected by the sub-linear dose response. Research in this area is a major focus of studies at NSRL. For some cancer sites and exposure conditions, for proton exposures, the NCRP model may be adequate. NSRL research is focused on reducing the uncertainties in the model through the establishment of tissue-specific models of human cancers, and collection of data at NSRL for a variety of ground-based analogs for Solar Particle Event (SPE) and Galactic Cosmic Rays (GCR).

Systems biology models provide a framework to integrate mechanistic studies of cancer risk across multiple levels of understanding (molecular, cellular, and tissues), and are the most likely approach to replace the NCRP model. Systems biology models are being developed by the Risk Assessment Project and several NSCORs, and, in conjunction with data collection, will improve the descriptions of cancer risk, laying a framework for future biological countermeasure evaluations and biomarker identification.
A critical question for the current phase of research is to establish possible threshold doses for specific CNS risks. Central Nervous System (CNS) risks from GCR are a concern due to the possibility of single HZE nuclei traversals causing tissue damage as evidenced by the light-flash phenomenon first observed during the Apollo missions. Also, as survival prognosis for patients irradiated for brain tumor treatment has improved, patients have shown persistent CNS changes at long times after treatment with gamma rays suggesting a possible CNS risk for a large SPE. Furthermore, animal studies of behavior and performance with HZE radiation suggest detrimental changes may occur during long-term GCR exposures. Currently, there is no projection model for CNS risks of concern to NASA. The values of possible thresholds for CNS risks and knowledge on how to extrapolate possible thresholds to individual astronauts is a key milestone in the long-term research plan.

Cataracts have long been a research focus of SR. More recently, several epidemiological studies, including results from the atomic-bomb survivors and nuclear reactor workers, have identified an increased risk of stroke and coronary heart disease (CHD) for low LET radiation at doses comparable to those of a Mars mission, or a lunar mission incurring a large SPE. Because the risk of heart disease is a recent finding, preliminary studies in these areas are seeking to establish possible distinctions in mechanisms for this risk between protons, HZE nuclei, and gamma rays. As an adjunct, SRPE will take advantage of studies by the European Union in this area, wherein the Union is supporting large-scale mouse studies of CHD. These studies should present new insights into the nature of the low LET (gamma-ray) risk at low dose-rates comparable to space conditions, and identify appropriate mouse strains to be used in future SR studies.

An increased risk of cataracts associated with low dose space radiation has been reported from past NASA missions, and is being followed up with a clinical study of cataract progression rates in current or retired astronauts. Several NSRL studies of risks are supported to improve the understanding of how protons and HZE nuclei induce cataracts, and to identify possible countermeasure approaches.

A variety of acute radiation syndromes are of concern following a large SPE exposure. Radiation sicknesses, i.e., the prodromal risks, include nausea, vomiting, diarrhea, and fatigue. These effects are manifested within 4 to 24 hours post-exposure for sub-lethal doses, with a latency time inversely correlated with dose. Furthermore, there is a reasonable concern of a compromised immune system, due to high skin doses from a SPE leading to burns, or other flight factors, albeit the possibility of acute death through the collapse of the blood forming systems is negligible. One research emphasis is to pursue the role of the immune system in acute risks. Animal and cell culture models and possible countermeasure approaches to acute risks are expected to be distinct from cancer and other radiation risks.

In the long-term, the SR will consider research on fertility, sterility, and hereditary risks from space radiation, and may request the NSBRI support these areas because of their unique nature.

Risk of Adverse Health Effects from Lunar Dust Exposure

The toxicological effects of lunar dusts have not been studied in sufficient depth to develop an exposure standard for operations on the lunar surface. Lunar dust is somewhat similar to volcanic ash, which is used by NASA as a lunar-dust stimulant; however, dusts on the lunar surface have worrisome properties in regards to human health. Lunar dusts have a high content in the respirable size range, they have a high surface area that is chemically reactive, and elemental iron "nano-particles" are imbedded in the dust. These unusual properties may cause the respirable dusts to be at
least moderately toxic to the respiratory system, and the larger grains to be abrasive to the skin & eye. NASA needs to set airborne exposure standards based on scientific evidence so that vehicle designs can effectively control exposure. Operations must be designed to minimize the risk of abrasion to skin and eyes.

The research approach is to evaluate and characterize each factor contributing to toxicity of the lunar dust, and then synthesize these data into a recommended standard via the Lunar Airborne Dust Toxicity Assessment Group (LADTAG). The HRP has committed to recommending this standard in 2010, when it is needed prior to development of Lunar Operations concepts.

Focused studies have already commenced to determine size distributions, shape characteristics, and chemical composition of lunar particulates. Lunar dust surface activation studies will attempt to replicate solar wind and micrometeorite bombardment. Understanding the process of both activation and of passivation in a habitable environment (water vapor and oxygen) will determine potential health effects and exposure limits occurring during mission-related tasks, as well as the mode of action within the human system. The generation of reactive oxygen species (ROS) will be one marker of potential toxicity. Active vs. non-active dust will be tested to determine the differences in toxicity due to chemical activation.

In vivo studies include inhalation toxicity and intratracheal instillation (ITI) testing of lunar dust. Gross pathology and histopathology will be performed to gather evidence of the degree and nature of lunar dust toxicity. Lung lavage will be used to determine the biochemical and cellular response of the lung to insult by lunar dust.

Several crewmembers reported dermal and ocular issues resulting from lunar dust exposure during Apollo missions. Other than these anecdotal reports, there is no objective scientific data to support an understanding of the dermal and ocular toxicity of lunar dusts. Ground studies will determine the extent to which dermal and ocular hazards may be present for visual decrement and vapor barrier loss during lunar operations, especially EVAs with dust inside. Periodic cleaning of the EVA suit is expected to mitigate this hazard.

Risk of Accelerated Osteoporosis and Risk of Bone Fracture

The two risks listed above comprise Sections 2.4.6 and 2.4.7, and are highly interrelated; the occurrence or mitigation of one risk possibly affects the other. The combined research risk approaches are presented below.

It is currently possible to 1) track the course of changes in bone mineral density and bone quality during long duration missions, 2) determine if bone losses will occur during a Mars visit, and 3) know such information to determine the risk of fracture upon return to Earth after a Mars mission. However, these capabilities are not a part of any requirements documents for Lunar or Mars missions. Even after 6-month missions, currently there are indications that bone quality/strength does not recover as quickly as bone mineral density. This may represent a long-term health effect (increased osteoporosis and fracture risk) related to this discordant recovery dynamic. This information is required to assess long-term health risks to returning crew.

While bone atrophy during spaceflight is known and requires mitigation; the time course of in-flight bone changes, the time course of post-flight recovery, and individual susceptibilities have not been determined. The 2007 NASA Research Announcement was utilized to solicit and select proposals to gather these space normal data. In addition, work is ongoing with the Space Medicine Division to
obtain long-term recovery data. The long-term goals are to develop and deliver countermeasures for long-term missions while tracking the efficacy of these countermeasures to prevent increased lifetime health risk. Due to schedule constraints, countermeasure development has been started in parallel with space normal data collection and technology development.

The fracture risk for bone is related to the applied load-to-bone ratio and to the fracture load of bone. Thus, the increased fracture risk induced by spaceflight is suggested collectively as an adaptive response by the accelerated loss of bone mass, by weightlessness, and by reduced gravity fields experienced during missions, as well as by the loads and torques that the skeleton is subjected to during tasks performed during the missions. The most critical work needed for this risk is the measures of in-flight changes in bone mass over the course of ISS missions. This allows the prediction of temporal changes in bone mass during Mars missions. Those data will provide a basis for evaluating whether the expected loads/torques to bone during human performance on a mission will exceed the failure load of bone (i.e., fracture load). This knowledge will drive mission operations planning.

The Risk of Bone Fracture deals with a fracture occurring during a mission. A fracture considered of “high” risk is characteristic of osteoporosis, a disease characterized by losses in bone mass and in structural deterioration. Therefore, gaps and tasks that fall under the Risk of Accelerated Osteoporosis are also mapped to the Risk of Bone Fracture. The only current independent gap for the Risk of Bone Fracture is the unknown incidence of vertebral compression fractures. The task associated with this independent gap is being completed by the Space Medicine Division.

Risk of Renal Stone Formation

Space normal must first be defined for this risk. Data mining tasks are ongoing. Once space “normal” is defined, the data will be presented to the HSRF and a decision of whether countermeasures need to be developed will be made.

The evidence establishing the risk factors and/or the likelihood of risk occurrence for renal stone formation is either known or in-progress. The activities in this area are intended to compile data related to the risk of renal stone formation, from medical data and from raw research data used for previously published reports. From this data, the task is to determine primary and other risk factors for renal stone formation, particularly regarding the types of stones formed (to identify the specific risk factor and appropriate countermeasure), the correlation with diet, and the time course for formation. Ground data mining and final analysis of the previous Renal Stone Flight Study will be used to determine if further work is warranted for this risk.

Risk of Cardiac Rhythm Problems

Heart rhythm disturbances have been seen among astronauts. Most have been related to cardiovascular disease, but it is unclear whether this was due to pre-existing conditions or to the effects of space flight. It is believed that advanced screening for coronary disease has greatly mitigated this risk. Other heart rhythm problems, such as atrial fibrillation, can develop over time, necessitating periodic screening of crewmembers’ heart rhythms. Beyond these terrestrial heart risks, some concern exists that prolonged exposure to microgravity may lead to heart rhythm disturbances. Although this has not been observed to date, further surveillance is warranted.

Space normal must first be defined for this risk and data mining tasks are ongoing. Once the definition is determined, the data will be presented to the HSRF and it will be decided if countermeasures need to be developed.
The HRP will conduct a comprehensive study that integrates the objectives of two NRA investigations and a SMO, involving both intramural and extramural investigators. In-flight testing will require Holter monitoring, two-dimensional (2D) echocardiography, and ambulatory blood pressure monitoring. After completion of the study, the clinical expression of cardiac atrophy during long duration spaceflight will be defined clearly, and its significance for cardiac systolic and diastolic function at rest and during gravitational transitions will be elucidated. In addition, preliminary information will be obtained regarding ventricular conduction and re-polarization that will provide either strong clinical reassurance, or pathophysiologic insight into the risk for cardiac arrhythmias. Based on the outcome of this investigation, the HRP will determine if countermeasures are necessary to prevent these conditions.

Risk of Adverse Health Effects Due to Alterations in Host-Microorganism Interactions

Current preventative measures limit the presence of many of the medically significant microorganisms during a mission, although infections are not completely eradicated. Alterations in some microbial characteristics have been observed in organisms grown in flight, including virulence (disease-causing potential), as indicated by recent evidence. Due to the evidence, the HRP plans to compare samples collected on the ground samples with on-orbit samples collected aboard ISS. Particular attention will be paid to equipment, the SHFH element, and air and water systems. This comparison will clarify the extent of possible alteration by microbes in spaceflight. Given operational controls that are in place onboard spacecraft now, the HRP will determine if potential microbial changes warrant retaining this risk, whether the existing controls are adequate, and whether additional mitigation techniques should be developed.

Risk of Crew Adverse Health Event Due to Altered Immune Response

There are no procedures currently in place to monitor immune function or its effect on crew health. Immune dysregulation has been demonstrated to occur during spaceflight, yet little in-flight immune data has been generated to assess whether or not this may be a clinical problem. Thus, HRP will conduct the “Integrated Immune SMO” to assess the clinical risks resulting from the adverse effects of space flight on the human immune system and will validate a flight-compatible immune monitoring strategy. The correlation between in-flight immunity, physiological stress and a measurable clinical outcome (viral reactivation) will be determined for long- vs. short-duration space flight. Data from this study will be combined with the Shuttle-based immune studies to inform and update health standards. Additionally, ground analogs such as NEEMO will be evaluated to determine if they represent a good analog for short-duration spaceflight. This immune dysregulation analog will be validated for some aspects of that dysregulation if it is observed in the NEEMO crews (similar to that already observed in flight crews during/following spaceflight). Data from ground studies and the Integrated Immune SMO will be assessed to determine countermeasure development needs.

Risk of Intervertebral Disk Damage

Evidence from medical operations indicates that astronauts have a higher incidence of intervertebral disk damage than the general population. Additional work to determine the extent of this problem should be done. Once completed, the findings will be used to guide the design of re-entry and post-flight protocols, as well as future re-entry spacecraft, as appropriate.
Space normal must first be defined for this risk; hence, data mining tasks are ongoing. Once space normal is defined, the data will be presented to the HSRF and it will be decided if countermeasures need to be developed.

**Risk of Orthostatic Intolerance due to Re-Exposure to Gravity**

Twenty percent of Shuttle crewmembers and up to 83% of returning ISS crewmembers suffer hypotension and presyncope or syncope during 10 minutes of upright tilt on landing day. This may constitute a risk when crewmembers experience Earth's gravity after exposure to microgravity. Currently available countermeasures are not effective in all crewmembers; in particular, women are more susceptible than men are. While it is well known that crewmembers can be incapacitated by orthostatic intolerance after six-month missions when they return to Earth’s gravity, it is not known the degree to which this may be ameliorated in the gravity environment on the Martian surface. Early surface operations may require astronauts to be upright and active soon after landing on Mars. A combination of countermeasures, both physical and pharmaceutical, should be pursued for this risk. It is not known if exposure to 1/6 g and 3/8 g will cause orthostatic intolerance or will have mitigating effects on orthostatic intolerance upon return to 1 g.

Space normal has been defined for this risk. Current research efforts are investigations for the efficacy of new countermeasures (i.e., Jobst stockings and pharmacological agents). The new lunar analog currently under development will be utilized to understand the role of the lunar gravity as protection from orthostatic intolerance. In addition, gender effects and the possibility for gender-specific countermeasures are also being investigated.

### 2.5 PROVIDE ADEQUATE MEDICAL CARE FOR THE CREW

(*Return to Table of Contents*)

#### 2.5.1 Risk of Inability to Adequately Treat and Ill or Injured Crew Member

#### 2.5.2 Risk of Therapeutic Failure Due to Ineffectiveness of Medication

**Risk of Inability to Adequately Treat an Ill or Injured Crew Member**

To address this broad risk, the ExMC has broken it down into seven categories that correspond with the seven requirements allocated to the ExMC from the HRP Program Requirements Document (PRD). Each of the seven categories is then analyzed individually to determine where gaps exist in satisfying the PRD requirements. Below are the seven categories into which the risk has been separated and an explanation of the strategy for addressing the different categories of gaps.

1.0 **Validate Standards:** The NASA HQ OCHMO Standards for Crew Selection and Retention will require changes as new medical information and spaceflight technology becomes available. Additionally, NASA exploration missions may require new knowledge and/or new technology development either to support current standards or to modify standards for mission success. In either situation, the ExMC Element Scientist, through Space Medicine, will determine research needs and develop the research requirements and/or tasks necessary to fulfill this responsibility. The NASA HQ OCHMO standards that pertain to this risk are Crew Selection and Retention Criteria. The Space Medicine Medical Operations Lead for standards, working with the ExMC Element Scientist, determines gaps in knowledge in the
current Crew Selection and Retention Criteria. Tasks are then identified to close those knowledge gaps.

2.0 **Quantify the Risk:** Because of the limited available operational and research data, incidence rates and outcomes for relevant medical conditions have large uncertainties associated with them. The Space Medicine Exploration Condition List is analyzed to determine gaps in our knowledge about medical conditions’ incidence rates and outcomes in spaceflight. Tasks are then assigned to further study, model, and use analog population data to better quantify the medical conditions.

3.0 **Mitigate the Risk:** Gaps in this section deal with our knowledge about effective training and telementoring programs for Exploration missions. The Space Medicine Medical Operations Lead for training, working with the ExMC Element Scientist, determines gaps in knowledge and techniques for developing future crew, flight surgeon and biomedical ground controller training and telementoring programs. Tasks are then identified to close those knowledge gaps.

4.0 **Monitor and Treat the Unmitigated Risk:** Based on the Space Medicine Exploration Condition List, each condition is analyzed for each Constellation Design Reference Mission (DRM) for the capabilities required to monitor and treat the condition. An analysis is performed to determine where gaps exist in current technologies or where efficiencies could be realized in the future. Based on when a technology needs to come online, a technology watch is implemented or a technology development project is initiated to deliver the technology to enable the mission.

5.0 **Provide Enabling Capabilities:** Provide data integration and management for HRP to ensure proper handling of data (e.g. Life Sciences Data Archive, Mission Extended Medical Enterprise). Gaps exist where these capabilities are either insufficient or incomplete.

6.0 **Comply with Agency Standards:** Follow best practices and programmatic guidelines as levied by the HRP PRD. There are currently no gaps associated with this requirement.

7.0 **Reduce Resource Requirements:** Wherever possible, reduce in flight and funding resources. There are currently no gaps associated with this requirement.

---

**Risk of Therapeutic Failure due to Ineffectiveness of Medication**

Better recordkeeping of medication use, its effectiveness, and the side effects produced (if any) should be instituted. This will provide evidence for or and should be a precursor to a formal assessment of Pharmacokinetics/Pharmacodynamics (PK/PD) on-orbit. It is thought that the reduction in gastrointestinal (GI) motility and function, is not an issue after the first few days of flight, and is offered as the first piece of evidence for this gap. In general, Space Medicine avoids prescribing oral medications during this period of the mission. It is not known to what extent different volumes of distribution might be a factor in flight. Drugs selected for the PK/PD studies should be commonly used, have few side effects, and different metabolic pathways. External consultants should be used to determine which drugs to test and to design testing protocols. Space Medicine needs to develop a process and procedures to systematically track crew medication use, including subjective comments on efficacy and side effects, particularly for ISS. It is very important to know what pharmaceuticals are taken prior to in-flight tasks.

The overarching strategy for this risk is to obtain better record keeping of medication use, efficacy, and side effects. This includes several data mining tasks, which will provide evidence for or against
this risk. If evidence indicates the ineffectiveness of medications, a pharmacokinetics/pharmacodynamics study will be performed in flight to obtain further information.

3.0 ELEMENTS INPUT DESCRIPTION LOCATED IN APPENDIX A

The format for the Elements’ inputs includes graphical depiction via Gantt charts and written discourse to clarify the Element approach. Each input follows the same form. The Risk is reported, along with the criticality to the Lunar Outpost mission and the Mars mission; the Operational Relevance is described; the strategy for mitigation is given; the gaps in knowledge are reported with a brief description; and the activity or activities necessary to address the gap are described. For each activity, the resulting product/deliverable, the required delivery milestone for the deliverable, the required platform, and the Project or organization responsible for implementing the activity are all defined.

3.1 RISKS

Each text description has a description of the risk. These descriptions are verbatim from the PRD, and are reprinted in the IRP as a matter of convenience for the reader. With the title of each risk, the criticality is given. Criticality ratings correspond to the criteria given in Section 1.4.1 of this document.

3.2 CONTEXT OF RISK FOR EXPLORATION

After each risk and description, a paragraph occurs entitled “Operational Relevance and Risk Context.” In this paragraph, a description of the relevance to the exploration mission is given. This section also provides the context of how the research plan is built for that risk and describes the need for the research at a very high level.

3.3 STRATEGY FOR MITIGATION

The approach strategy for the mitigation of the risk is outlined in this section. For instance, the strategy may be to first determine space normal physiology, then identify specific countermeasures.

3.4 GAPS

Gaps in our knowledge or in the evidence base exist for each risk. These gaps have several different forms. A gap may exist in our evidence base, which leaves greater uncertainty regarding the likelihood of the risk. A gap may exist in the identification of the appropriate countermeasure. For others, the gap may be in the flight validation of the appropriate countermeasure. For the purposes of this IRP, the gaps are not delineated by type; rather they are simply identified as a gap that must be filled before the risk is mitigated. In some cases, the gap may not require research to close it; the gap can be avoided altogether through specific Constellation design selection.

3.5 TASKS

For each gap, the task (s) required to fill that gap are listed. The task is named and a short description is given. In some cases, a task can address multiple gaps across multiple risks. To limit the size of this document, a task that addresses more than one gap is named and described once and the description is referred to in the other gaps that it is intended to fill. In addition, the project responsible for implementation of the task is listed, along with the anticipated procurement method.
In some cases, the project is not within the Element responsible for the risk. The responsible Element will coordinate with the appropriate project in those cases.

### 3.6 DELIVERABLES

Each task is designed to culminate in a deliverable. These deliverables are structured to feed into the Constellation Program, the Office of the Chief Health and Medical Officer, or the Mission Operations Directorate. Several different types of deliverables exist. The following are the types of deliverables used:

**Information for Standards**

An “Information for Standards” deliverable is used for a task that produces part of the information to update a standard. Because this information is incomplete, the program would not be in a position to recommend a standard update, but it would represent a significant step toward such a recommendation. These tasks can feed into other tasks that also have information for standards, or they can be combined with other “Information for Standards” deliverables to result in a recommended standard update (next deliverable).

**Recommended Standard Update**

A “Recommended Standard Update” deliverable is mandated when the program is ready to provide the OCHMO with a recommended update to health or performance standards. This is usually done using the results of several tasks and then integrated into one recommendation for update. A key test of when to use this as a deliverable is that the program should be ready to actually write the text for the recommended standard update. Since the standards are applied in a broad spectrum for design and operations, these deliverables can be linked to any of the system design or mission operations milestones shown in the blue section at the top of the chart. They should be applied as early in the design phase or mission operations development phase as is possible, so, most often, they are necessary prior to Systems Requirements Review.

**Informing Mission Operations**

This form of deliverable is needed when the information is directly useful to affect mission planning. Examples include when a deliverable may impose mission operations timelining constraints, such as a new flight rule for sleep schedules or exercise timelines. As the name implies, these deliverables will most often affect the Mission Operations line shown in the blue section of the top of the Gantt charts.

**Countermeasure**

When a specific protocol is developed and validated to prevent or reduce the severity of a negative outcome identified in one of the risks, this is the form of deliverable. A countermeasure may be medical, physical, or operational entities, such as pharmaceuticals, a device, or a specific exercise routine, respectively. Note that in some cases the countermeasure will also affect mission operations (in areas like timelines). Though there is no fixed rule on this crossover, the demarcation used for the countermeasure deliverable is that the protocol is specific and extensive enough to require validation in spaceflight. For instance, if a ground task results in a spaceflight task that is called “flight validation studies,” it likely is a countermeasure. Similarly, there is no set rule for
determining to which Constellation milestone a countermeasure would apply. Some general
direction on this, however, is that the countermeasure usually does not affect the design of the
spacecraft, and is applied in the mission operations phase as a solution to a problem; thus, the
countermeasure deliverables generally affect the mission operations PDR or CDR phases.

**Information to Other Elements**

This deliverable is used when the task result feeds a gap in some other HRP element. As the IRP
matures, we will identify critical dependencies for each gap. These critical dependencies will
include, in some cases, information developed under another gap. The need dates for these
deliverables are determined by when the other element needs the information, not by Constellation
milestones.

**Requirements to Other Programs or Elements**

The “Requirements to Other Programs or Elements” deliverable is chosen when a task will result in
a requirement (or requirements set) given to another program (usually the Constellation Program) or
to another element. The task may end up in the requirements on the lighting spectrum in the vehicle,
or a requirement may apply to the radiation shielding design, or requirements may be identified that
apply to the food system from nutritional risk work. These deliverables often feed the design of the
vehicle and its sub-systems. As requirements, they primarily are applied in the Systems
Requirements Review timeframe.

**Updates to the Human Systems Risk Forum**

When a task results in information that must be considered by the medical operations community
and/or OCHMO, this deliverable is used. This deliverable is applicable when the rating of the
likelihood or consequences of the RMAT may be affected. It is also applied when the results of the
study are anticipated by the space medical operations community. As such, the deliverable often is
applied in conjunction with the “Informing Mission Operations” deliverable.

### 3.7 REQUIRED DELIVERY MILESTONE

Key milestones within the Constellation Program development drive the required date for the HRP
deliverables. For instance, design requirements typically must be defined by the appropriate System
Requirements Review. Design solutions and technology typically must be defined to a TRL6 level
by the Preliminary Design Review. This section documents the schedule drivers for the delivery
milestones.

### 3.8 REQUIRED PLATFORMS

This section defines the platform required to perform the research. Platforms can be designated as
ground analog environments, such as NEEMO, Antarctica, etc., or the platform may be a space-
based one, such as the Shuttle or the ISS. Also, the lunar surface is a platform that is anticipated in
some research efforts. If the ISS is required, a summary of the following resource requirements is
given: Number of subjects, Initial Upmass, Upmass/Subject, Downmass, Crew Time/Subject, and
Post-Flight Baseline Data Collection Time.
3.9 PROJECT OR ORGANIZATION RESPONSIBLE FOR THE IMPLEMENTATION OF ACTIVITY

Within the HRP elements, there are one or many projects chosen to implement the element research plan. The project is identified in this section. In some cases, organizations outside the element are responsible for implementation of the research, such as the NSBRI or even an international partner. These organizations are identified within this section.

This section indicates the project with primary responsibility for implementing the activity. In some cases, the project is not within the element responsible for the risk. The element responsible will coordinate with the appropriate project in those cases.

Discipline teams include the participation of operations personnel, the NASA research discipline experts, and the NSBRI. In several cases, the primary responsibility is shown as that of NASA; however, that does not mean that the NSBRI is not participating at all. The NSBRI participates through the discipline teams, as well as through future solicitations.

3.10 GRAPHIC INPUT

Each graphic is supported with text that provides a more thorough level of detail. Figure 2 shows an example of a Gantt chart, labeling each section of the chart. Each Gantt chart is associated with one of the 27 PRD Risks. The element to which the risk is allocated is identified in the upper left corner. The research gaps are identified by name and number along the left side for each risk. Under each gap are the identified activities required to fill the gap. Each activity is identified by name and the acronym of the project or organization responsible for implementing the activity. In some cases, the organization responsible for implementing the activity may not be directly controlled by the element responsible for the risk. The schedule of each activity is shown on the graphic and an arrow shows deliverables resulting from the activity. The activities are color-coded per the legend given. A number on each text deliverable description relates the deliverable to the need date, shown by the gray numbered arrows at the top of the chart.

3.11 DECISION POINTS

Several key decision points have been placed in the plan. At these key decision points, the appropriate forward path for the research will be reevaluated. The decision points are cast in a “Yes/No” form, and it is anticipated that at these points, the responsible element will review the overall, current state of the evidence, and review the appropriate approach to the forward plan. Where applicable, the Science Management Office will concur and, if necessary, the appropriate Project Standing Review Panel may be convened to deliberate and make recommendations. Criteria for making the decision will be determined on a case-by-case basis and will be consistent with the overall management structure documented in the Science Management Plan. In many cases, a task addresses more than one risk.
Legend

Green – Ground Study
Gold – ISS/STS Study
Gold with Waves – Preparation for Flight
Purple – Data Analysis & Modeling
Turquoise – Add On to Other Study
Hatched – NSBRI Study
Yellow – Lunar
White-Dotted Box – Potential Early Start
Gray Bubble – Task To Be Determined After Decision Point
Stop Sign – Stop Task

October 2008
Deliverables

- Information for Standards
- Recommended Standard Update
- Informing Mission Operations
- Countermeasures
- Information to Other Elements
- Requirements to Other Programs
- Updates to Human System Risk Forum
APPENDIX A:

Risks
The Risks in this part of the Appendix are aligned with
Section 2.1 –
Ensure That the Crew Can Complete the Physical Tasks of the Missions
RISK OF IMPAIRED PERFORMANCE DUE TO REDUCED MUSCLE MASS, STRENGTH AND ENDURANCE – CRITICALITY: LUNAR OUTPOST – I, MARS – C

There is a growing research database that suggests that skeletal muscles, particularly postural muscles of the lower limb, undergo atrophy and structural and metabolic alterations during space flight. However, the relationships between in-flight exercise, muscle changes, and performance levels are not well understood. Efforts should be made to try to understand the current status of in-flight and post-flight exercise performance capability and what the goals/target areas for protection are with the current in-flight exercise program.

Context of Risk for Exploration

Successful lunar outpost and Mars missions will be dependent on the performance of human tasks that will require an adequate level of physical fitness. These tasks may range from simple intra-vehicular activities, to ambulation on a planetary surface, to construction of long standing outpost habitats. The decrements that occur to skeletal muscle strength and endurance in response to reduced gravitational forces could potentially make associated tasks difficult to perform. Thus, impaired muscle performance may affect crew performance and mission success, and in worst-case off-nominal scenarios may impact crewmember health and safety (e.g., muscle soreness, muscle injury). It is therefore essential to identify Critical Mission Tasks, evaluate the muscle performance costs of these tasks (as related to provided tools and equipment), quantify the expected muscle performance decrements during lunar and Mars missions, and design effective exercise countermeasures (exercise hardware and exercise prescriptions) that maintain physical fitness at a levels that allow for mission success and safety with minimal time cost to additional mission operations.

Strategy for Mitigation

This muscle performance data will be taken to the HSRF for review and direction. Due to scheduling constraints with the loss of the Mars transit analogue in 2020, concurrent exercise prescription optimization studies are ongoing on the ground and will be validated in flight.

Similarly, research is ongoing to characterize activities of different mission scenarios to help determine the fitness levels required to perform those tasks and therefore, determine the exercise prescription for crewmembers. Current research is defining metabolic costs of some of the critical tasks. In addition, gender effects, hydration effects and lunar EVA effects are all being examined as well as the possibility for gender specific countermeasures.

Gaps

M1: What is the current state of knowledge regarding exercise performance? This gap is closed; the deliverable has been met.

M7: Can the current in-flight performance be maintained with reduced exercise volume? This gap should determine the effects of reduced in-flight exercise; this is a high priority gap. Efforts should be made to try to improve efficiency of the current ISS regime. Identification of which combinations of CEVIS, TVIS, and RED will result in the optimum balance of fitness in the least amount of time could decrease the amount of required exercise time. These studies should be performed in combination with in-flight measurements of exercise performance, and will give broader insight into what is truly required for the maintenance of fitness with the current devices, as well as into what exercise hardware and exercise prescriptions will be required for the moon and Mars.
M8: What is the minimum exercise regimen needed to maintain fitness levels for tasks? This gap is also asking if exercise, in addition to EVA tasks, is required during 6-month stays on the moon. If exercise is required, what exercise hardware would be required and what would be the correct exercise prescription? In addition, assessment of reduced exercise volume on in-flight performance should be completed. The following questions should also be examined: a) how can suit/task related injuries be prevented b) is the current exercise regimen appropriate for 1/6g and c) is the current exercise regimen appropriate for 3/8g – this is a lower priority question for future work.

M9: What is the minimum set of exercise hardware needed to maintain those (M8) fitness levels? This gap should be filled in three parts. The second treadmill that is being built for ISS can be assessed for performance and reliability. New hardware should be developed as soon as possible for lunar missions. Development of hardware for Mars can be developed using information from the ISS and Lunar hardware. The Moon will serve as a test bed for the equipment that is selected for Mars.

M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars? Ground-based work should be conducted to carefully build and test potential exercise equipment. In addition to the physiologic outcomes, equipment should be designed and tested so that hardware reliability and functionality are ensured. A series of bed rest and other ground-based studies should be designed to supplement the work discussed above. All bed rest studies should employ a multi-discipline, multi-project approach. The studies should include appropriate multi-disciplinary performance measures. Listed are some suggestions for issues that could be addressed in bed rest studies: optimum loading on treadmill; optimum volume vs. intensity of exercise; multidisciplinary performance enhancers (pharmaceutical/diet, mechanical, etc.); develop EVA tasks during bed rest and test effects on physiological and performance measures; 1/6 g bed rest and performance measures; 3/8 g bed rest and performance measures.

Task: (ECP – via directed study)
Flywheel Prescription Optimization – TBD

A flywheel exercise device has been shown to be an effective countermeasure for muscle mass and strength in multiple ground-based flight analogs (lower limb suspension and bed rest), although to date it has not prevented the atrophy of the soleus muscle in humans during prolonged periods of unloading. Currently, the flywheel-based exercise device has only been used as a resistance exercise device. Recent modifications to the flywheel exercise device now accommodate aerobic exercise in a rowing machine configuration. New bed rest studies will compare a multi-functional flywheel to a flywheel for resistance exercise alone with the addition of traditional modes of aerobic exercise (e.g., flywheel for resistance exercise and cycle ergometer for aerobic exercise).

Deliverables: Results will determine if a single multifunctional flywheel device can adequately protect muscle function, bone health, and aerobic capacity or whether multiple pieces of exercise hardware will be required. The initial results will determine if follow-on flight validation studies to optimize the prescription further are required.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: The bed rest ground analog (6° head down tilt) is required for ground studies for countermeasure optimization. ISS will be required to validate any optimized countermeasures.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 (bed rest and ISS)</td>
<td>75 kg (if ISS required)</td>
<td>none (if ISS required)</td>
<td>none (if ISS required)</td>
<td>9 hours (if ISS required)</td>
<td>2 hours (if ISS required)</td>
</tr>
</tbody>
</table>
**Task:** (ECP – via directed study)
**ISS Exercise Prescription Study**
This study will apply principles learned from ground-based flight analogs to an in-flight platform in order to improve exercise countermeasures efficacy and efficiency by increasing exercise intensity and reducing exercise volume.

**Deliverables:** Data will guide decision of whether current exercise countermeasures are protective or if improved countermeasures requiring flight validation studies are needed. Data will be taken to HSRF for decisions regarding the exercise prescription and will be used to provide information to the muscle standard.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** ISS is required for prescription validation

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>9</td>
<td>2</td>
</tr>
</tbody>
</table>

**Task:** (Glenn Research Center ECL/ECP – via directed study)
**A New Harness for Use with Exercise Countermeasures – Validation of Improved Comfort and Loading with the Center for Space Medicine (CSM) Harness**
Treadmill use in microgravity requires the use of a harness and a system to provide a subject load to keep the crewmember in contact with the treadmill belt. A common complaint from returning ISS crewmembers is that the current harness is uncomfortable. The pain and chafing that occurs with the use of the current harness contributes to sub-optimal subject loading (approximately 65% of body weight). A new harness design will be tested to determine if it is more comfortable than the current harness and will allow for greater loading which is expected to result in better maintenance of muscle mass and bone density of the lower extremities.

**Deliverables:** Decision to change to newer CSM harness or continue with current harness during treadmill activities

**Required Delivery Milestone:** N/A

**Required Platforms:** ISS is required for use of the TVIS on orbit to evaluate loading and comfort of the new harness.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>2kg/Inc</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Task: (ECP – via directed study)  
Integrated Countermeasure Study – TBD

Studies will be conducted to examine the effects of combining non-exercise countermeasures (e.g. nutritional or pharmacological) with established exercise countermeasures. The integrated countermeasures approach has a goal of improving both the efficacy and efficiency of exercise countermeasures. An integrated countermeasure will result in the most effective protection of muscle strength, bone quality, and aerobic capacity while requiring the minimal amount of crew time performing exercise countermeasures.

Deliverables: Data will guide decision of whether current countermeasures are protective or if improved countermeasures requiring flight validation studies are needed. Data will be taken to HSRF for decisions regarding the prescription and will be used to provide information to the muscle standard.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: Bed rest is required for this task for evaluation of new exercise prescriptions. If necessary, this data will feed in with the ISS Exercise Prescription Study into a final flight validation study using the ISS as the Mars transit analog.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Task: (ECP – via directed study)  
New Hardware Development – TBD

ECP will evaluate novel hardware concepts for use in the crew exploration vehicle and lunar outpost. Expertise will be leveraged from multiple NASA centers and from external entities via Small Business Innovation Research (SBIR) initiatives. Candidate hardware will be evaluated in ambulatory individuals, flight-analogs and in then in flight if effective on the ground.

Deliverables: New exercise hardware will be delivered.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: This will be a ground-based study to develop the hardware; if required, a follow-on ISS flight validation study will occur.

Task: (NSRBI)  
Integrated Endurance and Resistance Exercise Countermeasures Using a Gravity-Independent Training Device

Extended spaceflight as well as existence on the moon and Mars will require exercise equipment and training protocols designed to maintain physical fitness and general health. NASA has determined that current flight-rated exercise hardware is not appropriate for use on the future Crew Exploration Vehicle. These studies will investigate protocols designed to maintain both cardiovascular and musculoskeletal fitness using a gravity-independent multi-mode exercise device (M-MED), which has been identified by NASA as potential flight hardware. M-MED can provide high-resistance either strength or low-resistance endurance-mode exercises. Phase I will include ground-based integrated strength and cardiovascular exercise training under normal weight-bearing conditions. Phases II and III will include application of this protocol with progressive levels of inactivity.

Deliverables: Data will guide the decision of whether the exercise prescription should be validated in flight.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.
**Task:** (NSRBI)
Integrated Endurance and Resistance Exercise Countermeasures Using a Gravity-Independent Training Device (cont'd)

**Required Platforms:** Initially this will be a ground-based study conducted at the PI institution. If a prescription should be validated, then ISS is required as the Mars transit analog.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>75</td>
<td>None</td>
<td>None</td>
<td>9 (if ISS required)</td>
<td>2 (if ISS required)</td>
</tr>
</tbody>
</table>

**Task:** (ECP – via NRA)
Hydration Effects on Muscle – TBD
Proposals were solicited in the 2008 NRA to answer the following questions. What are the effects of dehydration on muscle mass, strength, power, and fatigability? What are the mechanisms of those effects? What is the effect of gender? How do the effects of dehydration contribute to the muscle "deconditioning" associated with long-duration bed rest or hind limb suspension?

**Deliverables:** This data will feed into the ISS Exercise Prescription Study.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** TBD

**Task:** (ECP – via NRA)
Gender Effects on Muscle – TBD
Proposals were solicited in the 2008 NRA to answer the following questions. What are the mechanisms of the gender effects on loss of exercise capacity and muscle function (including muscle mass, strength, power, and fatigability) during long-duration bed rest? Are gender specific countermeasures needed? If so, what are the best countermeasures to protect both men and women?

**Deliverables:** This data will feed into the ISS Exercise Prescription Study.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** TBD

M3: **What tasks will be required for Exploration missions?** The muscle discipline should be part of a larger, multi-disciplinary group to define these tasks. They will be primarily EVA tasks, and study groups are currently evaluating these proposed EVA tasks.

M4: **What are the physiologic costs of Exploration mission tasks?** Much of this data exists within other groups (Desert Research and Technology Study (D-RATS), EPSP EVA Physiology, Systems and Performance, etc). The fitness effort for given tasks can be bracketed with available information. This information can be used to assess fitness requirements.

M6: **Can a standardized performance measure of readiness for Exploration mission tasks be developed?** This should be a cross-disciplinary protocol that includes sub-tasks and measures that cover all affected disciplines. Work should be done in conjunction with ongoing EPSP activities. The team emphasizes that the testing of individual should not be continued unless this data can be directly related to performance and function.
**Task:** (ECP – via directed study; collaborators include Constellation Program Ground and Mission Ops SIG and Constellation Program working groups (e.g., CEV Cockpit Working Group, etc.))

**Critical Mission Task (CMT) Assessment**

The human performance tasks that will be required in order to assure mission success and safety will be identified (e.g., post landing egress, suited 10-kilometer walk-back, and emergency crewmember rescue). The muscle performance requirements to perform these tasks will then be determined by biomechanical and metabolic analyses obtained during performance of these tasks.

**Deliverables:** Results from this study will feed into the Function Task Test task as well as the Lunar EVA task. It will also be used to provide information regarding the muscle standard.

**Required Delivery Milestone:** FY2013 – performance decrements information needed to support mission operations definition.

**Required Platforms:** Ground based studies utilizing the partial gravity simulator (POGO) and the Neutral Buoyancy Lab. Bed rest facilities including the lunar analog will be utilized if required. Validation of the tasks will require lunar surface operations.

**M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars?** Ground-based work should be conducted to carefully build and test potential exercise equipment. In addition to the physiologic outcomes, equipment should be designed and tested so that hardware reliability and functionality are ensured. A series of bed rest and other ground-based studies should be designed to supplement the work discussed above. All bed rest studies should employ a multi-discipline, multi-project approach. The studies should include appropriate multi-disciplinary performance measures. Listed are some suggestions for issues that could be addressed in bed rest studies: optimum loading on treadmill; optimum volume vs. intensity of exercise; multidisciplinary performance enhancers (pharmaceutical/diet, mechanical, etc.); develop EVA tasks during bed rest and test effects on physiological and performance measures; 1/6 g bed rest and performance measures; 3/8 g bed rest and performance measures.

**Tasks:**

- Lunar EVA Study – TBD
  This task is referenced within the HHC Infrastructure section – see gaps HHC1 and HHC2.
- Lunar Analog Bed Rest Development
  This task is referenced within the HHC Infrastructure section – see gaps HHC1 and HHC2.
- An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions
  This task is referenced within the Risk of Accelerated Osteoporosis section – see gap B15.

**SM7: Can an integrated post-flight functional task performance test be used on returning ISS crewmembers to obtain performance decrements?** This gap is meant to develop and validate operational tests to define the linkage between functional capabilities and physiological changes. This test should include planetary EVA-like activities The goal of this product is to define crewmembers’ post-flight capabilities and disabilities, and to educate them about their risk of injuries, which will help them consciously avoid potentially dangerous activities. This might also define capabilities during early days on a planetary surface. This product will also provide crewmembers and the rehabilitation team members with more objective information regarding their recovery. This test is not germane to understanding how crewmembers will perform during Lunar EVAs since the conditions (duration of microgravity exposure) during this testing are dissimilar to the Lunar surface.
Task: (ECP – via directed study)
STS/ISS Functional Task Test
During space flight, astronauts experience alterations in multiple physiological systems due to exposure to microgravity. These physiological changes include sensorimotor disturbances, cardiovascular deconditioning, loss of muscle mass, and strength. These changes lead to disruption in the ability to ambulate and perform functional tasks during the initial reintegration to a gravitational environment and may cause significant impairments in performance of operational tasks immediately following landing on a planetary surface. To date changes in functional performance that result from physiological changes have not been systematically documented. Therefore, the goal of this study is to develop and evaluate an integrated set of functional and physiological tests and then use these tests to determine how post-flight changes in sensorimotor, cardiovascular and muscle physiology impact post-flight functional performance. These tests will be performed pre and post-flight on astronauts exposed to short and long-duration space flight. The STS/ISS Functional Task Test will assess operational relevance of these changes by measuring the performance of specific exploration tasks (e.g., simulated seat egress, ladder climb, hatch opening, etc.). Additionally changes in functional performance will be mapped to standard muscular, neurological, and cardiovascular measures. Data obtained from this study will facilitate the design of countermeasures that specifically target the physiological systems responsible for impaired functional performance.

Deliverables: Crew performance space normal data and physiological systems that require countermeasures in order to preserve performance of functional tasks will be identified. Information will also be provided to the muscle standard as well as to HSRF.

Required Delivery Milestone: FY2013 – performance decrements information and a validated countermeasure are needed to support mission operations definition.

Required Platforms: STS (short term flights)
   ISS (long term flights)

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 (13 Shuttle and 13 ISS)</td>
<td>None</td>
<td>None</td>
<td></td>
<td>None</td>
<td>6.3</td>
</tr>
</tbody>
</table>

Task: (ECP – via directed study)
Bed Rest Functional Task Test
A battery of functional tasks (see STS/ISS Functional Task Test above) will be assessed before and after bed rest (simulated micro/partial gravity). The ability of targeted countermeasures to maintain performance of functional tasks will be examined.

Deliverables: Crew performance space normal data and physiological systems that require countermeasures in order to preserve performance of functional tasks will be identified. Information will also be provided to the muscle standard as well as to HSRF.

Required Delivery Milestone: FY2013 – performance decrements information and a validated countermeasure are needed to support mission operations definition.

Required Platforms: The bed rest ground analog (6° head down tilt) is required for ground studies.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Task: (ECP – via directed study)
Hypovolemia Factors of Influence Studies – TBD
The effects of specific human factors such as gender, initial fitness level and hydration status on the ability to perform functional mission tasks will be assessed as supplemental studies.

**Deliverables:** Results will feed into the Functional Task Test Study.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** This is a ground-based study.

Task: (ECP – via directed study)
Gender Factors of Influence Studies – TBD
The effects of specific human factors such as gender, initial fitness level and hydration status on the ability to perform functional mission tasks will be assessed as supplemental studies.

**Deliverables:** Results will feed into the Functional Task Test Study.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** This is a ground-based study.

Task: (ECP – via directed study)
Level of Fitness Factors of Influence Studies – TBD
The effects of specific human factors such as gender, initial fitness level and hydration status on the ability to perform functional mission tasks will be assessed as supplemental studies.

**Deliverables:** Results will feed into the Functional Task Test Study.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** This is a ground-based study.

**N9: Can nutritional countermeasures mitigate muscle loss?** This is a medium priority gap. Proposals for nutritional supplementation are appropriate for bed rest studies. They should contain protocols that can be easily implemented in an operational environment. All groups working on this gap should standardize their techniques and measurements. The team should rely on the clinical literature in support of this gap.

**N15: Can nutrition/nutrients mitigate O2/radiation risks?** This is a low priority gap; flight work should not go forward until the nutrition SMO and related ground studies are complete. Expanded collaboration with the radiation team is recommended.
**Task:** (NSBRI)
Redox Modulation of Skeletal Muscle Function in Microgravity

The current project evaluates selected compounds, nutritional supplements, and pharmacologic agents that may oppose oxidative stress in muscle and protect against weakness and fatigue. The experimental approach is designed to identify and develop countermeasures for human testing in the near-to-mid term. Initial experiments will define the loss of oxidant regulation that occurs with muscle unloading. Subsequent studies will evaluate compounds for protective effects on muscle function. The efficacy of each compound tested in this project is supported by preliminary data from animal studies, human trials or both. Each compound is approved for systemic administration to humans.

**Deliverables:** Based on results of this activity; HHC is determine if any future work will be done in this area.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** This is a ground-based study.
Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance

- (SM7) Integrated post-flight functional task performance test

Supports mission ops/deficiency

- Functional Task Test, Shuttle, ISS, Bed Rest (Bloomberg, Directed Study)
- Hypoalgesia Factor (TBD, Directed Study)
- Gender Factor (TBD, Directed Study)
- Level of Fitness Factor (TBD, Directed Study)
- Exploration tasks
  - (M3) Exploration tasks
  - (M4) Metabolic costs of Exploration tasks
  - (M6) Standardized performance measures

Critical Mission Task Assessment (Directed Study)

Use FTT as CM eval tool?

- Validation CM to mitigate risk
- Interm mission ops of performance decrements
- All FTT activities feed into a standard recommendation

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.

* These studies are listed multiple times to answer several gaps
### Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance

**Performing Exercise Volumes and Intensity**

<table>
<thead>
<tr>
<th>Volume (Wk)</th>
<th>Days per Week</th>
<th>Exercise Intensity</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>Moderate to Heavy</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>High</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>Very High</td>
<td>-</td>
</tr>
</tbody>
</table>

**Exercise Volume Progression (Wk)**

- **Week 1**: Initiate with low volume, moderate intensity exercises.
- **Week 2**: Increase volume slightly, maintain moderate intensity.
- **Week 3**: Continue increasing volume, adding more challenging exercises.
- **Week 4**: Maximal volume reached, focus on maintaining intensity.

**Equipment for Exercise**

- Resistance bands
- Weight plates
- Yoga mats

**Training Regimen**

- **Monday**: Back / Bicep / Tricep / Cardio
- **Tuesday**: Leg Day / Cardio
- **Wednesday**: Rest Day
- **Thursday**: Full Body Workout
- **Friday**: Rest Day
- **Saturday**: Optional Cross-Training / Cardio
- **Sunday**: Rest Day

**Maintenance of Endurance**

- **Endurance Training**: Incorporate long-distance runs, cycling, swimming.
- **Interval Training**: Short bursts of high-intensity activity interspersed with recovery periods.
- **Circuit Training**: High-intensity, short-duration workouts that target multiple muscle groups in sequence.

**Nutritional Considerations**

- **Protein**: Essential for muscle repair and growth. Aim for 1.2-1.8 g/kg body weight per day.
- **Carbohydrates**: Important for energy during training. Consume 3-4 g/kg body weight per day.
- **Fats**: Support overall health and provide energy. Consume 1-1.5 g/kg body weight per day.

**Supplements**

- **Creatine**: May enhance muscle growth and recovery. Take 20 g/day for 2 weeks, then 5 g/day.
- **Whey Protein**: Provides high-quality protein. Consume 30-40 g/day.

**Rest and Recovery**

- **Sleep**: Aim for 7-9 hours per night. Use recovery modes and techniques to enhance sleep quality.
- **Hydration**: Stay well hydrated throughout the day to support muscle function and recovery.
- **Stretching and Massage**: Incorporate into training regimens to improve flexibility and reduce muscle stiffness.

**Monitoring Progress**

- Track weekly metrics such as body weight, muscle mass, and performance levels.
- Adjust training programs as necessary based on feedback and performance goals.

---

*These activities are listed multiple times to ensure several days of rest per week.*
Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance

(Q9) Nutrition mitigate muscle loss?
(N15) Nutrition can mitigate oxidative risks?

Redox Modulation of Muscle Function (Rels)

Based on data from PI pursue study?
RISK OF REDUCED PHYSICAL PERFORMANCE CAPABILITIES DUE TO REDUCED AEROBIC CAPACITY – CRITICALITY: LUNAR OUTPOST – L, MARS – C

Astronauts’ physical performance during a mission, including tasks in microgravity and fractional gravity, is critical to mission success. Setting minimum fitness standards and measuring whether crew can maintain these standards will document the effectiveness of maintenance regimens.

Context of Risk for Exploration

In addition to reduced skeletal muscle strength and endurance, reduced aerobic capacity may put mission success at risk. Evidence demonstrates that aerobic capacity is markedly reduced in response to space flight and space flight analogs. Sustained sub-maximal activities (even walking on a planetary surface) could become difficult to perform given large enough decrements in aerobic capacity. As outlined for muscle performance it will also be essential to identify Critical Mission Tasks and associated aerobic costs in order to design and validate effective exercise countermeasures for mission success. Current collaborative efforts with ESA are obtaining in-flight measurements of VO\textsubscript{2}\text{max} aboard ISS. These measurements can be used as a baseline for future research to “optimize” or reduce the amount of in-flight exercise necessary to maintain performance. It was also recommended that VO\textsubscript{2}\text{max} should be obtained during 6° head down tilt bed rest for comparison purposes.

Strategy for Mitigation

Although the strategy to mitigate this risk will follow the general strategy of defining space normal, determining mechanisms and then developing countermeasures, the research planned will be closely tied to efforts investigating impaired performance due to reduced muscle mass, strength and endurance as well as hardware development.

Gaps

M1: What is the current state of knowledge regarding exercise performance? This gap is closed; the deliverable has been met and can be referenced in the TBR HRP Deliverables Database.

M7: Can the current in-flight performance be maintained with reduced exercise volume? This gap should determine the effects of reduced in-flight exercise; this is a high priority gap. Efforts should be made to try to improve efficiency of the current ISS regime. Identification of which combinations of CEVIS, TVIS, and RED will result in the optimum balance of fitness in the least amount of time could decrease the amount of required exercise time. These studies should be performed in combination with in-flight measurements of exercise performance, and will give broader insight into what is truly required for the maintenance of fitness with the current devices, as well as into what exercise types will be required for the Moon and Mars.

M8: What is the minimum exercise regimen needed to maintain fitness levels for tasks? This gap is also asking if exercise, in addition to EVA tasks, is required during 6-month stays on the Moon. If exercise were required, what would be the correct prescription? In addition, assessment of reduced exercise volume on in-flight performance should be completed. The following questions should also be examined: a) how can suit/task related injuries be prevented? B) is the current exercise regimen appropriate for 1/6g and c) is the current exercise regimen appropriate for 3/8g – this is a lower priority question for future work.

M9: What is the minimum set to equipment needed to maintain those (M8) fitness levels? This gap should be filled in three parts. The second treadmill that is being built for ISS can be assessed for performance and reliability. New hardware should be developed as soon as possible for lunar missions.
Development of hardware for Mars can be developed using information from the ISS and Lunar hardware. The Moon will serve as a test bed for the equipment that is selected for Mars.

M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars? Ground-based work should be conducted to carefully build and test potential exercise equipment. In addition to the physiologic outcomes, equipment should be designed and tested so that hardware reliability and functionality are ensured. A series of bed rest and other ground-based studies should be designed to supplement the work discussed above. All bed rest studies should employ a multi-discipline, multi-project approach. The studies should include appropriate multi-disciplinary performance measures. Listed are some suggestions for issues that could be addressed in bed rest studies: optimum loading on treadmill; optimum volume vs. intensity of exercise; multidisciplinary performance enhancers (pharmacological, diet, mechanical, etc.); develop EVA tasks during bed rest and test effects on physiological and performance measures; 1/6 g bed rest and performance measures; 3/8 g bed rest and performance measures.

### Tasks:

<table>
<thead>
<tr>
<th>Task</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flywheel Prescription Optimization – TBD</td>
<td>M7, M8, M9 and M10</td>
</tr>
<tr>
<td>ISS Exercise Prescription Study</td>
<td>M7, M8, M9 and M10</td>
</tr>
<tr>
<td>Integrated Countermeasure Study – TBD</td>
<td>M7, M8, M9 and M10</td>
</tr>
<tr>
<td>New Hardware Development – TBD</td>
<td>M7, M8, M9 and M10</td>
</tr>
<tr>
<td>Integrated Endurance and Resistance Exercise Countermeasures Using a Gravity-Independent Training Device</td>
<td>M7, M8, M9 and M10</td>
</tr>
</tbody>
</table>

M3: What tasks will be required for Exploration missions? The muscle discipline should be part of a larger, multi-disciplinary group to define these tasks. They will be primarily EVA tasks, and study groups are currently evaluating these proposed EVA tasks.

M4: What are the physiologic costs of Exploration mission tasks? Much of this data exists within other groups (Desert RATS, EPSP, etc). The fitness effort for given tasks can be bracketed with available information. This information can be used to assess fitness requirements.

M6: Can a standardized performance measure of readiness for Exploration mission tasks be developed? This should be a cross-disciplinary protocol that includes sub-tasks and measures that cover all affected disciplines. Work should be done in conjunction with ongoing EPSP activities. The team emphasizes that the testing of individual should not be continued unless this data can be directly related to performance and function.

### Task:

<table>
<thead>
<tr>
<th>Task</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Mission Task (CMT) Assessment</td>
<td>M3, M4 and M6</td>
</tr>
</tbody>
</table>
M10: What is the correct set of ground-based studies (bed rest and others) to optimize exercise prescriptions for Lunar Outpost and Mars? Ground-based work should be conducted to carefully build and test potential exercise equipment. In addition to the physiologic outcomes, equipment should be designed and tested so that hardware reliability and functionality are ensured. A series of bed rest and other ground-based studies should be designed to supplement the work discussed above. All bed rest studies should employ a multi-discipline, multi-project approach. The studies should include appropriate multi-disciplinary performance measures. Listed are some suggestions for issues that could be addressed in bed rest studies: optimum loading on treadmill; optimum volume vs. intensity of exercise; multidisciplinary performance enhancers (pharmacological, diet, mechanical, etc.); develop EVA tasks during bed rest and test effects on physiological and performance measures; 1/6 g bed rest and performance measures; 3/8 g bed rest and performance measures.

**Tasks:**
- **Lunar EVA Study** – TBD
  This task is referenced within the HHC Infrastructure section – see gaps HHC1 and HHC2.
- **Lunar Analog Bed Rest Development**
  This task is referenced within the HHC Infrastructure section – see gaps HHC1 and HHC2.
- **An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions**
  This task is referenced within the Risk of Accelerated Osteoporosis section – see gap B15.

CV2: What is VO2max in-flight and immediately post-flight? It has been discouraged to measure VO2max on R+0, because of the possibility of injury to the crewmember, so it has been suggested that a reasonable compromise would be to obtain in-flight measurements as late as feasible and obtain plasma volume measurements after landing. Also, the cardiovascular laboratory should work with the exercise physiology laboratory to ensure that muscle performance is measured in a similar timeframe as VO2max is measured. No further research into this area is recommended until this gap is filled. However, it is recommended that the cardiovascular discipline work with the muscle discipline and the Exercise Physiology Laboratory to find the minimum exercise prescription necessary to maintain in-flight VO2max.

M2: What is the current status of in-flight and post-flight exercise performance capability? What are the goals/targets for protection with the current in-flight exercise program? The relationships between in-flight exercise and fitness and performance levels are not well understood. It is not clear how the combination of the three types of available exercise (Crew Exercise Vibration Isolation System (CEVIS), Treadmill Vibration Isolation System (TVIS), and Resistive Exercise Device (RED)) lead to maintenance of fitness. Factors that limit understanding of crewmember fitness are: 1) the ISS exercise equipment has not been uniformly available to all crewmembers; 2) exercise programs are individualized for each crewmember, based on their individual preferences; 3) in-flight VO2max has not been possible; and 4) an arbitrary minimum amount of daily exercise time (2.5 hours) has been set and enforced. The impact of this limited knowledge is that it is difficult to make detailed recommendations about what types of exercise will be needed for future missions to the Moon and Mars, other than to recommend that the same suite of exercise equipment be manifested for these missions.
Task: (ECP – via directed study)
Evaluation of Maximal Oxygen Uptake (VO₂max) and Submaximal Estimates of VO₂max Before, During and After Long Duration International Space Station Missions

The specific aims of this evaluation are to measure VO₂max during and following long duration missions and to assess the validity of using submaximal measurements of heart rate (HR), oxygen consumption (VO₂) to track changes in aerobic capacity. In addition, non-invasive measurements of cardiac output (Qc) will be performed during exercise to determine if measurement of Qc will improve the accuracy of the submaximal estimations of VO₂max. For this proposed evaluation, crew members participating in ISS missions of ≥ 90 days will perform graded cycle exercise tests to their volitional maximum effort prior to, every 30 days during, and following flight. Measurements obtained during these tests will include HR, VO₂, and Qc. During these tests, ECG will be monitored real-time as a safety precaution. Expected results from this evaluation will include accurate VO₂max measurements from astronauts participating in long duration space flight and observation of the pattern of change across mission duration. Additionally, the evaluation will allow NASA to determine if submaximal exercise testing data will provide results that allow accurate estimation of the crewmembers’ aerobic capacity status during and after space flight.

Deliverables: Results from this study will determine if the current countermeasures are protective and need only optimization (e.g., reduced volume, time) or if improved countermeasures and flight validation studies are needed. In addition, results will be used to provide information to the aerobic capacity standard as well as inform the HSRF.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: ISS is required for the initial flight study; a concurrent ground-based flight analog bed rest will be initiated if initial results indicate an improved countermeasure is needed. The improved countermeasures will be validated on board the ISS.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>9.5kg/Inc</td>
<td>None</td>
<td>9</td>
<td>3</td>
</tr>
</tbody>
</table>

Task: (ECP – via directed study)
Hypovolemia as A Model Of Space Flight: Cardiovascular Exercise Effects
Loss of plasma volume is hypothesized to be a major contributing factor to reduced aerobic capacity in response to space flight. An established ground-based model of microgravity-induced hypovolemia will be used to determine the effect of reduced plasma volume on VO₂max.

Deliverables: Results from this study will feed into the VO₂max flight study.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: Ground-based hypovolemia model
Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity

Gaps: (M7-9) Exercise volumes, regimens, equipment; (M10) Ground-based studies to optimize exercise for Exploration

NSBRI
- Integrated CM Using Gravity-Independent Device (Adams)
- Flywheel Prescription Optimization* (TBD, Directed Study)
- New HWY Development* (TBD, Directed Study)
- Integrated CM Study* (TBD, Directed Study)
- ISS Exercise Prescription* (Directed Study)

ECP
- Hyperventilation Studies/VO2 add on* (Lee, Directed Study)
- ISS VO2 Max SMO* (Moore, Directed Study)

Note: These activities mitigate risk to a long-duration Lunar and Mars missions. The activities are conducted in the 2008-2022 timeframe because of the availability of ISS as a Mars transit analog.

Update SFHSS aerobic capacity standard
Inform mission ops about hardware actions and prescriptions
Based on data from all studies, recommend standard update

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.
These studies are listed multiple times to answer several gaps.
Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance

Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity

Gaps: (M3, M4, M6) What are Exploration tasks, their costs and performance measures?

ECP Critical Mission Task Assessment (Directed Study)

Gap: (M10) Correct Lunar ground-based studies?

ECP Lunar EVA Study (Directed Study)

FAP Lunar Analog development (Directed Study)

NSBRI Integrated Musculoskeletal CM for Lunar Missions (Lunar)

Supports mission sustainability

Lunar surface data
(Lunar analog and validation of lunar CMs)

Lunar validation studies
(Lunar CM)

Yes

Lunar Bed Rest CM Studies

1) Interim mission ops of potential Lunar CM YES

Is Lunar EVA protective?

Lunar Bed Rest CM Studies

NO

Lunar EVA Study

Lunar Bed Rest CM Studies

NO

Lunar Bed Rest CM Studies

Continue? Continue? Continue?

Valuable CM on Lunar surface?

C0 CM to mitigate risk

NO

54
RISK OF COMPROMISED EVA PERFORMANCE AND CREW HEALTH DUE TO INADEQUATE EVA SUIT SYSTEMS – CRITICALITY: LUNAR OUTPOST – I, MARS – I

Improperly designed EVA suits can result in the inability of the crew to perform as expected, and can cause mechanical and decompression injury. Suit developers must fully understand the impact of the suit design on crew performance and health to ensure properly designed mobility, pressures, nutrition, life support, etc.

Operational Relevance and Risk Context

Constellation Missions to the moon and Mars will include frequent EVAs involving exploration, science, construction and maintenance tasks. These missions may include up to 30 times more EVA hours than during the Apollo era. The effectiveness and success of these missions is dependent on designing EVA systems and protocols that maximize human performance capabilities. It would not be feasible to perform the Constellation EVAs using Apollo suit designs. Limited mobility, dexterity, center of gravity and other features of the suit required significant crew compensation to accomplish mission objectives.

Strategy for Mitigation

The Human Research Program has recommended that the EVA Physiology, Systems and Performance Project work with the Constellation EVA Systems Project to develop and execute an integrated human testing program across multiple environments. The testing program will collect the objective data needed to make informed design decisions to create EVA systems that optimize human health and performance across the spectrum of anticipated exploration operational concepts.

Gaps

EVA1 (new): What models & techniques are required to evaluate various suit designs and operational concepts to optimize crew health and performance?

Replaces old gaps:

EPSP6: What work efficiency indices (WEI) metrics of EVA can be used to measure evolution of EVA systems?

EPSP7: What surface ops concepts could maximize human performance of mission tasks as well as protect crew health?

M3: What tasks will be required for lunar sortie, outpost, and Mars missions?

SM8: No functional requirements for lunar and Mars surface ambulation have been devised
Task: (EPSP some studies will be in collaboration with Constellation EVA Systems Project Office (ESPO))

EVA Human Performance Data Collection Series I – Mark-III Suit

Conduct a series of studies to examine factors that may affect human performance while working in an EVA suit. Parameters to be examined include suit weight, mass, center of gravity (CG), pressure, biomechanics and mobility. Studies will be performed in a number of analog environments in both unsuited/’shirt-sleeve’ conditions and using the Mark-III technology demonstrator suit. Multiple analog environments are required because no single analog environment adequately simulates the range of partial gravity conditions required to evaluate all aspects of human performance contributing to EVA success. Each analog will provide a piece of the puzzle that will allow a more thorough understanding of EVA performance.

Test activities will include characterizations of ambulation and exploration type activities, such as ambulation on level and inclined surfaces, ambulation while carrying a load, rock collection, shoveling, kneeling, recovery from a fall, and simple exploration and construction tasks using hand tools and power tools. Data collected will include metabolic rates, subject anthropometrics, time series motion capture, ground reaction forces, subjective ratings of perceived exertion (RPE) and operator compensation using the modified Cooper-Harper rating scale. Any conditions that result in suit-induced trauma will also be noted.

Data collected in these studies will be used to create an EPSP human performance database, a repository in which data from a variety of operational concepts and testing conditions can be accessed and shared with other projects and Elements as necessary. Data from these studies will also be used to generate the suit controllability predictive algorithm, which is a model that can be used to predict several human performance variables based on suit characteristics, subject anthropometrics, and operations concepts. The algorithm is planned as a design tool to enable development of suits that increase efficiency in crew health and performance.

Deliverables:
- EPSP human performance database and database inputs
- Post-test reports resulting from individual tests within the data collection series
- Suit controllability predictive algorithm
- Data delivery to ECP, NxPCM, and SHFH per TBD data sharing agreements

Required Delivery Milestone: A majority of the studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1 (initial capability: launch/abort/entry (LAE) and microgravity EVA) Preliminary Design Review (PDR) (TBD FY09-10) and Suit Configuration 2 (lunar surface operations) Systems Design Review (SDR) (FY11). Follow-on studies to validate the algorithm will be conducted as needed to provide inputs to subsequent design reviews.

Studies to refine requirements for Mars suits may be performed during lunar operations (FY20 and beyond).
**Task:** (EPSP some studies will be in collaboration with Constellation EVA Systems Project Office (ESPO))
Human Performance Data Collection Series I – Mark-III Suit (cont’d)

**Required Platforms:**
Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), parabolic flight, and NASA Extreme Environment Mission Operations (NEEMO)
Lunar surface operations

**Resources Required:**
Crew and Thermal Systems Division (CTSD) personnel support and facility usage are required for all tests and provision of Mark-III suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all suited and matched shirtsleeve control tests and are desired for all other tests.

---

**Task:** (EPSP some studies will be in collaboration with Constellation ESPO)

**EVA Human Performance Data Collection Series II – I-Suit or Alternate Suit**

Where possible, EPSP will collect data comparable to the Mark-III testing series in using the I-Suit or alternate suit and during selected unsuited trials. The anthropometric range (95th percentile male) that the Mark-III suit effectively accommodates is limited due to the suit’s structure and weight. According to JSC Committee for the Protection of Human Subjects (CPHS) recommendations, further testing is required to allow expansion of subject population demographics. Use of the I-Suit or alternate will permit subjects of smaller build to complete the series of tests, thereby enhancing statistical power of the data set. In addition, data collection using a second suit will help to verify that Series I data truly reflect human performance parameters and not suit design characteristics, and will permit initiation of algorithm validation to specific analogs.

As with Series I, data collected in these studies will be used to populate the EPSP human performance database and, in turn, to generate the suit controllability predictive algorithm.

**Deliverables:**
EPSP human performance database and database inputs
Post-test reports resulting from individual tests within the data collection series
Suit controllability predictive algorithm
Data delivery to ECP, NxPCM, and SHFH per TBD data sharing agreements

**Required Delivery Milestone:** This test series is dependent upon the availability of the I-Suit or a comparable alternate suit. Due to delays in suit contractor selection, this series may be performed using a Constellation suit prototype. Series II data must be acquired and input into the suit controllability predictive algorithm with sufficient lead time to provide valid algorithm to Constellation by Suit 2 PDR (FY12). Additional follow-on studies to validate the algorithm may be conducted as needed to provide inputs to subsequent design reviews. Studies to refine requirements for Mars suits may be performed during lunar operations (FY20 and beyond).

**Required Platforms:**
Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), parabolic flight, and NASA Extreme Environment Mission Operations (NEEMO)
Lunar surface operations

**Resources Required:**
CTSD personnel support and facility usage are required for all tests and provision of Mark-III suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all suited and matched shirtsleeve control tests and are desired for all other tests.
**Task:** (EPSP some studies will be in collaboration with Constellation ESPO)

**Work Efficiency Index (WEI) Studies**

Total EVA work efficiency index (WEI) is defined as:

$$\frac{\text{EVA Time}}{(\text{Total suit, airlock prep + pre-breathe + airlock depress, repress + post EVA})}$$

Current NASA EVA Total WEI is 0.39 – 0.51. Constellation EVA Systems Project documentation contains requirements stating that EVA WEI shall be 3.0 or greater. Many factors contribute to WEI, including vehicle systems, suit systems, and operational protocols.

To address this gap, EPSP will perform evaluations of WEI based on current knowledge and concepts of operations. WEI evaluations will be performed during existing lunar analog studies and will measure the efficiency of different operations concepts and trends in WEI as operational concepts evolve. WEI evaluations will also be performed to address gaps EVA 4 and EVA 5 & 6.

**Deliverables:**

Recommendations for WEI metrics for EVA and methods to improve WEI per TBR Customer Service Agreements with Constellation ESPO.

WEI indices to inform Operational Concepts studies for optimizing human performance, crew safety, and mission operations.

**Required Delivery Milestone:** Inputs were provided in FY07 to EVA Level III SRR based on studies performed during NEEMO missions. Additional studies will continue through FY17, with inputs to Suit Configuration 2 and Surface Operations design reviews. Follow-on flight validation and optimization studies will occur during lunar surface operations.

**Required Platforms:**

Lunar analog testing environments, such as Neutral Buoyancy Laboratory (NBL), NASA Extreme Environment Mission Operations (NEEMO), Desert Research and Technology Study (D-RATS), and Haughton Mars Project (HMP)

Lunar surface operations

---

**Task:** (EPSP)

**Operations Concepts Studies**

Conduct analyses of studies performed in lunar analog environments to evaluate the impacts to human performance of various exploration EVA operations concepts provided by Constellation and/or Constellation Architecture Team – Lunar (formerly LAT-2). Results of these analyses, combined with data from the EPSP human performance database, will be used to generate Life Sciences Implications Reports pertaining to given design reference missions. Flight validation and optimization studies will occur during lunar surface operations.

**Deliverables:**

Inputs to Life Sciences Implications Reports which will include (but may not be limited to) metabolic and life support consumables profiles of lunar mission tasks.

Reviews of Constellation operational documents and comments via Review Item Discrepancies.

**Required Delivery Milestone:** Studies will be performed through FY17, with inputs to Suit Configuration 2 and EVA Mission Operations design reviews, including, respectively, SRR (FY10, 13), PDR (FY12, 14), Critical Design Review (CDR) (FY16, 15), and Suit 2 System Acceptance Review (SAR) (FY18). Follow-on flight validation and optimization studies will occur during lunar surface operations.

**Required Platforms:**

Lunar analog testing environments, such as NASA Extreme Environment Mission Operations (NEEMO), Desert Research and Technology Study (D-RATS), and Haughton Mars Project (HMP)

Statistical analysis and modeling capability

Lunar surface operations

---

**EVA 2 (new): What are the physiological and biomechanical stimuli associated with various suit designs and EVA tasks?**
Replaces old gaps:

EPSP1: What parameters of EVA suit design affect human performance, and how can these designs be modified to increase efficiency in crew health & performance?

EPSP2: How much cardiovascular and resistive exercise and ground reaction force (GRF) dose does EVA provide?

EPSP3: What are the metabolic costs and ground reaction force (GRF) doses associated with EVA tasks?

M4: What are the physiological costs of tasks required?

EPSP13: How can heat rejection/suit cooling capability be improved to enhance contingency responses?

B12: How does the EVA suit influence characteristics of falling?

B13: What are the acceptable load and torque ranges a crewmember can experience during a specific mission?

<table>
<thead>
<tr>
<th>Task: (EPSP in collaboration with ECP) Characterize EVA Stimuli</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assimilate all physiologic data collected during Human Performance Data Collection Series I &amp; II studies (see gap EVA1) into EPSP human performance database and share data within HRP. Calculate cardiovascular exercise and resistive exercise doses provided by exploration EVA tasks. Calculate ground reaction forces and estimate impacts to bone and other human systems for a variety of operations concepts and suit designs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantified cardiovascular &amp; resistive exercise</td>
</tr>
<tr>
<td>Quantified ground reaction forces</td>
</tr>
<tr>
<td>Identified maximum acceptable joint loads and torque ranges</td>
</tr>
<tr>
<td>Identified maximum acceptable heat storage capacity</td>
</tr>
<tr>
<td>TBD bone modeling</td>
</tr>
</tbody>
</table>

| Required Delivery Milestone: Metabolic rate requirements were provided to the Human Systems Integration Requirements (HSIR) document (CxP 70024) in FY07. Data deliveries will be provided to ECP based upon TBD data sharing agreements. Other inputs will be to Constellation documents via change request (CR) and Review Item Discrepancy (RID) processes for design reviews according to TBR customer service agreements. |

| Required Platforms: Statistical analyses and modeling capability; Biomechanics analysis software packages |

EVA 3 (new): What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health & safety?

Replaces old gaps:

EPSP1: What parameters of EVA suit design affect human performance, and how can these designs be modified to increase efficiency in crew health & performance?

M5: How will suit limit performance of lunar sortie, lunar outpost, and Mars missions?

SM9: Idealize design of EVA suit for optimized surface ambulation characteristics
EPSP4: What are the quantities of consumables required to support EVA in lunar sortie, lunar outpost, and Mars missions? How can these consumables be managed best?

EPSP5: What are the energy/hydration requirements and associated waste management requirements of EVA and what kind of integrated delivery/management systems can be supported in an EVA suit?

N8: What are the energy/nutrient requirements of EVA? What is the best delivery system for these nutrients?

EPSP6: What work efficiency indices (WEI) metrics of EVA can be used to measure evolution of EVA systems?

EPSP8: What are the biomedical monitoring requirements of an EVA suit for each phase of lunar & Mars missions?

EPSP9: What suit-human biomechanical interaction aspects of the EVA suit design affect protection of crew health, and what design changes or countermeasures can be implemented to protect crew health?

EPSP13: How can heat rejection/suit cooling capability be improved to enhance contingency responses?

SM8: No functional requirements for lunar and Mars surface ambulation have been devised

B12: How does the EVA suit influence characteristics of falling?

B13: What are the acceptable load and torque ranges a crewmember can experience during a specific mission?

Where replaced gaps overlap with those gaps replaced by new EVA4, the intent is that tasks for EVA3 are PERTINENT TO REQUIREMENTS DEFINITION.

| Task: (EPSP some studies will be in collaboration with Constellation ESPO) |
| Human Performance Data Collection Series I – Mark-III Suit |
| Human Performance Data Collection Series II – I-Suit or Alternate Suit |
| In addition to addressing gap EVA1, data provided by the Human Performance Data Collection Series’ will allow identification of suit characteristics, systems, and consumables that optimize human performance during performance of EVA tasks. These tests also provide a methodical, scientific approach to hardware evaluations such that future evaluations of suited human performance may be consistently performed. |

| Deliverables: |
| EVA Suit Test Standard Measures per TBR customer service agreements with Constellation ESPO. |
| Recommended requirements (pertaining to performance and crew health during EVA) for Level III & Level IV Constellation documents: |
| Suit design parameters (weight, mass, cg, pressure, kinematics, joint torques and loads) |
| Nutrition, hydration, and waste management |
| Physiological data sensors |
| Thermal regulation and consumables usage |

| Required Delivery Milestone: EPSP will provide task deliverables to Suit 1 and Suit 2 design reviews and appropriate corresponding Constellation documents per TBR Customer Service Agreements with Constellation EVA Systems Project Office. |

| Required Platforms: Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), parabolic flight, and NASA Extreme Environment Mission Operations (NEEMO) |
### Resources Required:
CTSD personnel support and facility usage are required for all tests and provision of I-Suit, alternate, or prototype suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all suited and matched shirtsleeve control tests and are desired for all other tests.

### Task: (EPSP with NBL and AFT)
**Determine Energy, Nutrient, Hydration and Waste Management Requirements**

Work with Flight Surgeons and with experts in the JSC Nutritional Biochemistry Laboratory (NBL) and Advanced Food Technology (AFT) Project to analyze data collected in the Human Performance Data Collection series’ to quantify the water, nutrients, and anticipated waste products required for surface EVA operations. These data will then drive requirements for waste management systems and EVA nutrition/hydration systems (see EVA4).

**Deliverables:** The results of this analysis will be compared with Level II requirements addressing nutrition, hydration, and waste management that are currently in the HSIR document and will be used to generate recommendations for Level III and Level IV requirements.

**Required Delivery Milestone:** Analysis will be complete by FY10 to provide inputs to Suit Configuration 2 SRR (~FY11).

**Required Platforms:** Statistical analysis and modeling

### Task: (EPSP)
**CG and Stability Evaluations**

Augment Human Performance Data Collection Series testing with specific measures to understand the role of suit center of gravity (CG) on stability and fall avoidance and recovery and in partial gravity environments. Studies will identify the cg location under varying conditions and measure the forces imparted to the body due to falling in an EVA suit. Prototype suits will also be evaluated.

**Deliverables:**
- Recommendations for suit center of gravity to avoid falling
- Recommendations to operational concepts to avoid falling
- Data for fall frequency and contact forces model

**Required Delivery Milestone:** Work will be complete by FY10 to provide inputs to Suit Configuration 2 SRR (~FY11). Follow-on studies will be performed as needed to evaluate prototype suits’ impact on stability/falling.

**Required Platforms:** Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), NEEMO, parabolic flight

**Resources Required:** Statistical analysis; modeling capability

### Task: (EPSP)
**Apollo Video Fall Frequency Analysis**

Analyze Apollo EVA video to estimate percentage of falls. Create model to analyze worst-case falls, such as from a ladder. Combine results with data collected in CG and fall forces studies to develop model of fall frequency and contact forces based on surface ops concepts.

**Deliverables:**
- Model of fall frequency and contact forces based on operations concepts
- Operations concepts to limit falls

**Required Delivery Milestone:** Initial modeling will be complete by FY11 to provide inputs to Surface Ops Systems Design Review. Model will be updated based on results from evaluation of prototype suites. Additional analysis will be performed as needed.
<table>
<thead>
<tr>
<th><strong>Required Platforms</strong>:</th>
<th>Statistical analysis and modeling capability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resources Required</strong>:</td>
<td>Statistical analysis; modeling capability</td>
</tr>
</tbody>
</table>
### Task: (EPSP) Develop Mission Metabolic Profiles

Project metabolic loads and determine mission metabolic profiles based on operational concepts provided by Constellation Program and/or Constellation Architecture Team – Lunar team. Profiles will be created for suited intravehicular operations and surface EVA tasks. Metabolic data collected in Human Performance Data Collection studies will be used to determine consumables quantities needed to support mission operations.

Studies and analyses will be performed to develop recommendations for suit design and operational concepts requirements. For example, an oronasal mask will be evaluated as a solution to minimize consumable usage.

**Deliverables:**
- Mission metabolic profiles
- Recommendations for consumables requirements
- Recommendations for operational concepts regarding consumables usage and management

**Required Delivery Milestone:** Preliminary studies and analyses will be completed in FY09 to provide inputs to Suit Configuration 1 PDR (TBD FY09). Additional inputs will be provided to Surface Operations and Suit Configuration 2 SRRs (~FY10) and PDRs (~FY12). Additional studies may be performed as operational concepts are updated. Validation studies will be performed during mission operations.

**Required Platforms:**
- Modeling capability, such as MATLAB
- Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), Rockpile, and Haughton Mars Project (HMP)
- Lunar surface operations

### Task: (EPSP) Biomedical Monitoring Requirements

Work with flight surgeons and biosensor technology experts to identify biomedical monitoring requirements for suited operations: launch/entry/abort, microgravity EVA, and surface EVA.

**Deliverables:**
- Recommendations for biomedical monitoring requirements

**Required Delivery Milestone:** Inputs were provided during FY07 to Level II documentation (HSIR) and ESPO documentation during the Level III and Level IV SRRs. Additional inputs will be provided as necessary during EVA Suit Configuration 1 and Configuration 2 PDRs (TBD FY09, FY12, respectively).

**Required Platforms:** Workshops, teleconferences/videoconferences

### Task: (EPSP in collaboration with Space Medicine and EVA Systems Project Office) Suit-Induced Trauma Data Mining

Perform retrospective data mining to identify suit-induced trauma that has occurred during NBL training and during microgravity EVAs. Create searchable database to track suit injury and populate with historical data. Continue to monitor suit-induced trauma in future Shuttle and ISS training and flight activities and enter cases in database. In addition, identify suit-induced trauma that occurs during suit development/evaluation tests and concept of operation studies for exploration missions.

**Deliverables:**
- Identify mechanisms of suit-induced injury/trauma
- Suit Injury Database

**Required Delivery Milestone:** Phase I of the database will be complete in FY09; implementation of phase II is TBD.

**Required Platforms:** N/A (data mining)
### Task: (EPSP) Suit/Human Biomechanical Interactions Studies

Conduct a series of studies to identify mechanism of suit-induced injury. Studies currently in progress include the following: 1) EMU shoulder harness assessment to investigate shoulder injuries due to limited range of motion; 2) studies to measure fingertip pressure and blood flow while working in suit gloves; 3) assessing the role of moisture in fingernail damage sustained while working in suit gloves; 4) studies to determine the magnitude of oxidative stress in EVA crewmembers. Additional studies will be performed as necessary if new injuries are encountered during development of Constellation EVA suits.

**Deliverables:**
Recommendations for suit design to mitigate suit-induced trauma

**Required Delivery Milestone:** A majority of the studies will be completed by FY10 in order to provide inputs to Suit Configuration 2 SRR (~FY11). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15, according to TBR customer service agreements with ESPO.

**Required Platforms:** Lunar analogs, including Partial Gravity Simulator (Pogo/ARGOS), Neutral Buoyancy Laboratory (NBL), parabolic flight, glove box

### Task: (EPSP in collaboration with CTSD personnel, Constellation ESPO and external consultants) Occupant Protection – Biodynamics Modeling

EPSP will work with a team of experts to determine appropriate methods for modeling and prediction of potential crew injuries. Activities include conducting data mining of injury databases (NASCAR, CIREN, IRL, military, etc); assessment of impact simulation and injury prediction methodologies, and cross-validation of multiple biodynamics models (MADYMO, LS-DYNA, THUMS and the Brinkley Model) using data from 6 driving CEV load cases and automotive racing crashes. The team will generate design concepts that implement automotive racecar occupant protection principles to a space suit/craft system which increasingly uses features of the suit for occupant protection. The objective of this task is to deliver a verified and validated operational model to support development of the best occupant protection system possible that maximizes crew safety during Orion vehicle ascent, ascent aborts, landing (water and contingency land landing), and through the post landing and recovery phase.

**Deliverables:**
Verification tool for occupant protection requirements
Recommend occupant injury prediction and impact simulation techniques (and limitations) appropriate for Orion command module
Recommend analysis techniques and models appropriate for use by Orion command module
Recommend and provide appropriate human mass properties data for use by Orion command module
Recommend appropriate impact acceleration/occupant injury criteria

**Required Delivery Milestone:** Preliminary results will be complete in early FY09 to provide inputs to Orion and Suit Configuration 1 PDRs (FY09). Follow-on analyses will be performed as needed through Suit Configuration 1 Critical Design Review (FY11).

**Required Platforms:** Modeling capability

**Resources Required:**
Availability of valid crash data from NASCAR and Indy Racing League
**Task:** (EPSP in collaboration with Space Medicine, Constellation ESPO and external consultants)

**Occupant Protection – Definition of Acceptable Risk**

EPSP will work with Space Medicine crew surgeons and other experts to systematically define the highest level of acceptable injury risk during CEV landings consistent with a successful program based on key mission drivers such as:

- crew health, safety and performance considerations in the immediate landing environment; long-term crew health considerations including medical policy and future flight status; programmatic success criteria in context of all mission phases; public opinion and ethical considerations; and balancing the risk vs. reward (utility) for the landing environment in context of all mission phases. The team will also provide context to put CEV landing risk in perspective with other military and civilian vehicle operations.

**Deliverables:**
- Define operationally relevant injury scale
- Define acceptable injury risk within programmatic and operational constraints

**Required Delivery Milestone:** Preliminary results will be complete in early FY09 to provide inputs to Orion and Suit Configuration 1 PDRs (FY09). Follow-on analyses will be performed and HSIR requirements updated as needed through Suit Configuration 1 CDR (FY11).

**Required Platforms:** Workshops, teleconferences/videoconferences, modeling capability

---

**Task:** (EPSP Studies using an EVA suit will be performed in collaboration with CTSD and Constellation ESPO)

**Liquid Cooling Garment Studies**

Conduct studies to evaluate current US and Russian liquid cooling and ventilation garments (LCVG) and prototype liquid cooling garments. Evaluations will be conducted during suit tests and in thermal chambers.

**Deliverables:**
- Post-test report detailing thermal performance and comparison of LCVG garments
- Recommendations for design of advanced liquid cooling garments to improve heat rejection/cooling capability
- Recommendations for improved thermal control to enhance contingency responses

**Required Delivery Milestone:** Preliminary studies will be complete by the end of FY09 in order to provide inputs to Suit Configuration 1 PDR (TBD FY09) and provide updates to HSIR document, Rev. D (FY09-10). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15 and according to TBR customer service agreements with Constellation ESPO.

**Required Platforms:** Partial Gravity Simulator (Pogo/ARGOS) and thermal chamber

**Resources Required:**
CTSD personnel support and facility usage are required for all tests and provision of EVA suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all tests performed in an EVA suit.

---

**EVA4 (new): What technologies and in-suit countermeasures can be integrated into the EVA suit to optimize crew performance, health & safety?**

Replaces old gaps:

EPSP4: What are the quantities of consumables required to support EVA in lunar sortie, lunar outpost, and Mars missions? How can these consumables be managed best?

EPSP5: What are the energy/hydration requirements and associated waste management requirements of EVA and what kind of integrated delivery/management systems can be supported in an EVA suit?

N8: What are the energy/nutrient requirements of EVA? What is the best delivery system for these nutrients?“
EPSP6: What work efficiency indices (WEI) metrics of EVA can be used to measure evolution of EVA systems?

EPSP9: What suit-human biomechanical interaction aspects of the EVA suit design affect protection of crew health, and what design changes or countermeasures can be implemented to protect crew health?

EPSP13: How can heat rejection/suit cooling capability be improved to enhance contingency responses?

Where replaced gaps overlap with those gaps replaced by new EVA3, the intent is that tasks for EVA4 are PERTINENT TO MEETING OR IMPROVING UPON REQUIREMENTS (i.e. new technologies).

<table>
<thead>
<tr>
<th>Task: (EPSP Studies using an EVA suit will be performed in collaboration with CTSD and Constellation ESPO) Suit Trauma Countermeasures Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Following work to identify mechanisms of suit-induced trauma (see EVA3), work with materials experts in CTSD to develop concepts and prototype of suit trauma countermeasure garment. Candidate concepts include airbags, strain-aligning material and crushable foam. Garment will be evaluated in tests conducted by EVA Systems Project Office to simulate landing loads and during suit tests conducted at lunar analogs. Subsequent studies will be performed to evaluate iterations of and improvements to garment design and to validate the countermeasures in suit prototypes, qualification units, and flight articles and during lunar surface operations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations for design of countermeasures to mitigate suit-induced trauma</td>
</tr>
</tbody>
</table>

| Required Delivery Milestone: Development and testing of preliminary concept will be complete in FY09 prior to Suit Configuration 1 PDR (TBD FY09-10). Results from further testing will be complete and recommendations provided prior to the Suit Configuration 2 PDR (FY12). |

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS) and parabolic flight</td>
</tr>
<tr>
<td>Lunar surface operations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resources Required:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTSD personnel support and facility usage are required for all tests and provision of EVA suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all tests performed in an EVA suit.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task: (EPSP Studies using an EVA suit will be performed in collaboration with CTSD and Constellation ESPO) Advanced LCVG Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on results of existing LCVG studies (see EVA3), provide recommendations for and evaluate advanced liquid cooling garments in Mark-III and prototype suits, qualification units, and flight articles. Validation studies with flight suits will occur during lunar surface operations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-test reports detailing performance of advanced liquid cooling garments using Mark-III, prototype, qualification units, and flight article EVA suits per standard measures, with inputs to design updates as needed</td>
</tr>
</tbody>
</table>

| Required Delivery Milestone: Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations. |

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS) and parabolic flight</td>
</tr>
<tr>
<td>Lunar surface operations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resources Required:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTSD personnel support and facility usage are required for all tests and provision of EVA suit is required for suited testing. Crewmembers assigned to the EVA Branch of the astronaut office are required as test subjects for all tests performed in an EVA suit.</td>
</tr>
</tbody>
</table>
**Task:** (EPSP with NBL, AFT Project, and Constellation ESPO)  
**Evaluate Concepts for Nutrient and Water Delivery System**  
Work with experts in Advanced Food Technology Project and the JSC Nutritional Biochemistry Lab to develop concepts for the format of nutrition and hydration sources (energy bar, gel, etc.). Work with crew office to evaluate concepts and obtain crew consensus. Work with suit design team to develop concepts for nutrition and hydration delivery systems and waste management systems. Evaluate concepts in ground tests.

**Deliverables:**
- Recommendations for nutrient and water delivery systems
- Recommendations for waste management systems

**Required Delivery Milestone:** Preliminary studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1PDR (TBD FY09-10) and further evaluations will result in recommendations prior to Suit Configuration 2 SRR (~FY11). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15 and according to TBD customer service agreements with Constellation ESPO.

**Required Platforms:** Lunar analog testing environments

**Resources Required:**
Astronaut test subjects or representatives to provide input to Crew Consensus Report

---

**Task:** (EPSP in collaboration with Constellation EVA Systems Project Office)  
**In-Suit Nutrient Delivery and Waste Management System Evaluations**  
Evaluate nutrition/hydration delivery systems and waste management systems in prototype and qualification unit suits. Work with crew office to evaluate delivery systems and obtain crew consensus. Work with suit design team to integrate systems for nutrition and hydration delivery systems and waste management into EVA suits. Follow-on flight validation and optimization studies with flight suits will occur during lunar surface operations.

**Deliverables:**
- Evaluation of prototype, qualification unit and flight article suits per standard measures with inputs to design updates as needed.

**Required Delivery Milestone:** Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review (SAR) in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations.

**Required Platforms:** Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS) and parabolic flight; Lunar surface operations

**Resources Required:**
Astronaut test subjects or representatives to provide input to Crew Consensus Report
### Task: (EPSP in collaboration with Exploration Medical Capability (ExMC))
**Biomedical Sensor Evaluations**
Work with Exploration Medical Capability (ExMC) Project to evaluate candidate biomedical sensors and integrated sensor systems during suit tests at lunar analog environments, such as Partial Gravity Simulator (Pogo/ARGOS), Desert Research and Technology Studies (D-RATS), Haughton Mars Project (HMP) or parabolic flight. Biomedical sensors to be evaluated may include non-adhesive electrodes, heart rate sensors, temperature sensors, CO$_2$ sensors and accelerometers.

**Deliverables:**
Recommendations for integrated biomedical sensor system concept

**Required Delivery Milestone:** A majority of the studies will be completed by the end of FY09 in order to provide inputs to Suit Configuration 1 PDR (TBD FY09-10) and Suit Configuration 2 SRR (~FY11). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15.

**Required Platforms:** Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS) and parabolic flight

---

### Task: (EPSP in collaboration with Constellation ESPO)
**Integrated Biomedical Sensor Systems Evaluations**
Evaluate integrated biomedical sensor systems provided by ExMC in existing and prototype suits, qualification units and flight articles. Validation studies with flight suits will occur during lunar surface operations.

**Deliverables:**
Post-test report, data from evaluations of sensor systems
Recommendations for integrated biomedical sensor system

**Required Delivery Milestone:** Suit Configuration 1 development and qualification testing will be complete by the System Acceptance Review in 2012. Suit Configuration 2 development and qualification testing will be complete by the System Acceptance Review in 2017. Evaluation of flight article suits will occur during lunar surface operations.

**Required Platforms:**
Lunar analogs such as Partial Gravity Simulator (Pogo/ARGOS) and parabolic flight
Lunar surface operations

**Resources Required:**
Astronaut test subjects or representatives to provide input to Crew Consensus Report

---

### Task: (EPSP)
**Bioadvisory Algorithm Laptop Demonstrator**
Develop bioadvisory algorithm laptop demonstrator that monitors biomedical and suit parameters, calculates metabolic rate, and uses voice recognition capability to interact with the crewmember. The algorithm will be evaluated using data collected during Human Performance Data Collection Series I & II and other suitable lunar analogs tests. Additional work will refine the algorithm equations and user notifications.

**Deliverables:**
Bioadvisory algorithm laptop demonstrator, with equations and logic flowchart describing functions of the algorithm

**Required Delivery Milestone:** Work will be completed by the end of FY09 in order to provide inputs to Suit Configuration 2 Systems Requirements Review (~FY11). Follow-on studies will be conducted as needed to provide inputs to subsequent design reviews in FY11-FY15 and according to TBR customer service agreements with Constellation ESPO.

**Required Platforms:** Statistical analysis, EPSP human performance database

---

### Task: (EPSP in collaboration with Constellation EVA Systems Project Office)
**Work Efficiency Index (WEI) Studies**
In addition to the WEI activities to address gaps EVA1 and EVA5-6, EPSP will evaluate suit components and systems that may improve WEI, such as integrated biosensor systems that are quick don/doff and drink bags that require less preparation time.

**Deliverables:** Recommendations for EVA WEI metrics and methods to improve WEI per TBR Customer Service Agreements with Constellation ESPO.

**Required Delivery Milestone:** Inputs were provided in FY07 to EVA Level III SRR based on studies performed during NEEMO missions. Additional studies will continue through FY17, with inputs to Suit Configuration 2 and Surface Operations design reviews. Follow-on flight validation and optimization studies will occur during lunar surface operations.

**Required Platforms:**
- Lunar analog testing environments, such as Neutral Buoyancy Laboratory (NBL), NASA Extreme Environment Mission Operations (NEEMO), Desert Research and Technology Study (D-RATS), and Haughton Mars Project (HMP)
- Lunar surface operations

**Resources Required:**
Astronaut test subjects or representatives to provide input to Crew Consensus Report

### EVA 5 (new): How can decompression sickness (DCS) risk be characterized, mitigated, and/or treated?

Replaces old gaps

EPSP10: What are the risks and risk definitions of decompression sickness (DCS)? How can DCS risk be managed?

EPSP11: What is the best way to acclimate to slightly hypoxic LSAM and lunar habitat environments?

**Task:** (EPSP)
Define Acceptable DCS Risk
Define acceptable DCS risk for different phases of lunar architecture (e.g. short-duration vs. long-duration missions) based on concept of operations. This activity will include several meetings with external experts to discuss DCS policy and definitions of mission success as well as predictive modeling.

**Deliverables:**
- Inputs/updates to DCS requirements HSIR document (CxP70024)
- Exploration DCS Risk and Contingency Plan
- Recommendations to operational concepts for mitigating DCS risk

**Required Delivery Milestone:** This work will be complete by mid-FY09, with annual updates to the Exploration DCS Risk and Contingency Plan

**Required Platforms:** Statistical analysis and modeling

**Task:** (EPSP)
Integrated DCS Predictive Model
Develop Integrated DCS Predictive Model, which is a tissue gas bubble dynamics model. The model will incorporate parameters such as: pre-breathe conditions, suit pressure, breathing gas composition, depress/repress rates, and duration of exposure. Data used to develop this model will be provided by numerous EPSP studies. The model will in turn be used to develop operations concepts to manage DCS risk and contingencies. Operational concepts will be validated during lunar surface operations

**Deliverables:**
- Integrated DCS Predictive Model
- Operational concepts/protocols to manage and treat DCS risk
<table>
<thead>
<tr>
<th><strong>Required Delivery Milestone</strong>: Concepts of operations will be defined and inputs provided to the Mission Operations SRR (FY13). Additional studies and analysis will be performed as needed to provide inputs to subsequent reviews and according to TBR customer service agreements with Constellation ESPO.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required Platforms</strong>:</td>
</tr>
<tr>
<td>Statistical analysis and modeling</td>
</tr>
<tr>
<td>Lunar surface operations</td>
</tr>
</tbody>
</table>

| **Task**: (EPSP) |
| Pre-breathe Protocol Development |
| Conduct a series of tests to develop a pre-breathe protocol for lunar surface operations that minimizes DCS risk while meeting WEI requirements. Initial studies will test accept criteria for worst-case scenario, and will involve a 36-hr saturation protocol. Subsequent studies will utilize an exercise-equivalent saturation protocol to evaluate intermittent recompression. Saturation procedure will be performed again to optimize the pre-breathe protocol and to validate procedures. Operational validation will also be performed during lunar surface operations. |
| **Deliverables**: Validated pre-breathe protocol(s) |
| **Required Delivery Milestone**: Testing will begin in FY10 and will be complete by FY17 for the Suit Configuration 2 / Surface Ops SARs (FY18). |
| **Required Platforms**: |
| Hypobaric chambers |
| Lunar surface operations |

| **Task**: (EPSP) |
| Work Efficiency Index (WEI) Studies |
| In addition to the WEI activities to address gaps EVA1 and EVA4, EPSP will perform WEI evaluations during development of improved pre-breathe protocols. |
| **Deliverables**: Recommendations for EVA pre-breathe protocol WEI metrics and methods to improve WEI per TBR Customer Service Agreements with Constellation ESPO. |
| **Required Delivery Milestone**: WEI studies will augment pre-breathe protocol development testing and will be complete by FY17 for the Suit Configuration 2 / Surface Ops SARs (FY18). Follow-on flight validation and optimization studies will occur during lunar surface operations. |
| **Required Platforms**: |
| Hypobaric chambers |
| Lunar surface operations |

<p>| <strong>Task</strong>: (EPSP) |
| Hypoxia Studies |
| Conduct studies to evaluate operations concepts and determine how human performance is affected due to transitions within and long-term exposures to hypoxic environments. Concepts will be validated during lunar surface operations. |
| <strong>Deliverables</strong>: Recommendations for concept of operations to acclimate to the Lunar Surface Access Module (LSAM) and lunar habitat environment |
| <strong>Required Delivery Milestone</strong>: Work to be complete by FY17 for the Suit Configuration 2 / Surface Ops SARs (FY18) |</p>
<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypobaric chambers</td>
</tr>
<tr>
<td>Lunar surface operations</td>
</tr>
</tbody>
</table>
## Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

**Gap (EVA1)** What models/techniques are required to evaluate various suit designs/ operational concepts to optimize crew health & performance?

**Gap (EVA3)** What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

---

### EPSP

**EVA Human Performance Data Collection Series**

- Mark III suit & associated studies
- Integrated Suit Tests (Pogo)
- IST2, IST3
- Neutral Buoyancy Lab
- Haughton-Mars Project
- G-8 Parabolic Flights
- Desert RATS

---

**TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements**

- Data points: EOB, N-FOC, and CTH

---

**Note:**

- Note 3: Mark III suit limits subject population to large persons (~5’2” T & ~160 lb wt.
- Note 4: Provide discipline expertise to CxP ESPO during evaluations using suit prototypes, quasi units, flight articles
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA1) How do different exploration EVA operational concepts impact crew health & performance?

Gap: (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

EPSP
EVA Human Performance
Data Collection Series II:
EVA3 distributor suit & associated studies

Integrated Suit Tests (Pogo)
TBD: IST-4.5 (5-Suit)

TBD: NEEMO

TBD Haughton-Mars Project

TBD Partial-Cycles Flights

TBD Desert RATS

Data/Assessment from Flight Testing Incorporated

TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements

Provide discipline expertise to CxP ESPO during evaluations using suit prototypes, qual units, flight articles
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA1) What models/techniques are required to evaluate various suit designs/operational concepts to optimize crew health & performance?

**EPSP Work Efficiency Index (WEI) studies**
- Data from Human Performance Data Collection Series 1 & 2 and Operational Concepts evaluations
- WEI analyses
- TBD: WEI studies
- Additional analysis due to changes to Ops Con?
- *Validate WEI during lunar surface operations*
- *Flight suits provided by CxP*

**EPSP Operations Concepts studies**
- Data from Human Performance Data Collection Series 1 & 2 and WEI studies
- Ops Con analyses
- TBD Ops Con studies
- Additional analysis due to changes to Ops Con?
- Validate performance during lunar surface operations
- *Flight suits provided by CxP*

Provide discipline expertise to CxP-ESPO during Ops Con evaluations
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

**EPSP**
- Determine energy, nutrient, hydration and waste management requirements and delivery concepts based on operational concepts.

**EPSP**
- Center of Gravity (CG) & Stability evaluations for lunar surface ops.

**Inputs to Suit 1 PDR & CDR, Suit 2 SRR**
- Data from Advanced Food Lab, CTSD

**Addition studies/analyses?**
- YES
- NO

**Additional Studies**
- YES
- NO

**TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements**
- Validate systems during lunar EVA

**Validate CG & Stability during lunar EVA**
- YES
- NO

**NO**
- Additional Studies

**Multiple Lunar Analog**
- YES
- NO

**Suit controllability predictive algorithm**
- YES
- NO

**Suit parameters database development**
- YES
- NO
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems
Gap: (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements

*ExMC provides candidate biosensors for evaluation
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

EPSP
Suit-induced trauma data mining and development of injury database

Data mining for suit-induced trauma during EVA training and flight activities

Identify cases of suit trauma during lunar EVA & landing

TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements

EPSP
Suit-human biomechanical interactions studies & countermeasures concepts

Multiple ground studies

Recommendations to ESPO for requirements/design concepts to mitigate suit trauma

Validate during lunar surface ops
### Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

**Gap:** (EVA3) What suit characteristics, systems, and consumables requirements are needed to optimize crew performance, health, & safety?

**EPSP** - Occupant Protection - Biodynamics Modeling

<table>
<thead>
<tr>
<th>EPSP</th>
<th>Occupant Protection - Definition of Acceptable Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recommendations to Orion Landing Tiger Team and ESPO for acceptable injury risk within programmatic/operational constraints</td>
</tr>
<tr>
<td></td>
<td>Additional Analyses</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

**TBD:** Transition to CxP ESPO Funding Per TBR Customer Service Agreements

<table>
<thead>
<tr>
<th>Program Level</th>
<th>Orion</th>
<th>EVA Suit</th>
<th>Lander</th>
<th>Mission Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRR</td>
<td>CDR</td>
<td>PDR-suit1</td>
<td>SRR-out2</td>
<td>PDR-out2</td>
</tr>
<tr>
<td>CDR-Initial Ops</td>
<td>PDR</td>
<td>CDR</td>
<td>CDR-out2</td>
<td></td>
</tr>
<tr>
<td>CDR</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Lunar Return</td>
<td>PDR-in-cap</td>
<td>CDR-in-cap</td>
<td>SRR-PDR</td>
<td>CDR</td>
</tr>
</tbody>
</table>

---

80
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA4) What technologies and in-suit countermeasures can be integrated into the EVA suit to optimize crew performance, health & safety?
Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems

Gap: (EVA4) What technologies and in-suit countermeasures can be integrated into the EVA suit to optimize crew performance, health & safety?

TBD: Transition to CxP ESPO Funding Per TBR Customer Service Agreements
Risk of Decompression Sickness (DCS) Due to Inadequate Acclimation or Rapid Depressurization

Gap: (EVA5) How can decompression sickness (DCS) risk be characterized, quantified, & treated?

Integrated DCS Stress Predictive Model (Tissue Bubble Dynamics) and operations concepts to manage DCS risk and contingencies.

Mission Operations Ops. Concepts to manage DCS risk:

- Develop & Refine Model
- Run model against various ops confs
- YES
- Does modeled DCS risk meet medical/mission constraints?
- NO
- Revise ops conf and/or develop countermeasure options

Exploration DCS Risk Definition & Contingency Planning

Initial Definition

Ops/Scenarios/Statistical Work

Annual Updates

DCS Treatment Modalities

- Chamber Trade Studies

- Dev. Real-time in-suit treatment concepts

Model validation on lunar missions
Risk of Decompression Sickness (DCS) Due to Inadequate Acclimation or Rapid Depressurization

**Gap (EVA5):** How can decompression sickness (DCS) risk be characterized, quantified, and treated?

---

**ISS V-5 Study (Use of exercise & partial DCS)**

- ISS V-5 Study
- Partial DCS

**EPSP**

- Met. Cost of Experimental
- Exercise Study
  - Directed: Webb (Brooks)

**Break-In Prebreathe Study**

- NASA-03-OBP-046: confines

**Nucleation Mechanisms Study**

- NASA-03-OBP-046: confine

**Prebreathe Exercise Equiv. Saturation Study**

- Refine prebreathe protocols

---

*Results of all studies inform gap EVA5 and annual Risk Definition updates"
RISK OF REDUCED SAFETY AND EFFICIENCY DUE TO AN INADEQUATELY DESIGNED VEHICLE, ENVIRONMENT, TOOLS OR EQUIPMENT – CRITICALITY: LUNAR OUTPOST – D, MARS – I

The habitability of the architecture, pressurized environment, tools, and equipment is critical for the existence of humans in space. Any inadequacies in the design of the environment or architecture can restrict or prevent the user from surviving in such extreme conditions and may impact safety and performance. Factors that affect the habitability must be assessed and properly addressed to ensure all potential hazards are mitigated or monitored. If the workspace, equipment and tools are not designed to be usable by the full range of crewmembers, and are not properly laid out, the likelihood of errors or crew inability to complete a task in a timely manner increases. Inconsistent design among subsystems and vehicles leads to negative transfer of training and increased likelihood of errors.

Operational Relevance and Risk Context

One of the most critical components for human presence in space has been ensuring that there are human systems standards in place that will provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards – SFHSS – (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure that there will be identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Strategy for Mitigation

The approach to mitigating this risk is to develop an understanding of the factors that contribute to this risk, identify gaps in our knowledge about these factors, and prioritize these gaps based on various criteria systematically applied. Then the highest priority gaps are addressed through directed or solicited research depending on the time frame and the complexity and specificity of the gap. Where there is a disconnect between critical gaps requiring addressing and a lack of funding, efforts are made to re-examine the programmatic priorities to ensure those of highest concern are being investigated.

The risk associated with reduced safety and efficiency due to inadequately designed vehicles, environments, tools or equipment focuses on the overall environment that the crew will live and work in. The focus can surround the development of hardware and interfaces, and how those interfaces will facilitate human performance and efficiency. Displays, controls, and procedures need to be appropriately designed and developed to allow for safe and efficient execution of tasks. Specific studies investigate the environment surrounding the crew, namely the acoustic environment, which can impact both health and performance. Other studies focus upon the vibration, acceleration and microgravity environment, again all having potential to impact human health and performance. The approach to mitigating this risk is to
develop a thorough understanding of the operational concepts, and determine methods, metrics and verification strategies to ensure that the hardware and environment are designed for human safety and productivity.

The strategy for mitigating this risk is closely connected to the strategy for addressing the Risk of Errors Due to Poor Task Design. The work captured under this risk contributes to understanding the capabilities and limits of human performance, which is essential to appropriate task design. When a task is designed, it is critical to determine if it can be accomplished by a single person or requires additional personnel, or assistance from robots or automation. When the spacecraft and equipment are designed, both the requirements of the task and the capabilities and limits of the crew have to be considered.

The specific selection choices of the highest priority gaps and tasks are based primarily on gap analyses. The SHFE project updates its gap analyses on an annual basis. This is necessary as research results and continual information drawn from crew debriefings has the potential of discovering additional gaps in knowledge. These updates assist in the preparation for the annual Science Review Panel. The original analysis carried out in 2006 was published as NASA/TP-2007-213739 (“Space Human Factors Engineering Gap Analysis Project Final Report,” C. Hudy and B. Woolford, 2007). An update was completed in spring 2007. The gaps are identified through reviews of the literature, of crew debrief summaries, and through interviews with more than a hundred users of human factors results, representing Engineering, Mission Operations, Flight Medicine, Training, the Crew Office, and others. We place particular emphasis on interviewing representatives from Constellation Program Office, the Human-System Integration Group, the Orion Project Office, the Cockpit Display Working Group, and other programmatic users of our products. The ‘small’ gaps or specific concerns identified from these sources are aggregated into more appropriate levels for which a specific task can be designed. For example, numerous users report gaps in design for workload: lack of consistency of definition; lack of easy to use methods to assess workload; lack of a way to verify that a requirement for workload has been met. These various individual-level concerns are captured in a gap, “There is no standardized non-intrusive measure of workload.”

After all concerns are mapped to gaps, the gaps are prioritized according to a number of criteria. Key criteria are importance to Constellation Program and need date. When we identify ‘TBRs’ or ‘TBDs’ in the Human Systems Integration Requirements, for example, these are assigned a very high priority. Ratings are solicited from management representatives of the offices from which gaps were identified.

After prioritization, the gaps that can be addressed within the budget are initiated through directed research or solicited through research announcements. Directed research is chosen for time critical results. Solicitations are used for gaps that are longer term and that can benefit from wider participation.

**Gaps**

**SHFE 2.1.8.1: How can we determine the effects of combined vibration and acceleration on task performance?**
### Tasks: (SHFE – Directed)

**Examining Human Performance Under Vibration and G-Load**

Unmitigated Ares first stage thrust oscillation produces unacceptably high vibrations to the crew in the Orion Command Module (CM). The health effects are well documented and requirements in CxP 70024 Human System Integration Requirements (HSIR) (Requirement HS3105) defines the ISO-weighted RMS values for allowable exposure.

Vibration also affects crew performance, and impacts reading, reaction time, and fine motor control. Specific vibration performance requirements are not provided in HSIR. Performance under vibration also depends on crew interfaces, tasks, and other induced environments. The task to conduct studies with:

- sixteen general population completed word or number reading task on fixed-base vibration platform
- sixteen general population trained and baselined on fixed-base platform, then completed number reading task on 20-G Centrifuge (G + Vibration)
- thirteen astronaut office subjects trained and baselined on fixed-base platform, then completed number reading and display rating tasks on 20-G (G + Vibration)

**Deliverables:**

- Data collection of astronaut office subjects
- Data Analysis and determination of effects of vibration and acceleration on performance

**Required Delivery Milestone:**

- FY09: Orion PDR Final Report on Centrifuge Study Results
- FY09: CR to NASA Standard and HIDH prior to Orion PDR

**Required Platforms:**

- Ground: Laboratory Test beds

---

### Tasks: (SHFE – New Directed Study or NRA)

**Examining Human Performance Under Vibration**

Unmitigated Ares first stage thrust oscillation produces unacceptably high vibrations to the crew in the Orion command module. The health effects are well documented and requirements in CxP 70024, Human System Integration Requirements (HSIR) (Requirement HS3105), defines the ISO-weighted RMS values for allowable exposure.

Vibration also affects crew performance, and impacts reading, reaction time, and fine motor control. Specific vibration performance requirements are not provided in HSIR. Performance under vibration also depends on crew interfaces, tasks, and other induced environments. The task to conduct studies with:

A simulated environment of the Lander vehicle and Lander Rover to assess the effect of vibration on performance in varying environments.

**Deliverables:**

- Data collection, analysis and determination of effects of vibration and acceleration on performance in each multiple, variable environments

**Required Delivery Milestone:**

- FY15: CR to NASA Standard and HIDH prior to Lander and Rover CDR
- FY15: Design solutions to Rover and Lander CDR

**Required Platforms:**

- Ground: Laboratory Test beds/Simulation Environments
**Tasks: (SHFE – Directed)**

*Examining Human Performance Under Vibration During Launch (SDBI 1904)*

Unmitigated Ares first stage thrust oscillation produces unacceptably high vibrations to the crew in the Orion command module. The health effects are well documented and requirements in CxP 70024, Human System Integration Requirements (HSIR) (Requirement HS3105), defines the ISO-weighted RMS values for allowable exposure.

Vibration also affects crew performance, and impacts reading, reaction time, and fine motor control. Specific vibration performance requirements are not provided in HSIR. Performance under vibration also depends on crew interfaces, tasks, and other induced environments. The task to conduct studies with:

Astronaut subjects performing specific reading tasks during Shuttle launches to assess effects of vibration. Data will be compared with results from Engineering DSO to measure actual vibration levels on Shuttle seats.

**Deliverables:**
- Data collection from astronaut subjects on Shuttle short duration missions
- Data Analysis and determination of effects of vibration on performance during launch conditions

**Required Delivery Milestone:**
- FY09: Shuttle data collection activities
- FY09: Design recommendations for Orion PDR
- FY10: Data analysis of Shuttle data sets
- FY10: Design solutions for Orion CDR
- FY10: CR to NASA Standard and HIDH to provide requirements for design solutions that mitigate effects of vibration

**Required Platforms:**
- Ground: Laboratory Test beds
- Flight: Shuttle (SDBI 1904)

**SHFE 2.1.9.1: How do we develop validated tools and models to verify Constellation vehicle acoustic design environment requirements?**

**Tasks: (SHFE – Directed)**

*Acoustic Modeling*

Acoustic modeling can be used to identify key noise sources, determine/analyze sub-allocated requirements, keep track of the accumulation of minor noise sources, and to predict vehicle noise levels at various stages in the development, first with estimates of noise sources, later with experimental data. Bench testing of isolated systems alone is not sufficient, as the installation effects are often not known. Acoustic modeling will be used to determine installation effects, reverberation (room geometry) effects, and will be used to identify propagation paths and possible noise controls, as well as develop an understanding of the resulting acoustic levels in the composite environment. Finally, acoustic modeling will be used to assist with the development and implementation of spaceflight acoustic materials and to predict their effectiveness including sound containment, absorption, and vibration isolation.

**Deliverables:**
- Determine, mockup, and model the effects on the Orion CM noise environment of closeout panel and stowage effects on airborne noise. Understand the relationship between mockup and model. Increase model fidelity.
- Determine, mockup, and model the effects on the Orion CM acoustic environment of ventilation system noise. Understand the relationship between mockup (real fan sources/geometry) and model. Use inputs of actual Orion fan noise to predict real Orion noise and evaluate Orion design. Increase model fidelity.
- Determine, mockup, and model the effects on the Orion CM noise environment of structure-borne noise. Understand the relationship between mockup (real fan vibration sources/geometry) and model. Increase model fidelity.
- Determine if mockup model complexity is adequate to address the needs of the Lander noise environment, and increase model fidelity accordingly.
**Required Delivery Milestones:**

FY09: Progress report on CEV mockup modeling including ventilation system
FY09: Progress report on CEV mockup modeling including Environmental Control and Life Support (ECLS) Wall, comparison of predictions with measurements
FY09: Progress report on CEV mockup modeling including realistic closeouts/stowage
FY09: Plan for validating structure borne noise model
FY09: Progress report on CEV mockup modeling including structure borne noise with SEA and FEM
FY09: Provision of mockup models for verification at PDR, detailed design
FY09: Delivery of Orion Model to Orion Project
FY10: SSDR Presentation for Orion ECLS
FY10: Submit RIDs and/or comments to Orion PDR based on evaluation using model
FY10: Provision of mockup models for verification at CDR, detailed design
FY10: Submit RIDs and comments to Orion CDR based on evaluation using 2g Model
FY10: CR to HIDH prior to Orion CDR to add acoustic requirements

**Required Platforms:**

Laboratory Test beds
Mockups

**SHFE 2.1a: What are the effects of habitable volume and architecture on safety and performance and how can an integrated evaluation of those effects be performed?**

**Tasks:** (SHFE – Directed)

**Effects of Architecture on Safety and Performance**

One of the first decisions made for any spacecraft module design is, what is the required habitable volume? This task will develop the knowledge to support this decision. Effects of volume on task efficiency will be one topic of study. Psychological effects of volume and architecture during long missions will be addressed. A decision support tool that organizes the results of this study will be developed. A standardized approach to evaluation of habitability features and to assessing their interactions will be developed in later work.

**Deliverables:**

Development of trade space tool for Lander to evaluate the effects of individual aspects of architecture on safety and performance as well as an evaluation of those effects from an integrated perspective
Refine the tool if needs of Lander necessitate further development
Develop and validate integrated Habitability evaluation model/tool with a focus on lunar short duration missions
Refine and modify the tool as required to accommodate 6 month lunar missions
Refine and modify the tool as required to accommodate lunar missions with a duration longer than 6 months
Refine and modify the tool as required to accommodate long duration surface system missions

**Required Delivery Milestones:**

FY13: Tradespace and evaluation tool delivery for Lander PDR
FY15: Evaluation tool for Lander CDR
FY18: Evaluation tool for Surface Systems
FY20: Evaluation tool for long duration Surface System missions

**Required Platforms:** Ground: Laboratory Test bed

**SHFE 2.3.a (SBIR): How can crews easily document human factors related issues that occur on orbit?**
**Tasks**: (SHFE – Directed)
Semantic Language and Tools for Reporting Human Factors Incidents

Operations in confined, isolated, and foreign environments can lead to impairments of human performance. This subtopic seeks methods for monitoring, modeling, and predicting human performance in the spaceflight environment for accurate and valid human system integration into vehicle design and operations. In particular, the Space Human Factors Engineering Project within the HRP is interested in obtaining timely and context-specific Human Factors (HF) incident data. Currently, space HF data come from crew debriefs. Such debriefs rely on retrospective recall, which could suffer delays of up to six months. Furthermore, opportunities to discuss HF issues in detail during these debriefs are limited. Consequently, the HRP sees the need to develop an automated human factors incident-reporting tool.

**Deliverables**:
Design, development, and implementation of informational database for reporting of human factors incidents

**Required Delivery Milestone**:
FY11 Preliminary database tool provided for Lander SRR
FY13 Final tool delivery for Lander PDR

**Required Platforms**:
Ground: Laboratory Test bed

**SHFE 2.3.1.1: How can we determine the effect of microgravity on spinal elongation?**

**Tasks**: (SHFE – Directed)
Spinal Elongation and its Effects on Seated Height in a Microgravity Environment

The purpose of the Spinal Elongation and its Effects on Seated Height in a Microgravity Environment study is to provide quantitative data as to the amount of change that occurs in seated height due to spinal elongation in microgravity environments. Spinal elongation has been observed to occur in crewmembers during space flight; however, it has only previously been recorded in the standing position with a limited number of subjects. Seated height data in microgravity is considered necessary to identify correctly the seated height projections of the crew in the Orion configuration. Correct projections of seated height should lead to a) proper positioning of the seats within the vehicle; b) maintaining adequate clearance for seat stroke in high acceleration impacts; c) providing proper fit in seats; d) proper placement of seats with respect to each other; and e) proper orientation to displays and controls. Additionally, data concerning the effects of spinal elongation on seated height would aid in the design of suit components as well as requirements for habitations and other vehicles.

**Deliverables**:
Spinal elongation induced seated height data for subjects exposed to microgravity environments.
Information relating to the seated height rate of change over time for astronauts subjected to microgravity.
Provide new information concerning seated height forward into the design of Constellation systems.

**Required Delivery Milestone**:
FY09: Completion of C-9 planning flights for hardware development, procedure validation
FY09 to FY11: Data collection on Shuttle and ISS subjects
FY09: Interim results/recommendations to Orion PDR
FY09: Interim results/recommendations to Orion PDR-Suit 1
FY09: CR to NASA Standard, HSIR, HIDH, and NASA Crewmember Medical Standards prior to Orion PDR and PDR-Suit 1 to add initial requirements based on initial results
FY10: Design solutions to Orion CDR
FY09: CR to NASA Standard, HSIR, HIDH, and NASA Crewmember Medical Standards prior to Orion CDR and CDR-Suit 1 to add initial requirements based on initial results
FY11: Design solutions to Orion CDR-Suit 1
FY11 to FY12: Data Analysis and Final Report on Results of Data Collection to Orion

**Required Platforms**:
Ground: Laboratory Test beds
Ground: C-9
Flight: Shuttle
SHFE 3.1.2.2.a: How do we ensure that the displays and control designs and technology developed for the operational environments of the Cx Program will improve performance and reduce errors?

***** This task also addresses the Risk of Error Due to Inadequate Information and the Risk of Error Due to Poor Task Design

<table>
<thead>
<tr>
<th>Tasks: (SHFE – Directed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information Presentation – Displays (Visual and Auditory)*****</td>
</tr>
</tbody>
</table>

Optimal displays are critical to crew performance and vehicle operations. Displays must meet the crew’s needs and be easy to use as Exploration missions may face the greatest autonomy challenge to date. The focus of visual displays is readability and usability of text, as well as display navigation. The focus of auditory displays is alarms. This is a requirements development activity, supplemented by some research or validation activities on the ground and in flight. This will result in the development of guidelines, requirements, and validation techniques for advanced information display solutions currently contemplated for the various Constellation Program spacecraft systems consistent with the smaller cockpit environments of the Orion CEV, the Lander, and surface rovers. These requirements and appropriate information will be provided to Orion, Constellation documentation (CxP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook.

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display design requirements</td>
</tr>
<tr>
<td>Display design recommendations</td>
</tr>
<tr>
<td>Assessment, selection, and test of display design enhancements that will maximize capability of Habitat</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY09 Display requirements and design recommendations to Orion PDR</td>
</tr>
<tr>
<td>FY09 CR to HSIR, HIDH, Orion Display Standards documentation prior to Orion CDR</td>
</tr>
<tr>
<td>FY10 Display design recommendations to Orion CDR</td>
</tr>
<tr>
<td>FY11 Display requirements to Lander SRR</td>
</tr>
<tr>
<td>FY13 Display design recommendations to Lander PDR</td>
</tr>
<tr>
<td>FY15 CR to HSIR, HIDH prior to Lander CDR</td>
</tr>
<tr>
<td>FY15 Design solutions to Lander CDR</td>
</tr>
<tr>
<td>FY17 Design enhancement recommendations for Habitat</td>
</tr>
<tr>
<td>FY19 Design enhancement solutions for Habitat displays</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground: Laboratory Test beds</td>
</tr>
<tr>
<td>Ground: Mockups</td>
</tr>
</tbody>
</table>
***** This task also addresses the Risk of Error Due to Inadequate Information and the Risk of Error Due to Poor Task Design

<table>
<thead>
<tr>
<th>Tasks: (SHFE – Directed)</th>
<th>Information Presentation – Controls****</th>
</tr>
</thead>
<tbody>
<tr>
<td>The development of proper controls is critical to preventing errors during human spaceflight. This becomes especially important when the majority of the controls will be software based. Crewmembers must be very aware of what they are manipulating on the screen, and must be able to do so under vibration and high-g, as well as in microgravity. They must be able to operate controls ungloved and with pressurized gloved hands. During launch and entry, crews will have no choice other than to use a remote cursor control device. If devices are inadequate for any of the above operational scenarios, crew safety will be compromised and risk loss of productivity. These requirements and appropriate information will be provided to Orion, Constellation documentation (CxP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control design requirements</td>
</tr>
<tr>
<td>Control design recommendations</td>
</tr>
<tr>
<td>Assessment, selection, and test of control design enhancements that will maximize capability of Habitat</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY09 Control requirements and design recommendations for Orion PDR</td>
</tr>
<tr>
<td>FY10 Control design solutions for Orion CDR</td>
</tr>
<tr>
<td>FY10 CR to HSIR, HIDH, Orion Display Standards Documentation prior to Orion CDR</td>
</tr>
<tr>
<td>FY11 Control requirements to Lander SRR</td>
</tr>
<tr>
<td>FY13 CR to update control requirements in HSIR, HIDH prior to Lander PDR</td>
</tr>
<tr>
<td>FY13 Control design recommendations to Lander PDR</td>
</tr>
<tr>
<td>FY15 CR to HSIR, HIDH for update to control requirements prior to Lander CDR</td>
</tr>
<tr>
<td>FY15 Design solutions for Lander CDR</td>
</tr>
<tr>
<td>FY17 Design enhancement recommendations to Habitat controls</td>
</tr>
<tr>
<td>FY19 Design enhancement solutions to Habitat controls</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground: Laboratory Test beds</td>
</tr>
<tr>
<td>Ground: Mockups</td>
</tr>
</tbody>
</table>
### Tasks: (SHFE – Directed)

**Information Presentation – Electronic Procedures and Fault Management**

Constellation Program vehicles will have much smaller interior volumes than the Shuttle, and a higher g and vibration profile during dynamic phases of flight. With crewmembers’ arms strapped to armrests, a “seated” operations mode will necessitate all crew-vehicle interactions being accomplished through one or more handheld devices. There will also be considerably less real estate available bringing real pressure to consolidate information onto as few displays formats as possible. Combined, these factors, along with hard pressures on the allowable mass of the vehicles, are forcing fundamental changes to the vehicle cockpits, dictating new and different concepts of vehicle operations. The design pressures are being strongly felt on operations that include performing and completing checklists of nominal and off-nominal procedures, and all checklists will be accessed and view on a customized electronic display format call an electronic procedures viewer (EPV). This task supports development, testing and validating the cockpit users interfaces needed to support procedure-related vehicles operations.

### Deliverables:

- Evaluation of advanced concepts for electronic procedures formatting and fault management
- Summary report on impacts of serial versus parallel access to fault-management related display information on fault management performance. Report will include preliminary recommendations and guidelines for the size and content of the EPV window during ascent/entry operations.
- Development of procedure standards for display of electronic procedures
- Investigation and development of enhancements for current designs and capabilities

### Required Delivery Milestone:

- **FY09:** Report summarizing “look-forward” and “look-back” behavior on the EPV.
- **FY09:** Report summarizing impacts of serial versus parallel access to fault-management related display information on fault management performance.
- **FY09:** Procedure design recommendations for Orion PDR
- **FY09:** CR to HIDH, HSIR, Orion Display Standards Documentation to add initial requirements prior to Orion PDR
- **FY10:** Procedure design solutions for Orion CDR
- **FY11:** Procedure requirements to Lander SRR
- **FY13:** Procedure design recommendations for Lander PDR
- **FY15:** Procedure design recommendations for Lander CDR
- **FY17:** Design enhancement recommendations for Habitat
- **FY19:** Design enhancement solutions for Habitat

### Required Platforms:

- Laboratory Test beds
- Mockups
### Tasks: (SHFE – Directed)

**Information Presentation – Human Performance Modeling**

In next-generation cockpits, there will be the capability to automate a wider spectrum of spacecraft operations that is the case today. When combined with the steady advances that are taking place in human-machine interface technologies, for any particular task or vehicle operation, the increasing options for human-machine functional allocation, and the increasing suite of interfaces that could support those options, something close to a combinatorial explosion in the space of possible operational concepts and supporting interfaces is occurring. Both potential deficiencies with targeted designs, and optimal design solutions, could well be missed in a highly resource-limited development environment that targets only a small number of candidate designs for human-in-the-loop evaluation. Fully validated Human Performance Modeling tools could be used to more exhaustively explore and prune the design space for targeted operational concepts, particularly those that involve performance shaping functions (such as vibration or sustained g) that render human-in-the-loop evaluations of more than a small handful of point solutions impractical.

### Deliverables:

- Model-based capability to generate complete sequence of behavioral primitives associated with the task of detecting, isolating, and recovering from ADAPT test bed malfunctions during dynamic phases of flight.
- Capability to generate variability in number and order of behavioral primitives that replicate levels of intra- and inter-participant variability obtained in FY 07 empirical evaluation
- Report on the approach to expanding capabilities of human oculometric model (HOM) to model and predict effects of vibration on spacecraft operational tasks.
- Capability to model effects of crewmember and vehicle vibration on fault management performance.
- Capability to model impacts of a variety of display design variables such as font size, color, and display clutter.
- Integrated suite of auditory, visual, and possible haptic interfaces between crewmember and ACAWS (i.e., root-cause and vehicle impact systems management software), including speech-based alarms, to help minimize time to determine root-cause failures and provide more effective aids for off-nominal situation management in high-vibration (dynamic phase of flight) environments. Perform human factors evaluations of off-nominal situation management with integrated interface display suite.
- Analyses of oculomotor behavior from Activity A to extend the stochastic capabilities of the ARC human performance model to the point where the model can accept, as input, a targeted spacecraft operational concept (such as fault detection, isolation, and recovery from an onboard systems malfunction) and generate the sequence of information acquisition activities (behavioral primitives) associated with performing the task. Also, initiate the process of expanding the model’s capabilities to generate predictions of operational impacts of performance shaping functions such as cabin vibration.

### Required Delivery Milestone:

- **FY09:** Model-based sequence of behavioral primitives associated with the task of detecting, isolating, and recovering from ADAPT test bed malfunctions during dynamic phases of flight.
- **FY09:** Capability to generate variability in number and order of behavioral primitives that replicate levels of intra- and inter-participant variability
- **FY09:** Report on the approach to expanding capabilities of human oculometric model (HOM) to model and predict effects of vibration on spacecraft operational tasks.
- **FY09:** CR to HIDH to add information obtained from human performance modeling research
- **FY10:** Fault management performance model of vibration of crew and vehicle.
- **FY10:** Modeling of display design variables.
- **FY10:** Integrated suite of auditory, visual, and (anticipated) haptic interfaces between crew and Advanced Caution and Warning System (ACAWS)
- **FY10:** Final Report on Analyses of Oculomotor Behavior

### Required Platforms:

- **Ground:** Laboratory Test beds
- **Ground:** Mockups

---

**SHFE 2.3.b:** How can existing models be modified to adequately represent the specified user population (e.g. field of view, visibility) in reduced gravity and be portable to other simulations environments?
**Tasks:** (SHFE – New Directed Study or NRA)

**Model Development and Applicability**

During equipment design and task planning, graphical computer models of humans can save time and avoid numerous design flaws by enabling visualization of the human interaction with the physical environment. Aircraft designers, automobile designers, and other industries rely heavily on human modeling. For NASA’s needs, the target population is different than the standard ones used by industry, and the varying gravity environments affect stature and posture, and may affect strength. This task will identify the critical differences that need to be captured in adapting commercially available models to NASA’s application.

**Deliverables:**

- Determine what population characteristics are critical to model development
- Model modification/test/validation/application

**Required Delivery Milestone:**

- FY13: Initial input based on results from model development to Lander PDR
- FY15: Final model delivered for use in Lander CDR
- FY15: CR to HIDH and HSIR based on information obtained from model development and application
- FY16: Final model delivery for use with Habitat

**Required Platforms:**

- Ground: Laboratory Test beds
- Ground: Mockups
Risk of reduced safety and efficiency due to an inadequately designed vehicle, environment, tools or equipment.

2.1 Effects of induced environment on performance

Gap: SHFE 2.1.3.1 How can we determine the effects of combined vibration and acceleration on task performance?

Effects of Vibration and Acceleration on Performance. (Directed Study)

SDBI 1904 – Effects of Vibration during Launch

Recommended and eventual CR to NASA Standard, HBDH

Required for input to Orion PDR

Required for input to Rover CDR

Required for input to Lander CDR

Design solutions for Lander CDR

Design solutions for Rover CDR

Simulation studies – Lunar Lander/Rover scenarios

(1) Recommendations for Orion PDR

(5) CR to NASA Standard and HBDH prior to Lander and Rover CDR

(3) CR to NASA Standard and HBDH prior to Lander and Rover CDR

(4) Design solutions for Lander CDR

(2) Design solutions for Rover CDR
Risk of reduced safety and efficiency due to an inadequately designed vehicle, environment, tools or equipment.

2.1 Effects of induced environment on performance

Gap: SHFE 2.1.3.1: How do we develop validated tools and models to verify Constellation vehicle acoustic design environment requirements?

Acoustic Modeling (Spacecraft Internal Acoustic Environmental Modeling Directed Research Project)
Risk of reduced safety and efficiency due to an inadequately designed vehicle, environment, tools or equipment.

2.3 Design of workspace, equipment, and tools

Gap: SHFE 3.1.2.a: How do we ensure that the displays and control designs and technology developed for the operational environments of the Orion Program will improve performance and reduce errors?

Displays (auditory/visual) Development (Information Presentation Directed Research Project) **

** Directed study also addresses other two SHFE Risks
Risk of reduced safety and efficiency due to an inadequately designed vehicle, environment, tools or equipment.

2.3 Design of workspace, equipment, and tools
Gap: SHFE 1.1.2.a: How do we ensure that the displays and control designs and technology developed for the operational environments of the CE Program will improve performance and reduce errors?

**Directed study also addresses other two SHFE Risks**
Risk of reduced safety and efficiency due to an inadequately designed vehicle, environment, tools or equipment.

2.3 Design of workspace, equipment, and tools

Gap: SHFE 3.1.2.a: How do we ensure that the displays and controls designs and technology developed for the operational environments of the Cx Program will improve performance and reduce errors?
Risk of reduced safety and efficiency due to an inadequately designed vehicle.

Design of workspace equipment.

Noise generated and its impact on the environment.

Vehicle design considerations.
The Risks in this part of the Appendix are aligned with
Section 2.2 –
Ensure That the Crew Can Accomplish the Cognitive,
Behavioral, and Team Aspects of the Mission
RISK OF BEHAVIORAL AND PSYCHIATRIC CONDITIONS – CRITICALITY: LUNAR OUTPOST – D, MARS – C

Behavioral issues are inevitable among groups of people, no matter how well selected and trained. Spaceflight demands can heighten these issues. The Institute of Medicine (IOM) report, Safe Passage, notes that Earth analog studies show an incidence rate of behavioral problems ranging from 3-13 percent per person per year. The report transposes these figures to 6-7 person crews on a 3-year mission to determine that there is a significant likelihood of psychiatric conditions emerging. Impacts of behavioral issues are minimized if they are identified and addressed early. The HRP must provide the best measures and tools to monitor and assess mood and to predict risk for and management of behavioral and psychiatric conditions prior, during and following spaceflight.

Operational Relevance Assessment and Recommendations

BHP research addresses the risk of behavioral and psychiatric conditions developing during or following an Exploration Mission. Early detection of stress or other risk factors during spaceflight is imperative to deter development of behavioral or psychiatric conditions which could seriously harm and negatively impact the individual or the crew, and pose serious consequences for accomplishing mission objectives or jeopardizing the mission altogether. Toward this end, BHP is developing methods for monitoring behavioral health during a Lunar and Mars Mission, and adapting/refining various tools and technologies for use in the spaceflight environment. These measures and tools will be used to monitor, detect and treat early risk factors. BHP will utilize analogs to test, further refine, and validate these measures for Exploration Missions. BHP also develops countermeasures for maintaining behavioral health and enhancing performance during long duration isolated, confined, and highly autonomous missions; provides recommendations regarding space medicine best practices; and, provides updates for behavioral health and performance standards.

The BHP element includes two additional risks – increased human performance errors due to sleep loss, fatigue, work overload, and circadian desynchronization; and, increased errors due to poor team cohesion and performance during long duration isolated, confined, and highly autonomous missions; provides recommendations regarding space medicine best practices; and, provides updates for behavioral health and performance standards.

Risk Mitigation Strategy

The risk mitigation strategy of the BHP Element follows the larger strategy of the HRP “from Evidence to Products” principle, while being driven primarily by Medical Operations. BHP holds an annual working group meeting of subject matter experts who work with BHP and Medical Operations, and Mission Ops to identify gaps in knowledge and gaps in mitigation. Specific tasks are defined to address the gaps and provide clear, deliverables for Constellation, ensuring an evidence and operationally-based end item. Working with research and operational experts, BHP systematically identifies the appropriate analog to address the gaps prior to validating in spaceflight. To ensure relevancy, stakeholders are engaged in the process at the beginning. Findings from BHP research inform operations and standards as well as update the evidence base for the BHP Risks.

Gaps

BMed1: What are the optimal methods to prevent decrements in behavioral health (which may negatively affect performance) during exploration missions?
BMed2: What are the optimal methods to predict decrements in behavioral health (which may negatively affect performance) during exploration missions?

Individuals with the greatest likelihood of having a behavioral and psychiatric emergency in flight are eliminated during the selection process; they never become astronauts. While the current NASA select-out system is very thorough, the predictive ability of all selection systems diminishes over time. Therefore, new criteria may be necessary for astronaut selection for long duration exploration missions. Neuropsychiatric assessment may be helpful in this process, as the biological basis of mood disorders suggests neural biomarkers may provide a more objective method for assessing some psychiatric conditions such as depression.

<table>
<thead>
<tr>
<th>Tasks: (NSBRI)</th>
<th>Near-infrared Neuroimaging (NIN) for Predicting Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008-2011: Lab Studies: Biomarkers of Depression (Strangman)</td>
<td>Laboratory study evaluating and validating a flight-capable, noninvasive neuroimaging technology (near-infrared spectroscopy and imaging, or NIRS imaging) for its ability to detect biomarkers of depression, and its severity.</td>
</tr>
<tr>
<td>2012: Determine if technology is ready for spaceflight. If no, then define subsequent tasks. If yes: 2013-2016: Flight feasibility study</td>
<td>If it is determined that mobile neuroimaging of psychiatric conditions (including, but not limited to, depression) is appropriate for in-flight use during long duration exploration missions (as a detection tool), a feasibility/validation study will be conducted on the ISS. If not, additional neuroimaging studies to address other conditions may be conducted.</td>
</tr>
<tr>
<td>2023 + Validate in Lunar Long missions</td>
<td>If not ready for spaceflight, determine which tasks should be conducted</td>
</tr>
</tbody>
</table>

| Deliverables: | Updates to Human System Risk Forum/Recommendations to Medical Operations regarding biomarkers of depression, as select-out criteria for exploration (and possibly for in-flight use) |
| Inform Standards | Based on outcome of flight study, mobile neuroimaging of psychiatric conditions may be delivered as a countermeasure for Medical Operations for long duration exploration missions |

**Required Delivery Milestone:** Updates to Human System Risk Forum / Recommendations for Medical Ops to be delivered in 2016 regarding biomarkers for depression diagnosis and depression severity. Mobile neuroimaging technology may be delivered as in-flight countermeasure for long duration exploration missions, in 2023 for Lunar Ops and Mars Ops Development.

**Required Platforms:** Ground and space effort

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Very Low</td>
<td></td>
<td></td>
<td>Very Low</td>
<td></td>
</tr>
<tr>
<td>2023 + Validate in Lunar Long Missions</td>
<td>Very Low</td>
<td></td>
<td></td>
<td>Very Low</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Very Low</td>
<td></td>
<td></td>
<td>Very Low</td>
<td></td>
</tr>
</tbody>
</table>
**Tasks:** (Directed)
Prediction of Incidence of Depression in Astronauts
2009-2011: Literature Review and Meta-Analysis
Literature review and meta-analysis to predict the incidence of depression in astronauts.

**Deliverables:** Updates to Human System Risk Forum / Recommendations to Medical Operations regarding incidence rates of depression in astronauts.

**Required Delivery Milestone:** Updates to Human System Risk Forum / Recommendations for Medical Ops to be delivered by 2011.

**Required Platforms:** This ground effort primarily involves evidence gathering. Findings from this activity will inform what additional tasks need to be conducted to address this gap.

**BMed3: What are the optimal methods to detect and assess decrements in behavioral health (which may negatively affect performance) during exploration missions?**

Astronauts must maintain high-level performance while experiencing demanding workload and work schedules, extreme environmental risks, and psychosocial stressors in space (for example, isolation and confinement). Stress, affect, and fatigue can jeopardize their cognitive performance and neurobehavioral status. Due to the delayed communication that will exist between the space crew and the ground during an Exploration Missions, flight surgeons have stated the need for unobtrusive monitoring tools that will help detect if an astronaut is demonstrating or otherwise evidencing continual high levels of stress, fatigue, and negative mood. These tools are to require minimal crew time and effort. The tools should allow the crewmember the ability for self-assessment, providing immediate feedback so that countermeasures can be administered in a timely manner, if necessary.

Currently, two monitoring technologies are planned. These technologies are to be adapted specifically for Exploration Missions. The facial monitoring tool (known as the optical computer recognition (OCR) system) is currently under development through previous work of the researcher with other agencies. NASA is able to leverage such technologies, and with some refinement, adaptations, and validation, provide these tools for Lunar and Mars Missions.

**Tasks:** (NSBRI)
Unobtrusive Tool – Facial Monitoring Technology (Optical Computer Recognition (OCR))
2008-2012: Lab Development
Laboratory studies are evaluating whether optical computer recognition algorithms based on changes in facial expressions can discriminate stress induced by low versus high workload. Assess the effectiveness of the tool using archival video footage or footage that is streamed from ISS to the ground. This step may allow for the validation of the tool for spaceflight operations without the use of ISS crew time.
2009-2010: NEEMO
Evaluate technology in high fidelity analogs such as NEEMO that contain neurobehavioral stressors relevant to spaceflight.
2009-2010: RCS-105
Evaluate technology in high fidelity analogs such as the Russian Chamber Study-105 that contain neurobehavioral stressors relevant to spaceflight.
2013: Prep for Flight
2014-2018 (or earlier): Flight Validation Studies, if deemed necessary
Following assessments using flight footage video, and refinement/enhancement of the tool to detect changes despite fluid shifts that can occur during spaceflight, determine if the technology is needed to assess behavioral health during LDM Exploration missions, and if a flight study is needed. If so, a flight study will be implemented
Deliverables: Facial Monitoring Technology as a countermeasure for long duration exploration missions

Required Delivery Milestone: Countermeasure to be delivered to flight medical operations for long duration exploration missions.

Required Platforms: Ground studies to help adapt technologies for spaceflight; analogs include NEEMO and the RCS-105. Require the ISS for validation (either through the use of video footage or flight study) because of the parameters being monitored may be affected by microgravity. The ISS will emulate the transit environment to Mars. Involves collaboration with NSBRI.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2014-2018 (or earlier): Flight Validation Studies, if deemed necessary

2020-2023: Lunar Validation

Tasks: (TBD)

Unobtrusive Tool – Voice Acoustics Monitoring Technology

A former NSBRI investigation looked at speech monitoring technology to automatically and unobtrusively monitor the effects of stress and neurological impairment on astronauts’ ability to perform in extended missions. The system detects cognitive decrements resulting from hypoxia and radiation, and can discriminate between high and low stress conditions.

2009: Review of Technologies

Review tool developed through the NSBRI and other existing voice acoustic monitoring technologies to determine feasibility for spaceflight.

2011-14: Ground Validation Studies

If tools are deemed feasible for spaceflight, validate the tool in analog environments.

2016: Prepare for Flight

2017-2020: Flight Validation Studies, if deemed necessary

Following assessments in analog environments, determine if the technology is needed to assess behavioral health during LDM Exploration missions, and if a flight study is needed. If so, a flight study will be implemented.

2020-2023: Lunar Validation

Deliverables: Voice Acoustics Monitoring Technology (unobtrusive, passive technology that assesses individual responses to stress, as well as radiation and hypoxia effects)

Required Delivery Milestone: Countermeasure to be delivered to flight medical operations for long duration exploration missions.

Required Platforms: Ground studies to evaluate existing technologies in analog environments. Require the ISS for validation (either through the use of video footage or flight study) because of the parameters being monitored may be affected by spaceflight environment. The ISS will emulate the transit environment to Mars.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2017-2020: Flight Validation Studies, if deemed necessary

2020-2023: Lunar Validation

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2020-2023: Lunar Validation

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
BMed4: What aspects, if any, of cognitive performance change during missions? If there are changes –do they persist post-mission? If so, for how long?

BMed5: What are the optimal methods for detecting and assessing cognitive performance during exploration missions?

Based on past spaceflight experiences, various types of behavioral and psychiatric conditions are expected to be a risk for future exploration missions. While current selection and countermeasure strategies have prevented the occurrence of any behavioral health emergencies that could jeopardize mission success, the uniquely long durations and distances of future exploration missions necessitates comparisons with analog environments that might indicate what other types of occurrences could be expected.

Some evidence from Antarctic research suggests clinical cognitive changes may occur in individuals exposed to ICE environments, such as space, for long periods of time. Investigators studying animal research have further speculated that behavioral changes in such environments may even be attributable to the effects of chronic stress on the hippocampus. Physical aspects of the environment can also result in cognitive changes. Exposure to radiation, for example, can damage the subcortical basal ganglia and hippocampus, both of which are critical to cognitive functioning.

**Tasks:** (NRA)

Changes in Cognition and Psychological Well-Being in Long-Duration Spaceflight

2009: Literature Review
Review of validated measurement tools for detecting changes in cognition

2010: Workshop

2011: Prep for Flight

2012-2015: Flight Study
Data collection to characterize cognition during long duration space missions, and determine measurement tools for detecting changes in cognition.

2016-2019: Additional flight studies and/or ground studies, if needed
If evidence reveals further studies are needed, assess whether spaceflight duration is sufficient for additional studies (i.e. missions lasting a year or more). If so, implement flight study to further evaluate this gap. If not, ground based studies in appropriate analog to be conducted.

2023+ Validate in Lunar Long missions

**Deliverables:** Update to HSRF/Medical Operations with recommendations regarding clinical cognition during long duration spaceflight missions.

**Required Delivery Milestone:** Update HSRF/Medical Operations in 2015 with recommendations for long duration exploration missions.

**Required Platforms:** Review a ground based effort, with flight study implemented with crews on ISS (to detect potential clinical cognitive changes) and validation on Lunar Long mission.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>
**Tasks:** (NRA)
Changes in Cognition and Psychological Well-Being in Long-Duration Spaceflight

2009: Literature Review
- Review of validated measurement tools for detecting changes in cognition

2010: Workshop

2011: Prep for Flight

2012-2015: Flight Study
- Data collection to characterize cognition during long duration space missions, and determine measurement tools for detecting changes in cognition.
- 2016-2019: Additional flight studies and/or ground studies, if needed

If evidence reveals further studies are needed, assess whether spaceflight duration is sufficient for additional studies (i.e. missions lasting a year or more). If so, implement flight study to further evaluate this gap. If not, ground based studies in appropriate analog to be conducted.

2023+ Validate in Lunar Long missions

**Deliverables:** Update to HSRF/Medical Operations with recommendations regarding clinical cognition during long duration spaceflight missions.

**Required Delivery Milestone:** Update HSRF/Medical Operations in 2015 with recommendations for long duration exploration missions.

**Required Platforms:** Review a ground based effort, with flight study implemented with crews on ISS (to detect potential clinical cognitive changes) and validation on Lunar Long mission.

**Tasks:**
CNS1: Radiation Exposure Acute Functional CNS Effects
- As per SRPE IRP

**Tasks:** (NSBRI (laboratory/animal studies))
Evaluate CNS/Neurostructural Changes

2008-2012: Lab studies- animals- assess neurostructural changes (Hienz)
- Animal studies to assess the likelihood of space radiation producing immediate and/or long-term functional changes in the CNS.
- 2013- TBD

**Deliverables:**
- Update to HSRF/Medical Operations with Recommendations regarding CNS effects/neurostructural changes based on evidence
- Information to Radiation Element
- Inform Standards

**Required Delivery Milestone:** Due to the fact that radiation effects may be a current issue, update HSRF/Medical Operations with recommendations in 2012.

**Required Platforms:** Ground based effort, involving laboratory studies.

**Tasks:** CogGague (SBIR)
2008: Phase I Requirements Development

Develop requirements for a prototype cognitive assessment tool that is designed specifically for long duration exploration missions. The tool will detect clinical cognitive decrements as a result of fatigue or other stressors of spaceflight; support crew members with an entertaining assessment activity(s); and support autonomy by providing objective feedback directly to the crewmember regarding their behavioral health. CogGague will serve as a diagnostic tool, indicating not only if crew members are below baseline, but also potential causes for these decrements.

2009-2010: Phase II Prototype Development

2011-2012: Prep for spaceflight validation

2013-2016: Validate technology on ISS

Collect and analyze data on ISS in order to validate CogGague in spaceflight environment.

**Deliverables:**

Diagnostic Tool for Medical Operations

**Required Delivery Milestone:** Update Lunar Ops & Input Mars Ops Development by 2023.

**Required Platforms:** Ground development. Spaceflight feasibility studies to occur on ISS. This deliverable requires spaceflight because of issues related to the long duration spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

2009-2013: Validate PVT Self-Test on ISS

BMerg6: What psychosocial characteristics predict success in an isolated, confined and extreme environment?

In order to select individuals most likely to be successful in long duration exploration missions, it is helpful to understand the psychosocial characteristics (including personality data) of individuals who have already proven to be successful in isolated, confined, and extreme environments. These individuals may include, but are not necessarily limited to, submariners, navy seals, firemen, and wintering-over Antarctic personnel. Essential to this task is establishing an operationally accurate definition of “success”. Training can subsequently be designed to target the traits that are most malleable.
**Tasks:** (TBD)

**Identify Trait/Malleable Characteristics of High-Performing Individuals**

**2009-2010: Review of Literature/Assessment of Operations**

Review literature on ICE population groups to define and outline what psychosocial characteristics are most predictive of success. Collaborate with BHP Ops to establish a definition of “success” that most adequately captures what is needed in a long duration astronaut. Assess what is already operational known about the success of previous long duration flyers. Identify traits/malleable characteristics of high performing individuals.

**2011-2015: Revise Gap and Tasks**

Based on the above information, determine whether additional studies are needed. If studies are needed, determine whether BHP will be able to gather data needed from previous interviews and sources; or, if it is necessary to interview astronauts for additional information. Revise and define the gap and activities with goal of providing training recommendations to Ops by 2015.

**Deliverables:** Updates to Human System Risk Forum / Recommendations to Medical Operations regarding information that may help determine training criteria.

**Required Delivery Milestone:** Updates to Human System Risk Forum / Recommendations for Medical Operations to be delivered for long duration exploration missions.

**Required Platforms:** Review is ground study, with future tasks/deliverables to be subsequently defined.

**BMed7: What are the optimal countermeasures for maintenance, restoration and enhancement of behavioral health during exploration missions?**

As discussed in the B-Med Evidence Book, although the incidence of reported psychiatric disorders on short duration missions has not been significant, as the length of the mission increases, the incidence of behavioral and psychiatric disorders is also expected to increase. Additionally, the ramifications of a disorder developing inflight are severe if left unresolved, particularly for long duration exploration missions. Anecdotal and empirical evidence from spaceflight and incidence rates from space analogs suggest that assessing, preventing, and treating behavioral health problems are essential to protecting the health of crewmembers, and consequently, the success of the mission.
**Tasks:** (NSBRI)

**Tool:** Mitigation of Depression, and

**Task:** Tool : Mitigation of Stress and Anxiety

Currently a computerized “psychologist” is under development through the NSBRI, in conjunction with Medical Operations; this “smart” technology allows a crewmember on a long duration Lunar or Mars Mission to evaluate signs or symptoms of early depression and anxiety, and receive therapy as desired.

The computer-based aid for addressing depression (based on problem-solving therapy), is not designed to replace the clinician; rather, it will complement the service of the aerospace psychiatrist during a long duration Exploration Mission. The tool enhances privacy, confidentiality, and support of the astronaut during autonomous missions such as the Mars Mission which will have considerable communication delays between space crew and ground support. It allows the astronaut to educate him/herself, augmenting the one-on-one private physician consultation. At times when such consultation is not feasible, it will serve as a diagnostic tool and autonomous countermeasure that is available 24/7, with feedback to the individual, aerospace psychiatrist, and the crew surgeon.

There is a second NSBRI task developing self-directed, autonomous, interactive, multi media module to train crewmembers how to recognize, assess, prevent and manage stress and anxiety on extended spaceflights. The countermeasure could be used in preflight training, with booster sessions on interventions available in orbit as needed. In this model of implementation, the skills learned prior to a mission would help to inoculate crews to severe stress reactions thereby enhancing flight-task performance and crew health, safety and efficiency. The countermeasure will comprise empirically supported stress and anxiety-management strategies.

2008-2012: Two NSBRI ground based studies (laboratory and Antarctic) to refine and test the effectiveness and feasibility of tool.

2012: Prepare for Flight

2013-2016: ISS validation/feasibility study

2017: Determine if additional countermeasure studies are needed

2017-2020: Conduct ground studies, if needed

2023+ Validate in Lunar Long environment

**Deliverables:**

Countermeasure: technology to detect and treat depression, as well as stress and anxiety

Update to HSRF for operationalizing protocol for ISS


**Required Platforms:** Ground studies, with flight validation on ISS. The ISS will emulate the transit environment to Mars.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>
Tasks: (NRA)

Journals

2008-2010: ISS Studies

This activity involves a systematic analysis of astronaut journals maintained during ISS increments. Findings will yield recommendations regarding countermeasures for behavioral health during long duration spaceflight mission, making it most applicable for Lunar Habitat and Mars Missions. Findings from this activity will also inform knowledge and mitigation gaps within the Sleep, Team, and B-Med Risks.

2011: Determine if additional studies are needed

Tasks to be subsequently defined

Deliverables: Recommendations regarding countermeasures for behavioral health

Required Delivery Milestone: Updates to HSRF/Med Ops in 2011.

Required Platforms: Task involves analysis of astronaut journals from ISS, and therefore requires spaceflight.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>

Tasks: (TBD)

Architectural Recommendations for Behavioral Health and Performance

2010: Review

This activity will help BHP to determine if studies are needed to define architectural requirements for lunar habitat design (or other related aims.)

Deliverables: TBD

Required Delivery Milestone: TBD

Required Platforms: TBD

Tasks: (TBD)

Countermeasures: Adaptation to ICE Environments

2010: Review

This activity will help BHP to determine if studies are needed

Additional Tasks TBD

Deliverables: TBD

Required Delivery Milestone: TBD

Required Platforms: TBD
**BMed8: What are the most appropriate and effective ways for crews to use behavioral health medications in spaceflight?**

Space analogs, such as Antarctica, confirm mood deterioration and increased stress occur in individuals in isolated, confined and extreme environments (ICE). Psychotropic medications may be considered helpful in mediating these deleterious effects and in treating behavioral or psychiatric conditions that may arise during Exploration Missions.

Over the next decade, the field of psychopharmacology will undoubtedly continue to develop new medications for the treatment of behavioral and psychiatric disorders. In preparation for long duration Exploration Missions, BHP will collaborate with Medical Operations to review state-of-the-art medications and provide a compendium of best practices. A pharmaceutical armamentarium that covers a broad range of mental disorders, produces minimal side effects, requires no laboratory monitoring and has minimal storage requirements will be needed for long duration Exploration Missions.

<table>
<thead>
<tr>
<th>Tasks: (TBD)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop Behavioral Medications Database</td>
<td></td>
</tr>
<tr>
<td>In collaboration with Medical Operations and Subject Matter Experts, workshop and data mining to review literature on performance, safety, and side effects of state-of-the-art medications for behavioral and psychiatric disorders.</td>
<td></td>
</tr>
</tbody>
</table>

| Deliverables: Behavioral Medications Database.                            |                           |
| Required Delivery Milestone: Update to Lunar and Mars Ops Development for long duration missions. |                           |
| Required Platforms: Primarily a ground based effort.                     |                           |
Risk of Behavioral and Psychiatric Conditions

BMed1 What are the optimal methods to prevent decrements in behavioral health (which may negatively affect performance) during exploration missions?

BMed2 What are the optimal methods to predict decrements in behavioral health (which may negatively affect performance) during exploration missions?
What are the optimal methods to detect and assess decrements in behavioral health (which may negatively affect performance) during exploration missions?

1. Update HSRR/PSM Ops For ISS
2. Update Lunar Operations & Input to Mars OPM (Data Request TBD)

Are technologies adequate?

Lunar Study

Is unobtrusive technology feasible to assess behavioral health during LEO Exploration?

Lab Development

Flight Validation Studies

Flight Validation Studies

Rev. of Tech

Approach Feasible?

NO

YES

Rev. of Other Techs

Approach Feasible?

NO

YES

NEEMO

RCS

HHRP FRD Req’t: Element: BHP

Constellation

SS & Shuttle

Crew Capability  ▲ Shuttle Refueling  ▲ End of US Commitment

Program Level

▲ PDR  ▲ CDR Initial Ops  ▲ PDR  ▲ CDR

Orion

▲ PDR  ▲ CDR  ▲ Full Ops Capability

EVA Suit

▲ PDR suit1  ▲ CDR suit1

SDR suit2  ▲ PDR suit2  ▲ CDR suit2

Lander

▲ ATP  ▲ SDR  ▲ PDR  ▲ CDR

Mission Operations

▲ PDR-init cap  ▲ CDR-init cap  ▲ SRPDR

Unobtrusive Tool - Facial Monitoring Technology (NSBRI) (Dinges)

Unobtrusive Tool - Voice Acoustic Monitoring Technology (TBD)

Unobtrusive Technologies (TBD)
Risk of Behavioral and Psychiatric Conditions

BMed? What are the optimal countermeasures for maintenance, restoration and enhancement of behavioral health during exploration missions?

**BHP**
- Tool: Mitigation of Depression (NSERI) (Cortisol)
- Tool: Mitigation of Stress and Anxiety (NSERI) (Rest)
- Journals (NSERI) (Shuttle)
- Architectural recommendations for behavioral health and performance (TED)
- CM: behavioral health/adaptation to ICE env. (TBD)

**Constellation**
- Program Level
  - SRP
  - CDR: Initial Ops
  - PDR
  - CDR
  - Human Lunar Return
- Orion
  - PDR
  - CDR
  - Full Ops Capability
- EVA Suit
  - PDR-suite 1
  - CDR-suite 1
  - PDR-suite 2
  - CDR-suite 2
- Lander
  - ATP
  - SRP
  - CDR
- Mission Operations
  - PDR-init cap
  - CDR-init cap
  - SRP
  - CDR

**Refine, Validate in Analogs**

**ISS validation/feasibility study**

**ISS Studies**

**(1) Operationalize Protocol For ISS**

**Ground-based CM Studies**

**(2) Technology to detect and treat depression**

**Validate in Lunar Long**

**Update Human Ops & Input to Mars Ops Dev!** (Date Required TBD)

**Are additional countermeasure studies needed?**

**Are additional studies needed?**

Gaps and Activities to be subsequently revised/defined

**Are additional studies needed?**

Gaps and Activities to be subsequently revised/defined

122
**Risk of Behavioral and Psychiatric Conditions**

**BMed8** What are the most appropriate and effective ways for crews to use behavioral health medications during exploration missions?

**BHP** Develop Behavioral Medications Database (TBD)
Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload – Criticality: Lunar Outpost – D, Mars – D

Fatigue occurs during spaceflight and may jeopardize health and performance. This risk may be influenced by artificial and transmitted light exposure, individual vulnerability to sleep loss and circadian dynamics, and work/sleep schedules. Efforts are needed to improve sleep hygiene, and to identify and improve conditions that interfere with sleep quality. Research areas may include: development of a self-assessment tool for cognitive function and fatigue, light therapy for phase shifting, alertness and mood disorders, and other means to improve sleep quality and reduce fatigue.

Operational Relevance Assessment and Recommendations

Research demonstrates that aspects of the spaceflight environment may disrupt circadian rhythms and reduce sleep; anecdotal evidence from spaceflight reveals that fatigue and work overload can also occur. Ground research has consistently demonstrated that lack of adequate amounts of good quality sleep, as well as circadian desynchronization, can adversely affect performance capability and safety.

Lunar surface activities will be both strenuous and fatiguing, and will involve shift work. Furthermore, sleep and fatigue are risk factors for the other two Behavioral Health and Performance Risks (Risk of Performance Errors Due to inadequate Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation; Risk of Behavioral and Psychiatric Conditions), as well as other aspects related to human health. It is therefore essential to develop countermeasures for issues related to sleep loss, fatigue, circadian desynchronization and work overload. BHP research activity aims to assess this risk as well as provide adequate standards and countermeasures for Exploration Missions.

Risk Mitigation Strategy

The risk mitigation strategy of the BHP Element follows the larger strategy of the HRP “from Evidence to Products” principle, while being driven by Operations. BHP holds an annual working group of subject matter experts who work with BHP and Medical Operations to identify gaps in knowledge and gaps in mitigation. Specific tasks are defined to address the gaps and provide clear, specific deliverables for Constellation, ensuring an evidence and operationally-based end item. Working with research and operational experts, BHP systematically identifies the appropriate analog to address the gaps prior to validating in spaceflight. To ensure relevancy, stakeholders are engaged in the process at the beginning. Findings from BHP research inform operations and standards as well as update the evidence base for the BHP Risks.

Gaps

Sleep 1: What are the best measures and tools to use for assessing performance relative to fatigue and other aspects of spaceflight?

Ground evidence clearly demonstrates that performance impairments can occur when sleep is attained in quantities similar to that attained by astronauts in flight. A correlation between sleep quantity and performance in spaceflight however has not been documented. A means to objectively assess decrements during mission operations and provide information to the crew surgeon and astronaut may be helpful, so that appropriate countermeasures, if necessary, can be implemented. The assessment of performance in space relative to fatigue, using the right measures, will also aid in accurately characterizing and quantifying this human health risk.
Tasks: (PVT Self Test on ISS is a BHP Directed Study, with NSBRI supporting PVT Self Test development and validation in analogs)

Refine, Validate, and Standardize Psychomotor Vigilance Task Self-Test (PVT)

2007-2008: NEEMO
Collect data in NEEMO to develop normative database of astronaut performance on PVT.

2009-2010: Russian Chamber Study
Validate the PVT in analogous environments, including the Russian – Chamber 105 day study.

2008-2011: Lab development
Development and enhancements of the PVT in laboratory studies so that it serves as a self-assessment measure for the astronaut and provides automatic feedback to flight surgeons and crews during autonomous missions.

2009-2013: Validate PVT Self-Test on ISS
Collect and analyze data on ISS in order to validate the PVT in spaceflight environment.

2014: Determine if additional tools are needed

2014-2020: Implement ground/flight studies if applicable

2020-2023: Validate PVT Self-Test on Lunar Surface
Collect and analyze data on Lunar Surface in order to validate the PVT in Lunar environment.

Deliverables:

PVT Self-Test for Medical Operations
Information to the SHFH Element
Update to HSRF/Med Ops with measures validated in Lunar sortie environment.


Required Platforms: Analogs, including the Russian Chamber Study 105-day and NEEMO. Laboratory development. Spaceflight validation to occur on ISS. This deliverable requires spaceflight because of sleep loss and fatigue issues related to microgravity and other spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment. Validate on Lunar surface.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2009-2013: Validate PVT Self-Test on ISS

2014-2020: Implement ground/flight studies if applicable

2020-2023: Validate PVT Self-Test on Lunar Surface

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2020-2023: Validate PVT Self-Test on Lunar Surface

Tasks: Cognitive Assessment Tool (CAT) (SBIR)

2008: Phase I Requirements Development
Develop requirements for a prototype cognitive assessment tool that is designed specifically for long duration exploration missions. The tool will detect cognitive decrements as a result of fatigue or other stressors of spaceflight; support crew members with an entertaining assessment activity(s); and support autonomy by providing objective feedback directly to the crewmember regarding their behavioral health

2009-2010: Phase II Prototype Development

2011-2012: Prep for spaceflight validation

2013-2016: Validate technology on ISS
Collect and analyze data on ISS in order to validate the CAT in spaceflight environment.

Deliverables:

Cognitive Assessment Tool for Medical Operations
**Required Delivery Milestone**: Update Lunar Ops & Input Mars Ops Development by 2023.

**Required Platforms**: Ground development. Spaceflight feasibility studies to occur on ISS. This deliverable requires spaceflight because of issues related to spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009-2013: Validate PVT Self-Test on ISS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>

**Tasks**: (BHP NRA)

Sleep-Wake Actigraphy Study

2008-2012: Validate Actiwatch in-flight

As discussed in the Sleep Evidence Report, studies have shown that self-report of just how much sleep an individual actually gets is unreliable and inaccurate. Therefore, to accurately assess to what degree sleep is disrupted on-orbit, an unobtrusive, objective measure of sleep-wake activity is needed. Objective sleep data during the course of a mission provides important operational feedback for the astronaut as well as the flight surgeon, particularly prior to performing critical mission tasks, and planning sleep shifting during mission operations.

**Deliverables**:

Actiwatch Protocol to ISS Medical Operations

(See Sleep 6): Recommendations based on evidence

**Required Delivery Milestone**: Update HSRF/Medical Operations in 2010 for operationalizing Actiwatch protocol as an ISS medical requirement.

**Required Platforms**: Spaceflight validation to occur on ISS. This deliverable requires spaceflight to ensure the tool is appropriate for monitoring sleep-wake activity and light exposure in the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td>Very Low</td>
<td></td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>
**Tasks:** (SBIR)

*Individualized Fatigue Meter*

While the current Actiwatch technology is useful, it is suspected that it does not gather a very precise assessment of light exposure. The Actiwatch also requires a skilled investigator to download, analyze, and interpret the data before the feedback can be of use to flight surgeons and astronaut crews. There is a need for an individualized meter that precisely measures environmental (e.g., light exposure) and physiological signals (e.g., sleep wake activity, heart rate, etc.) to determine individual fatigue levels, and automatically provides the user (e.g., astronaut/flight surgeon, MOD/ground support) with feedback about potential decrements in performance ability. Such a measure will also provide information on circadian phase to indicate levels of potential risk due to fatigue.

2009: Phase I, Evaluation/ Requirements Definition

Market analysis and literature review document to assess physiological and environmental sensors; circadian state & sleep assessment; neurobehavioral performance test analysis; a review of existing models and identification of any major gaps in current modeling knowledge; and a technical development plan for developing a spaceflight ready Individualized Fatigue Meter.

2010-2011: Phase II, Prototype Development

Develop spaceflight ready prototype of Individualized Fatigue Meter.

2012: Prep for Spaceflight


2020-2023: Validate PVT Self-Test on Lunar Surface

Collect and analyze data on Lunar Surface in order to validate the PVT in Lunar environment.

**Deliverables:**

- Individualized Fatigue Meter to become requirement for Medical Operations
- Update Lunar Ops & Input Mars Ops Development
- Update to HSRF/Med Ops with measures validated in Lunar sortie environment


**Required Platforms:** Ground evaluations and laboratory development. Spaceflight validation to occur on ISS. This deliverable requires spaceflight to ensure the tool is appropriate for the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020-2023: Validate PVT Self-Test on Lunar Surface</td>
<td>24</td>
<td>Very Low</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sleep2: How is performance in spaceflight affected by sleep loss, circadian desynchronization, fatigue and work overload?**

As discussed in the Sleep Evidence Book, ground evidence clearly demonstrates that performance impairments can occur when sleep is attained in quantities similar to that attained by astronauts in flight. A correlation between sleep quantity and performance in spaceflight however has not been documented. The assessment of performance in space relative to fatigue, using the right measures, will also aid in accurately characterizing and quantifying this human health risk, and helping to determine what additional countermeasures need to be developed, as necessary, and/or policies/standards enforced.
**Tasks:** (PVT Self Test on ISS is a BHP Directed Study, with NSBRI supporting PVT Self Test development and data collection in analogs)

**PVT ST Performance Data** (these tasks are also described in Sleep1)

- **2007-2008: NEEMO**
  Collect data in NEEMO to develop normative database of astronaut performance on PVT ST.

- **2009-2010: Russian Chamber Study**
  Collect performance data the in analogous environments, including the Russian – Chamber 105 day study.

- **2008-2011: Lab development**
  Development and enhancements of the brief PVT self test in laboratory studies so that, based on performance data gathered, it serves as a self-assessment measure for the astronaut and provides automatic feedback to astronauts and flight surgeons during autonomous missions.

- **2009-2013: Collect Performance Data with PVT Self-Test on ISS**
  Collect and analyze data on ISS in order to capture performance with the PVT ST in the spaceflight environment.

- **2014: Determine if additional performance studies are required**

- **2014-2020: Implement ground/flight studies if applicable**

- **2020-2023: Collect PVT ST performance data on Lunar Surface**
  Collect and analyze data from Lunar Surface in order to characterize performance with the PVT ST in the Lunar environment.

**Deliverables:**

- Recommendations for flight and ground crews re: fatigue and performance, based on evidence gathered
- Information to the SHFH and HHC Elements
- Inform Standards
- Update to HSRF/Med Ops regarding cognitive and motor performance in Lunar Sortie environment


**Required Platforms:** Analogs, including the Russian Chamber Study 105-day and NEEMOO. Laboratory development. Data collection to occur on ISS and Lunar surface. This deliverable requires spaceflight because of sleep loss and fatigue issues related to microgravity and other spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2009-2013: Collect Performance Data with PVT Self-Test on ISS</strong></td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2020-2023: Collect PVT performance data on Lunar Surface</strong></td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Tasks:** (TBD)

**Motor Performance / Dual Task Tests**
- 2009: Review of Measures
  - Conduct review of validated measures for assessing motor performance in flight.
- 2009-2010: Planning for Flight Study
- 2010-2014: Motor/Dual Task Performance Data
  - Collect motor performance data on ISS.
- 2014: Determine if additional performance studies are required
- 2014-2020: Implement ground/flight studies if applicable
- 2020-2023: Collect motor performance data on Lunar surface
  - Collect and analyze data from Lunar surface in order to characterize motor performance in the Lunar environment.

**Deliverables:**
- Recommendations for flight and ground crews re: fatigue and performance, based on evidence gathered
- Information to the SHFH and HHC Elements
- Inform Standards
- Update to HSRF/Med Ops regarding motor performance in Lunar Sortie environment


**Required Platforms:** Ground assessment of validated measures for assessing motor performance. This deliverable requires spaceflight because of sleep loss and fatigue issues related to microgravity and other spaceflight environmental factors, and to ensure the test is appropriate for the spaceflight environment.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>20</td>
<td></td>
<td>Low</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2010-2014: Motor/Dual Task Performance Data

2020-2023: Collect motor performance data on Lunar surface

**Tasks:** (TBD)

**Hypoxia/Altitude/CO2**
- 2010: Review
  - Conduct review of the effects of hypoxia/altitude on sleep and performance.
- 2011: Determine if studies are needed.
  - Gaps and future activities to be subsequently revised/defined.

**Deliverables:** Inform BHP regarding subsequent tasks/gaps.

**Required Delivery Milestone:** TBD

**Required Platforms:** TBD

**Sleep3: Does sleep loss continue on long duration missions or is there adaptation?**

Previous studies have revealed that space crews are at times not sleeping for the duration of their scheduled sleep period. Crewmembers experience frequent shifts in their sleep/wake schedules, and in addition, various environmental factors affect sleep quality and quantity. Studies have shown that self-
report of just how much sleep one is actually getting can be inaccurate. Therefore, in order to assess accurately to what degree sleep is disrupted on-orbit, an unobtrusive, objective measure of sleep-wake activity is needed. Objective sleep data during the course of a mission provides important operational feedback for the astronaut as well as the flight surgeon, particularly prior to performing critical mission tasks.

**Tasks:** (NRA)

**Sleep/Wake Activity Study (Czeisler/Barger)**

2007-2011: ISS/STS Data Collection

Collect inflight data using an Actigraph watch to objectively document sleep and wake times and capture light exposure relative to sleep/wake activity, and a sleep log for subjective information on countermeasure use, and factors related to sleep loss during spaceflight. Data are collected during shuttle and ISS missions to quantify spaceflight and light-exposure-related sleep disturbances, examine sleep shift schedules on sleep, and use of countermeasures (i.e. lighting, medication).

2012: Determine if, based on evidence, additional countermeasure studies are needed

2012-2018: Implement ground/flight studies if applicable

2020-2023: Lunar Surface data collection

Collect sleep-wake data on the lunar surface (through enhanced actiwatch or individualized fatigue meter identified in Sleep1). Data to be collected on Lunar to quantify environmental (i.e. light-exposure-related) sleep disturbances, examine sleep shift schedules on sleep, and use of countermeasures.

**Deliverables:**

Operationalize Actiwatch protocol as med requirement to monitor sleep/wake (Sleep1)

Recommendations based on objective assessment of sleep on long duration missions

Data collected also informs modeling efforts outlined in Sleep4, and task in Sleep1

Inform Standards

Recommendations based on objective assessment of Sleep on Lunar missions

If applicable, countermeasures to aid in adaptation, validated in lunar environment


**Required Platforms:** Requires the STS and ISS because of sleep-related issues associated with spaceflight. Requires continued participation by STS crews because of the wide variation across missions. Requires ISS because to date, relatively little is known about sleep quantity and quality on the ISS. Will require lunar environment to accurately assess the nature of sleep in lunar setting. Study provides information important for exploration planning. There is a high acceptability for participating in this study and high compliance among the astronauts participating in study.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2007-2011: ISS/STS Data Collection

See Sleep1-Sleep Wake Actigraphy Study

2020-2023: Lunar Surface data collection

See Sleep 1- Enhanced Actiwatch

Upmass per subject = [Complete if ISS or Lunar Surface is required. This is the upmass that must be sent for each subject (for instance, a specific device that each crewmember wears.) Specify Very High, High, Medium, Low, Very Low where Very High = 100 kg; High = 50 kg; Medium = 25kg; Low = 12 kg; Very Low = 6 kg]

**Sleep4:** How can individual astronauts’ vulnerabilities to sleep loss and circadian rhythm disruption best be determined?
While it is necessary to determine how to best mitigate the impact of environmental factors on sleep and performance, individual characteristics also contribute to the quality and quantity of sleep, and the depth of disruption to circadian system, in space. As discussed in the Sleep Evidence Book, recent studies have documented that there are large stable (trait-like) differences among individuals in the degree of cognitive deficits experienced during sleep loss (Van Dongen, Baynard et al. 2004; Klerman and Dijk 2005). BHP therefore is working to determine optimal ways for identifying individual vulnerabilities to sleep loss and circadian desynchronization.

**Tasks:** (NSBRI)
- Develop Modeling Software (Klerman)
  2009-2012: Refine and validate models; incorporate additional factors
  Using Actigraph data from astronauts on STS and ISS, enhance software based on validated a mathematical model of the human circadian pacemaker. Mathematical model to incorporate individual vulnerabilities, identification of the best countermeasure application, optimal timing for implementing countermeasures, etc., to ensure performance during critical mission tasks.
  2013: Prep for flight
  2014-2017: Validate modeling software on ISS
  2020-2023: Validate modeling during Lunar Study

**Deliverables:**
- Modeling software that provides individualized countermeasure for flight (and ground) crews
- Modeling data for integration with other modeling efforts
- 2) Validate integrated model during Lunar sortie

**Required Delivery Milestone:** Software to HSRF/Medical Operations in 2017 for Lunar Sortie Medical Operations implementation. Data from modeling software to inform integration efforts. Validated, integrated model to update Lunar Ops and Input to Mars Ops Development.

**Required Platforms:** Ground based effort, with validation activity to occur in-flight.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
<td></td>
</tr>
</tbody>
</table>

**Tasks:** (TBD)
- Integrate Models
  Several validated models related to sleep and circadian rhythms, and performance exist. These models each capture different factors relevant for spaceflight. BHP aims to integrate these models into one useful model specific to the Mars and Lunar environment. It is unclear at this time the specific efforts required to enhance and integrate these models.
  2009: Conduct a workshop with investigators/operations
  2010-
  Gaps and Activities to be subsequently revised/defined

**Deliverables:**
- TBD
  Efforts from this task should help inform flight study of modeling software.

**Required Delivery Milestone:** TBD

**Required Platforms:** TBD
### Tasks: (ExMC)

**Develop Sleep Module of Integrated Medical Model**

The ExMC Program Element is conducting this task.

2009-2010: Statistical and Clinical Validation.

**Deliverables:**
- ExMC to include sleep module as part of deliverable;
- Modeling information for integration with other modeling efforts

**Required Delivery Milestone:** As per ExMC

**Required Platforms:** As per ExMC

### Tasks: (TBD)

**Biomarkers**

2010: Review

Conduct a review of assessing biomarkers to determine individual vulnerabilities to sleep loss and circadian desynchronization.

2011: Determine if studies are needed.

Gaps and future activities to be subsequently revised/defined.

**Deliverables:** Inform BHP regarding subsequent tasks/gaps.

**Required Delivery Milestone:** TBD

**Required Platforms:** TBD

### Tasks: (Directed Study)

**Evaluate Individual Risk Factors for Circadian Entrainment to Martian Sol- Ground Crews**

2008-2010: Phoenix Mars Lander Study (Barger)

Ground crews supporting Mars robotic missions have chosen to maximize the use of the rovers on the surface of Mars by adopting the Mars sol. As a result, these engineers and scientists live/work on a 24 hour and 39 minute schedule. After 10 days, these individuals are shifted by six and a half hours. Trying to maintain such a schedule has proven challenging for crews. Those supporting the Mars Pathfinder, Spirit and Opportunity Rovers have struggled with fatigue and other issues. NASA BHP is conducting a directed study with the ground crew supporting the Mars Phoenix Scout Lander. This study will evaluate individual vulnerabilities to sleep loss and circadian desynchronization. Urine samples for instance will be evaluated in order to observe the relationship between melatonin and morningness/eveningness, for instance. Educational material and light exposure will be utilized as countermeasures for sleep loss, circadian alignment, fatigue, and workload problems.

2011: Determine if additional studies are needed. If so,

2013-2015: Ground Studies: Crews Supporting Mars Mission

Follow-up study from Phoenix Mars Lander, implementing “lessons learned” and new relevant aims to protocol.

**Deliverables:** Recommendations based on individual risk factors for ground and flight crews during Mars missions (manned and robotic), and application for LDM

**Required Delivery Milestone:** Recommendations for managing sleep loss, circadian misalignment, fatigue, and workload based on individual risk factors and performance related to sleep wake schedules for ground and flight crews during Mars missions (manned and robotic), and application for LDM

**Required Platforms:** Ground effort.
Sleep5: How can light be used to optimally minimize circadian problems in space?

Preliminary studies indicate that light exposure can correct difficulties in sleep patterns that occur with shift work, jet lag, and sleep disorders. The timing, duration, intensity, geometry and wavelength of the light impact countermeasure effectiveness. Current efforts aim to investigate optimal lighting requirements for the space vehicle, as well as safe and efficacious methods for implementing lighting as a countermeasure.

<table>
<thead>
<tr>
<th>Tasks: (NSBRI)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies to Determine Efficacy of Shorter-Wavelength-Enriched for Phase Shifting (NSBRI/Czeisler)</td>
<td></td>
</tr>
<tr>
<td>2009-2012: Lab Studies, RCS-105</td>
<td></td>
</tr>
<tr>
<td>Research has shown shorter-wavelength-enriched white light to facilitate circadian phase shifts. This task tests the efficacy of exposure to shorter-wavelength-enriched light at a standard intensity for pre-launch and in-flight phase shifting. In addition to a laboratory experiment, a study will also be conducted during the RCS-105.</td>
<td></td>
</tr>
<tr>
<td>2013-</td>
<td></td>
</tr>
<tr>
<td>Follow up tasks to be outlined below</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform Standards</td>
<td></td>
</tr>
<tr>
<td>Inform Requirements to Constellation for Lander Lighting Characteristics</td>
<td></td>
</tr>
<tr>
<td>Recommendations on best operational approach for utilizing light for circadian entrainment and alertness.</td>
<td></td>
</tr>
</tbody>
</table>

**Required Delivery Milestone:** The task will be conducted in ground laboratory studies and in analogs offering isolation and lighting challenges, such as RCS-105 will be utilized.

**Required Platforms:** Ground effort.

<table>
<thead>
<tr>
<th>Tasks: (NSBRI, with study aim looking at blue light for enhancing alertness, supported in part through BHP Directed Study)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies to Determine Alerting, Hormonal, and Circadian Effects of Artificial and Ambient Light (NSBRI)</td>
<td></td>
</tr>
<tr>
<td>Brainard plus-blue light for enhancing Alertness (Directed)</td>
<td></td>
</tr>
<tr>
<td>2008-2012: Lab Studies</td>
<td></td>
</tr>
<tr>
<td>This task characterizes the alerting, hormonal, and circadian potency of solid-state light sources being considered for the planned Crew Exploration Vehicle and the lunar habitat. Additional studies on human volunteers will determine the potency of the ambient light that is transmitted though the spacesuit visor during extravehicular activities.</td>
<td></td>
</tr>
<tr>
<td>2013-</td>
<td></td>
</tr>
<tr>
<td>Follow up tasks to be outlined below</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform Standards</td>
<td></td>
</tr>
<tr>
<td>Inform Requirements to Constellation for Lander Lighting Characteristics</td>
<td></td>
</tr>
<tr>
<td>Inform updates to HRFS/ Medical Operations on best operational approach for utilizing light for circadian entrainment and alertness.</td>
<td></td>
</tr>
</tbody>
</table>

**Required Delivery Milestone:** Requirements due by 2013 for Lunar Lander PDR. Updates to HRFS/Medical Operations for Lunar Sortie, on the best operational approach for utilizing light in-flight (duration, timing, etc.), due by 2014.

**Required Platforms:** The task will be conducted in ground laboratory studies.
### Tasks: (NSBRI)
**Characteristics of Light Exposure Necessary for Development of Optimal Countermeasures** *(NSBRI/Lockley)*

2009-2012: Lab Studies

Task to investigate whether effects of bright light (phase-shifting the circadian pacemaker, suppressing pineal melatonin, enhancing subjective alertness, improving performance and alertness) that are seen during studies at night, depend on the intensity and duration of light and that the changes in spectral sensitivity during the day. While blue light therapy to facilitate circadian adaptation and alertness has been proposed based largely on the effects of melatonin suppression at night, these data may not be transferable to the effects at other times of day (when melatonin is not produced) or for other effects of light.

2013-

Follow up tasks to be outlined below

#### Deliverables:
- Inform Standards
- Inform Requirements to Constellation for Lander Lighting Characteristics
- Inform updates to HRFS/ Medical Operations on best operational approach for utilizing light for circadian entrainment and alertness.

#### Required Delivery Milestone:
Requirements due by 2013 for Lunar Lander PDR. Requirements Updates to HRFS/Medical Operations for Lunar Sortie, on the best operational approach for utilizing light in-flight (duration, timing, etc.), due by 2014.

#### Required Platforms:
The task will be conducted in ground laboratory studies.

---

### Tasks: (NSBRI)
**Validation of ISS LED Lighting Efficacy/Effectiveness, Visual and Biological** *(NASA/NSBRI)*

2009-2011: Lab Studies

Task to validate the new lighting equipment on ISS, in terms of alertness and entrainment.

2013-

Follow up tasks to be outlined below

#### Deliverables:
- Inform Standards
- Inform Requirements to Constellation for Lander Lighting Characteristics
- Inform updates to HRFS/ Medical Operations on best operational approach for utilizing light for circadian entrainment and alertness.

#### Required Delivery Milestone:
Requirements due by 2013 for Lunar Lander PDR. Updates to HRFS/Medical Operations for Lunar Sortie, on the best operational approach for utilizing light in-flight (duration, timing, etc.), due by 2014.

#### Required Platforms:
The task will be conducted in ground laboratory studies.
Following findings from the Lighting Tasks,
Follow-on Tasks: (NSBRI)
2013: Decision regarding if/what additional studies are needed (flight and/or ground)
2015: Prep for ISS Study, if deemed necessary
2016-2019: ISS study to validate lighting recommendations.
2020-2023: Lunar validation studies
Data collected to validate lighting protocols on lunar environment.
While there are currently several tasks investigating the use of light as a countermeasure, these tasks will inform updates to HSRF/Medical Operations and hardware requirements. Following these tasks, BHP will determine what other research is necessary to close this gap. One protocol will be implemented on the Lunar surface that will validate the findings that result from this task. Therefore, the details surrounding Lunar validation will be described just once, below:

Deliverables:
Inform Requirements to Constellation for Habitat Lighting Characteristics
Validated recommendations on best operational approach for utilizing light for circadian entrainment and alertness
Recommendations and Requirements validated on Lunar environment

Required Delivery Milestone: Requirements due by 2020 for Lunar Habitat PDR. Updates to HRFS/Medical Operations for Lunar Sortie, on the best operational approach for utilizing light in-flight (duration, timing, etc.), due by 2014. Validated recommendations for utilizing light in-flight (duration, timing, etc.), delivered in 2020. Validated recommendations in lunar environment due by 2023 for update to Lunar and Mars Ops development.

Required Platforms: The task will be conducted in ground laboratory studies and in analogs offering isolation and lighting challenges, such as RCS-105 will be utilized.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>TBD; depends on findings related to timing and duration of light exposure, etc.</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>TBD; depends on findings related to timing and duration of light exposure, etc.</td>
<td></td>
</tr>
</tbody>
</table>

Sleep6: What are the performance risk/benefits of specific sleep/wake medications in flight?

As discussed in the Sleep Evidence Report, spaceflight evidence shows that sleep medications are one of the most commonly used medications during spaceflight. Flight surgeons have requested an electronic database that will make information regarding the effects of sleep-wake medications readily available to them. Some medications are suspected to work differently in space than on Earth; other medications may be required in-flight, and the potential interactions between these and sleep medications are yet to be determined.
### Tasks: (BHP Directed study)

**Develop Electronic Sleep Wake Medication Database (Dinges)**

*2007-2009:*

- Develop database and provide to operations.

**Deliverables:** Update HSRF/ISS Medical Operations with Electronic Sleep Medication Database

**Required Delivery Milestone:** Database to be delivered in 2008 and implemented in 2009, with subsequent updates every few years. Update database for HSRF/Lunar Medical Operations in 2015.

**Required Platforms:** This effort, at this time, is primarily data mining and building the database. Results from the planned Crew Quarters Sleep/Wake medications study (see Sleep7) will provide additional information on performance effects following medication use. Involves collaboration with HHC/Pharmacology and ExMC.

### Tasks: (TBD)

**Sleep/Wake Medications- Assess Interactions**

*2010: Review*

Conduct a review of the evidence related to potential interactions and carry-over effects. Determine if a study is needed. Subsequent tasks following this review to be defined.

**Deliverables:**

- Review will help inform BHP in regards to subsequent tasks and deliverables, as well as future updates to database deliverable
- TBD

**Required Delivery Milestone:** TBD

**Required Platforms:** This effort, at this time, involves a ground based evidence review.

### Tasks: (TBD)

**Sleep/Wake Medications- Pharmacokinetics/Efficacy**

*2010: Review*

Conduct a review of the evidence related to the absorption and effectiveness of sleep/wake medications in microgravity. Determine if a study is needed. Subsequent tasks following this review to be defined.

**Deliverables:**

- Review will help inform BHP in regards to subsequent tasks and deliverables, as well as future updates to database deliverable
- TBD

**Required Delivery Milestone:** TBD

**Required Platforms:** This effort, at this time, involves a ground based evidence review.
Sleep7: What are the best individual dosing requirements/protocols for Sleep and alertness medications during spaceflight?

Tasks: (BHP Directed study / Ops (TBD))
Individualized Protocols Sleep/Wake Medications

2009-12: Pilot and Ground Study, Develop and Implement Operational Ground Testing Protocols to Individualize Astronaut Sleep Medication Efficacy and Individual Effects (Johnston)

This task is a ground based study to test the percentage change in sleep inertia from using a medications (commonly used during spaceflight) compared to normal sleep inertia. The study will test the feasibility of a protocol for use with astronauts and other NASA personnel (e.g., flight surgeons, flight directors and flight controllers) to assess potential carry over effects from sleep medications used during spaceflight operations, overseas training periods, and following an abrupt awakening from sleep. This information is needed to establish optimal and individually tailored protocols for usage of sleep medications by key personnel relative to operational demands.

2012: Determine if Spaceflight studies are needed
If so, prepare for spaceflight study
   2013: Prep for spaceflight
2014-2017: Validate protocols in-flight
If not, determine if ground studies are needed
   If so,
   2013-2016: Additional ground studies
   If not, stop tasks
2020-2023: Lunar study to assess effects of medications in Lunar environment

Deliverables:
Recommendations for best operational approach for utilizing sleep medications during training / flight;
individualized recommendations for sleep medications.
Recommendations for best operational approach for utilizing sleep medications during flight
Recommendations regarding effects of medication in Lunar environment

Required Delivery Milestone: Update to HSRF/ISS Med Ops following the findings of the first study, in 2012. Update to HSRF/ Med Ops for Lunar Operations in 2016 and/or 2017, following findings of subsequent ground and/or flight study. Update Lunar Ops and Input to Mars Ops Development in 2023.

Required Platforms: This effort involves ground studies using astronauts. Possible ISS data collection efforts to aid in determining if medications ingested in flight were as effective as when taken on the ground. Involves collaboration with HHC/Pharmacology and ExMC as well as SD and CB.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
</tr>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
</tr>
</tbody>
</table>

Sleep8: How are physical and cognitive workloads managed optimally in space relative to fatigue and recovery?

While the evidence is largely anecdotal, strict adherence to timelines has been reported to be fatiguing and stressful for astronauts. Furthermore, individuals on analog missions where there are unusual light...
cues (i.e. twenty-four hour sunlight in the Arctic) have reported that they continue to work for hours on end without feeling a need for sleep, a potential concern since lack of sleep and fatigue can affect performance. In future space missions to the Moon or Mars, crewmembers will be given more autonomy to plan and carry out their activities due to the long distances involved and the tasks that will be needed to explore a planetary surface, and they will also be exposed to light cues unlike those on Earth. Recommended optimal work rest schedules need to be provided so that crews can make informed decisions around work and rest.

**Tasks:** (Redirected NRA)
- Impact of Increased Work Autonomy on Performance (Kanas)
  - 2009: Autonomy Workshop
  - 2009-2010: Analogs: NEEMO
    - Conduct studies in NEEMO to evaluate performance under high autonomy, versus low autonomy, conditions. This data will provide insight into optimal work-rest schedules within these conditions, and will serve as a feasibility study in preparation for a study on ISS.
  - 2009-2010:
    - Conduct studies in the Russian-Chamber 105 day study.
  - 2011: Preparation for spaceflight
    - 2011-2015: Data collection on ISS. Study will evaluate performance in high autonomy versus a low autonomy environment and provide insight into optimal work-rest schedules within both of these conditions. Requires the ISS because of sleep-related issues associated with microgravity, and to emulate accurately the spaceflight high-tempo, remotely scheduled and controlled environment. The ISS will emulate the transit environment to Mars.
  - 2016: Determine if additional studies are needed
  - 2016-2020: Additional ground task to be defined, if deemed necessary
  - 2020-2023: Validate recommendations to aid schedules/performance in Lunar environment

**Deliverables:** Recommendations for optimal work-rest schedules to prevent mental and physical fatigue during operations


**Required Platforms:** Ground analogs, such as NEEMO and RCS, the ISS, and Lunar surface.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011-2015: Data collection on ISS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020-2023: Validate recommendations to aid schedules/performance in Lunar environment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
</tr>
</tbody>
</table>

**Tasks:** (ITA with Ames. Involves collaboration with SHFH)
- SPIFe
  - 2008-2012: Develop scheduling software SPIFe for autonomous operations
    - This tool may be incorporated in NEEMO studies and ISS study described above. Details TBD.

**Deliverables:** Scheduling software for operations as part of recommendations for optimal work-rest schedules to prevent mental and physical fatigue during operations

**Required Platforms:** As part of study listed above, may be validated in ground analogs such as NEEMO, the ISS, and Lunar surface.

**Tasks:** (TBD)
Impact of Sleep Loss, Fatigue and Workload on Learning, Memory, and Psychosocial Adaptation
2010: Review
Conduct a review of the evidence related to effects of workload, fatigue, sleep loss, etc.

**Deliverables:**
Review will help inform BHP in regards to subsequent tasks and deliverables
TBD

**Required Delivery Milestone:** TBD

**Required Platforms:** This effort, at this time, involves a ground based evidence review.

**Sleep9: What are the countermeasures needed to recover from chronic partial sleep loss and/or slam shifting?**

Despite medication use, sleep loss does occur during spaceflight, with some crewmembers reporting minimal amounts of sleep, particularly prior to conducting critical mission tasks. Many factors can affect sleep quality and quantity in the spaceflight mission environment including high noise levels, shifting schedules, high tempo workloads, thermal temperature changes, microgravity adjustment, and close proximity to others. Flight surgeons have requested information that can aid individual astronauts on improving their sleep quality and quantity during spaceflight. Given the complexity of spaceflight missions, and the effects of sleep loss on fatigue and performance, such information will be instrumental for not only crewmembers, but also their families, ground support teams, and other medical personnel regarding strategies to improve sleep quantity and quality. Information will help inform current standards as well as those for future missions.

**Tasks:** (NSBRI)
Sleep Dose Recovery
2008-2009: Lab studies
This laboratory effort evaluates the effect of different doses of sleep time on performance and cognition. The knowledge gained has the potential to change work scheduling (Sleep8) and further understand the effect of sleep loss and the mitigating impact of naps on neurobehavioral function in spaceflight.

**Deliverables:** Data gathered will feed Recommendations regarding recovery sleep
2) Inform Standards.

**Required Delivery Milestone:** Update HSRF/Medical Operations in 2009.

**Required Platforms:** Laboratory studies.

**Tasks:** (BHP Directed Study)
Jet-Lag/Crew Training/MOD Shifting
2009: Pilot Study
2010-2013: Ground Studies
This task is to evaluate effectiveness of countermeasures currently being used for slam shifting and training overseas. This effort will also inform subsequent gaps and tasks to help inform Ops for lunar operations. Following this task, future tasks (if any) will be determined.
Deliverables: Recommendations for astronauts, management, and ground support on strategies for improving sleep quality and quantity during human spaceflight missions.

Required Delivery Milestone: Update HSRF/Medical Operations by 2014.

Required Platforms: Ground studies.

Tasks: (TBD)
Optimal Countermeasures for Lunar
2009: Review
Conduct a review of the evidence related to mitigation strategies for shift-workers, etc., in order to assess additional countermeasures relevant to the lunar environment

Deliverables:
Review will help inform BHP in regards to subsequent tasks and deliverables
TBD

Required Delivery Milestone: TBD

Required Platforms: This effort, at this time, involves a ground based evidence review.

Sleep10: What flight rules and requirements improve sleep, circadian desynchronization, fatigue and work overload, to reduce performance errors?

Aspects of spaceflight missions and the spaceflight environment can adversely impact sleep and circadian rhythms. While some factors (such as noise) cannot be controlled, others (such as lighting and schedules) may be informed by research. BHP aims to assess current flight rules and requirements in order to develop recommendations for constellation.

Tasks: (Directed Study/Locke)
Sleep Quality and Strategies Questionnaire
2009: Systematic review of flight rules and requirements regarding sleep
2008-2011: Ground Studies
Data collection from crews returning from flight regarding their sleep quality on-orbit, and in comparison to their terrestrial sleep and during various training activities. This questionnaire is designed to assess what factors impact sleep quality and quantity and seeks suggestions regarding strategies for improving sleep on-orbit for future flyers.
2011: Determine if additional studies are needed
2012-2014: Ground based studies, if deemed necessary
2020-2023: Validate recommendations on lunar surface

Deliverables:
Recommended updates to flight rules and requirements
Inform Standards to protect sleep, minimize fatigue, and maintain performance.

Required Delivery Milestone: Updates to HSRF/Medical Operations provided in 2011. Subsequent updates (if deemed necessary) provided in 2014, and following Lunar validation in 2023 for Lunar Ops and Mars Ops Development.

Required Platforms: Primarily ground effort with validation on lunar surface. This includes a data mining effort in collaboration with CB and Med Ops.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td>Very Low</td>
<td></td>
</tr>
</tbody>
</table>

2020-2023: Validate recommendations on lunar surface
<table>
<thead>
<tr>
<th>Tasks: (Directed Study)</th>
<th>Determine Sleep Performance Countermeasures for Martian Sol – Flight and Ground Crews</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008-2010: Ground Studies</td>
<td></td>
</tr>
<tr>
<td>Ground crews supporting Mars robotic missions have chosen to maximize the use of the rovers on the surface of Mars by adopting the Mars sol. As a result, these engineers and scientists live/work on a 24 hour and 39 minute schedule. After 10 days, these individuals are shifted by six and a half hours. Trying to maintain such a schedule has proven challenging for crews. Those supporting the Mars Pathfinder, Spirit and Opportunity Rovers have struggled with fatigue and other issues. NASA BHP is conducting a directed study with the ground crew supporting the Mars Phoenix Scout Lander. This study will evaluate countermeasure effectiveness for attempting to manage sleep over a Mars schedule.</td>
<td></td>
</tr>
<tr>
<td>2011: Determine if additional studies are needed. If so,</td>
<td></td>
</tr>
<tr>
<td>2013-2015: Ground Studies: Crews Supporting Mars Mission</td>
<td></td>
</tr>
<tr>
<td>Follow-up study from Phoenix Mars Lander, implementing “lessons learned” and new relevant aims to protocol.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations to aid flight rules and requirements for Ops</td>
</tr>
<tr>
<td>Recommendations to aid flight rules and requirements for Ops ground and flight crews during Mars missions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations based on evidence to inform Mission Ops in 2010 and 2015.</td>
</tr>
<tr>
<td>Lunar validation in 2023 for Lunar Ops and Mars Ops Development.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground effort with validation on Lunar surface.</td>
</tr>
</tbody>
</table>
Step 1: What are the best tools to monitor and assess decrements due to fatigue, sleep loss, and other spaceflight factors? 

- Refine and Validate Psychomotor Vigilance Test (PVT) 
- Self Test (NSBRI/Directed) (Dinges) 
- PVT Self Test on ISS (Directed) (Dinges) 
- Cognition Assessment Tool (CAT) (SBIF) 
- Sleep-Wake Light Exposure Actigraphy Study (NRA) (Czeisler/Barlow) 
- Individualized Fatigue Meter (SBIR/T30) 

**Input:** 
- Update HSRRFMed Ops 
- Update PVT/Class Test 
- Right Validation Studies 

**Output:** 
- Select best measures 
- Are measures adequate? 
- Are additional or improved technology monitoring/assessment tools needed? 
- CAT as new requirement for Exploration to assess cognitive performance prior to critical tasks 
- Individualized Fatigue Meter/Emotion Actwatch to become new requirement operational tool
Risk of Performance Errors Due to Sleep, Circadian Desynchronization, Fatigue, and Work Overload

**Objective:**
How can light be used optimally to minimize circadian problems in space?

**Studies to determine:**
- Efficacy of shorter-wavelength-enriched for phase shifting (NSBR/Zeisel)
- Alerting, hormonal, and circadian effects of artificial and ambient light (NSBR/Brandt plus Blue light for enhancing Alertness (Directed))
- Characteristics of Light Exposure Necessary for Development of Optimal Countermeasures (NSBR/Lockley)

**HP Validation of ISS LED lighting efficacy/efficacy, visual and biological (NASA/NSERI)**
HRP-47

& Shuttle
6 Crew Capability ▲  ▲ Shuttle Retired ▲ End of US Commitment

Program Level
▲ PDR ▲ CDR ▲ SRP ▲ CDR Initial Ops ▲ PDR ▲ CDR ▲ Full Ops Capability

Option
▲ PDR ▲ CDR

EVA Suit
▲ PDR-sub1 ▲ CDR-sub1 ▲ PDR-sub2 ▲ CDR-sub2

Lander
▲ ATP ▲ SDR ▲ PDR ▲ CDR

Mission Operations
▲ PDR initial ▲ CDR initial ▲ SDR ▲ CDR

Intrusion of Performance Errors Due to Sleep Loss, Circadian Synchronization, Fatigue, and Workload

sp6 What are the performance risk/benefits of specific sleep/wake medications in flight?

Develop Sleep Wake Medications Database (Directed/Med Ops)

Sleep Wake Medications - Assess Interactions (NRA)

Sleep Wake Medications - Pharmacokinetics/Efficacy (TBD)

Rev. of Med

(1, 2) Electronic Sleep Medication Database

(2) Electronic Sleep Medication Database Update

2 Update HSRF/Med Ops

(3) Electronic Sleep Medication Database Update

Is study needed?

Rev.

Gaps and Activities to be subsequently revised/defined

NO

Is study needed?

Rev.

Gaps and Activities to be subsequently revised/defined

147
Step 9: What are the countermeasures needed to recover from chronic partial sleep loss and/or sleep shifting?

1. Recommendations for Flight Med Ops related to recovery sleep
2. Recommendations for Flight Med Ops related to jet lag, training, MOD, shift work CM
3. Recommendations for Flight Med Ops related to sleep shifting

- Are countermeasures adequate for Mars surface?
  - Yes: Update Lunar Ops & Input to Mars Ops Dev't (Data Required TBD)
  - No: Lunar CM Studies
- Are additional studies needed?
  - Yes: Gaps and Activities to be subsequently revised/defined
  - No: Gaps and Activities to be subsequently revised/defined

P: Sleep Dose Recovery (NSBRP) (Dinges)

- This task also informs modeling efforts in Sleep

P: Jet-Lag / Crew Training
- MOD Shifting
- Countermeasure Study (NASA/NSBRP)
- This task also informs gap: Sleep

P: Optimal countermeasures for Lunar (TED)
Human performance errors may occur due to problems associated with working in the space environment and incidents of failure of crews to cooperate and work effectively with each other or with flight controllers have been observed. Interpersonal conflict, misunderstanding and impaired communication may impact performance and mission success. However, the history of spaceflight crews regarding team cohesion, team performance, and ground-crew interaction has not been systematically documented. Tools, training, and other support methods should be provided to reduce the likelihood of this risk and improve crew performance, crew cohesion, and crew-ground interaction.

Operational Relevance Assessment and Recommendations

While little empirical data have been collected regarding the impact of interpersonal and intrapersonal factors on spaceflight performance, it is possible that crew conflict could jeopardize long duration Exploration Missions. Reports from MIR reveal that several missions may have been terminated earlier than planned due to interpersonal frictions between crewmembers, and some veteran NASA astronauts have reported crew conflict during previous space travels. Understanding the potential negative impacts of interpersonal and intrapersonal issues from spaceflight and relevant, high fidelity analog environments is critical for identifying actions required to help crewmembers succeed during new types of missions (e.g., Mars Missions). Few individuals have spent one year or longer in isolated and confined environments, and a Mars Mission could be as long as three years in duration. Thus, observations and “lessons learned” from previous space missions and from relevant analog environments are important sources of information required to inform these efforts. In preparation for Exploration Missions, BHP research focuses on preventing and mitigating the risk of performance errors due to inadequate Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation. Monitoring tools, countermeasures, training requirements, and selection/composition recommendations are needed to aid flight crews and ground support teams so that optimal performance may be realized.

Strategy for Mitigation

The risk mitigation strategy of the BHP Element follows the larger strategy of the HRP “from Evidence to Products” principle, while being driven by Operations. BHP holds an annual working group of subject matter experts who work with BHP and Medical Operations to identify gaps in knowledge and gaps in mitigation. Specific tasks are defined to address the gaps and provide clear, specific deliverables for Constellation, ensuring an evidence and operationally based end item. Working with research and operational experts, BHP systematically identifies the appropriate analog to address the gaps prior to validating in spaceflight. To ensure relevancy, stakeholders are engaged in the process at the beginning. Findings from BHP research inform operations and standards as well as update the evidence base for the BHP Risks.

The strategy for mitigation for this area of research is to develop an empirical-based approach to first identify the most relevant and serious threats to team performance, team cohesion, and crew-ground interaction. Utilizing a common set of criteria will allow for the systematic review and analysis of knowledge as well as current practices/policies in implementing BHP operations. Once these threats have been identified, the most effective ways to monitor and measure these threats as well as the identification of optimal countermeasures to mitigate these threats will be determined. To further mitigate the risk, specific factors have been identified (e.g., crew composition, communication, autonomy, etc.) as highly
relevant to long duration space missions. Thus, these gaps will focus specifically on understanding the true impact of these factors on long duration missions.

**Gaps**

**BHP Gap Team1: What are the most likely and most serious threats to crew cohesion, crew performance, and crew-ground interaction expected for exploration missions? (Priority 1)**

The most serious and relevant threats to crew performance, crew cohesion, and crew-ground interaction have not been systematically analyzed and documented. This approach will take an empirically based approach to identify which threats are most relevant and serious to the set criteria. As noted in the Team Evidence Book, existing threats may negatively affect cohesion and crew-ground interaction, both of which ultimately preclude optimal performance. Thus, it is necessary to identify those threats that are most likely to influence these criteria negatively.

**Tasks:** (Directed Study, BHP In-House)

**Systematic Query: Crew History**

2010: Literature/Ops Review

Review of existing crew information and literature from analogs to examine small groups in extreme environments.

2011: Develop Questionnaire

Develop questionnaire for current and future long-duration crews regarding their experiences, emphasizing interpersonal factors. Systematically implement questionnaire and analysis.

**Deliverables:** Crew History Report – provides recommendations based on existing spaceflight and analog experience of crews, including training, in-flight, and post-flight events.

**Required Delivery Milestone:** Initial Crew History Report based on current anecdotal evidence and analog evidence delivered in 2010. Updates to HSRF/Medical Operations made in 2012 (once 30 subjects have been evaluated), with subsequent updates following every four years. Report/Recommendations required by 2014 for Human Risk Forum/Lunar Med Ops and 2023 for Lunar Habitat Mission Ops.

**Required Platforms:** Ground based data collection

**Tasks:** (BHP In-House)

**Risk Assessment: Crew Cohesion**

2009-2010: Literature/Ops Review

Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to crew cohesion.

**Deliverables:** Crew Cohesion Report – provides a summary of literature and current operations and identifies most relevant and serious threats in relation to crew performance. Also includes a recommendation based on evidence gathered on whether studies are needed.

**Required Delivery Milestone:** Initial Crew Cohesion Report based on literature review and assessment of current practices delivered at the end of 2010. Report/Recommendations required by the beginning of 2011 to determine if studies are needed. If applicable, HSRF/Medical Ops Update for Lunar Long in 2019, Mars Update in 2023.

**Required Platforms:** Ground based data collection
### Tasks: (BHP In-House)

**Risk Assessment: Crew Performance**

2009-2010: Literature/Ops Review

Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to crew performance.

**Deliverables:** Crew Performance Report – provides a summary of literature and current operations and identifies most relevant and serious threats in relation to crew performance. Also includes a recommendation based on evidence gathered on whether studies are needed.

**Required Delivery Milestone:** Initial Crew Performance Report based on literature review and assessment of current practices delivered at the end of 2010. Report/Recommendations required by the beginning of 2011 to determine if studies are needed. If applicable, HSRF/Medical Ops and Mission Ops Update for Lunar Long in 2019, Mars Update in 2023.

**Required Platforms:** Ground based data collection

### Tasks: (BHP In-House)

**Risk Assessment: Crew-Ground Interaction**

2009-2010: Literature/Ops Review

Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to crew-ground interaction.

**Deliverables:** Crew-Ground Interaction Report – provides a summary of literature and current operations and identifies most relevant and serious threats in relation to optimal crew-ground interaction. Also includes a recommendation based on evidence gathered on whether studies are needed.


**Required Platforms:** Ground based data collection

---

**BHP Gap Team2: What are the most optimal ways to monitor and measure crew cohesion, crew performance, and crew-ground interaction for exploration missions? (Priority 1)**

Given the importance of threats identified in the first gap in relation to crew performance, crew cohesion, and crew-ground interaction, monitoring tools and other measures will need to be developed to assess these relationships. During Exploration Missions, and especially during a Mars Mission, real time communication between the crew and flight surgeons will not be available as it is now on ISS. Flight surgeons have stated the need for unobtrusive monitoring tools that are transparent to crews, require minimal crew time or effort, and that help detect if crews are having difficulties coping with the spaceflight environment by utilizing indicators of performance, cohesion, and crew-ground interaction.

The aim of the current gap is to identify the most optimal tools that will detect changes in crew cohesion, crew performance, and/or crew-ground interaction. One task specifically relates to the creation of a tool that will monitor changes in crew cohesion. Monitoring tools identified in the Risk of Behavioral and Psychiatric Conditions may also provide an assessment of team cohesion. These tools (e.g., voice acoustics and facial expression recognition) will be validated in ground studies through 2010, and validated in flight through 2017 if deemed necessary (more information can be found in BMed3).
**Tasks: (NRA)**

**Assess measures for Monitoring Crew Cohesion**

2009-2012: Test Measures in Analogs:
Activities include evaluating various existing techniques for assessing team cohesion through crew communication, validating these techniques in analog and/or operational environments (i.e. during astronaut training), and validating on ISS.

2013: ISS Prep

2014-2016: ISS Validation Studies:
Preferred techniques will be developed into Requirements for an automated, unobtrusive tool to be utilized during Exploration Missions.

2017-2023: Ground and Flight Studies, if needed
If after undergoing validation utilizing ISS Studies these techniques are found to be not effective, additional ground studies and flight validation studies to identify optimal tools will be conducted. The optimal technological tools from these studies will be validated in lunar studies. New Requirements will then be delivered by 2023 for informing Human Subjects Risk Forum/Med Ops and Input to Mars Ops Development.

**Deliverables:**
Requirements for Crew Communications Technology (unobtrusive, passive measures that assesses changes in crew communication patterns as a measure of modified cohesion).
Updates to Standards (if applicable).

**Required Delivery Milestone:** This deliverable is to support long duration Lunar and Mars. Update therefore to Human Subjects Risk Forum/Med Ops in 2017, and in 2023 (for input into Lunar long and Mars Ops development.)

**Required Platforms:** Ground studies to adapt technology for spaceflight and may include analog studies in Isolated, Confined and Extreme (ICE) Environments and/or studies in operational environments. Validate on ISS, as the ISS will emulate the transit environment to Mars.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

**Tasks: (BHP In-House)**

**Assess Additional Measures for Monitoring Crew Cohesion**

2010-2011: Literature/Ops Review
Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to those measures that best assess crew cohesion.
**Deliverables**: Monitoring Tool/Measures Report – provides a summary of literature and current operations and identifies optimal measures and monitoring tools for crew cohesion. Also includes a recommendation based on evidence gathered on whether future studies are needed.


**Required Platforms**: Ground based data collection.
Tasks: (BHP In-House)
Assess Additional Measures for Monitoring Crew Performance
2010-2011: Literature/Ops Review
Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to those measures that best assess crew performance.

Deliverables: Monitoring Tool/Measures Report – provides a summary of literature and current operations and identifies optimal measures and monitoring tools for crew performance. Also includes a recommendation based on evidence gathered on whether future studies are needed.


Required Platforms: Ground based data collection.

Tasks: (BHP In-House)
Assess Additional Measures for Monitoring Crew-Ground Interaction
2010-2011: Literature/Ops Review
Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to those measures that best assess crew-ground interaction.

Deliverables: Monitoring Tool/Measures Report – provides a summary of literature and current operations and identifies optimal measures and monitoring tools for crew-ground interaction. Also includes a recommendation based on evidence gathered on whether future studies are needed.


Required Platforms: Ground based data collection.

BHP Gap Team3: What additional approaches would enhance current in-flight interventions and countermeasures for supporting crew cohesion, crew performance, and crew-ground interaction for exploration missions? (Priority 1)

Once the threats have been identified and the optimal ways to measure and monitor these threats and their impact on crew performance, crew cohesion, and crew-ground interaction has been developed, it may be necessary to develop additional countermeasures that enhance current practices to mitigate these threats, particularly for long duration exploration missions. The Team Evidence Book clearly states that countermeasures are needed in order to reduce any negative impact on crew performance. Thus, the development of strategies and countermeasures, including development of training protocols and new monitoring methods and tools, may be addressed in this gap.
<table>
<thead>
<tr>
<th>Tasks: (BHP In-House)</th>
<th>Identify Optimal Countermeasures to Support Crew Cohesion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2010-2011: Literature/Ops Review</td>
</tr>
<tr>
<td></td>
<td>Review of past and current literature and assessment of operations to ascertain current best practices/policies to identify optimal countermeasures to support crew cohesion</td>
</tr>
<tr>
<td>Deliverables:</td>
<td>Countermeasure Report – provides a summary of literature and current operations and identifies optimal countermeasures to support crew cohesion. Also includes a recommendation based on evidence gathered on whether future studies are needed.</td>
</tr>
<tr>
<td>Required Platforms:</td>
<td>Ground based data collection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (BHP In-House)</th>
<th>Identify Optimal Countermeasures to Support Crew Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2010-2011: Literature/Ops Review</td>
</tr>
<tr>
<td></td>
<td>Review of past and current literature and assessment of operations to ascertain current best practices/policies to identify optimal countermeasures to support crew performance</td>
</tr>
<tr>
<td>Deliverables:</td>
<td>Countermeasure Report – provides a summary of literature and current operations and identifies optimal countermeasures to support crew performance. Also includes a recommendation based on evidence gathered on whether future studies are needed.</td>
</tr>
<tr>
<td>Required Platforms:</td>
<td>Ground based data collection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (BHP In-House)</th>
<th>Identify Optimal Countermeasures to Support Crew-Ground Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2010-2011: Literature/Ops Review</td>
</tr>
<tr>
<td></td>
<td>Review of past and current literature and assessment of operations to ascertain current best practices/policies to identify optimal countermeasures to support crew-ground interaction</td>
</tr>
<tr>
<td>Deliverables:</td>
<td>Countermeasure Report – provides a summary of literature and current operations and identifies optimal countermeasures to support crew-ground interaction. Also includes a recommendation based on evidence gathered on whether future studies are needed.</td>
</tr>
<tr>
<td>Required Platforms:</td>
<td>Ground based data collection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (TBD)</th>
<th>Inform SHFH: Psychosocial Food Requirements Food Ops (TBD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2011-2014: Activities TBD</td>
</tr>
<tr>
<td>Deliverables:</td>
<td>Recommendations based on evidence gathered</td>
</tr>
<tr>
<td>Required Delivery Milestone:</td>
<td>Information to SHFH TBD</td>
</tr>
<tr>
<td>Required Platforms:</td>
<td>Ground based data collection.</td>
</tr>
</tbody>
</table>
BHP Gap Team4: What are the most optimal ways to compose crews to ensure crew cohesion, optimize crew performance, and facilitate crew-ground interaction for exploration missions? (Priority 2)

Group composition plays an important role in team performance: research included in the Team Evidence Book indicates that team composition is a key differentiating factor between high- and low-success teams. Furthermore, research demonstrates that composition can also influence cohesion and interpersonal interaction among crewmembers. Therefore, it seems necessary to examine and implement practices to secure the best crew composition for Exploration Missions. BHP places this gap as a second priority within the Team Risk to address recommendations for team composition for Exploration Missions.

<table>
<thead>
<tr>
<th>Tasks: (BHP In-House (Review); NRA (ISS Study))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crew Composition Studies</td>
</tr>
<tr>
<td>2010-2011: Literature/Ops Review</td>
</tr>
<tr>
<td>Review of past and current literature and assessment of operations to ascertain current best practices/policies to identify optimal composition factors that influence crew cohesion, crew performance, and crew-ground interaction. Collaborate with BHP Ops.</td>
</tr>
<tr>
<td>2011-2012: ISS Prep</td>
</tr>
<tr>
<td>2012-2019: ISS Studies</td>
</tr>
<tr>
<td>Assess composition factors of ISS crew and how those are related to measures of cohesion, performance, and crew-ground interaction. Develop composition recommendations for Exploration Missions. This task is anticipated to last approximately eight years in order to allow for an adequate number of teams (as opposed to individual subjects.)</td>
</tr>
<tr>
<td>2022-2025: Lunar Studies</td>
</tr>
<tr>
<td>Follow-up validation of composition recommendations on lunar missions; will want to validate recommendations using the context of a lunar environment.</td>
</tr>
</tbody>
</table>

| Deliverables:                                  |
| Recommendations regarding optimal team composition. |
| Update Standards.                             |

| Required Delivery Milestone: Recommend Update to Inform HSRF/Medical Ops for Lunar Habitat missions in 2019 and 2025. |
| Updated Standards for Crew Composition by 2019 for Lunar Long and Mars. |

| Required Platforms: This effort involves ground studies and data mining effort, as well as an ISS study with in-flight questionnaires and assessment of composition. Also, plan to validate using lunar studies. |

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 teams</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td>Very Low</td>
</tr>
<tr>
<td>5 teams</td>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

2012-2019: ISS Studies

2022-2025: Lunar Studies
**Tasks: (TBD)**

**Validate Measures for Composition**

Conducting ground studies to determine which composition tools optimally predict crew cohesion, crew performance, and crew-ground interaction. Plan to validate these tools utilizing lunar long missions.

*2014-2021: Ground Studies*

Tentatively plan to incorporate knowledge gained from previous task (review literature and Ops assessment) and use a ground study setting to validate the composition tool.

**Deliverables:**

Recommendations regarding optimal measures for team composition for long duration exploration missions.

Update Standards.

**Required Delivery Milestone:** Inform HSRF/Med Ops for Lunar Habitat missions in 2021. Recommendations required by 2025.

**Required Platforms:** This effort is primarily ground studies although lunar studies will also be utilized to validate the tool.

---

**BHP Gap Team 5: What are the optimal ways to train crews, leaders, and ground support to ensure crew cohesion, optimize crew performance, and facilitate crew-ground interaction for exploration missions? (Priority 2)**

Crews on ISS are diverse (multiculturally, racially, etc.), and this diversity will most likely continue for Exploration Missions. As noted in the Team Evidence Book, finding adequate time for crews to train together continues to remain a challenge. Current plans for astronaut teams include reducing the times spent together training even further, and subsequently these changes will likely increase conflict and performance-related decrements.

These factors make it essential to determine what acceptable alternatives to traditional team training methods (i.e. virtual team training) exist. In addition, the type of team training activities (role playing, etc.) and the duration of the training are important factors in designing the most efficient and effective training model that will improve crew performance, crew cohesion, and crew-ground interaction. It is critical to capture what type, dose, style and length of training can most adequately cover multiple competencies to ensure efficiency of the astronauts’ time while promoting mastery of the required competencies for a successful mission.

**Tasks: (Directed)**

**Training Studies: Crew Cohesion and Crew Performance**

*2009-2013: Evaluate Training*

Evaluate training using analog studies (and/or studies in operational environment) to validate optimal training methods. Analogs may include NEEMO and HMP.

*2013-2014: ISS Prep*

*2014-2018: ISS Studies*

Evaluate Training Requirements during spaceflight on ISS to determine if Training Requirements are adequate. If further Training Requirements are needed, studies will commence and will be followed by a phase of simultaneous in-flight and lunar studies. The optimal training tools from these studies will be validated in lunar studies. New Requirements will then be delivered by 2023 for informing Human Subjects Risk Forum/Med Ops and Input to Mars Ops Development.

**Deliverables:**

Recommendations, crew training for team cohesion and optimal performance.

Information to ExMC and SHFH
**Required Delivery Milestone:** Recommendations to Inform Mission Ops by 2013. Studies will be completed by 2018 (status provided in 2015 with subsequent updates.)

**Required Platforms:** Activities include assessing training in analog and/or operational environments, and validating on ISS and in lunar studies.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 teams</td>
<td></td>
<td></td>
<td></td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>

**Tasks:** (TBD)

**Training Studies: Crew-Ground Interaction**

2010-2013: Evaluate Crew-Ground Interaction

Evaluation for Crew-Ground Interaction TBD

**Deliverables:**

Requirements for crew-ground interaction TBD

Update to Standards, if applicable.

**Required Delivery Milestone:** TBD

**Required Platforms:** TBD

**BHP Gap Team6: How does increased work autonomy impact crew cohesion, crew performance, and crew-ground interaction for exploration missions? (Priority 3)**

As crews begin operations for long duration missions beyond low Earth orbit, they will need to exercise increasing command and control of their daily activities. The distance for Mars Missions will result in loss of capability for real-time communication, downlink, and commanding. Likewise, the crew will have to augment and adapt their schedules based on real time changes in their schedules. Medical Operations has requested a study of crew autonomy while we are still in low Earth orbit, to identify the impact (if any) of increased autonomy on crew dynamics and performance.

**Tasks:** (Directed)

**Task: Impact of Increase Work Autonomy on Performance**

2008-2010: Analog Studies

Conduct studies in NEEMO to evaluate impact of increased autonomy on cohesion and performance.

2009-2010: RCS

Conduct studies in the Russian-Chamber 105 day study, observing impact of increased autonomy on cohesion and performance.

2010: Autonomy Workshop

Conduct Autonomy Workshop to examine preliminary results from analog studies and further define role of autonomy in Mars exploration and its effects on crew performance and crew dynamics.

2010-2011: Prep

2011-2015: ISS Studies

Studies on ISS to observe crew performance and cohesion, working under a low autonomy condition versus a high autonomy condition.

If evidence exists that increased autonomy impacts crew dynamics and performance, the need for countermeasures in addition to what BHP has developed/is developing, will be considered. Recommendations will be provided and ground and flight studies will then commence with plans to validate in lunar missions.

**Deliverables:** Recommendations based on the impact (if any) of increased autonomy in analogs and spaceflight.

Required Platforms: Requires analogs (NEEMO, RCS) and ISS.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Tasks: (Re-directed NRA)

SPIFe
2009-2011: SPIFe Tool
Conduct studies to develop SPIFe in relation to increases in autonomy.
If tool is ready for spaceflight by 2011, will then be used with findings from task above in ISS studies. If not, will then conduct analog studies.

Deliverables: Recommendations based on the impact (if any) of increased autonomy in analogs and spaceflight.


Required Platforms: May require ISS.
**Tasks: (TBD)**

**Autonomy, Cohesion, and Performance Review**

2010-2011: Literature Review

Review of past and current literature and assessment of operations to ascertain current best practices/policies in relation to autonomy and its impact on cohesion and performance in isolated environments.

**Deliverables:** Autonomy Report- provides a summary of literature and current operations and identifies changes in autonomy in relation to cohesion and performance. Also includes a recommendation based on evidence gathered on whether studies are needed.

**Required Delivery Milestone:** Initial Autonomy Report based on literature review and assessment of current practices completed at the end of 2011. Report/Recommendations required by the beginning of 2012 to determine if studies are needed.

**Required Platforms:** Ground based data collection TBD.

---

**BHP Gap Team7: What aspects of communication impact crew cohesion, optimize crew performance, and facilitate crew-ground interaction for exploration missions?**

When considering the context of long duration missions, communication is likely to be a key factor to positive interpersonal interactions and will likely influence crew cohesion, crew performance, and crew-ground interaction. This is especially true when considering the communication delay between crewmembers and ground control during long duration missions. Data summarized in the Team Evidence Book suggests that communication can affect interactions among crewmembers when dealing with task-related issues and/or interpersonal-related issues. Thus, it is necessary to identify in what way communication may impact the identified criteria.

**Tasks: (NSBRI)**

**Conflict Management for Crew Cohesion**

NSBRI funded the development of a technology that guides astronauts through conflict resolution.

2009-2012: Analog Tests

The effectiveness of this technology should be evaluated in analogs, such as the Antarctic, where groups of individuals are stationed for months at a time, in extreme, isolated environments where conflict has been known to occur.

2012-2013: ISS Prep

2013-2015: ISS Studies

The technology should then be made available on ISS, and its effectiveness with astronauts, when used, should be evaluated.

If flight data collected reveals that additional countermeasures are needed to address cohesion and communication, additional studies will be developed to help design and test new strategies. If necessary, will utilize ground and flight studies, with a desire to validate those optimal countermeasures in lunar missions.

**Deliverables:**

Technologies that provide conflict management support and guidance for crewmembers, particularly for autonomous operations.

Updates to Standards, if applicable.

**Required Delivery Milestone:** In-flight validation of Conflict Management Technology to begin in 2012, with technology delivered by 2015.

**Required Platforms:** Conflict management technology to be evaluated in analogs, including the Antarctic. Flight validation of technology to occur on ISS.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>
Tasks: (Directed Studies)
Optimal Communication Strategies: Crew-Ground Interaction
2010-2011: Literature/Ops Review
Conduct a review of best practices for optimal communication strategies, between and within groups, from the military and other agencies.
Will obtain and analyze data of communications between space and ground crews as well as conduct a literature review in order to develop recommendations for improved communication strategies related to performance of mission objectives.

Deliverables:
Recommendations for optimal communication strategies
Updates to Standards, if applicable.

Required Delivery Milestone: Initial Crew Communication Report based on literature review and assessment of current practices delivered at the end of 2011. Report/Recommendations required by the beginning of 2012 to determine if additional studies are needed.

Required Platforms: Analysis of ISS/MOD communications can be collected / analyzed from the ground.

Tasks: (NSBRI)
Optimal Communication Strategies: Crew Performance
2008-2013: Lab Studies
Conduct lab studies that examine the impact of environmental stressors, incentives, and crew configuration changes on communication and performance within simulated space crews and between simulated space and ground crews.

Deliverables:
Recommendations for optimal support system for Exploration
Updates to Standards, if applicable.

Required Delivery Milestone: Human Subjects Risk Forum to be informed by 2014 with Recommendations for Optimal Communication Strategies

Required Platforms: Ground studies TBD.
Risk of Performance Errors Due to Poor Team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation

What are the most likely and most serious threats to crew cohesion, crew performance, and crew-ground interaction expected for exploration missions?

Evidence Gathering: Systematic Data Collection with Returning Crews

1. Update HSRRF/MD or Ops
   (1) Recommendations based on crew experience
   (2) Updated recommendations
   (3) Updated recommendations

2. Update Linear Ops & Input to Mass Ops DB (Date Required TBD)
   (2) Risk Performance Updates

Risk Assessment: Crew Cohesion (BHP)

Risk Assessment: Crew Performance (BHP)

Risk Assessment: Crew-Ground Interaction (BHP)
What additional approaches would enhance current in-flight interventions and countermeasures for supporting crew cohesion, crew performance, and crew-ground interaction for exploration missions?
1. A lack of Performance Errors Due to Poor Cohesion and Performance, adequate Selection-Team Composition, adequate Training, and Poor Psychosocial adaptation.

2. What are the most optimal ways to compose crews to ensure crew cohesion, optimize crew performance, and facilitate crew-ground interaction for exploration missions?

P

Crew Composition Studies (BHP NRA)

P

Validate measures for Composition (TBD)
HRP-47

171
RISK OF ERRORS DUE TO POOR TASK DESIGN – CRITICALITY: LUNAR OUTPOST – D, MARS – I

If roles and responsibilities for accomplishing tasks are not clearly defined, there will be a risk of serious errors of omission or commission. This risk may relate to interaction between multiple crewmembers, to interactions between crew, robotics, and automation, and between crew and ground control. Understanding the characteristics of the elements involved, how each communicates, and establishing guidelines to adhere to during task design and procedure development are all essential to mission success.

Operational Relevance and Risk Context

One of the most critical enablers of human presence in space is human systems standards that provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards – SFHSS – (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Strategy for Mitigation

The approach to mitigating this risk is to develop an understanding of the factors that contribute to this risk, identify gaps in our knowledge about these factors, and prioritize these gaps based on various criteria systematically applied. Then the highest priority gaps are addressed through directed or solicited research depending on the time frame and the complexity and specificity of the gap. Where there is a disconnect between critical gaps that should be addressed and a lack of funding, efforts are made to re-examine the programmatic priorities to ensure those of highest concern are being investigated.

The risk associated with designing tasks focuses specifically on the process of assigning roles and responsibilities to individual crewmembers, a group of crewmembers, automation, and ground support alone or in combination. The Behavioral Health and Performance Element has primary responsibility for addressing risks related to team dynamics. SHFE specifically studies issues in designing tasks to be performed jointly by humans and automation, or deciding how much responsibility to assign to an automated system. The approach to mitigating this risk is to develop and specify “best practices” for human-automation function allocation; crew-automation interface design, how to incorporate considerations of crew workload and situational awareness in mixed-initiative operations concept design, and determining methods to ensure effective levels of trust between the crew and automation while avoiding unacceptable levels of crew complacency.
The strategy for addressing this risk is intertwined with the strategies for addressing the Risk of Reduced Safety and Efficiency Due to an Inadequately Designed Vehicle, Environment, Tools or Equipment, and the Risk of Errors due to Inadequate Information. The work described under this risk focuses on planning how a given task or mission objective will be accomplished. This risk addresses how to decide what skills, tools, equipment and information are needed to accomplish a task, and what amounts of automation or human involvement are required. The Risk Due to an Inadequately Designed Vehicle, Environment, Tools, or Equipment captures the factors that lead to inappropriate human interfaces for the habitat and equipment. Work under the Risk of Errors due to Inadequate Information contributes to the crew having adequate knowledge, skills, and information at the time the task needs to be performed.

The specific selection choices of the highest priority gaps and tasks are based primarily on gap analyses. The SHFE project updates its gap analyses on an annual basis. This is necessary as research results and continual information drawn from crew debriefings has the potential of discovering additional gaps in knowledge. These updates assist in the preparation for the annual Standing Review Panel. The original analysis carried out in 2006 was published as NASA/TP-2007-213739 (“Space Human Factors Engineering Gap Analysis Project Final Report,” C. Hudy and B. Woolford, 2007). An update was completed in spring 2007. The gaps are identified through reviews of the literature, of crew debrief summaries, and through interviews with more than a hundred users of human factors standards and guidelines, representing Engineering, Mission Operations, Flight Medicine, Training, the Crew Office, and others. We place particular emphasis on interviewing representatives from Constellation Program Office, the Human-System Integration Group, the Orion Project Office, the Cockpit Display Working Group, and other programmatic users of our products. The ‘small’ gaps or specific concerns identified from these sources are aggregated into more appropriate levels for which a specific task can be designed. For example, numerous users report gaps in design for workload: lack of consistency of definition; lack of easy to use methods to assess workload; lack of a way to verify that a requirement for workload has been met. These various individual-level concerns are captured in a gap, “There is no standardized non-intrusive measure of workload.”

After all concerns are mapped to gaps, the gaps are prioritized according to a number of criteria. Key criteria are importance to Constellation Program and need date. When we identify ‘TBRs’ or ‘TBDs’ in the Human Systems Integration Requirements, for example, these are assigned a very high priority. Ratings are solicited from management representatives of the offices from which gaps were identified.

After prioritization, the gaps that can be addressed within the budget are initiated through directed research or solicited through research announcements. Directed research is chosen for time critical results. Solicitations are used for gaps that are longer term and that can benefit from wider participation.

**Gaps**

**SHFE 1.1.1.2.1: How can standard measures or tools be developed that can unobtrusively measure workload?**

| Tasks: (SHFE – Directed, Collaboration with HRP BHP) |
| Development of Workload and Human Performance Evaluation Methods |

Available research shows that the relationship between workload and performance is a nuanced one. Simple approaches that attempt to maintain overall workload at an intermediate value are unlikely to achieve the desired results. The successful management or evaluation of workload must include a consideration of the nature of individual tasks that operators must perform, the combinations of tasks that are performed during a work period, priorities among tasks, and individual differences among operators. This task will look at the relationship between workload and performance with the goal of producing more effective methods for evaluating proposed designs and operating procedures for space applications.
### Tasks: (SHFE – Directed, Collaboration with HRP BHP)

#### Development of Workload and Human Performance Evaluation Methods (cont’d)

#### Deliverables:
- A review of all workload measurement techniques, simple task analysis techniques, and operator performance metrics.
- A simple-to-use guide offering practical guidance in using these techniques when evaluating designs and procedures for using automation systems.
- Preliminary development of an empirical evaluation of the guide/techniques that are produced.
- Flight validation and analysis of workload guide and techniques.
- Assessment of new workload allocation technology and design capabilities for application to Habitat.

#### Required Delivery Milestone:
- FY09 Final Review of Workload Measurement Techniques
- FY09 Guidelines for Using Workload Measurement Techniques
- FY09 Preliminary Evaluation of Workload Guidelines and Techniques
- FY10 Workload Allocation Recommendations to Orion CDR
- FY11 Design solutions for workload allocation for Lander SRR
- FY11 Transmittal of preliminary results to BHP
- FY13 Prelim flight results/recommendations to Lander PDR
- FY15 CR to HSIR, HIDH requirements prior to Lander CDR
- FY18 Information/recommendations regarding potential new technology applications for Habitat
- FY19 Requirements/design solutions for Habitat

#### Required Platforms: Ground: Laboratory Test beds, ISS Flight Validation

### SHFE 1.1.1.3.1: How do we design tasks to ensure adequate situational awareness?

#### Tasks: (SHFE – New Directed Research or NRA)

#### Situational Awareness Evaluation

Situational awareness is a complex concept that combines both consciously identifying all salient aspects of a current state, and connecting those aspects to prior knowledge about the task. It focuses on the connections between perceptions and long-term memory – are the important cues perceived? Are they matched to the appropriate responses? Issues with respect to situational awareness arise when tasks are complex and cues to the exact state of the system are not sufficiently strong. In partially automated tasks, deficiencies in recognizing the state of the automated system or the state of the environment are common sources of errors that can result in loss of mission objectives. This task will identify the best available methods to assess situational awareness and develop an approach to evaluating task and equipment designs to ensure that sufficient cues for situational awareness are available.

#### Deliverables:
- Review of situational awareness techniques and analysis tools as well as operator performance metrics
- Preliminary development of metric evaluation system and guide to measure situational awareness

#### Required Delivery Milestone:
- FY13 Design recommendations for Lander PDR
- FY15 CR to HIDH to add design solutions/requirements for enhancement of situational awareness
- FY15 Design solutions to Lander CDR
- FY15 Design solutions for Habitat CDR

#### Required Platforms: Ground: Laboratory Test beds
SHFE 1.1.2.1.1: How can performance, efficiency, and safety guidelines be developed for appropriate task automation and the effective allocation of tasks between humans and automation?

**Tasks:** (SHFE – Directed)

**Automation Interface**

The automation design community needs methods that are usable by designers early in the design process to meet demands for the development and testing of automation for space exploration. The objective of this task is to develop a set of methodologies and tools to automate the design and evaluation of the human-computer interaction concepts. The research plan is to integrate existing foundational research results into Human Automation Interaction (HAI) methods and tools usable by designers.

**Deliverables:**

Documentation of Application Domain – To adequately model the process and perform the task decomposition, researchers have to develop a deep knowledge of the domain, the process, and culture of the organization. This is vital to ensuring that the resulting method/toolset is compatible with the end-users enterprise environment.

Process Modeling and Metrics Instrumentation - To develop process information and metrics that adequately describe characteristics of Human Automation Interaction performance.

Task Decomposition – Continue to develop and validate a usable task decomposition and analysis application

Human Performance Modeling – A human performance analysis capability that does not require Human Automation Interaction expertise to use. The intention is that the required data for the tool will be generated by the task decomposition and analysis tool

Tool Integration – Develop and validate an automation prototyping environment that is useful for Constellation. Integrate the methods that have been developed in the previous tasks into tool suites that are usable by designers without requiring extensive Human Computer Interaction expertise. Provide quantitative assessments of the performance of an automation design and its interface for a specific task on a given design.

Demonstrations & Testing – All of the studies are focused on delivering tools to help designers make better Human-Automation Interaction decisions early in the operations concept design process. Specifically, as described earlier, the first year of the task will focus on developing tools that are usable by the ISS Attitude Direction and Control team.

Assessment of new technology and capabilities – Evaluation of new tools that can enhance developed tools to further aid users in allocation of tasks. Additionally, test and validate enhancements in simulated environments to determine efficacy and applicability.

**Required Delivery Milestone:**

FY09 Final report on beta analysis package for ISS ADCO application domain.
FY09 Final report on generation of computational human performance model.
FY09 Validated task decomposition/analysis application and final report.
FY10 Human performance analysis capability
FY10 Validated automation prototyping environment.
FY10 Final report on demonstration and test of automation integration tools.
FY13 Design recommendations to Lander PDR regarding new technology/capabilities to enhance current tool
FY15 Requirements to Lander and Habitat CDR for implementation of tool enhancements

**Required Platforms:** Ground: Laboratory Test beds
SHFE 1.1.2.2.1: How can we develop standard measurement techniques and metrics for evaluating the quality of user interfaces with specific attention to the usability of an interface?

**** These tasks also address the Risk of Error Due to Inadequate Information

<table>
<thead>
<tr>
<th>Tasks: (SHFE – Directed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usability Evaluation****</td>
</tr>
<tr>
<td>Usability measures and metrics that will help formulate verifiable usability requirements based on quality components. Usability refers to the quality of an interface or hardware. It can be represented by five quality components: learnability, efficiency, memorability, errors, and satisfaction (Nielsen, 2003). Learnability refers to the ease of accomplishing basic tasks when users encounter the design for the first time. Efficiency is the time needed to accomplish a task after users are already familiar with the design. Memorability can be measured by the change in performance following a period of not using the interface. Errors can be counted during task execution and rated based on severity. User satisfaction is a metric indicating how pleasant the design is to use. Some of these can be represented by objective measures, while others are subjective. However, they provide a good picture of the overall usability of a system. Furthermore, they can provide evidence for any return on investment that may result from redesigns of a system, thus making usability and human factors quantifiable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and propose usability metrics that can be applied in the space science area, along with recommended usability methodologies for collecting the metrics. The focus will be on challenges such as error definition, acceptable error rates, and error classification and weighting.</td>
</tr>
<tr>
<td>Research and develop a consistency scale that can be validated and standardized.</td>
</tr>
<tr>
<td>Field test and validate usability measures, metrics, and methodologies in one or more real life projects. Document methodology and measurement techniques in a standardized way that will help NASA practitioners to used them in a reliable way. Define requirements language based on proposed usability metrics.</td>
</tr>
<tr>
<td>Continuous assessments of advancements in State of the Art technology determination of appropriate applicability areas for Lander and Habitat.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY09 Report on Proposed Usability Measures and Metrics</td>
</tr>
<tr>
<td>FY09 Summary Report on Usability Field Testing, Methodology and Measurement Techniques</td>
</tr>
<tr>
<td>FY10 Usability recommendations to Orion CDR</td>
</tr>
<tr>
<td>FY11 Usability recommendations to Lander SRR, design solution to Lander PDR</td>
</tr>
<tr>
<td>FY13 Design enhancement recommendations to Lander PDR</td>
</tr>
<tr>
<td>FY15 Design solutions to Lander CDR</td>
</tr>
<tr>
<td>FY16 Design solutions to Habitat CDR</td>
</tr>
<tr>
<td>FY18 Design improvements to Habitat</td>
</tr>
</tbody>
</table>

| Required Platforms: Ground: Laboratory Test beds |
SHFE 3.1.2.2.a: How do we ensure that the displays and control designs and technology developed for the operational environments of the Cx Program will improve performance and reduce errors?

<table>
<thead>
<tr>
<th>Tasks: (SHFE – Directed)</th>
</tr>
</thead>
</table>
| **Information Presentation – Displays (Visual and Auditory)**  
Optimal displays are critical to crew performance and vehicle operations. Displays must meet the crew’s needs and be easy to use, particularly as Exploration mission operations venture farther from the Earth and real-time ground-based operational assistance becomes degraded or unavailable. The focus for visual displays is readability and usability of text, and effective display navigation. The focus of auditory displays is caution and warning system alarms. This is a requirements development activity, supplemented by some research or validation activities on the ground and in flight. This will result in the development of guidelines, requirements, and validation techniques for advanced information display solutions currently contemplated for the various Constellation Program spacecraft systems consistent with the smaller cockpit environments of the Orion CEV, the Lander, and surface rovers. These requirements and appropriate information will be provided to Orion, Constellation documentation (CxP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook. |

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
</table>
| Display design requirements  
Display design recommendations  
Assessment, selection, and test of display design enhancements that will maximize capability of Habitat |

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
</table>
| FY09 Display requirements and design recommendations to Orion PDR  
FY09 CR to HSIR, HIDH, Orion Display Standards documentation prior to Orion CDR  
FY10 Display design recommendations to Orion CDR  
FY11 Display requirements to Lander SRR  
FY13 Display design recommendations to Lander PDR  
FY15 CR to HSIR, HIDH prior to Lander CDR  
FY15 Design solutions to Lander CDR  
FY17 Design enhancement recommendations for Habitat  
FY19 Design enhancement solutions for Habitat displays |

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
</table>
| Ground: Laboratory Test beds  
Ground: Mockups |
**Tasks:** (SHFE – Directed)  
**Information Presentation – Controls****

The development of proper controls is critical to preventing errors during human spaceflight. This becomes especially important when the majority of the controls will be software based. Crewmembers must be very aware of what they are manipulating on the screen, and must be able to do so under vibration and high-g, as well as in microgravity. They must be able to operate controls ungloved and with pressurized gloved hands. During launch and entry, crews will have no choice other than to use a remote cursor control device. If the input control devices are inadequate for any of the above operational scenarios, crew safety will be compromised and operational capability will be compromised. These requirements and appropriate information will be provided to Orion, Constellation documentation (CxP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook.

**Deliverables:**
- Control design requirements
- Control design recommendations
- Assessment, selection, and test of control design enhancements that will maximize capability of Habitat

**Required Delivery Milestone:**
- FY09 Control requirements and design recommendations for Orion PDR
- FY10 Control design solutions for Orion CDR
- FY10 CR to HSIR, HIDH, Orion Display Standards Documentation prior to Orion CDR
- FY11 Control requirements to Lander SRR
- FY13 CR to update control requirements in HSIR, HIDH prior to Lander PDR
- FY13 Control design recommendations to Lander PDR
- FY15 CR to HSIR, HIDH for update to control requirements prior to Lander CDR
- FY15 Design solutions for Lander CDR
- FY17 Design enhancement recommendations to Habitat controls
- FY19 Design enhancement solutions to Habitat controls

**Required Platforms:**
- Ground: Laboratory Test beds
- Ground: Mockups
Risk of errors due to poor task design

1.1 Design Task for combination of humans and automation

Gap: SHFE 1.1.1.2.1: How can standard measures or tools be developed that can unambiguously measure workload? (with HBP)

Development assessment, validation of proposed tools and guidelines for workload measurement

Flight validation of workload tools/guidelines

Workload Tools & Guidelines – New FY09 DRP
(Workload Directed Research Project)
### Risk of errors due to poor task design

#### 1.1 Design Task for combination of humans and automation

**Gap:** SHFE 1.1.1.3.1: How do we design tasks to ensure adequate situational awareness?

1. **Situational Awareness (SA)**
2. **Evaluation**
   - (New Directed Research Project or NRA)

#### Situational Awareness (SA) Development, assessment, validation of proposed metrics for evaluation of situational awareness

1. Design Recommendations for Lander PDR
2. Design solutions for Lander CDR
3. Design recommendations for Habitat
4. CR to HIDP for design solutions to enhance SA

#### Constellation

**Program Level**
- PDR
- CDR: Initial Ops
- PDR
- CDR
- Human Lunar Return

**Mission Operations**
- PDR-init cap
- CDR-init cap
- SRPDR
- CDR

**Leade**
- ATP
- SDR
- PDR
- CDR

**EVA Suit**
- PDR
- CDR

**End of US Commitment**
- FY'09
- FY'10
- FY'11
- FY'12
- FY'13
- FY'14
- FY'15
- FY'16
- FY'17
- FY'18
- FY'19
- FY'20
- FY'21
- FY'22
- FY'23
- FY'24
- FY'25
Risk of errors due to poor task design

1.1 Design Task for combination of humans and automation

1.2 Design Tasks for multiple humans

Gap: SHFE 1.1.2.1.1: How can performance, efficiency and safety guidelines be developed for appropriate task automation and the effective allocation of tasks between humans and automation?

Automation/Interface Design Tool (A/IDT) (Directed Study)
Risk of errors due to poor task design

1.1 Design Task for combination of humans and automation

1.2 Design Tasks for multiple humans

[Diagram showing task design process with steps and decision points]

[Text continues on the right side of the page, providing details on the design process and considerations for ensuring task design is effective.

*Note: The text is partially cut off and not fully legible due to the image resolution.*
Risk of errors due to poor task design

1.1 Design Task for combination of humans and automation

1.2 Design Tasks for multiple humans

Gap: SHFE 3.1.2.2a: How do we ensure that the displays and control designs and technology developed for the operational environments of the Hx Program will improve performance and reduce errors?

** Directed study also addresses other SHFE risks
RISK OF ERROR DUE TO INADEQUATE INFORMATION – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Information presentation, acquisition, and processing significantly affect human task performance. The extent to which information needed to support a task or mission operation can be easily accessed and easily processed is vital to all space missions. Therefore, further research regarding proper information presentation will enable development of requirements and guidelines to optimize presentation of information, its timeliness, the user’s level of awareness of the information, modes of information presentation, proper information comprehension, training methods, and development of procedures.

Operational Relevance and Risk Context

One of the most critical enablers of human presence in space has been ensuring that there are human systems standards in place that will provide for crew health as well as standards for habitability, environmental, and human factors. The Space Flight Human System Standards – SFHSS – (and the companion Human Integration Design Handbook – HIDH) require that each human spaceflight program derive program-specific, verifiable requirements to comply with the standards, and require that each human spaceflight program establish a human factors process involving health and human factors experts. This is to ensure that there will be identification of any standards in the SFHSS that are not applicable (or altered) and the rationale for non-applicability; that all program level health and human factors requirements are based on the HIDH, cited empirical evidence, or known best practices; and that end-items are in compliance with SFHSS, and agency and program level requirements and specifications.

The activities cited reflect the need to work toward the mitigation of identified SHFE risks by continuing to inform the standards, by engagement in the development of the requirements that will implement the standards based upon the resulting products, as well as providing content to the HIDH that will serve as the implementation guide. In addition, products resulting from these activities may provide valuable information to spaceflight programs that can inform the requests for trade studies.

To ensure operational relevance of the deliverables from the tasks, all tasks leaders will identify stakeholders who will work with them in framing the questions and approach. The stakeholders will participate by identifying specific issues requiring research or technology development, by reviewing progress, and by suggesting operational evaluations. Depending on the specific tasks, stakeholders may include engineers or operations personnel.

Strategy for Mitigation

The approach to mitigating this risk is to develop an understanding of the factors that contribute to this risk, identify gaps in our knowledge about these factors, and prioritize these gaps based on various criteria systematically applied. Then the highest priority gaps are addressed through directed or solicited research depending on the time frame and the complexity and specificity of the gap. Where there is a disconnect between critical gaps requiring addressing and a lack of funding, efforts are made to re-examine the programmatic priorities to ensure those of highest concern are being investigated.

The risk associated with error due to inadequate information focuses on identifying the causes of risk, for example, the lack of situational awareness that might be due to poorly designed interfaces or tasks, and the subsequent development of information presentation standards for reducing operator errors in spaceflight through adequate understanding of the causes and mitigations of the errors. As the topic of inadequate information is comprehensive, the approach to mitigating this risk is to focus on the display of information, the types of controls that interface between the human and the displays, and the procedures to accomplish tasks.
It is not possible to separate the strategy for mitigating this risk from the strategy for dealing with the risk of Errors due to Poor Task Design. The information that is needed to perform a task at a given time depends substantially on the nature of the task and the crewmembers’ roles and responsibilities. The work described under this risk presumes the task is well designed and focuses on the problems of ensuring the necessary information is presented in such a way as to enable timely, accurate performance.

The specific selection choices of the highest priority gaps and tasks are based primarily on gap analyses. The SHFE project updates its gap analyses on an annual basis. This is necessary as research results and continual information drawn from crew debriefings has the potential of discovering additional gaps in knowledge. These updates assist in the preparation for the annual Science Review Panel. The original analysis carried out in 2006 was published as NASA/TP-2007-213739 (“Space Human Factors Engineering Gap Analysis Project Final Report,” C. Hudy and B. Woolford, 2007). An update was completed in spring 2007. The gaps are identified through reviews of the literature, of crew debrief summaries, and through interviews with more than a hundred users of human factors results, representing Engineering, Mission Operations, Flight Medicine, Training, the Crew Office, and others. We place particular emphasis on interviewing representatives from Constellation Program Office, the Human-System Integration Group, the Orion Project Office, the Cockpit Display Working Group, and other programmatic users of our products. The ‘small’ gaps or specific concerns identified from these sources are aggregated into more appropriate levels for which a specific task can be designed. For example, numerous users report gaps in design for workload: lack of consistency of definition; lack of easy to use methods to assess workload; lack of a way to verify that a requirement for workload has been met. These various individual-level concerns are captured in a gap, “There is no standardized non-intrusive measure of workload.”

After all concerns are mapped to gaps, the gaps are prioritized according to a number of criteria. Key criteria are importance to Constellation Program and need date. When we identify ‘TBRs’ or ‘TBDs’ in the Human Systems Integration Requirements, for example, these are assigned a very high priority. Ratings are solicited from management representatives of the offices from which gaps were identified.

After prioritization, the gaps that can be addressed within the budget are initiated through directed research or solicited through research announcements. Directed research is chosen for time critical results. Solicitations are used for gaps that are longer term and that can benefit from wider participation.

Gaps

SHFE 3.1.1.a: How can we develop objective training measures to determine operator proficiency during and after ground training?

<table>
<thead>
<tr>
<th>Tasks: (SHF – Directed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training for Effective Space Flight Resource Management</td>
</tr>
</tbody>
</table>

Ground-based pre-flight training and in-space just-in-time training and task rehearsal will continue to be an important driver for exploration missions. On-board training systems will enhance the autonomy and effectiveness of exploration crews. Long-duration missions preclude the possibility of easily substituting new crewmembers from the ground that have been specially trained on specific emerging problems, new tasks, and scientific or mission operations.

Human spaceflight will continue to depend even more on the deep knowledge astronauts acquire of the idiosyncrasies of the flight systems they live with and the tasks they have to perform. However, given the nature of the missions, onboard training opportunities for individuals and teams will be necessary, such as in reconfigurable training and mission rehearsal systems. These systems will enable the crews to keep their skill levels up to par and to develop new skills or practice new procedures to resolve new challenges as they arise.
## Deliverables:
Develop an MOD-specific non-technical (i.e., independent of spacecraft systems) framework (such as a game structure) that can be used to train SFRM skills (such as situation awareness, communication, and decision-making).

Development of training events using the SFRM Paper Sim that could be used to reliably predict the likelihood of a trainee’s success in acquiring good SFRM skills.

## Required Delivery Milestone:
- **FY09**: SFRM Generic Paper Sim – Proof of Concept Study
- **FY09**: Interim delivery of SFRM tool to Mission Ops and MOD
- **FY10**: SFRM Generic Paper Sim – Predictive Training Events Concept Study.
- **FY10**: Delivery of final SFRM tools for Mission Ops PDR and MOD

## Required Platforms:
- Ground: Laboratory Test beds
- Ground: Mockups

## Tasks: (SHFH – New Directed Study or NRA)
**Training Proficiency Metrics and Methods Development**

Space Flight Resource Management (SFRM) training is based on years of study and experience with industries other than space. Although there are very good reasons to feel confident in this approach, it is critical to assess the effectiveness of the changes to the Mission Operations flight controllers’ training flow. As the changes are introduced into the training, the study will be tracking students’ performance and continuously evaluating the success of the training. However, it will take time to appreciate the full effect of the new training approach. It will require having enough flight controllers who complete the new training flow and start working on console to be able to compare the results of this new training with those obtained in the previous training flow. This will provide for a continuous feedback loop and ongoing revisions and improvements to the new training program as soon as it is implemented.

A training continuum spans a full range from initial training, to recurrent and refresher training, to just-in-time training (JITT). Previous work examined aspects of the initial medical training, focused on JITT, explored the issues relevant to refresher training, and will now address requirements for the full medical training continuum and develop metrics to assess training methods and proficiency.

## Deliverables:
Assessment and development of training metrics to evaluate training methods and proficiency in other focus areas such as vehicle and habitat

## Required Delivery Milestone:
- **FY14**: Prelim metrics to training proficiency assessment delivered for Missions Ops PDR
- **FY14**: CR to HIDH to add requirements for training metrics prior to Mission Ops CDR
- **FY15**: Results of validation of metrics for training proficiency assessment to Lander CDR
- **FY16**: Training metrics for training proficiency assessment to Habitat CDR
- **FY18**: Training metrics for training proficiency assessment, continued development, Habitat project

## Required Platforms:
- Ground: Laboratory Test beds
- Ground: Mockups
- Ground: DESERT RATS
SHFE 3.1.1.b: How do we develop training methods and tools for space medical application if time is minimal?

**Tasks:** (SHFH – Directed)

**Training for Effective Medical Operations**

Ground-based pre-flight training and in-space just-in-time training and task rehearsal will continue to be an important driver for exploration missions. On-board training systems will enhance the autonomy and effectiveness of exploration crews. Long-duration missions preclude the possibility of easily substituting new crewmembers from the ground who have been specially trained on specific emerging problems, new tasks, and scientific or mission operations.

Human spaceflight will continue to depend even more on the deep knowledge astronauts acquire of the idiosyncrasies of the flight systems they live with and the tasks they have to perform. However, given the nature of the missions, onboard training opportunities for individuals and teams will be necessary, such as in reconfigurable training and mission rehearsal systems. These systems will enable the crews to keep their skill levels up to par and to develop new skills or practice new procedures to resolve new challenges as they arise.

**Deliverables:**

- Exploratory Evaluation of Tools of Just-In-Time Training for an Emergency Procedure- provides a better understanding of performance times and types of errors associated with display devices.
- Evaluation of the Flight Surgeon Performance Support Tool prototype – “Flight Surgeon Response to ISS Emergencies.” A detailed task analysis examining the role of the flight surgeon during an on-board emergency will be completed. The task analysis will contribute to updated design options.
- Computer implementation for Just-in-Time training – The paper prototype that will be evaluated in FY09 will be implemented in a computer program in FY10. This implementation will allow the Flight Surgeon to have access to the tool on their laptop computers, and will allow us to embed layers of information providing further details beyond the necessary immediate actions.
- A training continuum spans a full range from initial training, to recurrent and refresher training, to just-in-time training. FY10 explores the issues relevant to refresher training.

**Required Delivery Milestone:**

- FY09: Summary Report on Just-In-Time Training Comparison
- FY09: Flight Surgeon Design Decision Support Tool evaluation report
- FY09: Interim delivery of medical procedure/training process to Mission Ops and SD
- FY10: Develop an evaluation plan for refresher training and conduct evaluations
- FY10: Delivery of final medical procedures/training process to Mission Ops PDR and ExMC

**Required Platforms:**

- Ground: Laboratory Test beds
- Ground: Mockups

SHFE 3.1.2.a: How can a capability for semi-autonomous planning and dynamically replanning of crew schedules be developed?

Need for on-board crew to semi-autonomously plan and dynamically replan their schedules and activities. Scheduling, rescheduling, and real-time changes are done manually and are labor intensive.
### Tasks: (SHFE – Directed, Partnership with HRP BHP)

**Science Planning Interface to Engineering (SPIFe) – Scheduling Tool**

Future mission concepts will require a significantly more efficient planning process and tools. The ultimate goal of this effort is to allow an on-board crew to semi-autonomously plan and dynamically replan their activity. Based on a firm understanding of ground-based replanning in several domains, the activity will be well positioned to understand and develop tools for on-board use. The SPIFe tool considers a wide range of the dynamic resources constraining schedule and allows the crewmember to schedule tasks and check that the resources required to execute the task will be available, and that there are no unintended consequences of scheduling the task at a particular time (such as not being able to execute another required task at a later time). Development of this tool is almost complete, and then a decision will be made regarding its utility for spacecraft operations planning and if required, the tool will be validated in an operationally intensive ground analog (e.g. NEEMO). A functional prototype could be run alongside existing tools to collect valuable data on the tool and its capability to optimize a schedule.

**Deliverables:**

The product is an understanding of at least one additional Constellation analog domain that will implement tools and processes that improve planning efficiency by an order of magnitude, and to understand and prototype tools that can be used for tactical on-board re-planning by the crew of Constellation missions. Refinement of tool for ground analog autonomy study by HRP BHP

**Required Delivery Milestone:**

- FY09: Mission Operations PDR-Initial Capability
- FY09: Delivery of SPIFe tool to BHP for continued use in NEEMO and similar ground analog missions

**Required Platforms:**

- Ground: NEEMO
- Ground: Flight Analogs Bed rest Study

### SHFE 3.1.2.2.a: How do we ensure that the displays and control designs and technology developed for the operational environments of the Cx Program will improve performance and reduce errors?

***** This task also addresses the Risk of Reduced Safety and Efficiency Due to an Inadequately Designed Vehicle, Environment, Tools, or Equipment and the Risk of Error Due to Poor Task Design

**Tasks: (SHFE – Directed)**

**Information Presentation – Displays (Visual and Auditory)**

Optimal displays are critical to crew performance and vehicle operations. Displays must meet the crew’s needs and be easy to use as Exploration missions may face the greatest autonomy challenge to date. The focus of visual displays is readability and usability of text, as well as display navigation. The focus of auditory displays is alarms. This is a requirements development activity, supplemented by some research or validation activities on the ground and in flight. This will result in the development of guidelines, requirements, and validation techniques for advanced information display solutions currently contemplated for the various Constellation Program spacecraft systems consistent with the smaller cockpit environments of the Orion CEV, the Lander, and surface rovers. These requirements and appropriate information will be provided to Orion, Constellation documentation (CxP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook.

**Deliverables:**

- Display design requirements
- Display design recommendations
- Assessment, selection, and test of display design enhancements that will maximize capability of Habitat
**Required Delivery Milestone:**
- FY09 Display requirements and design recommendations to Orion PDR
- FY09 CR to HSIR, HIDH, Orion Display Standards documentation prior to Orion CDR
- FY10 Display design recommendations to Orion CDR
- FY11 Display requirements to Lander SRR
- FY13 Display design recommendations to Lander PDR
- FY15 CR to HSIR, HIDH prior to Lander CDR
- FY15 Design solutions to Lander CDR
- FY17 Design enhancement recommendations for Habitat
- FY19 Design enhancement solutions for Habitat displays

**Required Platforms:**
- Ground: Laboratory Test beds
- Ground: Mockups

***** This task also addresses the Risk of Reduced Safety and Efficiency Due to an Inadequately Designed Vehicle, Environment, Tools, or Equipment and the Risk of Error Due to Poor Task Design

**Tasks:** (SHFE – Directed)
**Information Presentation – Controls****
The development of proper controls is critical to preventing errors during human spaceflight. This becomes especially important when the majority of the controls will be software based. Crewmembers must be very aware of what they are manipulating on the screen, and must be able to do so under vibration and high-g, as well as in microgravity. They must be able to operate controls ungloved and with pressurized gloved hands. During launch and entry, crews will have no choice other than to use a remote cursor control device. If devices are inadequate for any of the above operational scenarios, crew safety will be compromised and risk loss of productivity. These requirements and appropriate information will be provided to Orion, Constellation documentation (CXP70024 Human System Integration Requirements; Orion Display Standards) and the Space Flight Human System Standards Human Integration Design Handbook.

**Deliverables:**
- Control design requirements
- Control design recommendations
- Assessment, selection, and test of control design enhancements that will maximize capability of Habitat

**Required Delivery Milestone:**
- FY09 Control requirements and design recommendations for Orion PDR
- FY10 Control design solutions for Orion CDR
- FY10 CR to HSIR, HIDH, Orion Display Standards Documentation prior to Orion CDR
- FY11 Control requirements to Lander SRR
- FY13 CR to update control requirements in HSIR, HIDH prior to Lander PDR
- FY13 Control design recommendations to Lander PDR
- FY15 CR to HSIR, HIDH for update to control requirements prior to Lander CDR
- FY15 Design solutions for Lander CDR
- FY17 Design enhancement recommendations to Habitat controls
- FY19 Design enhancement solutions to Habitat controls

**Required Platforms:**
- Ground: Laboratory Test beds
- Ground: Mockups
**SHFE 3.1.2.2.a** How do we ensure that the displays and control designs and technology developed for the operational environments of the Cx Program will improve performance and reduce errors?

<table>
<thead>
<tr>
<th>Tasks: (NSBRI – Sensorimotor Adaptation Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensorimotor Display and Controls – Enhancing the Safety of Human/Machine Cooperation During Lunar Landing (SM11)</td>
</tr>
<tr>
<td>Lunar landing depends on the selection and identification of an appropriate location that is level and free of hazards, along with a stable controlled descent to the surface. During crewed landings, astronauts are expected to interact with automated systems, based upon improved terrain maps and sensor updates, to perform tasks such as manual re-designation of landing point, adjustment of descent trajectory or direct manual control. However, sensorimotor limitations, both vestibular and visual, are likely to interfere with performance and safety. This integrated project examines the nature of the anticipated spatial disorientation and terrain perception limits as they affect the transition from automatic to manual control and develops advanced display countermeasures to overcome these limitations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examination of the nature of anticipated sensorimotor difficulties (e.g., spatial disorientation, limits on terrain perception) as they affect the transition from automatic to manual control.</td>
</tr>
<tr>
<td>Development and evaluation of advanced display countermeasures for enhancing situation and terrain awareness and for overcoming performance limitations caused by reduced visibility associated with lunar lighting, terrain reflectivity and the absence of atmosphere utilizing Draper Laboratory's fixed-base lunar lander cockpit simulator for full human-in-the-loop evaluation.</td>
</tr>
<tr>
<td>Evaluation of the effectiveness of the cockpit displays during human-in-the-loop manual control in the NASA Johnson Space Center Tilt-Translation Sled during &quot;critical&quot; and &quot;hover&quot; tasks testing the tilt-translation and tilt-gain illusions of altered acceleration sensitivity as it applies to lunar gravity following a period of weightlessness.</td>
</tr>
<tr>
<td>Performance of a series of evaluations of the displays using the U.S. Army Aeromedical Research Laboratory’s six-degree-of-freedom helicopter simulator as a lunar landing analog for replicating lunar lighting and the various parameters associated with dust “brownout” conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY10: Input to Lander SRR regarding design requirement for interfaces, displays, and C&amp;W Systems</td>
</tr>
<tr>
<td>FY11: CR to HIDH to update design requirements prior to Lander PDR</td>
</tr>
<tr>
<td>FY12: Data obtained from research study shared with HHC Element</td>
</tr>
<tr>
<td>FY12: Design solutions to Lander PDR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground: Laboratory Test beds</td>
</tr>
<tr>
<td>Ground: Tilt-Translation Sled</td>
</tr>
<tr>
<td>Ground: 6 DOF Helicopter Simulator</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (NSBRI Sensorimotor Adaptation Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Displays for Efficient Training and Operation of Robotic Systems (SM12)</td>
</tr>
<tr>
<td>The goal is to improve the efficiency of robotic training through the modification of current procedures and development of new teaching tools. Improved training methods provide a framework for designing future in-flight training procedures during long-duration missions. The project will also demonstrate how individual differences affect performance of a critical operational skill and will provide initial designs of controls, displays, and procedures that better match the operators’ cognitive skills with task demands. The long term objectives of this project are: to develop tests of astronaut spatiomotor abilities that predict the need for remedial training or performance in final telerobotic qualification tests; and to improve teleoperation training techniques and develop new teleoperator interfaces that improve the efficiency of teleoperation training and flight operations.</td>
</tr>
</tbody>
</table>
Deliverables:
To improve NASA teleoperation training efficiency by scientifically customizing remedial training based on the measured spatial abilities of individual astronauts. We have examined whether NASA JSCs current Aptitude for Robotics Test (ART) predicts the need for remedial work in Generic Robotic Training (GRT) and Shuttle manipulator training or whether additional psychometric tests will sharpen performance predictions.

To perform a series of experiments using the MIT Remote Manipulation System Simulator to quantify how a trainee's individual spatial and manual control abilities, use of camera views and choice of hand controller reference frame impacts learning and final level of performance as a primary operator. Secondary operator performance in a clearance detection and estimation task is assessed using a signal detection/situation awareness probe paradigm.

Required Delivery Milestone:
FY10: Recommendations to Orion CDR for interface design, displays, and C&W systems in relation to spatial orientation
FY11: Input to Lander SRR regarding design requirements for interfaces, displays, and C&W systems
FY11: Results from research shared with HHC Element
FY11: CR to HIDH to update design requirements prior to Lander PDR
FY12: Design solutions to Lander PDR

Required Platforms:
Ground: MIT Remote Manipulation System Simulator
Ground: Basic Operational Robotics Instructional Systems (BORIS) training virtual environment

SHFE 3.1.2.2.1.2: How can we develop standard measurement techniques and metrics for evaluating the quality of user interfaces with specific attention to the usability of an interface?

**** These tasks also address the Risk of Error Due to Poor Task Design

Tasks: (SHFE – Directed)
Usability Evaluation****
Usability measures and metrics that will help formulate verifiable usability requirements based on quality components. Usability refers to the quality of an interface or hardware. It can be represented by five quality components: learnability, efficiency, memorability, errors, and satisfaction (Nielsen, 2003). Learnability refers to the ease of accomplishing basic tasks when users encounter the design for the first time. Efficiency can be defined as time needed to accomplish a task after users are already familiar with the design. Memorability can be measured by the change in performance following a period not using the interface. Errors can be counted during task execution and rated based on severity. User satisfaction is a metric indicating how pleasant the design is to use. Some of these can be represented by objective measures, while others are subjective. However, they provide a good picture of the overall usability of a system. Furthermore, they can provide evidence for any return on investment that may result from redesigns of a system, thus making usability and human factors quantifiable.

Deliverables:
Develop and propose usability metrics that can be applied in the space science area, along with recommended usability methodologies for collecting the metrics. The focus will be on challenges such as error definition, acceptable error rates, and error classification and weighting.
Research and develop a consistency scale that can be validated and standardized.
Field test and validate usability measures, metrics, and methodologies in one or more real life projects. Document methodology and measurement techniques in a standardized way that will help NASA practitioners to used them in a reliable way. Define requirements language based on proposed usability metrics.
Continuous assessments of advancements in State of the Art technology determination of appropriate applicability areas for Lander and Habitat.
**Required Delivery Milestone:**
FY09 Report on Proposed Usability Measures and Metrics
FY09 Summary Report on Usability Field Testing, Methodology and Measurement Techniques
FY10 Usability recommendations to Orion CDR
FY11 Usability recommendations to Lander SRR, design solution to Lander PDR
FY13 Design enhancement recommendations to Lander PDR
FY15 Design solutions to Lander CDR
FY16 Design solutions to Habitat CDR
FY18 Design improvements to Habitat

**Required Platforms:** Ground: Laboratory Test beds

**SHFE 3.1.2.2.1 (SM11): Can crewmember spatiomotor abilities be more accurately predicted and countermeasures and training techniques developed to mitigate spatial disorientation during spaceflight?**

**Tasks:** (NSBRI – Sensorimotor Adaptation Team)

**Modeling and Mitigating Spatial Disorientation in Low-Gravity Environments (SM11)**

The goal of this industry-university research and technology development project is to extend Alion’s spatial disorientation (SD) mitigation software, originally developed for aeronautical use, to NASA applications in the Shuttle, Crew Exploration Vehicle, Lunar Surface Access Module (LSAM), and Mars exploration mission programs. Alion’s Spatial Disorientation Analysis Tool (SDAT) is used for post-hoc analyses of aircraft trajectory data mishaps from the United States Navy, United States Air Force, and National Transportation Safety Board to determine the presence or absence of vestibular SD.

The Spatial Orientation Aiding System (SOAS) is a real-time cockpit aid that has been evaluated in simulators with rated pilots. Both tools incorporate models of the vestibular system and assessor heuristics to predict the epoch and probability of an SD event such as leans, coriolis or graveyard spiral illusions, and any other disparities between actual and perceived pitch attitude (somatogravic), roll rate or yaw/heading rate. SOAS assesses multi-sensory workload to determine the types of countermeasures to trigger and when to trigger them. SDAT also will help human factors engineers analyze past Shuttle landing incidents and will aid CEV/LSAM landing and ascent trajectory planning. It can aid LSAM cockpit displays, caution and warning system design, workload evaluation, and crew training and mission simulation. SDAT could assist flight surgeons with post-flight medical debriefings.

**Deliverables:**

Enhance the utility of SDAT/SOAS by including comprehensive mathematical models for vestibular and visual sensory cues, help translate CNS gravitoinertial force resolution into perceived tilt and translation estimates, and revalidate existing aeronautical data sets

Extend the models to describe zero gravity and Shuttle/LSAM landing illusions, validating the models using Shuttle data sets and existing (e.g. ROTTR) theory

Extend SDAT/SOAS to consider multiple visual frames of reference (inside and outside), panel and heads-up (HUD) orientation displays, the effects of visual attention and sensory workload, and the cognitive costs of mental rotation and reorientation. The enhanced SDAT/SOAS from Aims 1-3 will be validated via flight experiments

SOAS will be tailored for a lunar landing using multi-sensory workload to choose appropriate countermeasures and their timing.
### Required Delivery Milestone:

- FY10: Recommendations to Orion CDR for interface design, displays and C&W systems in relation to spatial orientation
- FY11: Input to Lander SRR regarding design requirements for interfaces, displays, and C&W systems
- FY11: CR to HIDH to update requirements prior to Lander PDR
- FY11: Input to Lander PDR regarding design solutions for interface design, displays and C&W systems in relation to spatial orientation
- FY11: Research results delivered to HHC Element

### Required Platforms:

- Ground – Parabolic Flight
- Ground – Simulators

### Tasks:

- (NSBRI – Sensorimotor Adaptation Team,)
  
  Enhancement of Spatial Orientation Capability of Astronauts on the Lunar Surface (SM11)

  The scientific goal of this project is to develop a Lunar Astronaut Spatial Orientation and Information System (LASOIS) that will enhance an astronaut's spatial orientation capability and reduce sensorimotor risks during manned and landed lunar mission operations. Supported by LASOIS, astronauts will be capable of overcoming disorientation in lunar surface operations caused by microgravity and the altered visual environment through spatial information provided by the Earth control center and collected by a coordinated group of sensors from lunar orbit, descending path and ground. The developed spatial orientation strategy, system, and training will allow astronauts to have a systematic preparation for complex mission scenarios where spatial operations, efficient interactions and communications are required among the Earth-based control center, lander(s), lunar vehicle(s), outposts and astronauts. This capability is extremely important for lunar operations that will have an extensive traversing region (around 100 km). This project directly supports the key sensorimotor risk by providing the advanced LASOIS to reduce/remove the disorientation risk. Risks can be significantly reduced by improving the spatial orientation capability through use of the proposed LASOIS system.

### Deliverables:

- To investigate methods for removal and/or alleviation of astronaut disorientation in a lunar surface operations setting by using integrated information technology, and psychological and cognitive research on spatial orientation and navigation;
- To develop the LASOIS; and
- To train astronauts to enhance their spatial orientation capability in a LASOIS-supported simulated lunar environment.

### Required Delivery Milestone:

- FY10: Recommendations to Orion CDR for interface design, displays and C&W systems in relation to spatial orientation
- FY11: Input to Lander SRR regarding design requirements for interfaces, displays, and C&W systems
- FY11: CR to HIDH to update requirements prior to Lander PDR
- FY11: Input to Lander PDR regarding design solutions for interface design, displays and C&W systems in relation to spatial orientation
- FY11: Research results delivered to HHC Element

### Required Platforms: TBD
**SHFE 3.1.2.3.2: How do we develop computer interface requirements that will ensure the commonality of the interface designs across multiple Constellation vehicles?**

**Tasks:** (New SHFE – Directed)

**Interface Design and Commonality**

As the development of Constellation vehicles (Orion, Lander, surface system habitats, rovers) spans years, it is fairly certain that technologies will advance and multiple contractors will be involved in the design development and eventual construction. With the desire to use the most current hardware and software system technology and materials, there is a risk that disconnects between the vehicles will occur – disconnects that have the potential to demand increased training for the crew, limited utility amongst and between the vehicles if replacements and spares are required, and that interface conventions may not be common. A simple hardware example is a light switch that when activated in the upward direction is an indicator for “on” in one vehicle, but when activated upward is an indicator for “off” in another vehicle. This will introduce confusion and risks for the safety of the crew, as well as their performance. What is desired are common conventions across these interfaces no matter where they are utilized? Computer interfaces are no different in approach. Common computer interface design solutions and standards need to be developed.

**Deliverables:**

Development, assessment and validation of proposed solutions/standards for design of common interfaces

**Required Delivery Milestone:**

FY10: Development of proposed solutions/standards

FY11: Lander SRR common computer interface requirements

FY12: CR to provide initial information for human system standards (HIDH and HSIR)

FY13: CR to update final standards/solutions for human system standards and design handbook (HIDH and HSIR).

FY13: Design solutions to Lander PDR

**Required Platforms:**

Ground: Laboratory Test beds

Ground: Mockups

---

**SHFE 3.2.2.2.2: How can we integrate multiple types of information and prioritize it appropriately to ensure mission success?**

**Tasks:** (New SHFE – Directed Study or NRA)

**Information Integration and Presentation**

During critical events, or when acquiring a new skill, information ‘overload’ can be as harmful as lack of information. The purpose of this task is to develop systematic methods of integrating information from multiple sources and providing it in a prioritized way that supports the crewmember’s immediate needs. Organization schemes, coding schemes will be developed and evaluated in simulators and in flight tests.

**Deliverables:**

Assessment and development of information integration and prioritization model.

Flight/simulation validation of model.

Data analysis.
### Required Delivery Milestone:

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY13</td>
<td>Initial information and approach delivered for Lander PDR</td>
</tr>
<tr>
<td>FY15</td>
<td>CR to HSIR, HIDH to provide initial requirements prior to Lander CDR</td>
</tr>
<tr>
<td>FY16</td>
<td>Initial study results and recommendations to Lander CDR</td>
</tr>
<tr>
<td>FY16</td>
<td>CR to HSIR and HIDH to provide final requirements to Lander and Habitat</td>
</tr>
<tr>
<td>FY17</td>
<td>Final results from data analysis to Lander and Habitat</td>
</tr>
</tbody>
</table>

### Required Platforms:

- **Ground**: Laboratory Test beds
- **Ground**: Mockups
Risk of Error due to Inadequate Information

1. Acquire information: training

- SHF 3.1.1.1: How can we develop objective training sources to determine operator proficiency during and after ground training?

Spaceflight Resource Management Training
- New Directed Study or NRA, Training Proficiency Methods Development

- SHF 3.1.1.2: How do we develop training methods and tools for space medical application line is minimal?

Medical Proficiency Training
- Training Directed Research Project

- Develop integrated procedure/training process to optimize emergency medical response

1. Required ASAP to improve existing training
2. Develop SFPM Tool to MOD
3. New training materials for use by MOD
4. Complete training materials with integrated space resource management concepts

5. Training metrics for habitat CDR
6. Training metrics for LEO habitat

7. Preliminary metrics for training proficiency assessment – Mission Ops PDR
8. Validated metrics for training proficiency assessment – Mission Ops CDR
9. Training metrics for training proficiency assessment – habitat CDR
10. Training metrics for training proficiency assessment – continued development – habitat project
11. CR to HMD to add requirements for training metrics prior Mission Ops CDR
1. Risk of Error due to Inadequate Information

**2. Information Presentation**

SHFE 3.1.2.a: How can a capability for autonomous planning and dynamically adjusting crew schedules be developed?

Science Planning
- Interface to Engineering (SPFE)
- Scheduling Tool
  - Directed Study (Directed Study)
Risk of Error due to Inadequate Information

**1.2 Information Presentation:**

- **SHF 3.1.2.2a (SMI 1 & SMII):** How do we ensure that the displays and controls are designed and technology developed for the rational environments of the crew program improve performance and reduce errors?

  **Coordinator Displays and Controls to enhance safety of Human/Machine Interaction (During Lunar Landing)**

Advanced displays for Efficient Training and Operation of Robotic Systems (NSBRI)

<table>
<thead>
<tr>
<th>Program Level</th>
<th>Installation</th>
<th>Orion</th>
<th>EVA Suit</th>
<th>Lander</th>
<th>Mission Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PDR</td>
<td>CDR</td>
<td>PDR</td>
<td>CDR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDR</td>
<td></td>
<td>CDR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDR</td>
<td></td>
<td>CDR</td>
<td></td>
</tr>
</tbody>
</table>

(1) Recommendations to Orion CDR for interface design, displays, and C&W systems in relation to spatial orientation
(2) Input to Lander SRR regarding design requirements for interfaces, displays, and C&W systems
(3) Design solutions for displays and controls for Lander PDR
(4) CR to HMD to update design recommendations/solutions for displays and controls
RISK OF IMPAIRED ABILITY TO MAINTAIN CONTROL OF VEHICLES AND OTHER COMPLEX SYSTEMS – CRITICALITY: LUNAR OUTPOST – D, MARS – I

It has been shown that long duration Spaceflight alters sensorimotor function which manifests as changes in locomotion, gaze control, dynamic visual acuity, and perception. These changes have not specifically been correlated with real time performance decrements. The possible alterations in sensorimotor performance are of interest for Mars missions due to the prolonged microgravity exposure during transit followed by landing tasks. This risk must be better documented and NS changes must be better correlated with performance issues.

Context of Risk for Exploration

New evidence regarding landing performance indicates that research into these types of issues is not a high priority for Shuttle or ISS. However, since Mars operational scenarios are still TBD, it is agreed that the ISS should be utilized to gather the data required to define the research that might be needed to enable future Mars mission operations. Therefore, this risk is considered to have a higher priority than the others within the sensorimotor discipline do. Spaceflight data should be collected (RMS, SSRMS, docking, glove box ops, Soyuz landings, etc.). In addition, performance related to neurosensory dysfunction should be used to determine the need for further research and countermeasure development.

Strategy for Mitigation

Space normal must first be defined for this risk; hence, data mining tasks are ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed. In addition, the NRA solicitation process was utilized to obtain proposals to determine any manual and visual control deficits.

Gaps

SM1: What is the relationship between the mode of in-flight exercise and post-flight sensorimotor performance? The sensorimotor team should data mine to determine if data exist for this gap.

<table>
<thead>
<tr>
<th>Task:</th>
<th>(NxPCM – via directed study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensorimotor Performance Data Mining</td>
<td></td>
</tr>
<tr>
<td>It is proposed that the type and amount of in-flight exercise performed by crewmembers may influence post-flight disturbance in balance and locomotion. Exercise logs for both US and Russian crewmembers will be evaluated to determine the relationship between the types of in-flight exercise performed and post-flight sensorimotor performance.</td>
<td></td>
</tr>
</tbody>
</table>

| Deliverables: | Data will be collected and passed to HSRF. It will also be used to inform ECP of any exercise and sensorimotor issues and used to provide any updates to the sensorimotor standard. |

| Required Delivery Milestone: | There is no required delivery milestone for this task. |
| Required Platforms: | Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study. |

SM2: What is the time course of recovery of sensorimotor function after long duration space flight? This data can be used to make scheduling recommendations for planetary post-landing operations.
**Task**: (NxPCM – via directed study)

Sensorimotor Performance Recovery Data Mining

After long duration space flights, astronauts require time to return to pre-flight sensorimotor performance. This study will compile the recovery data from previous long duration astronauts to determine the average amount of time that is required for sensorimotor function recovery.

**Deliverables**: Data will be collected and passed to HSRF. It will also be used to inform Flight Medicine of any recommended recovery protocols and used to provide any updates to the sensorimotor standard.

**Required Delivery Milestone**: There is no required delivery milestone for this task.

**Required Platforms**: Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

---

SM4: **Can previous performance data be correlated with clinical observations?** Attempts should be made to obtain ISS EVA performance data from previous missions. If that is not feasible, a strategy should be developed to gather forward data. No research should be undertaken until this evidence is obtained.

**Task**: (NxPCM – via directed study)

Performance Data Mining

This study will compile data recorded from previous missions regarding ISS EVAs. The purpose of this data-mining task is to gain additional operational data. Lessons learned from this analysis can be applied to the Constellation Program to ensure that the evidence for sensorimotor changes in crew performance as a result of space flight is thoroughly assessed.

**Deliverables**: Initial product is space normal data from a data-mining task. If results indicate that no data exist, then data should be obtained using ISS flight studies.

**Required Delivery Milestone**: There is no required delivery milestone for this task.

**Required Platforms**: Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

---

SM5: **What are the effects of disorientation and inter-individual differences on supervisory control, docking, RMS etc?** Evidence must be gathered to support this gap. No research should be undertaken until this evidence is obtained.

**Task**: (NxPCM – via directed study)

Performance Data Mining

This study will compile data recorded from previous missions regarding manual control and landing. The purpose of this data-mining task is to gain additional operational data and insight regarding Shuttle landings that occurred outside the operational limits to determine the multi-factorial causes that led to the landing outcomes. Lessons learned from this analysis can be applied to the Constellation Program to ensure that the evidence for sensorimotor changes in crew performance as a result of space flight is thoroughly assessed. Data will also be gathered from available data from RMS operations, EVAs, and Shuttle/Soyuz docking operations relevant to manual control.

**Deliverables**: Initial product is space normal data from a data-mining task. If results indicate that no data exist, then data should be obtained using ISS flight studies.

**Required Delivery Milestone**: There is no required delivery milestone for this task.

**Required Platforms**: Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study.

If data do not exist, the ISS is required.
SM6: Can a seated manual/visual performance assessment after long-duration spaceflight be completed? It is necessary to determine if a crewmember can land a vehicle after six months in microgravity. This gap needs to be placed in the context of the expected operating environment of future vehicles. Design of future vehicles should account for human factors in the cockpit and task design to avoid provocative movements or physically difficult tasks.

**Task:** (NxPCM – via NRA)

**Manual/Visual Control Study – TBD**

Proposals were solicited in the 2008 NRA to answer the following questions. What is the decrement in manual/visual performance following long-duration spaceflight? What are the mechanisms of the decrement? What countermeasures are needed?

**Deliverables:** Initial product will be completion of an ISS pre- and post-flight study to determine seated manual/visual control performance (i.e., landing a spacecraft).

**Required Delivery Milestone:** FY2023 – countermeasure required for exploration missions

**Required Platforms:** ISS is required for this study; long-duration crews are needed.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>2.5</td>
</tr>
</tbody>
</table>

**Task:** (NxPCM – with ESA)

**Ambiguous Tilt and Translation Motion Cues After Space Flight/Otolith Assessment during Post-Flight Re-adaptation**

This experiment is designed to explore the physiological basis for disorientation and tilt-translation disturbances reported by crewmembers when making head movements following re-entry, and to evaluate adverse operational implications of these disturbances. In addition, it is intended to examine assess human otolith function by measuring: unilateral otolith-ocular responses (OOR); an estimation of subjective visual vertical (SVV) during unilateral otolith stimulation; and unilateral vestibular evoked myogenic potentials (VEMP) during post-flight re-adaptation. This is a joint HRP/ESA investigation.

**Deliverables:** The product will be further information regarding sensorimotor adaptations to spaceflight.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** ISS is required for this study; long-duration crews are needed.

**Task:** (NSBRI)

**Development of Countermeasures to Enhance Sensorimotor Adaptation**

This study is developing a comprehensive training program that will enhance astronauts' ability to "learn how to learn," leading to rapid adaptation to a new gravity environment. The training program involves exposure to modified visual flow along with alterations in the support surface designed to enhance subject adaptability. The researchers will also determine the short- and long-term (10 days to 6 months) retention rates after the training program.

**Deliverables:** Initial product will be a ground-based evaluation of a potential countermeasure.

**Required Delivery Milestone:** FY2023 – countermeasure required for exploration missions

**Required Platforms:** This is a ground-based investigation.
**SM3: What is the appropriate rehabilitation protocol for sensorimotor function?** There is no research required for this gap; it will be taken to HSRF to determine any closeout actions.

**SM10: There are no stated acceptable ranges of cognitive and psychomotor performance.** HHC has closed this gap; it has been incorporated into BHP. Refer to The Risk of Performance Errors Due to Sleep Loss, Fatigue, Circadian Desynchronization and Work Overload, Gap Sleep2 for details.

**SM13:** Incorporate vestibular assessments within the in-flight periodic exams.

**SM15:** Need to adopt a multi-disciplinary approach to identify crewmembers at greatest risk of falls; also need to implement and track directed rehabilitation.

**SM16:** Need to insure that astronauts at risk of falls are accompanied until the risk diminishes to acceptable levels.

**SM17:** Require an astronaut post-flight fall risk assessment that should be a coordinated effort between crew surgeons, ASCRs, and discipline researchers. There is no research required for these gaps; they will be taken to HSRF to determine any closeout actions.

**SM11:** Need to provide alternate sources for spatial orientation.

**SM12:** Need to develop standards for spaceflight cockpit control displays and inputs. HHC has closed these two gaps; they have been incorporated into SFFH. Refer to the Risk of Error due to Inadequate Information gaps SHFE3.1.2.2.1 and SHFE3.1.2.2a for details.
Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems

Gap: (S1) Relationship between in-flight exercise and post-flight sensorimotor performance.

- Pass into ECP for exercise CM development

Gap: (S2) What is time course of recovery of sensorimotor function after long duration space flight?

- Recommended recovery prescriptions to Flight Medicine
Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems

Gaps: (SM6) Seated Manual/Visual performance assessment after long-duration spaceflight; (SIM2) Develop standards for spaceflight cockpit control displays and inputs

<table>
<thead>
<tr>
<th>nxPC</th>
<th>ZAG/Orilith (current ESA Joint study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>nsbri</td>
<td>CM to Enhance SM Adaptation (Bloombury NASA)</td>
</tr>
<tr>
<td>nxPC</td>
<td>Manual/Visual Control Study (TBD NASA)</td>
</tr>
</tbody>
</table>

CM required for exploration missions to mitigate risk

---

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.

* These studies are listed multiple times to answer several gaps
The Risks in this part of the Appendix are aligned with Section 2.3 –
Ensure That the Crew Receives Adequate Nutrition
The Risks in this part of the Appendix are aligned with Section 2.3 – Ensure That the Crew Receives Adequate Nutrition
OUTPOST – D, MARS – C

It is critical that crewmembers be adequately nourished before and during missions. Critical research areas within this risk include validation of the correct nutritional needs; assessment of the stability of nutrients during long duration flight; correct packaging and preservation techniques; effects of countermeasures on nutrition; and use of nutrients as countermeasures.

Context of Risk for Exploration

As mission duration increases, the risk of nutrient deficiencies becomes greater. Nutrient requirements, nutrient delivery requirements, and the need to preserve the nutrient content in food will increase as the frequency and duration of EVAs increase and during the very long Mars missions. Nutritional countermeasures can influence all systems.

Strategy for Mitigation

Space normal must be defined for this risk; hence, the Nutrition Supplemental Medical Objective (SMO) is ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed. In addition, several studies are ongoing to determine the optimal dose of vitamin D.

Gaps

N1: Are nutrients in food stable during space flight? This gap and all the tasks associated with it are being filled by AFT within SHFH; please refer to the Risk of Inadequate Food System, Gap AFT2 for further information.

N2: What is the optimal dose of vitamin D supplementation? It is unknown if the current vitamin D dosage is optimized, further work needs to be completed.

| Task: (NxPCM – via directed study) |
| Vitamin D Status in an Antarctic Ground Analog of Spaceflight |
| This task will support a vitamin D supplementation study that will evaluate efficacy in this model. Ultimately, the findings will provide long-duration spaceflight crewmembers with evidence-based vitamin D supplement recommendations for optimal vitamin D status before, during, and after flight. |

| Deliverables: Initial product is ground-based study to determine optimal vitamin D dosing. |
| Required Delivery Milestone: No delivery milestone is required for this task. |
| Required Platforms: Ground-based models with limited sunlight exposure are necessary for evaluating vitamin D supplementation efficacy. One such model is subjects spending the winter in Antarctica, where UV-Β radiation levels are zero during the winter. |
### Vitamin D Supplementation in an Antarctic Ground Analog of Space Flight: Study of Supplementation Protocol and Relationship to Immune System Function

A supplement of 2000 IU/d raised serum 25-hydroxyvitamin D to acceptable levels, but compliance was an issue that needs to be overcome. In the study proposed here, we will investigate whether a weekly dose of 10000 IU vitamin D could be substituted for this daily 2000-IU dose, and we will investigate the effects of vitamin D supplementation on immune function in an environment known to suppress immune function. The proposed ground analog study will enable us to provide long duration spaceflight crewmembers with evidence-based vitamin D supplement recommendations for optimal vitamin D status before, during, and after flight.

**Deliverables:** Initial product is ground-based study to determine optimal vitamin D dosing.

**Required Delivery Milestone:** No delivery milestone is required for this task.

**Required Platforms:** Ground-based models with limited sunlight exposure are necessary for evaluating vitamin D supplementation efficacy. One such model is subjects spending the winter in Antarctica, where UV-B radiation levels are zero during the winter.

### Task: (NxPCM – via directed study)

**Vitamin D Supplementation: Evaluation of Dosing Regimen**

In this study, we will investigate whether a weekly or monthly dose of vitamin D could be substituted for a daily dose. Data from this study will help us to provide long-duration space flight crewmembers a safe, effective, and evidence-based recommendation for vitamin D supplementation to achieve and maintain optimal vitamin D status before, during, and after flight.

**Deliverables:** Initial product is ground-based study to determine optimal vitamin D dosing.

**Required Delivery Milestone:** No delivery milestone is required for this task.

**Required Platforms:** Ground-based models with limited sunlight exposure are necessary for evaluating vitamin D supplementation efficacy. One such model is subjects spending the winter in Antarctica, where UV-B radiation levels are zero during the winter.

### Task: (NxPCM – via Directed Study)

**Nutrition Status Assessment – SMO O16E: Nutrition SMO**

This is a directed study that seeks to expand the Medical Requirement 016L testing in three ways: 1) include in-flight blood and urine collection, 2) expand nominal testing to include makers of normative markers of nutritional assessment, and 3) add an R+30 session to allow evaluation of post flight nutrition and implications for rehabilitation. Additional markers of bone metabolism (helical peptide, OPG, RANKL, IGF-1) will be measured to better monitor health and countermeasure efficacy. New markers of oxidative damage will be measured (8-iso-prostaglandin F2α, protein carbonyls, oxidized and reduced glutathione) to better assess the type of oxidative insults during space flight. The array of nutritional assessment parameters will be expanded to include serum folate, plasma pyridoxal 5'-phosphate, and homocysteine to understand better changes in folate, vitamin B6 status, and related cardiovascular risk factors during and after flight. Additionally, stress hormones and hormones that affect bone and muscle metabolism will be also measured (DHEA, DHEA-S, Cortisol, testosterone, estradiol). This additional assessment would allow for better health monitoring, and allow for more accurate recommendations to be made for crew rehabilitation. These additional parameters were added due to the recommendation of an extramural panel that met to define nutritional standards and requirements in 2005. If data indicate countermeasures are necessary for cardiovascular issues and/or bone loss, additional ground-based studies will be initiated. These countermeasures will be validated on board the ISS.

**Deliverables:** The SFHSS nutrition standard will be updated and nutritional requirements will be delivered to AFT. Updates regarding nutritional status in-flight will be delivered to the Human System Risk Forum. All deliverables are scheduled for delivery in the FY2011 timeframe.

**Required Delivery Milestone:** ISS is required to ensure that the data represents space normal.
Nutrition Status Assessment – SMO O16E: Nutrition SMO (cont’d)

Required Platforms: The ISS is required to validate the countermeasure.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>31 kg/Inc</td>
<td>5.1 kg + TBD cold stowage/Inc</td>
<td>22.5</td>
<td>3.2 (Time shared with Medical Operations Time)</td>
</tr>
</tbody>
</table>

N3: How do nutritional status/nutrition requirements change during spaceflight?

Task:
Nutrition Status Assessment – SMO O16E: Nutrition SMO
See this Risk – Gap N1, N2 for details.

N6: What impact does flight have on oxidative damage?

N15: Can nutrition/nutrients mitigate O2/radiation risks?

Task: (NxPCM – via directed study)
NEEMO Rapid Operational Investigation (ROI) study: Characterization of Oxidative Damage during a 12-day Saturation Dive

Oxidative damage resulting from radiation and or oxygen exposure (e.g., during EVAs) is a concern for space travelers. The underwater analog, NEEMO, is a valuable ground-based model for space flight in terms of oxidative damage and changes in iron metabolism. In six (6) subjects from NEEMO5, there was evidence of oxidative damage similar to what is observed during long-duration spaceflight. In this study, the main objective is to confirm and extend the physiological systems that were affected during the previous NEEMO study. Oxidative damage will be assessed before, during, and after the 12-day mission in the NEEMO habitat. As a result of this study, we will have a better understanding of the type of oxidative damage that occurs in an elevated oxygen environment, and the data can be used to better design countermeasures against this type of damage.

Deliverables: Initial product is completion of NEEMO study and final report of findings. Study results will be combined fed into the solicitation for the oxidative damage study being solicited through NIH.

Required Delivery Milestone: There is no required delivery milestone for this task.

Required Platforms: Ground-based studies, NEEMO underwater analog facility
<table>
<thead>
<tr>
<th><strong>Oxidative Damage Stud</strong> – TBD</th>
</tr>
</thead>
<tbody>
<tr>
<td>This work is to be solicited through NIH.</td>
</tr>
</tbody>
</table>

**Deliverables:** TBD

**Required Delivery Milestone:** If a countermeasure is required, it is needed as soon as possible.

**Required Platforms:** Ground-based studies, ISS required for validation of any needed countermeasures

**N4: Do countermeasures impact nutrition?** This gap is closed; nutritional requirements are constantly being modified and updated.
Task Factor of Inadequate Nutrition

p: (N2) Optimal dose of Vitamin D supplementation?

- PCM Polar Vitamin D ROI (Smith Directed Study)
  - Inform Med Ops of modified CM

- PCM Polar Vitamin D II ROI (Smith Directed Study)
  - Inform Med Ops of modified CM

- PCM Vitamin D Dosering ROI (Smith Directed Study)
  - YES

- PCM Nutrition SMO (Smith Directed Study)
  - ISS Study

Diet modification?

- These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.
- These studies are listed multiple times to answer several gaps
RISK OF INADEQUATE FOOD SYSTEM – CRITICALITY: LUNAR OUTPOST – D, MARS – C

If the food system does not adequately provide for food safety, nutrition, and acceptability, then crew health and performance and the overall mission may be adversely affected. Furthermore, if the food system uses more than its allocated mission resources, then total required mission resources may exceed capabilities, the mission deemed unfeasible, or allocation of resources to other systems may be unduly constrained.

The Advanced Food Technology (AFT) Project is responsible for optimizing methods required to preserve, package, and ship, stow and prepare the food while still preserving the nutritional value. The nutritional content of the flight food items is not currently measured. However the retort, irradiation, and freeze-drying processes used to produce shelf stable products, reduce the nutrient content. The nutrient levels in prepared foods will be measured to ensure that they meet the requirements of nutrition. If the nutrient levels are not adequate, other preservation methods that maintain the nutrient contents of the foods will be investigated. Further, shelf lives of the current thermostabilized food products have never been determined. Food items with varied formulations and bulk food ingredients have been placed in accelerated shelf life testing. The approach will provide critical information about the quality changes of the food items and susceptibility of vitamins in the space food system to adverse environmental factors and storage encountered during space missions.

Reducing the flight resources required for the food system is a major goal due to the significant ratios of rocket size to mass per pound of cargo delivered on an exploration mission. Methods to reduce packaging mass and volume overhead will be studied. These studies must overcome significant challenges of storing food for long periods of time (18 months for ISS to 5 years for a long duration exploration mission with pre-positioned food). Food packaging materials must be developed that minimize mass required while providing an adequate oxygen and moisture barrier to maintain the required shelf lives.

Operational Relevance and Risk Context

The paramount importance of the food system in a long duration manned exploration mission cannot be underestimated. The food system provides not only the nutrients needed for the survival and health of the astronauts, but it also enhances the psychological well being of the crew by being a familiar element in an unfamiliar and hostile environment. Inadequacy of a food system can be influenced by four criteria: safety, nutrition, acceptability and an imbalance of vehicle resources such as mass, volume and crew time. Since quality loss, which includes the critical components of nutrition and acceptability, will occur over the shelf life of the food, additional research is needed to improve the understanding of the nutritional content of the food when consumed and how much variety, acceptability, and ease of use is required for different duration missions. Research areas may include shelf life studies including the effects of time, temperature, and radiation; improvement in food preservation; improvement in food packaging, and evaluating the effect of the space environment and length of mission on food acceptability, variety, and ease of use. Research is also required for the food systems necessary to support EVA and contingency suited operations. The research will consider requirements to comply with the mission resources such as mass, volume, power, and crew time.

There is considerable overlap between the food system, nutrition requirements, and crew behavior and performance. The nutrition an astronaut receives is a function of both the nutritional content of the food and the amount of food that is actually consumed. Nutritional requirements are determined by looking at the physiological needs of the crew due to microgravity, space radiation, or stress, as examples. The food system delivers nutrition in the food. Any nutritional losses in the food due to shelf life, exposure to the outside environment, or through processing, need to be taken into account. The acceptability of the food system is closely related to crew performance since higher acceptability or variety of the food will
improve the well-being of the crewmember. Crewmembers tend to reduce food consumption when confronted with a lack of variety or unacceptable foods.

**Strategy for Mitigation**

The approach the AFT Project has taken is to determine the technology gaps for a given mission. It may be that for missions of short duration there is no need for mitigation. Another type of mitigation is one based on less available upmass and volume allowed for food. Once the risk for the specific mission has been identified, then the AFT Project determines whether there are commercially available technologies that can mitigate the risk. If that is the case, then the project further evaluates the technology to determine whether the technology must be modified to approve the technology for flight.

If there is not a commercially available technology, then the AFT Project must develop the technology by initially determining the requirements of the new technology. Once the requirements are identified, the AFT Project determines whether to develop the technology internally in the Space Food Systems Laboratory, partner with other HRP Projects, or through a contract with external researchers. An alternative approach, which leverages Human Research Program funding by partnering with the Department of Defense Combat Feeding Directorate (DoD CFD), uses a Military Interdepartmental Purchase Request (MIPR) between the AFT Project and DoD CFD.

**Gaps**

**AFT1: How can the food system deliver the required level of nutrition throughout the mission?**

The nutrition requirements, determined by the Human Health and Countermeasures Element, are delivered via the food system and through supplementation. There are requirements for nominal operations and contingency operations, as well as EVAs. Packaged foods, rehydratables, thermostabilized, and irradiated products, are processed, which can reduce the nutritional content. In addition, extended storage of these foods and exposure to a variety of environmental conditions such as heat, oxygen, and space radiation will often affect the stability of the vitamins.

<table>
<thead>
<tr>
<th>Tasks: (AFT – Directed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Suit Food for Contingency Operations</td>
</tr>
<tr>
<td>HSIR Requirement [HS11008] – The system shall provide the capability for nutrition consumption as specified in HS6062 by a crewmember in a pressurized suit during unpressurized vehicle survival operations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements for food structure (gel, bars, thick liquid) and shelf life on suited food delivery system</td>
</tr>
<tr>
<td>Nutrient-dense foods needed for food delivery system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements for food delivery system for EVA Suit Configuration-1 needed by SRR. Foods needed for food delivery for EVA Suit Configuration-1 needed by CDR.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground</td>
</tr>
<tr>
<td>Tasks: (AFT – Directed)</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>HSI Requirement [HSI1007] – The system shall provide the capability for nutrition consumption as specified in HS6062 during the EVA by a crewmember performing surface EVA operations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements for food structure (gel, bars, thick liquid) and shelf life on suited food delivery system</td>
</tr>
<tr>
<td>Nutrient-dense foods needed for food delivery system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements for food delivery system for EVA Suit Configuration-2 needed by SRR. Foods needed for food delivery for EVA Suit Configuration-2 needed by CDR.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (AFT – Directed)</th>
<th>Effect of Processing on the Nutritional Content of Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nutritional content of the flight food items is not measured for NASA’s flight food. The actual macronutrients and some minerals are determined chemically. However, the other nutrients such as vitamins are determined through a computer program that calculates the combined nutritional content based on the food products formulation. The computer program does not take into account the loss of nutrients during the thermostabilization process.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review literature to better understand the potential effects of the retort, irradiation, and freeze drying processes</td>
</tr>
<tr>
<td>Optimize time/temperature processing conditions for each specific thermostabilized and freeze-dried food product that NASA produces</td>
</tr>
<tr>
<td>Measure nutritional content of the finished product at time of production, 1 year and 3 years</td>
</tr>
<tr>
<td>Develop improvements to the current ISS flight food using highly nutritious foods or emerging technologies such as high pressure processing and microwave sterilization if nutritional content of the foods do not meet the nutritional requirements</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide nutritional content post-processing and after 1 and 3 years</td>
</tr>
<tr>
<td>FY2015 – Required as a design solution to support the food system for operations on the Lunar surface. However, if information is available prior to this, it could be used to influence the food system for the ISS.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (NxPCM with collaboration by AFT – Directed)</th>
<th>Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>This protocol involves investigative physical/chemical analyses of both medications and food items returned from STS and ISS along with corresponding lot-matched controls stored on ground in a controlled environment. This experiment has two (2) sub-payloads attached to it. See the Risk of Therapeutic Failure Due to Ineffectiveness of Medications for the Pharmacology sub-payload. The Nutritional Sub-Payload will identify vitamins and amino acids at risk for degradation in the space food supply; identify changes in fatty acids of foods flown on ISS; and characterize degradation profiles of the unstable nutrients. This study will provide critical information about the preservation of vitamins and nutrients in food during space flight and susceptibility of vitamins in the space food system to adverse environmental factors and storage conditions encountered during space missions.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyses will determine whether low earth orbit environment (radiation) affects the nutritional content of the food.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The data will determine whether further ground based studies will be required to develop a design solution for Lunar mission CDR. If the results suggest that the loss in nutrients is not due to space radiation but instead to time or processing, the results will be fed into the DoD Collaboration task.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Platforms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISS required for proper radiation doses on food samples.</td>
</tr>
</tbody>
</table>
AFT2: How can the nutrition and acceptability of the food system be maintained throughout the mission?

Nutrition and acceptability are related. The literature suggests that food quality (color, texture, etc.) may provide a general indication of nutritional loss of the food. The activities in this gap are those that measure both nutrition and acceptability. If the food is not acceptable to the crew, the crew will not eat an adequate amount of the food and will be compromised nutritionally. Freeze-dried, thermostabilized, and irradiated foods are processed, which can reduce the quality including acceptability and nutritional content. In addition, extended storage of these foods and exposure to a variety of environmental conditions such as heat, oxygen, and space radiation will often affect the quality of the products.

Tasks: (AFT – Directed)

Thermostabilized Shelf-Life Study

Shelf lives of the current thermostabilized food products have never been determined. Thirteen food items with varied formulations have been placed in accelerated shelf life testing. In addition, three bulk ingredients (for preparation for a Lunar outpost mission) were placed into accelerated shelf life testing. Sensory and analytical changes are measured throughout the three-year test.

Deliverables: This task will ultimately result in a list of foods and/or preparation methods that maintain their stability to support a Lunar mission. It will also identify weaknesses of product types used in the current system allowing for enhancement of existing products or development of improved products. Information about food product weaknesses will also support the DoD Collaboration task.

Required Delivery Milestone: FY2015 – Required as a design solution to support the food system for operations on the Lunar surface (Lunar Mission CDR). However, if information is available prior to this, it could be used to influence the food system for ISS.

Required Platforms: Ground

Tasks: (AFT – Directed Study in collaboration with DoD)

Department of Defense (DoD) Collaboration

Although NASA’s food requirements are not compatible with those of the commercial food industry, they are compatible with those of the Combat Feeding Program (DoD). Both NASA and DoD require long shelf life, shelf stable food items with high barrier packaging. Both also require minimal packaging. The DoD Combat Feeding Program, when conducting their research, uses collaborations of subject matter experts from industry, government, and academia experts. Currently, the DoD has an on-going packaging research program as well as a program to investigate emerging preservation technologies. These preservation technologies should result in FDA approval of high-pressure processing and microwave sterilization for shelf stable products. Both processes have a high potential for long duration Space Flight missions.

Deliverables:

Testing of advanced food packaging and preservation technologies for shelf stable foods
Recommendations for advanced food packaging and preservation technologies for shelf stable foods

Required Delivery Milestone: FY2023 (NOTE: Need date for Lunar outpost CDR is TBD) – Food system requirements definition needed for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be applied to the ISS food system if it would positively impact its long-term nutrient stability or reduce food logistics. 56 HRP-47065

Required Platforms: Ground
Effect of Space Radiation on Shelf Life

Destruction of even a single vitamin in the space food system could be catastrophic to astronauts on a 3-year mission to Mars. Although about 60 different foods have been approved for irradiation to ensure the safety of these foods from microorganisms, very little testing has been conducted on the effect of radiation on the stability of nutritional content. The Joint Expert Committee on Food Irradiation (JECFI) convened by the Food and Agriculture Organization of the United Nations, the World Health Organization, and the International Atomic Energy Agency, concluded in 1980 “the irradiation of any food commodity” up to an overall average dose of 10 kGy “presents no toxicological hazard” and requires no further testing. In other words, the research has been concentrated on the toxicological effects and not nutritional stability.

Preliminary results from some NASA-funded research indicate that some functionality and quality changes occur in foods and food ingredients at lower radiation levels. If results from the ground and flight stability studies indicate nutrient loss due to radiation, further research will be required to determine quality changes at appropriate dosage levels for Mars and Lunar missions and the appropriate countermeasures.

Deliverables:
Summary of radiation effects on food using literature and NASA-funded research.
If the data suggests that there is a nutritional or quality loss due to radiation exposure to the food, then further research will be conducted to determine the changes in quality and nutritional content of foods over time when exposed to the appropriate dose of radiation.
Food system design solutions as countermeasures to the effects of radiation. 53 HRP-47065

Required Delivery Milestone: Constellation Program informed of food system requirements in 2010. Required as a design solution to support food system for ops on lunar surface (Lunar mission CDR).

Required Platforms:
Ground based study.
Further ISS or Lunar testing may be required depending on results from ISS Stability Study and other data collected.

AFT3: How can the acceptability of the food system be maintained throughout the mission?

If the food is not acceptable to the crew, the crew will not eat an adequate amount of the food and will be compromised nutritionally. Anecdotal reports have suggested that the food does not taste the same in microgravity. Other reports indicate that the crew craves different foods on-orbit as compared to on-Earth. In addition, the crew has reported that they tire of certain foods over the 6-month ISS mission.

Tasks: (AFT – External research)
Sensory Qualities in Microgravity
Determine effect of changes in aroma detection due to fluid shift and lack of air circulation in microgravity.
Determine effects of “long term acceptability.”
Validate with ISS study incorporating surveys of food quality and acceptability.

Deliverables: Requirements for a food system intended for long-duration operations

Required Delivery Milestone: FY2017 (NOTE: Need date for Lunar Outpost PDR is TBD.)- Food system requirements definition needed for long-duration Lunar outpost and Mars Missions. However, if information is available prior to this, it could be used to influence the food system for ISS.

Required Platforms:
Ground
Possible validation on ISS
Tasks: (AFT – External research)
Variety, Acceptability, and Usability Requirements Development (TBR-7)
Determine requirements for the food system specific to variety of foods, taste acceptability, and usability
(perform primarily through taste panels and surveys).

Deliverables: Requirements on the food system for long-duration operations

Required Delivery Milestone: FY2017 (NOTE: Need date for Lunar outpost PDR is TBD) – Food system
requirements definition needed for long-duration Lunar outpost and Mars Missions. However, if information is
available prior to this, it could be used to influence the food system for the ISS.

Required Platforms: Ground

Tasks: (BHP – Directed Study or External)
Psychosocial Requirements of Food Operations (eating together, holiday foods, etc)
Requirements and guidelines development process requiring little if any research. The requirements development
will consist of recommendations to mission ops for eating times, group meals, special foods, holiday foods, etc. Requirements will be developed in conjunction with the crew office and the AFT Project.

Deliverables: Requirements of food system and mission operations

Required Delivery Milestone: FY2017 (NOTE: Need date for Lunar outpost PDR is TBD) – Food system
requirements definition needed for long-duration Lunar outpost and Mars Missions. However, if information is
available prior to this, it could be used to influence the food system for ISS.

Required Platforms: Ground

**AFT4: What technologies can be developed that will efficiently balance appropriate vehicle resources such as mass, volume, and crew time during exploration missions with the safety, nutrition, and acceptability requirements?**

The balancing of resources with nutrition and acceptability is dependent on the specific mission. For example, the 2-week initial missions to the Moon will consider mission resource utilization of primary importance due to the small usable volume in the vehicle. Since the missions are shorter, nutrition and acceptability may not be as critical. Ineffective use of vehicle resources such as mass, waste, and crew time can jeopardize mission success. Mass of the packaged food system is based on mass of the food and the packaging surrounding the food. Food packaging produces a significant amount of waste. A bioregenerative food system, while providing the crew with fresh foods and using less packaged food, will require more crew time, power needs and water. Trade studies will be required to determine the best use of resource utilization while balancing the other food system requirements.

Current preflight procedures and existing research plans incorporate good manufacturing processes (GMP) to insure food safety. However, with new processes planned Lunar and Mars missions, GMP will need to be developed to reduce the risk of food borne illness.
**Tasks: (AFT – Directed for Packaging Workshop and Comparative Packaging Study, SBIR is funded through SBIR Program and External Research Project)**

**Advanced Packaging Material Development**

Currently the packaging used for freeze-dried foods and natural form foods does not have adequate oxygen and moisture barrier properties to allow for an 18-month shelf life for ISS. Therefore, those foods are over wrapped with a second foil-containing package that has higher barrier properties. The packaging material used for the thermostabilized, irradiated, and beverage items contain a foil layer to maintain product quality over at least the required 18-month shelf life. Although foil in the packaging material provides excellent oxygen and moisture barrier properties, it is not compatible with microwave sterilization and high pressure processing. These emerging preservation technologies have the potential of providing NASA with a higher quality food system. The foil layer within the food package may also provide complications if the decision is made to incinerate the trash on the Lunar or Martian surface. Therefore, research to develop a packaging material that has the barrier properties of foil without the presence of foil is necessary.

- Comparative Packaging Study – determine whether any current flight packaging can be used as the primary package for freeze-dried and natural form foods.
- Small Business Innovative Research (SBIR) Program – evaluate SBIR deliverables and integrate if acceptable with current food system
- External Research Project – development of new high barrier, foil-free packaging material

**Deliverables: Food packaging technologies that reduce the overall mass and volume required for the food system**

**Required Delivery Milestone: FY2015 – Required as a design solution to support the food system for operations on the Lunar surface (Lunar Mission CDR). However, if information is available prior to this, it could be used to influence the food system for ISS.**

**Required Platforms: Ground**

---

**Tasks: (AFT – Directed)**

**Packaged food mass reduction trade study**

In order to provide a lower mass and volume food system for the Constellation Program, changes in product formulation may be necessary. Changes under consideration include removing some water from the total food system, increasing fat content, or increasing nutrient density of the food items.

**Deliverables:**

- Trade study to consider options to reduce mass of food. Determine best-case scenario for further development.
- Determine commercial availability of foods with preferred scenario.
- Develop technologies for food product development if not commercially available.

**Required Delivery Milestone: Food system requirements for first Orion mission (2015)**

**Required Platforms: Ground**
### Tasks: (AFT – Directed)
#### Total System Approach to Packaging Material Selection
There is a need for a total systems approach when the goal is maximizing shelf life and minimizing packaging mass. The packaging material is only one portion of the system, and must not be considered the main focus of the packaging system. Defining and improving key result areas of the packaging process will increase the shelf life of foods without increasing total mass.

**Deliverables:**
- Define existing packaging system – temperature, heat seal width, times, vacuum, materials, septums, gases, packaging design
- Literature review – available materials, pinholes/defects, modified atmosphere or gas flushing, shelf life
- Document possible improvements to existing system
- Recommendations for future work

**Required Delivery Milestone:** Packaging options to reduce mass and improve food quality by Lunar mission PDR

**Required Platforms:** Ground

### Tasks: (AFT – Directed)
#### Bulk Overwrap Packaging Alternative
Using a bulk overwrap system instead of individual package overwrap will save on mass and volume for longer duration missions. The overwrap can also be used as a flexible container to save on mass and volume in the shorter duration Orion missions.

**Deliverables:**
- Select materials to test
- Develop efficient method for packaging – vacuum packaging, gas flushing, heat sealing
- Evaluate scavenger systems
- Evaluate the possibility of creating innovatively shaped packages
- Compare mass of bulk overwrap system vs. individual overwrap
- Compare mass of bulk overwrap system vs. current ISS rigid container system

**Required Delivery Milestone:**
- Required as a design solution to support food system Orion missions as “food container” for Orion CDR
- Food system requirements for Lunar SRR and Mars missions

**Required Platforms:** Ground
## Tasks: Partial Pressure Effects on Food Processing and Preparation

Heat and mass transfer are affected by reduced atmospheric pressure. When preparing raw foods into edible ingredients, it is necessary to reach a certain temperature/time combination to ensure safety and functionality. It is being proposed that the Lunar habitat will maintain an 8-psi atmospheric pressure. At that pressure, the boiling temperature for water is 181°F. If incomplete heating does occur, research will be required to determine countermeasures.

**Deliverables:**
- Determine whether there is incomplete cooking.
- If there is incomplete cooking, what is the mitigation strategy?
- Used as an input to the trade study (see next task).
- Ultimately results in requirements on the Lunar Outpost Food System regarding food preparation and/or processing equipment.

**Required Delivery Milestone:** Lunar Outpost SRR is scheduled for early FY2012. At that time, the trade study for which this task is to feed into would require completion by end of FY 2011. This task and the upcoming trade study are not scheduled in time to provide input by Lunar Outpost SRR.

**Required Platforms:** Ground with validation on ISS or Lunar surface

## Tasks: Food Processing vs. Packaged Food System Trade Study (TBR-9)

Preliminary studies suggest total mass of the food system can be reduced if the food system moves towards a bioregenerative food system. In a bioregenerative food system, vegetables, and fruit would be grown on the Lunar or Mars surface and baseline crops such as soybeans, wheat, rice, peanuts, and dried beans would be grown or launched in bulk from Earth. The baseline crops would be processed into edible ingredients. The edible ingredients and freshly grown fruits and vegetables would be used in preparing meals in the galley. Some packaged food would likely be required.

Further studies are required to determine the magnitude of mass savings and the effect on other mission resources such as power, crew time, and recycling of water used for food processing. These studies will also identify the equipment that would be required to be built for the Lunar surface test.

A trade study that considers efficiencies and adequacies of the two food systems with a recommendation to the Program is required.

**Deliverables:**
- Requirements on vegetable, fruit and baseline crops growth – could range from hobby to full bioregenerative food system
- Requirements for the Lunar Outpost Food System regarding food preparation and/or processing equipment
- Mass and volume requirements for various levels of food processing and food preparation
- Recommendation to Constellation Program on whether to develop food preparation and food processing technologies for the Lunar Outpost

**Required Delivery Milestone:** Lunar Outpost SRR is scheduled for early FY2012. This trade study supports the decision process on whether to develop food preparation and food processing technologies and if so, to what extent. This trade study is not scheduled in time to provide input by Lunar Outpost SRR.

**Required Platforms:** Ground
<table>
<thead>
<tr>
<th>Tasks: (AFT – Directed or External)</th>
<th>Develop Processing and Preparation Equipment and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>if a bioregenerative food system is used, then miniaturized processing equipment will need to be built. It is unlikely that there will be commercial equipment appropriately sized for a Lunar or Mars mission. The preparation equipment for the galley will likely be commercially available gourmet kitchen appliances that will need to be modified for the Lunar missions.</td>
<td></td>
</tr>
<tr>
<td>Deliverables: Food system processing and packaging technologies for a Lunar outpost or Mars mission.</td>
<td></td>
</tr>
<tr>
<td>Required Delivery Milestone:</td>
<td></td>
</tr>
<tr>
<td>FY2019 (NOTE: Need date for Lunar outpost SRR is TBD) to provide design solution for the food system for long-duration Lunar outpost and Mars Missions.</td>
<td></td>
</tr>
<tr>
<td>Follow-on validation and optimization for Mars missions to occur in Lunar ops (Date TBD).</td>
<td></td>
</tr>
<tr>
<td>Required Platforms: Ground with validation on Lunar surface</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (AFT and/or Crop Systems team (TBD) – Directed or External)</th>
<th>Vegetable Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>In order to provide the crew with fresh food on the Lunar surface and Mars missions, fruits, and vegetables will be grown hydroponically in environmentally controlled growth chambers. Significant research has been conducted to determine growth conditions and plant sensitivities to environmental changes. However, further research is required to finalize the environmental conditions for plant growth. Since the fruits and vegetables may be consumed uncooked, research is required to determine the handling procedures pre- and post-harvest to ensure safety.</td>
<td></td>
</tr>
<tr>
<td>Deliverables:</td>
<td></td>
</tr>
<tr>
<td>Growth procedures for fresh vegetables and fruits</td>
<td></td>
</tr>
<tr>
<td>Handling procedures to ensure safe, uncooked foods</td>
<td></td>
</tr>
<tr>
<td>Required Delivery Milestone: FY2019 (NOTE: Need date for Lunar outpost SRR is TBD) to provide design solution for the food system for long-duration Lunar outpost and Mars Missions.</td>
<td></td>
</tr>
<tr>
<td>Required Platforms: Ground with validation on Lunar surface</td>
<td></td>
</tr>
</tbody>
</table>
## Risk of an Inadequate Food System

### Mission Operations

<table>
<thead>
<tr>
<th>System</th>
<th>EVA Operations</th>
<th>EDU</th>
<th>Crew</th>
<th>Cargo</th>
<th>NASA Planetary</th>
<th>Proposed Planetary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Directive Study</td>
<td>200</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>

### Requirements

- Food needed on the EVA Food Delivery System
- Food delivery system required on the EVA Food Delivery System
- Food delivery system required on the EVA Food Delivery System
- Requirements for the EVA Food Delivery System
- Requirements for the EVA Food Delivery System
- Requirements for the EVA Food Delivery System

### In-Situ Food for Lunar

<table>
<thead>
<tr>
<th>System</th>
<th>EVA Operations</th>
<th>EDU</th>
<th>Crew</th>
<th>Cargo</th>
<th>NASA Planetary</th>
<th>Proposed Planetary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Directive Study</td>
<td>200</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>

### Shuttle

<table>
<thead>
<tr>
<th>System</th>
<th>EVA Operations</th>
<th>EDU</th>
<th>Crew</th>
<th>Cargo</th>
<th>NASA Planetary</th>
<th>Proposed Planetary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Directive Study</td>
<td>200</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>

### Conclusion

- To deliver the required level of nutrition throughout the mission.
- To satisfy the needs for food delivery on the EVA Food Delivery System.
Risk of an Inadequate Food System

T1: How can the food system deliver the required level of nutrition throughout the mission?

- Effect of Processing on Nutritional Content of Food (Directed Study)
- PCM Stability SMO (Directed Study)

T2: How can the nutrition and acceptability of the food system be maintained throughout the mission?

- Thermostabilized ShelfLife (Directed Study)

<table>
<thead>
<tr>
<th>Program Level</th>
<th>SRM</th>
<th>Initial Ops</th>
<th>PDR</th>
<th>CDR</th>
<th>Human Lunar Return</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orion</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
<td>Full Ops Capability</td>
</tr>
<tr>
<td>EVA Suit</td>
<td>PDR-out1</td>
<td>CDR-out1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lander</td>
<td>ATP</td>
<td>SDR</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
</tr>
</tbody>
</table>

Ground-based Study

- Provide nutritional content post-processing and after 1 and 3 years to NACPM

Are nutrients stable?

- Yes
- No

Food with nutrients that remain stable for the mission duration.

Required as a design solution to support food system for ops on lunar surface (Desirable before this to improve ISS food quality)

Are nutrients stable?

- Yes
- No

Input into DoD Collaboration task

Food with nutrients that maintain stability for the mission duration.
T2: How can the nutrition and acceptability of the food system be maintained throughout the mission?

Advanced Packaging Dev

Advanced preservation technologies adequate?

NO

Further Packaging Dev

NO

Advanced packaging technologies adequate?

Formulation Options

Formulation options adequate?

Evidence Gathering

Evidence of no radiation effect?

YES

Radiation Stability Study

NO

Countermeasure Development

YES

Food with nutrients that remain stable for the mission duration.
T3: How can the acceptability of the food system be maintained throughout the mission?

**T** Sensory Qualities in Microgravity
   (Directed Study or External)

**FT** Variety, Acceptability, and Usability Requirements Development
   (Directed Study or External)

**HP** Psychosocial Requirements On Food Operations (Eating Together; Holiday Foods, etc)
   (Directed Study or External)

**Q2** Food system requirements for long duration operations.
Risk of an Inadequate Food System

T4: What technologies can be developed that will efficiently balance appropriate vehicle resources such as mass, volume, and crewtime during exploration missions with the safety, trination, and acceptability requirements?

- Advanced Packaging Material Development
  - Comparative Packaging Study (Directed Study)
  - External Research
    - SBIR Phase II (SBIR)
  - Packaged Food Mass Reduction Trade Study (Directed Study)

Are any of these technologies adequate for long duration missions?

- Ground-based Study
  - NO

Are any of these materials adequate for long duration missions?

- Ground-based Study
  - NO

Food packaging technologies for Lunar mission design

(1) Solutions that reduce the mass and volume of food

(2) Food packaging technologies for Lunar mission design

- Can mass be reduced with available technologies?
  - YES

- (1) Mass and volume of Orion food system

- Required as a design solution to support food system for lunar outpost & Mars (Need data for Lunar Outpost CDR TBD) (Desirable before this to improve ISS food logistics)

- Justification - Currently overweight - Challenged to reduced mass from 4 lbs to 2.5 lbs per day
Risk of an Inadequate Food System

T4. What technologies can be developed that will efficiently balance appropriate vehicle resources such as mass, volume, and crew time during exploration missions with the safety, nutrition, and acceptability requirements?

- Total System Approach to Packaging Material Selection (Directed Study)
  - Ground-based Study
    - Alternative for hard container that protects food
    - Bulk packaging technologies for Lunar and Mars missions

- Bulk Overwrap Packaging Alternative (Directed Study)
  - Ground-based Study
    - Required as a design solution to support food system Orion missions as "food container" for Orion CDR
    - Overarching processing and packaging requirements that will improve product quality
  - Define requirements for long-duration lunar outpost & Mars missions
    (Need data for Lunar Outpost PDR is TBD) (Desirable before this to improve ISS food logistics)
Risk of an Inadequate Food System

T4: What technologies can be developed that will efficiently balance appropriate vehicle resources such as mass, volume and crewtime during exploration missions with the safety, trition, and acceptability requirements?

T Partial pressure effects on food processing and preparation (RFP or Directed Study)

T Food Processing vs. Packaged Food System (Directed Study)

T Develop processing and Preparation Equipment and Procedures (Directed Study or RFP)

T Vegetable Growth (Directed Study or RFP)
The Risks in this part of the Appendix are aligned with Section 2.4 – Protect the Crew from Environmental Hazards
Near-term goals for cancer research focus on reducing the uncertainties in risk projections through the development of tissue specific models of cancer risks, understanding the underlying mechanisms of these models, and appropriate data collection at the NASA Space Radiation Laboratory (NSRL). In the long-term, extensive validation of these models with mixed radiation fields is envisioned and research on biological countermeasures and biomarkers will be pursued if needed. Research on improving cancer projections has two major emphases: 1) validating the application of the National Council on Radiation Protection (NCRP) model and 2) reducing the uncertainties in the coefficients that enter into the cancer projection model. Validation of the NCRP model relies on studies at the NSRL observing qualitative differences in biological damage between HZE nuclei and gamma rays and the establishment of how these differences relate to cancer risk. There are distinct mechanisms of cancer induction across and within major tissue sites, and uncertainty reduction requires tissue specific risk estimates. NRA and NASA Specialized Center of Research (NSCOR) selections focus on these major sites: lung, breast, colon, stomach, esophagus, the blood system (leukemias), liver, bladder, skin, and brain. There are differences in radiation sensitivity based on genetic and epigenetic factors and research in these areas aids the development of tissue specific cancer models.

The approach to uncertainty reduction is based on evaluations of the assumptions in the current model for projecting cancer incidence and mortality risks for space missions. The cancer rate is the key assumption in the evaluation; representing the probability at a given age and years since exposure of observing a cancer. The life-span study of the atomic-bomb survivors is the primary source for gamma-ray data, however more recently meta-analysis of patients exposed to radiation or reactor workers for several tissues has become available and is used to check or replace the Japanese data. Other assumptions in the model are made with regard to the transfer of risk across populations, the use of average rates for the US population, the age, and age-after exposure dependence of risk on radiation quality and dose-rate, etc.

Collaborative research with the Department of Energy (DoE) Low Dose Research Program is a key component of the strategy. The DoE program focus is on low Linear Energy Transfer (LET) irradiation; however, collaborative grants are selected from proposals that contain one or more Specific Aims addressing NASA interests using the NSRL. This research augments SR research with a number of grants using state-of-the art approaches including genetics, proteomics, and transgenic animal models. The DoE research is an important component in reaching the goal to identify biomarkers of cancer risk.

Determining the shape of the dose-response model for cancer induction is a near-term focus that is enumerated in biological terms through various cancer Gaps. In the NCRP model, the dose-response is linear and the slope coefficient is modulated by radiation shielding. Non-targeted models of cancer risk describe processes where cells traversed by HZE nuclei or protons produce cancer phenotypes in regions of tissues not limited to the traversed cells. Non-targeted effects are the major mechanism that has been identified that is in disagreement with the NCRP model, and leads to a sub-linear dose response. The implications of a sub-linear dose response for cancer risk are large since such a model predicts a reduced effectiveness for radiation shielding, and on the importance of mission length. Research in this area is a major focus of studies at NSRL. For some cancer sites and exposure conditions, e.g., proton exposures, the NCRP model may be adequate, and research here is focused on reducing the uncertainties in the model through the establishment of tissue specific models of human cancers, and collection of data at NSRL for a variety of ground-based analogs for Solar Particle Event (SPE) and Galactic Cosmic Rays (GCR).

Systems biology models provide a framework to integrate mechanistic studies of cancer risk across multiple levels of understanding (molecular, cellular, and tissues), and are the most likely approach to replace the NCRP model. Systems biology models are being developed by the Risk Assessment Project and several NSCOR’s, and in conjunction with data collection will improve the descriptions of cancer
risks and to lay a framework for future biological countermeasure evaluations and biomarker identification.

**Operational Relevance and Context of Risks for Exploration**

Permissible exposure limits (PEL) for Space Radiation limit the allowable mission and career exposure to the space radiation environment based on the projected risk of developing cancer. The PEL’s protect against the upper 95% percent confidence level in the career radiation limits because the uncertainties in risk projection models are significant (>4-fold) such that the use of a median risk estimate could greatly over-estimate or under-estimate the actual risk to crews.

Mission, vehicle, and crew selection requirements are outcomes of the Space Radiation PELs, including requirements on vehicle design, mission duration, and age, gender, or past mission history for crew selection. Current estimates of mission duration limits that result from cancer fatality risks alone are shown in Table 1, comparing estimates made in 2001 without the benefit of the most recent research knowledge, to current estimates.

<table>
<thead>
<tr>
<th>Age, yr</th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>54</td>
<td>112</td>
</tr>
<tr>
<td>35</td>
<td>62</td>
<td>132</td>
</tr>
<tr>
<td>40</td>
<td>73</td>
<td>150</td>
</tr>
<tr>
<td>45</td>
<td>89</td>
<td>182</td>
</tr>
<tr>
<td>50</td>
<td>115</td>
<td>224</td>
</tr>
</tbody>
</table>

**TABLE 1. INCREASING SAFE DAYS IN SPACE WITH REDUCTION IN UNCERTAINTIES**

Research to reduce uncertainties in risk projection models are expected to increase NASA’s ability to select crew, extend mission duration, and reduce cost through possible reductions in shielding requirements. Improved knowledge of dose-rate and radiation effects will allow for EVA time lines to be extended in deep space and on the lunar or Mars surface. Furthermore, research approaches that narrow uncertainties in risk models will no-doubt evolve into countermeasure discovery and validation approaches that have large benefits on crewmembers.

The NASA PEL’s for fatal cancer risk may be exceeded for several lunar scenarios including a large SPE, cumulative career exposure, and mission length dependent on crew age and gender. The Operational relevance of these conditions is obviously critical and could delay, reduce the length of missions, or make the costs to prevent PEL violation far too excessive. Reducing the uncertainties in risk projections through NSRL research, which are part of the radiation PELs, could possibly alleviate cancer risk projections below PELs. Possible mitigation approaches such as parasitic radiation shielding are very costly for SPE’s and may prove prohibitive for GCR. The final solution may be a combination of uncertainty reduction, shielding, mission length, and crew selection with effective biological countermeasures. Biological countermeasures to mitigate the risk or improve treatment are in early stages
of development and projections of their effectiveness highly uncertain. The NASA PELs for fatal cancer risk are projected to be violated under all possible Mars scenarios at this time making the radiation cancer risk critical as the mission cannot be undertaken without further breakthrough leading to uncertainty reduction in risk projection models or to the development of biological countermeasures.

**Dependent on new research results, the cumulative risk from CNS and Degenerative when combined with Cancer risks will likely have major negative impacts on mission design, costs, schedule, and crew selection. Thus risk projection model development and PELs will begin with Cancer Risks, but eventually incorporate projection capabilities for Acute, CNS, and Degenerative Tissue Risks.**

**Strategy for Mitigation**

SRPE plans to conduct a phased implementation approach to reduce the uncertainty associated with space radiation effects and develop countermeasure recommendations in support of Lunar and Mars vehicle and mission planning. A breakthrough research strategy is utilized because of the large scientific challenges needed to understand and mitigate human risks to space radiation. Examples of breakthroughs that have occurred in recent years are the hallmark molecular changes in cancer stem cells in cancer research. Breakthroughs create large perturbations in research plans and schedules, and have large benefits to achieving SRPE goals. Future breakthroughs are expected, albeit not possible to predict.

Biological countermeasure research will be conducted at a low level in the near-term, however will be increased after experimental (biological) models of human risks are established and uncertainties are significantly reduced. This is due to a need to understand the biological targets for countermeasures and to ensure the ability to assess properly their potential effectiveness. Similar phased approaches are followed for biomarker research.

The SRPE established a scientific approach that follows a progression of activities designed to feed the development of an integrated risk model with acceptable uncertainty for exploration missions, followed by activities targeting risk mitigation and monitoring. These activities are not necessarily implemented in serial, but emphasis is placed on 1 to 3, the successful completion of which should facilitate model development to enable mission durations required for currently planned lunar missions. Successful completions of 4 to 7 are needed to enhance model development to enable Mars missions. Items 4 to 7 are being pursued at a minimal level in the current program. As activities essential for lunar missions are completed, greater effort will be spent in activities essential for Mars missions.

The activities required to develop the cancer risk projection model are as follows:

1) Establish Mechanisms of Cancer and CM Action
2) Develop Tissue and Risk Specific Experimental Models
3) Understand radiation quality effects on biological damage to quantify risk
4) Understand the dependence of risk on dose-rates in space
5) Extrapolation from experimental data to humans to quantify risk
6) Understand individual radiation-sensitivity to quantify risk
7) Develop countermeasures, technologies, and models for Risk Mitigation and Monitoring
Figure 1 graphically illustrates components of the research approach.

**Components of Research Approach**

- **Basis for Knowledge of Modifying Factors:** Quality, Dose-rate, Individual Sensitivity, Countermeasures
- **Epidemiology Updates:** Shielding, Physics, Dosimetry, Other Outside Inputs
- **Mechanistic Studies**
- **Animal/Tissue Models of Specific Risks**
- **Risk Modeling**
- **Countermeasures**
- **Risk Projections, PELs, Requirements, Other Outputs, Deliverables**
- **Epidemiology Updates, Shielding, Physics, Dosimetry, Other Outside Inputs**

**Overview of Research Approach**

The level of tolerance in projection model uncertainties depends on the acceptable level of mortality risk (3%) and the projection of risk for each class of mission. Cancer projections for 40-yr females on STS, ISS, and 180-day lunar, and Mars missions are currently estimated at about 0.01, 0.35, 0.7, and 5%, respectively. Therefore, a much lower tolerance can be accepted for lunar or Mars mission than mission in LEO to assure risk acceptance levels are not exceeded, and more accurate and mechanistic models of risk must be developed for these missions. This constraint leads to a major goal for research approaches followed by SRPE with uncertainties less than 2-fold needed for long-term lunar stays, and less than +50% for a Mars mission. See Figure 2 for the timeline for reducing uncertainties.

In order to understand whether research has achieved the level of tolerance in cancer risk projections required; interactions are needed between risk assessment research and biological mechanisms and data research. The first Gantt chart in Appendix D shows a major decision point in the research plan related to assessment of uncertainty reduction. If sufficient uncertainty reduction is achieved in the near-term, research on biological countermeasures and minor tissue sites is envisioned to occur in 2014 and out.

**Biological Risk Research**

The large number of GCR nuclei type, energies, SPE doses, and dose-rates, in combination with the multiple tissue and cancer types makes the performance of large-scale animal or 3D human cell culture studies of cancer risk at NSRL prohibitive. Therefore, a mechanistic approach is needed and has been segmented into major mechanistic research areas (Gaps Cancer 1, 2, and 7-9). These areas may find synergy in the types and range of biological models employed however will differ in the complicated hypothesis questions being addressed. Ultimately, mechanistic studies must progress to determine quantitative data sets for estimating probabilities for increase risk of carcinogenesis that in conjunction with research on Risk Assessment models will be used to extrapolate risks from experimental model to risks in astronauts on specific exploration missions.
There are distinct mechanisms of cancer induction across and within major tissue sites; thus uncertainty reduction requires tissue specific risk estimates (Gap Cancer 3-5). NRA and NSCOR selections focus on current estimates of major sites for cancer risks, which include lung, breast, colon, stomach, esophagus, the blood system (leukemias), liver, bladder, skin, and brain. There are differences in radiation sensitivity based on genetic and epigenetic factors (Gaps Cancer 5) and research in these areas aids the development of tissue specific cancer models. Hypothesis directed studies to establish the underlying mechanisms for the risks, and the possibility of synergistic effects with SPE’s or other flight factors may also be considered. NRA, NSCOR, or joint DoE-NASA studies in this area will use state-of-the art animal models (including transgenic mice) and genetically engineered human cell culture models to answer a variety of questions related to the Gaps in biological mechanisms. These studies are critical in establishing the level of proof that underlies NASA risk projection models. As research understanding is improved, extended duration validation studies with a finite number of animal or 3D human cell culture models using mixed fields representing GCR and SPE will be performed at NSRL using the existing exposure cave or potentially a new cave with improved capability for extended duration GCR simulations.

The cancer risk related NSCOR studies are 5-year studies and allow for long-term animal or sequential mechanistic studies with multiple components.

**Risk Assessment**

The SRPE approach to uncertainty reduction is based on studying the current model NASA uses as model recommended by the NCRP for projecting cancer incidence and mortality risks for space missions. This model employs the double-detriment life table for calculating the risk of radiation induced cancers against the background of cancers in the general population and competing mortality risks. The cancer rate (Hazard function) is the key quantity in the evaluation; representing the probability at a given age and years since exposure of observing a cancer. The NCRP model assumes the cancer incidence or mortality rate is scalable to human epidemiology data for gamma rays using a linear-energy transfer dependent radiation quality factor, Q(LET), and a dose and dose-rate reduction factor (DDREF). Other assumptions in the model are made with regard to the transfer of risk across populations, the use of average rates for the US population, the age, and age-after exposure dependence of risk on radiation quality and dose-rate, etc. These models will be updated as new data from biological mechanism and data are obtained as described by Gaps- Cancer 3-7.

Systems biology models provide a framework to integrate mechanistic studies of cancer risk across multiple levels of understanding (molecular, cellular, and tissues), and are the most likely approach to replace the NCRP model. Systems biology models are being developed by the Risk Assessment Project and several NSCOR’s, and in conjunction with data collection will improve the descriptions of cancer risk and to lay a framework for future biological counter-measure evaluations and biomarker identification (Gap Cancer 14).

**Shielding Physics & Dosimetry**

The evaluation of radiation shielding effectiveness for GCR is currently hindered by data on radiation quality effects and the shape of the dose-response curve for cancer induction. However, controlling secondary neutron components through material selections and developing computer tools for shielding evaluations is a near-term focus for spacecraft design applications as carried out by the Design Tools project under Gap Cancer 13. A goal of the Design Tools project is to provide fast and reliable tools for optimization in support of engineering shielding designs. Radiation physics improvements will be developed in support of these analysis efforts (Gap Cancer 11). SRPE will also support tasks that integrate data from lunar or Martian robotic probes to improve analysis capabilities (Gap Cancer 12).
**Biological Countermeasures**

The long-term phase of research will likely involve research on biological countermeasure (BCM) evaluation. BCM is a lower criticality in the current phase of the program for three reasons: 1) the uncertainties in cancer projections prevent the evaluation of the need for BCM. 2) An improved understanding of the mechanisms of cancer risk is needed to be able to extrapolate results from BCM studies in experimental models to astronauts on exploration missions, and 3) identify effective surrogate markers to perform testing of potential BCMS. Research related to Gap Cancer 8 will evolve from new knowledge gained from biological mechanisms and risk assessment research. Current NRA studies with anti-oxidants and related agents may be expanded to target specific molecular pathways and tissues, which make the largest contribution to cancer risks. Cell and animal models and appropriate endpoints will be identified and combined with new systems biology tools to obtain quantitative projections of BCM effectiveness for astronauts in specific exploration missions.

**Gaps**

The following gaps are a culmination of research questions identified through the Bioastronautics Roadmap Development, National Academy of Science – Institute of Medicine Review, National Council for Radiation Protection Reviews, Recommendations and Reports, Radiation Discipline Working Group advisory panel recommendations, annual Radiation PI workshops, and the Sept '06 Discipline Review.

More recently the National Academy of Sciences (NAS) Institute Of Engineering has reported on approaches to Manage Lunar radiation risks (NAS, 2008), and the NAS Institute of Medicine (IOM) has reviewed the Evidence based review of the four major risks and associated Gaps.

Based on the above recommendations, a total of 14 Gaps have been re-formulated for the Risk of Radiation Carcinogenesis from Space Radiation. Due to the reliance on NRA and NSCOR research, many tasks address several Gaps, making it difficult to list each task under each gap. The SPRE has chosen to provide a table of Gaps followed by a table of current tasks identifying whether it is solicited, directed, or NSCOR (which are all solicited) and the gaps addressed by that research.

<table>
<thead>
<tr>
<th>Cancer 1: How can experimental models of tumor development for the major tissues (lung, colon, stomach, breast, liver, and leukemias) be developed to represent the major processes in radiation carcinogenesis and extrapolated to human risk projections?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer 2: How can experimental models of tumor development for the other tissues (bladder, skin, esophagus, brain, etc) be developed to represent the major processes in radiation carcinogenesis and extrapolated to human risk projections?</td>
</tr>
<tr>
<td>Cancer 3: How can models of cancer risk be applied to reduce the uncertainties in radiation quality effects from SPE's and GCR?</td>
</tr>
<tr>
<td>Cancer 4: How can models of cancer risk be applied to reduce the uncertainties in dose-rate dependence of risks from SPE's and GCR?</td>
</tr>
<tr>
<td>Cancer 5: How can models of cancer risk be applied to reduce the uncertainties in individual radiation sensitivity including genetic and epigenetic factors from SPE and GCR?</td>
</tr>
<tr>
<td>Cancer 6: How can models of cancer risk be applied to reduce the uncertainties in the age and gender dependence of cancer risks from SPE's and GCR?</td>
</tr>
<tr>
<td>Cancer 7: How can systems biology approaches be used to integrate research on the molecular, cellular, and tissue mechanisms of radiation damage to improve the prediction of the risk of cancer and to evaluate the effectiveness of CM's? How can epidemiology data and scaling factors support this approach?</td>
</tr>
<tr>
<td>Cancer 8: What biological countermeasures should be used to reduce SPE and GCR cancer risks? What side effects should be tolerated vs. Mission risks?</td>
</tr>
<tr>
<td>Cancer 9:</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>Cancer 10:</td>
</tr>
<tr>
<td>Cancer 11:</td>
</tr>
<tr>
<td>Cancer 12:</td>
</tr>
<tr>
<td>Cancer 13:</td>
</tr>
<tr>
<td>Cancer 14:</td>
</tr>
</tbody>
</table>

**Tasks:**

<table>
<thead>
<tr>
<th>NRA’s, NSCOR:</th>
<th>Peer-Reviewed and directed research to determine mechanisms of radiation carcinogenesis in major tissues. (Cancer 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRA’s, NSCOR:</td>
<td>Peer-Reviewed and directed research to determine mechanisms of radiation carcinogenesis in other tissues. (Cancer 2)</td>
</tr>
<tr>
<td>NRA’s, NSCOR:</td>
<td>Develop countermeasures for cancer risks. (Cancer 8) NOTE: Combined with Countermeasure tasks in Acute, Degenerative, and CNS risks also.</td>
</tr>
<tr>
<td>NRA’s, NSCOR:</td>
<td>Research on Spaceflight Synergy. (Cancer 9)</td>
</tr>
<tr>
<td>NRAs, DOE Low-Dose Collaboration:</td>
<td>Research to establish new quality functions for space radiation. (Cancer 3)</td>
</tr>
<tr>
<td>Risk Assessment Directed Study, NRA’s, NSCOR:</td>
<td>Improve mechanistic understanding for the variability of dose-rate dependencies for cancer. (Cancer 4)</td>
</tr>
<tr>
<td>Risk Assessment Directed Study, NRA’s, NSCOR:</td>
<td>NCRP Analysis of individual sensitivity research, Ethics and Legal assessments. (Cancer 5)</td>
</tr>
<tr>
<td>Risk Assessment Directed Study, NRA’s, NSCOR:</td>
<td>Determine how genetic and epigenetic factors influence radiation safety. (Cancer 5)</td>
</tr>
<tr>
<td>Risk Assessment Directed Study, NRA’s, NSCOR:</td>
<td>Peer-reviewed and directed research to determine age and gender dependencies on cancer risks from SPEs and GCR. (Cancer 6)</td>
</tr>
<tr>
<td>Risk Assessment Directed Study, NRA’s:</td>
<td>Construct mathematical network models using systems biology approach. (Cancer 7)</td>
</tr>
<tr>
<td>NCRP:</td>
<td>Commentary on Cancer Synergistic Risks. (Cancer 9)</td>
</tr>
<tr>
<td>NCRP/NAS, Risk Assessment Directed Study:</td>
<td>Determine if spaceflight validation of ground results is necessary. (Cancer 10)</td>
</tr>
<tr>
<td>SRPE Directed Study:</td>
<td>Update Design Tools. (Cancer 11)</td>
</tr>
</tbody>
</table>
SRPE Directed Study: Improve Nuclear Models/1-D transport. (Cancer 12)

SRPE Directed Study: Develop Advanced nuclear model and transport codes –Pseudo 3-D codes. (Cancer 12)

SRPE Directed Study: Develop and validate design tools (Cancer 13). NOTE: Development of these design tools uses input from all radiation research and crosses all radiation risks.

**Deliverables and Required Delivery Milestones:**

Products include integrated risk models to quantify the risk of carcinogenesis; validated space permissible exposure limits; countermeasures to mitigate the risk of carcinogenesis; and tools and technologies to support the evaluation, mitigation and monitoring of risk/exposure during missions; as well as requirement recommendations for lunar sortie and outpost. Detailed deliverables, as identified in the graphics are listed below:

<table>
<thead>
<tr>
<th>Product</th>
<th>Delivery Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Risk Projection models and Updates supporting Sortie SRR, Outpost SRR, and Crew Selection</td>
<td>2010, 2014, 2020</td>
</tr>
<tr>
<td>Space Radiation Permissible Exposure Limits supporting Sortie SRR, Outpost SRR, and Crew Selection</td>
<td>2010, 2014, 2020</td>
</tr>
<tr>
<td>Countermeasures for SPE supporting Sortie Operations</td>
<td>2018</td>
</tr>
<tr>
<td>Countermeasures for SPE plus GCR supporting Outpost Operations</td>
<td>2023</td>
</tr>
<tr>
<td>Space Radiation Transport Codes supporting Lander and Outpost PDR design cycles</td>
<td>2010, 2015</td>
</tr>
</tbody>
</table>

**Required Platforms:**

NASA Space Radiation Lab (NSRL);

Mars Robotic Precursor mission/MSL-RAD (Mars2009 & 2017 for solar min)

ISS (existing nominal ops (MRID) and measurement data) (i.e. NOT research/experimental)

**Project/Organization Responsible for Implementation of Activity:**

SRPE

Via NRAs, NSCORs, NASA-DoE Collaborative Research, and Directed Studies
Cancer 1: How can experimental models of tumor development for the major tissues (lung, colon, stomach, breast, liver, and leukemia) be developed to represent the major processes in radiation carcinogenesis and extrapolated to human risk projections?

SRPE, NRA, NSCOR, DOE Low Dose
Mechanisms of radiation carcinogenesis

Leukemia mouse lifespan data for iron
3D Human Lung and Breast Data for iron
Initiation vs. Promotion Findings for HZEs
Mouse lifespan data for Major Solids with iron, silicon, and proton

Do RBE’s apply to heavy ions?
Yes: Continue major tissues for individual sensitivity
No: Continue Gap 1

Is the Uncertainty in Cancer Risk Projections <2-fold?
YES: Shift Research Focus to gap 2, lung, bladder & brain cancer
NO: Continue Gap 1

Is the Uncertainty in Cancer Risk Projections <10%?
YES
NO: Continue Risk Research Gaps 2, 3

Cancer 2: How can experimental models of tumor development for the other tissues (bladder, skin, esophagus, brain, etc.) be developed to represent the major processes in radiation carcinogenesis and extrapolated to human risk projections?

SRPE, NRA, NSCOR, DOE Low Dose
Mechanisms of radiation carcinogenesis

3D Human tissue results for minor solids
Mouse lifespan results for minor solids
### Risk of Carcinogenesis from Space Radiation

**SRP Activities**
- Monitoring of Exposure
- Export Deliverables

**Cancer 5:** How can models of cancer risk be applied to reduce the uncertainties in individual radiation sensitivity including genetic and epigenetic factors from SPE and GCR?

**SRPE NRCP Analysis of Individual Sensitivity Research, Ethics & Legal Assessments**

- Determine how genetic and somatic factors influence radiation sensitivity

**NIH/DoE results on single nucleotide polymorphisms (SNPs)**

**Ground Research Individual Radiosensitivity**
- Identity mouse strain to establish F1, F2 model genetic variability colonies
- EBIS OCR cells with genetic variant colonies

**RAP Data Integration**
- Biomedical/Bedcometry Requirements
- I. PEL Recommendations
- Independent Review (NAS or NRC) Research
- Results on tissue specific cancer initiation, promotion and progression
- Report on Initial Individual Sensitivity Research, Ethics & Legal Assessment
- Primary Individual Sensitivity Research, Ethics & Legal Assessment
Risk of Carcinogenesis from Space Radiation

Cancer - 12: What level of accuracy do NASA's space environment, transport code and cross sections describe radiation environments in space (ISS, Lunar, or Mars)?

SRPE Measurements & Transport, and Risk Assessment Projects

NRA for Experimental Measurements

Further Code Development

Exp. Meas

Acceptable accuracy for Design and Verification

No

Yes

Adv. Nuclear Model and Transport - pseudo 3-D

HZETRN2015

IVS3

Accuracy and Gap assessment

Define Accuracy

Improving Nuclear Models and 3D transport

HZETRN2010

10. Orion PDR

Supports Lander PDR design cycle at SRR

Access gaps

Experimental Meas, Data Mining

Exp. Meas

Supports Outpost Design Cycle at PDR + 18 months

Access gaps

9. Outpost PDR

8. Lander PDR

Support Outpost Design Cycle at PDR + 18 months

4. Shuttle retired
Risk of Carcinogenesis from Space Radiation

Cancer - 13: What are the most effective approaches to integrate radiation shielding analysis codes with collaborative engineering design environments used by spacecraft and planetary habitat design efforts?

SRPE Design Tools Project
Baseline Design Tool

Use Case development and Design Integration

Integrate HZETRN 2005/2010
Integrate HZETRN 2013

Integrate Vehicle & Body Geometries
Int. Environments

Phase A/B Design Tool
Phase C/D Simulation Tool

AVN user Interface
Design Tools to Opex

Forward backward neutrons
Validated Lunar Environment and design interface

Acid Mars Interface
Validated Mars Environment and design interface

LRD data

MES data
Existing Earth High Altitude Balloon data (BE33, CAP/CE)
RISK OF ACUTE RADIATION SYNDROMES DUE TO SOLAR PARTICLE EVENTS I x I

There is a variety of acute radiation syndromes of concern following a large SPE exposure. Through careful evaluation of SPE frequency and size probabilities, dose-rates, likely shielding conditions, and dose distribution at specific organs, the SRPE Risk Assessment Project has determined that the likelihood of acute risks IVA is extremely small. There are scenarios, however, during lunar, trans-lunar, or Mars EVAs where acute radiation sickness may occur. Radiation sicknesses, i.e., the prodromal risks, include the risks of nausea, vomiting, diarrhea, and fatigue. These effects are manifested at about 4 to 24 hours post-exposure for exposures at sub-lethal doses with a latency time inversely correlated with dose. Furthermore, albeit the possibility of acute death through the collapse of the blood forming organs (BFO) is negligible, there is a reasonable concern of a compromised immune system due to high skin doses from a SPE leading to burns, which could increase the risk to the BFO. Because the mechanisms of acute risks from SPE’s will not differ substantially from X-rays and gamma-rays where experimental models have already been developed, research on acute risks is largely a data collection activity with appropriate proton energies, doses, and dose-rates to represent major SPEs.

In the long-term, the SRPE will consider research on fertility, sterility, and hereditary risks from space radiation, and may request the NSBRI support these areas because of their unique nature compared to other risk areas (Acute Gap 4).

Operational Relevance and Context of Risks for Exploration

Acute radiation risks are averted through radiation shielding inside most shielding habitats or lunar transfer vehicles; however, radiation exposure limits could be exceeded during deep space transit, including Venus swing-by (<0.5 AU) or extensive lunar surface EVAs, making this risk important for NASA’s goals. Disruptions include reducing EVA times by several hours or requiring excessive radiation shielding. EVA programs will have to be significantly reduced if risk assessment not improved and countermeasures developed.

Strategy for Mitigation

As discussed in the Risk of Radiation Carcinogenesis from Space Radiation, SRPE plans to conduct a phased implementation approach to address the acute radiation risk.

Biological countermeasure research will be conducted at a low level in the near-term, however will be increased after experimental (biological) models of human risks are validated. The SRPE approach that follows a progression of activities designed to feed the development of an integrated risk model with acceptable uncertainty for exploration missions, followed by activities targeting risk mitigation and monitoring is used for the acute risk. These activities are not necessarily implemented in serial, but since the knowledge associated with acute risk is much further along than other risks, emphasis is placed on 1 to 6, the successful completion of which should facilitate model validation to enable mission durations required for currently planned lunar and Mars missions. The activities required to validate the Acute Radiation Syndromes risk projection model are as follows:

1) Establish Mechanisms of radiation-induced acute radiation syndrome and CM Action
2) Understand radiation quality effects on biological damage to quantify risk
3) Understand the dependence of risk on dose-rates in space
4) Extrapolation from experimental data to humans to quantify risk
5) Understand individual radiation-sensitivity to quantify risk

6) Develop countermeasures, technologies, and models for Risk Mitigation and Monitoring

Figure 1 graphically illustrates components of the research approach.

Figure 1. Flow Chart of Components in the SRPE Research Approach

**Biological Risk Research**

Research on acute risks related to EVA conditions must factor in the role of dose-rate over an EVA time course, the additional exposure IVA for a terminated EVA, and other spaceflight factors that could modify expected dose response models for acute risks. Animal and cell culture models appropriate for these acute risks will be used in the research to study protons effects at various doses, dose-rates, and proton energies including simulation of solar particle event spectra (Gap Acute 1). A research emphasis on the role of the immune system and possible synergistic effects on acute risks are needed (Gap Acute 3). This area is under review by the NCRP. Because acute risks are manifested soon after exposure and there is an existing data based on gamma-ray induced risks, the research is expected to be completed in about a 5-year period by the NSBRI team.

**Risk Assessment**

The Risk Assessment Project has developed acute radiation risk models using a logistic scoring approach and is modifying these models to account for proton and secondary radiation biological effectiveness data. These models will be updated with results from the proposed NSBRI research team when available. A graphical user interface (GUI) of the resulting model will be developed and tested for use in an operational setting (Gap Acute 2). Probabilistic models of SPE are being developed by the Risk Assessment project and in coordination with new results from SMD (Gap Acute 5).

**Shielding Physics & Dosimetry**

Optimization of radiation shielding (Gap Acute 6), dosimetry, and alert approaches (Gap Acute 5) is supported with operational research in these areas by both SRPE (Design Tools and Risk Assessment Projects) and the NSBRI and in collaboration with Space Mission Directorate (SMD) Living with the Star
Program (Gap Acute 5). The Design Tools project will develop tools to minimize shielding mass during vehicle design, and the Risk Assessment project will develop probabilistic models appropriate for acute risk protection for mission planning purposes. The development of reliable, lightweight EVA dosimetry is a goal of the research.

**Biological Countermeasures**

The important distinctions in the types of biological models, possible BCMs, and exposure conditions between acute, and the risks of cancer, CNS, and degenerative risks suggests a unique approach. Therefore, the SRPE has requested the NSBRI form a focus team in this area (Gap Acute 7). This team will pursue research on the mechanisms of acute radiation risks and possible BCM development. Studies from radiation oncology of anti-nausea drugs will be considered as well as existing drugs used in spaceflight. The role of synergisms of radiation and other space related insults will be an important thrust of this research.

**Gaps**

The following gaps are a culmination of research questions identified through the Bioastronautics Roadmap Development, National Academy of Science – Institute of Medicine Review, National Council for Radiation Protection Reviews, Recommendations and Reports, Radiation Discipline Working Group advisory panel recommendations, annual Radiation PI workshops, and the Sept '06 Discipline Review.

More recently the National Academy of Sciences (NAS) Institute Of Engineering has reported on approaches to Manage Lunar radiation risks (NAS, 2008), and the NAS Institute of Medicine (IOM) has reviewed the Evidence based review of the four major risks and associated Gaps.

Based on the above recommendations, a total of 8 Gaps have been formulated for the Risk Acute Radiation Syndromes Due to Solar Particle Events. As with other, the SPRE relies heavily on NRA and NSCOR research, making it difficult to list each task under each gap. The SPRE has chosen to provide a table of Gaps followed by a table of current tasks identifying whether it is solicited, directed, or NSCOR (solicited) and the gaps addressed by that research. The NSBRI has formed the Center for Acute Radiation Research similar in function to an NSCOR, thus this task will be identified as an NSCOR.

| Acute – 1: | What are the probabilities for various acute effects from SPE’s including RBE’s and dose-rate modifiers? |
| Acute – 2: | What quantitative procedures or theoretical models are needed to extrapolate molecular, cellular, or animal results to predict acute radiation risks in astronauts? How can human epidemiology data best support these procedures or models? |
| Acute – 3: | Are their synergistic effects arising from other spaceflight factors (microgravity, stress, immune status, bone loss, etc.) that modify acute risks from space radiation including modifying thresholds for such effects? (post PPBE) |
| Acute – 4: | What are the probabilities of hereditary, fertility, and sterility effects from space radiation? |
| Acute – 5: | What are the optimal SPE alert and dosimetry technologies for EVAs? |
| Acute – 6: | What are the most effective shielding approaches to mitigate acute radiation risks, how do we know, and implement? |
| Acute – 7: | What are the most effective biomedical or dietary countermeasures to mitigate acute radiation risks? |
| Acute – 8: | How can Probabilistic risk assessment be applied to SPE risk evaluations for EVA, and combined EVA+IVA exposures? |
**Tasks:**

| NCRP/NAS Ground Based Research at NSRL: | Research on prodromal syndrome and skin injury (Acute 1) |
| NCRP/NAS Ground Based Research at NSRL: | Define the RBE for protons of relevant energies (Acute 1) |
| NCRP/NAS Ground Based Research at NSRL: | Determine dose rate dependence for protons over the relevant range of dose rates (Acute 1) |
| NSBRI CARR Ground Based Research at NSRL: | Determine the dose and dose rate dependencies of ARS from protons (Acute 1) |
| NSBRI CARR Ground Based Research at NSRL: | Determine impact of a large skin dose on the immune system (Acute 1) |
| NSBRI CARR Ground Based Research at NSRL: | Determine alterations of dose response of the blood system (Acute 1) |
| NSBRI CARR Ground Based Research at NSRL: | Determine microgravity and stress impacts on dose-response for prodromal risks (Acute 3) |
| NSBRI CARR Ground Based Research at NSRL: | Determine the efficacy of FDA-approved CMs for radiation doses and dose rates of protons (Acute 7) NOTE: Combined with Countermeasure tasks in Carcinogenesis, Degenerative, and CNS risks also. |
| NSBRI CARR Ground Based Research at NSRL: | Determine side effects and alteration of their effectiveness in space (Acute 7) NOTE: Combined with Countermeasure tasks in Carcinogenesis, Degenerative, and CNS risks also. |
| Risk Assessment Directed Study: | Development of kinetic models of prodromal and blood systems (Acute 2) |
| Risk Assessment Directed Study: | Development of track models of RBE’s in tissues (Acute 2) |
| Risk Assessment Directed Study: | Couple GI Tract with blood module (Acute 2) |
| Risk Assessment Directed Study: | Couple Acute Risk Software with Real-Time Alert data (Acute 2) |
| Risk Assessment Directed Study: | Develop shielding requirements for Constellation (Acute 6) NOTE: Combined work with shielding requirements from other radiation risks. |
| NRA: | Research to address risk of heredity and fertility (Acute 4) |
| SRPE Directed Study: | Determine dosimetry requirements for lunar surface (Acute 5) |
| SRPE Directed Study: | Determine Dosimetry requirements for Lunar and Mars Precursor missions (as needed) (Acute 5) |

**Deliverables and Required Delivery Milestones:**

Products include acute radiation risk models; validated space permissible exposure limits; countermeasures to mitigate acute risks; and tools and technologies to support the evaluation, mitigation and monitoring of acute risk/exposure during missions; as well as requirement recommendations for lunar sortie and outpost vehicles and mission operations. Detailed deliverables, as identified in the graphics are listed below:
<table>
<thead>
<tr>
<th>Product</th>
<th>Delivery Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpost Mission Operations planning and SRR</td>
<td></td>
</tr>
<tr>
<td>EVA alert dosimetry and monitoring supporting sortie operations</td>
<td>2012, 2016</td>
</tr>
<tr>
<td>Validated Space Permissible Exposure Limits (as necessary) supporting</td>
<td>2012, 2015</td>
</tr>
<tr>
<td>Mission Ops SRR and operations</td>
<td></td>
</tr>
<tr>
<td>Dosimetry requirement recommendations for Lunar Surface supporting</td>
<td>2012</td>
</tr>
<tr>
<td>Mission Ops SRR</td>
<td></td>
</tr>
<tr>
<td>Sortie and Outpost program SRR</td>
<td></td>
</tr>
</tbody>
</table>

**Required Platforms:**

NASA Space Radiation Lab (NSRL)

**Project/Organization Responsible for Implementation of Activity:**

SRPE & NSBRI

Via NRAs, NSCORs, NASA-DoE Collaborative Research
Acute Risks from Space Radiation

Acute-5: What are the optimal SPE alert and dosimetry technologies for EVAs?

SRPE/Cx

Determine Dosimetry Requirements for Lunar Surface

EVA Office- Spaceout, Tool Box, Rover?

Lunar Dosimetry Requirements

Identify if additional lunar pre-cursor measurements are needed

Mars Dosimetry Requirements

Identify if additional Mars pre-cursor measurements are needed

Are EVA technologies sufficient?

NSBRI EVA Alert Dosimetry

Acute-6: What are the most effective shielding approaches to mitigate acute radiation risks, how do we know, and implement?

Risk Assessment Proj Design Tools

ESAS

Lunar Studies CAT

Lunar Architecture Studies CAT

q. Additional Shielding Updates (TBD)

Design Tool

Acute Risk Model V1

Acute Risk Model V2
RISK OF ACUTE OR LATE CENTRAL NERVOUS SYSTEM EFFECTS FROM RADIATION EXPOSURE 1 x C

A critical question for the current phase of research is to understand whether there is a significant risk of CNS effects and establish possible threshold doses for specific CNS risks. Central Nervous System (CNS) risks from GCR are a concern due to the possibility of single HZE nuclei traversals causing tissue damage, as evidenced by the light-flash phenomenon first observed during the Apollo missions. As survival prognosis for patients irradiated for brain tumor treatment has improved, patients have shown persistent CNS changes at long times after treatment with gamma rays suggesting a possible CNS risk for a large SPE. Furthermore, animal studies of behavior and performance with HZE radiation suggest detrimental changes may occur during long-term GCR exposures. Currently, there is no projection model for CNS risks of concern to NASA. Research at NSRL is using a variety of animal and cellular models to study the dose and radiation quality dependence of CNS risks. The extrapolation of model data to astronauts will be the major focus of CNS research in the immediate future. The values of possible thresholds for CNS risks and knowledge on how to extrapolate possible thresholds to individual astronauts is a key milestone in the long-term research plan to allow development of a CNS-specific risk projection model.

Operational Relevance And Context Of Risks For Exploration

The NASA PELs for CNS risk was developed based on existing animal data from heavy ion exposures. Although animal data and brain cancer irradiation evidence suggests CNS structural and functional impacts from radiation exposure, additional research is required to fully understand and quantify this risk. This risk has considerable uncertainty associated with it and no acceptable model for projecting CNS risk is currently available. The PEL could be violated under possible scenarios, including following a large SPE or long-term GCR exposure, however, without a clear understanding of the CNS risk, it has been rated Important for both the lunar and Mars missions. Ongoing research in this area is intended to quantify this risk to determine criticality for both extended duration missions. New research results could lead to cumulative risk from CNS and Degenerative tissue Disease which when combined with Cancer risks have major negative impacts on mission design, costs, schedule, and crew selection.

Strategy For Mitigation

As discussed in the Risk of Radiation Carcinogenesis from Space Radiation, SRPE plans to conduct a phased implementation approach to address the CNS risk. The same breakthrough research strategy is utilized due to the large scientific challenges needed to understand and mitigate CNS risks from space radiation. An example of a breakthrough that has occurred in recent years with regard to CNS is the discovery of neurogenesis in CNS research. Breakthroughs create large perturbations in research plans and schedules, and have large benefits to achieving SPRE goals. Future breakthroughs are expected, albeit not possible to predict.

Biological countermeasure research will be conducted at a low level in the near-term, however will be increased after experimental (biological) models of human risks are established and uncertainties are significantly reduced. The SRPE approach that follows a progression of activities designed to feed the development of an integrated risk model with acceptable uncertainty for exploration missions, followed by activities targeting risk mitigation and monitoring is also used for the CNS risk. These activities are not necessarily implemented in serial, but emphasis is placed on 1 to 3, the successful completion of which should facilitate model development to enable mission durations required for currently planned lunar missions. Successful completions of 4 to 7 are needed to enhance model development to enable Mars missions. Items 4 to 7 are being pursued at a minimal level in the current program. As activities essential for Lunar missions are completed, greater effort will be spent in activities essential for Mars missions.
The activities required to develop the CNS risk projection model are as follows:

1) Establish Mechanisms of CNS and CM Action
2) Develop Tissue and Risk Specific Experimental Models
3) Understand radiation quality effects on biological damage to quantify risk
4) Understand the dependence of risk on dose-rates in space
5) Extrapolation from experimental data to humans to quantify risk
6) Understand individual radiation-sensitivity to quantify risk
7) Develop countermeasures, technologies, and models for Risk Mitigation and Monitoring

Figure 1 graphically illustrates components of the research approach.

### Components of Research Approach

![Diagram of components of research approach]

Figure 1. Flow chart of components in the SRPE research approach.

**Biological Risk Research**

A critical question for the current phase of research is to establish possible threshold doses for specific CNS risks. It is likely that although acute CNS risks occur only above a dose threshold (Gap CNS-1) and that the lifetime risks for CNS diseases, such as Alzheimer’s, will have distinct dose dependence with the additional questions related to latency to disease of primary interest (Gap CNS-2). The values of possible thresholds for CNS risks and knowledge on how to extrapolate possible thresholds to individual astronauts will be a key milestone in the long-term research plan. An important component of this research is to factor in the variation of CNS risk with genotype or other CNS injury (Gap CNS-3). A variety of mechanisms must be understood including the roles of neurodegeneration, inflammation, microvasculature damage, and changes to specific neuron-chemical pathways. These research areas will have overlaps in usage of NSRL, and potential animal or cellular models employed, however individual NRA or NSCOR projects will pursue distinct hypothesis driven research questions leading to distinct
endpoints and biological assays. Hypothesis directed studies to establish the underlying mechanisms for the risks (Gap CNS 1-3, 5, 6), and the possibility of synergistic effects with SPE’s or other flight factors will also be considered (Gap CNS-8).

The CNS risk related NSCOR study is a 5-year study allowing for long-term animal or sequential mechanistic studies with multiple components.

**Risk Assessment**

Research approaches are establishing the biochemistry of CNS impacts by HZE nuclei. Since projection based on scaling to human data as done for cancer risk is not possible, a systems biology approach for individual CNS risks may be needed to form a basis for animal to human extrapolation, and will rely on understanding of biochemical changes in the CNS caused by space radiation (Gaps CNS 5, 6). Because of the large number of GCR nuclei types and energies, comprehensive studies under mixed-field SPE or GCR simulation conditions for extended time periods (hours to a few weeks) may be needed at NSRL. Extended duration studies will be useful in addressing SRPE gaps in synergistic risks from other spaceflight factors and radiation damage to the CNS.

**Biological Countermeasures**

Biological countermeasure and biomarker research for CNS risks is a lower priority in the near-term research strategy until the nature and magnitude of the CNS risk is more firmly established. Several studies on oxidative damage and anti-oxidants are supported; however, this is not a significant emphasis of SRPE’s approach. The future need for BCM research will be driven by the levels of risk determined by current research and may transition to become a major long-term focus. It is expected that the mechanistic understanding acquired from near-term research will set the course for effective countermeasures approaches in the future as needed (Gap CNS-4).

**Shielding Physics**

The development of new biological understanding of CNS risks will determine if shielding protection for CNS is distinct from other shielding approaches to other radiation risks. Preliminary assessments suggest HZE nuclei with Z>10 or slow neutrons may be a higher relative concern for CNS than other risks, and may place more emphasis on shielding these components (Gap CNS-7).

**Gaps**

The following gaps are a culmination of research questions identified through the Bioastronautics Roadmap Development, National Academy of Science – Institute of Medicine Review, National Council for Radiation Protection Reviews, Recommendations and Reports, Radiation Discipline Working Group advisory panel recommendations, annual Radiation PI workshops, and the Sept '06 Discipline Review.

More recently the National Academy of Sciences (NAS) Institute Of Engineering has reported on approaches to Manage Lunar radiation risks (NAS, 2008), and the NAS Institute of Medicine (IOM) has reviewed the Evidence based review of the four major risks and associated Gaps.

Based on the above recommendations, a total of 8 Gaps have been formulated for the Risk of Acute or Late Central Nervous System Affects from Radiation Exposure. As with carcinogenesis, the SPRE relies heavily on NRA and NSCOR research, making it difficult to list each task under each gap. The SPRE has chosen to provide a table of Gaps followed by a table of current tasks identifying whether it is solicited, directed, or NSCOR (which are all solicited) and the gaps addressed by that research.
CNS – 1: Is there a significant probability that space radiation would lead to immediate or acute functional changes in the CNS during a long-term space mission and if so what are the mechanisms of change? Are there threshold doses for these effects?

CNS – 2: Is there a significant probability that space radiation exposures would lead to long-term or late degenerative CNS risks if so what are the mechanisms of change?

CNS – 3: How does individual susceptibility including hereditary pre-disposition (Alzheimer’s, Parkinson’s, apoE) and prior CNS injury (concussion or other) alter significant CNS risks? Does individual susceptibility modify possible threshold doses for these risks in a significant way?

CNS – 4: What are the most effective biomedical or dietary countermeasures to mitigate CNS risks? By what mechanisms are the countermeasures likely to work?

CNS – 5: How can new knowledge and data from molecular, cellular, tissue and animal models of acute CNS risks or clinical human data, including altered motor and cognitive function and behavioral changes be used to estimate acute CNS risks to astronauts from GCR and SPE?

CNS – 6: How can new knowledge and data from molecular, cellular, tissue and animal models of late CNS risks or clinical human date be used to estimate late CNS risks to astronauts from GCR and SPE?

CNS – 7: What are the best shielding approaches to protect against CNS risks, and are shielding approaches for CNS and cancer risks synergistic?

CNS – 8: Are there significant CNS risks from combined space radiation and other physiological or space flight factors (e.g., sleep deprivation, psychological, microgravity, immune-endocrine systems or other)?

Tasks:

SRPE NCRP/NAS:
Independent review of CNS research results including NSCOR, NRA and DOE-Low Dose. (CNS1)

SRPE NCRP/NAS:
NCRP Commentary development to assess synergies between other physiological and space flight factors. (CNS8)

SRPE NRAs, DOE Low-Dose Collaboration:
Research to determine probability and mechanisms for long-term or late degenerative CNS risks. (CNS2)

SRPE Risk Assessment Directed Study, NRAs and NSCOR:
Individual hereditary CNS susceptibility and threshold studies (CNS3)

SRPE Risk Assessment Directed Study, NRAs and NSCOR:
Dietary countermeasure development. (CNS4) NOTE: Combined with Countermeasure tasks in Acute, Degenerative, and Carcinogenesis risks also.

SRPE Risk Assessment Directed Study, NRAs and NSCOR:
Assessment of molecular, Cellular, tissue and animal models for applicability to CNS risk estimation. (CNS5, CNS6)

SRPE Risk Assessment Directed Study:
Assessment of shielding for CNS mitigation. (CNS7) NOTE: Combined work with shielding requirements from other radiation risks.

Deliverables and Required Delivery Milestones:

Products include risk models to quantify the risk of acute and late CNS effects; validated space permissible exposure limits; and countermeasures to mitigate the risk of CNS effects.
Detailed deliverables, as identified in the graphics are listed below:

<table>
<thead>
<tr>
<th>Product</th>
<th>Delivery Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline CNS Risk Model and updates</td>
<td>2017, 2020</td>
</tr>
<tr>
<td>CNS Space Permissible Exposure Limits supporting Outpost SRR and Operations</td>
<td>2014, 2020</td>
</tr>
<tr>
<td>Countermeasures for SPE supporting Sortie Operations</td>
<td>2018</td>
</tr>
<tr>
<td>Countermeasures for SPE plus GCR supporting Outpost Operations</td>
<td>2023</td>
</tr>
</tbody>
</table>

**Required Platforms:**

NASA Space Radiation Lab (NSRL)

**Project/Organization Responsible for Implementation of Activity:**

SRPE

Via NRAs, NSCORs, NASA-DoE Collaborative Research, Directed Studies
CNS-7: What are the best shielding approaches to protect against CNS risks, and are shielding approaches for CNS and cancer risks synergistic?

SRPE
RAP
Design Tools

CNS-8: Are there significant CNS risks from combined space radiation and other physiological or space flight factors (e.g., sleep deprivation, psychological, microgravity, immune-endocrine systems or other)?

SRPE
NAS/NCRP

SRPE HHC
NRA

CNS Synergies Assessment
NCRP Commentary

Do spaceflight factors modify CNS risk?

NSRL Research

Data on Synergies to RAP

Yes on CNS
Gap 2 and/or 3 systems biology model to incorporate ion type, rate, and crew factors

CNS Shielding Assessment
CNS synergies NCRP comments, CNS Synergies Update Review, Information exchange with HHC on synergistic risk
RISK OF DEGENERATIVE TISSUE OR OTHER HEALTH EFFECTS FROM RADIATION EXPOSURE I x C

Cataracts have long been a research focus of NASA. More recently, however, several epidemiological studies, including results from the atomic-bomb survivors and nuclear reactor workers, have identified a significant risk of stroke and coronary heart disease (CHD) for low LET radiation at doses comparable to those of an extended lunar mission or a Mars mission, or a short-duration lunar mission with a large SPE. An increased risk of cataracts associated with low dose space radiation from past NASA Missions has been reported and is being followed up with a clinical study of cataract progression rates in current or retired astronauts. Several NSRL studies of cataract risks are supported to improve the understanding of how proton and HZE nuclei induce cataracts, and to identify possible countermeasure approaches. Since the risk of heart disease is a recent finding, preliminary studies in these areas are seeking to establish possible distinctions in mechanisms for this risk between protons and HZE nuclei and gamma rays. Furthermore, the SRPE will take advantage of studies supported by the European Union in this area, which is supporting large-scale mouse studies of CHD. These studies should present new insights into the nature of the low LET (gamma-ray) risk at low dose-rates is comparable to space conditions, and identify appropriate mouse strains to be used in future SR studies.

Operational Relevance And Context Of Risks For Exploration

The NASA PELs for cataract and heart risks are based on existing human epidemiology data. Although animal and clinical astronaut data show a significant increase in cataracts following exposure and a reassessment of atomic bomb data suggests an increase in CHD from radiation exposure, additional research is required to fully understand and quantify this risk. This risk has considerable uncertainty associated with it and no acceptable model for projecting degenerative tissue risk is currently available. The PEL could be violated under possible scenarios, including following a large SPE or long-term GCR exposure, however, without a clear understanding of the risk, it has been rated Important for both the lunar and Mars missions. Ongoing research in this area is intended to quantify this risk to determine criticality for both extended duration missions. New research results could lead to cumulative risk from CNS and Degenerative Tissue Disease which when combined with Cancer risks have major negative impacts on mission design, costs, schedule, and crew selection.

Strategy For Mitigation

As discussed in the Risk of Radiation Carcinogenesis from Space Radiation, SRPE plans to conduct a phased implementation approach to address the degenerative tissue risk. The same breakthrough research strategy is utilized due to the large scientific challenges needed to understand and mitigate degenerative tissue risks from space radiation. Breakthroughs create large perturbations in research plans and schedules, and have large benefits to achieving SPRE goals. Future breakthroughs are expected, albeit not possible to predict.

Biological countermeasure research will be conducted at a low level in the near-term, however will be increased after experimental (biological) models of human risks are established and uncertainties are significantly reduced. The SRPE approach that follows a progression of activities designed to feed the development of an integrated risk model with acceptable uncertainty for exploration missions, followed by activities targeting risk mitigation and monitoring is also used for the degenerative tissue risk. These activities are not necessarily implemented in serial, but emphasis is placed on 1 to 3, the successful completion of which should facilitate model development to enable mission durations required for currently planned lunar missions. Successful completions of 4 to 7 are needed to enhance model development to enable Mars missions. Items 4 to 7 are being pursued at a minimal level in the current program. As activities essential for Lunar missions are completed, greater effort will be spent in activities essential for Mars missions.
The activities required to develop the Degenerative Tissue risk projection model are as follows:

1) Establish Mechanisms of radiation-induced Cataract and Coronary Heart Disease and CM Action
2) Develop Tissue and Risk Specific Experimental Models
3) Understand radiation quality effects on biological damage to quantify risk
4) Understand the dependence of risk on dose-rates in space
5) Extrapolation from experimental data to humans to quantify risk
6) Understand individual radiation-sensitivity to quantify risk
7) Develop countermeasures, technologies, and models for Risk Mitigation and Monitoring

Figure 1 graphically illustrates components of the research approach.

**Biological Risk Research**

Preliminary assignments of PEL’s for Degenerative risks have been assigned based on human epidemiology data for gamma ray or x-ray irradiation. Cell or animal models of degenerative risks will be developed and applied to determine the mechanisms for degenerative risks and to determine appropriate risk assessment data for models including relative biological effectiveness and dose-rate dependencies for different space radiation ions at NSRL (Gaps Degen 1-4). In the near-term, NRA research will support a small number of studies on heart and lens risks. A long term-focus will be to support an NSCOR in this area in 2014 and beyond. As mission duration increases, there could be degenerative risks to other tissues related to digestive diseases and pulmonary changes that become a concern. A long-term goal will be to consider such possible changes in animal validation studies made at a possible extended duration GCR facility developed at NSRL in the future. The NASA Study of Cataracts in Astronauts (NASCA) is collecting data on the incidence and progression rates of cataracts in over 230 current or retired astronauts. The possibility of synergistic risks with other flight factors must also be considered (Gap Degen -7)
**Risk Assessment**

An increased risk of cataracts associated with low dose space radiation from past NASA Missions has been reported and is being followed up with a clinical study (NASCA) of cataract progression rates in current or retired astronauts. Several NSRL studies of cataract risks are supported to improve the understanding of how proton and HZE nuclei induce cataracts, and to identify possible countermeasure approaches. The NASCA study and NSRL research will be used by the Risk Assessment Project to project cataract risks for specific space missions. Risk assessment models for cataract risk will be developed (Gap Degen 5) through biophysical models of new or existing radiobiology data. New models for other degenerative risks will be developed after studies of biological mechanisms have matured.

**Biological Countermeasures**

Research on BCMs (Gap Degen 6) for other degenerative risks is envisioned after studies of biological mechanisms have matured. Timelines to begin research on BCM for the Degenerative Risks are dependent on progress in Cancer and CNS research within the current SRPE research prioritization plans, and perhaps based on the findings of the initial biological mechanisms research phase of the research plan.

**Gaps**

The following gaps are a culmination of research questions identified through the Bioastronautics Roadmap Development, National Academy of Science – Institute of Medicine Review, National Council for Radiation Protection Reviews, Recommendations and Reports, Radiation Discipline Working Group advisory panel recommendations, annual Radiation PI workshops, and the Sept '06 Discipline Review.

More recently the National Academy of Sciences (NAS) Institute Of Engineering has reported on approaches to Manage Lunar radiation risks (NAS, 2008), and the NAS Institute of Medicine (IOM) has reviewed the Evidence based review of the four major risks and associated Gaps.

Based on the above recommendations, a total of 7 Gaps have been formulated for the Risk of Degenerative Tissue or Other Health Effects from Radiation Exposure. As with carcinogenesis, the SPRE relies heavily on NRA research, making it difficult to list each task under each gap. The SPRE has chosen to provide a table of Gaps followed by a table of current tasks identifying whether it is solicited, or directed, and the gaps addressed by that research.

<table>
<thead>
<tr>
<th>Degen – 1:</th>
<th>How can tissue specific risk models be developed for the major degenerative tissue risks, including heart, circulatory, endocrine, digestive, lens and other tissue systems in order to estimate GCR and SPE risks for degenerative diseases?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degen – 2:</td>
<td>What are the mechanisms of degenerative tissues risks in the heart, circulatory, endocrine, digestive, lens and other tissue systems? What surrogate endpoints do they suggest?</td>
</tr>
<tr>
<td>Degen – 3:</td>
<td>What are the progression rates and latency periods for degenerative risks, and how do progression rates depend on age, gender, radiation type, or other physiological or environmental factors?</td>
</tr>
<tr>
<td>Degen – 4:</td>
<td>How does individual susceptibility including hereditary pre-disposition alter degenerative tissue risks? Does individual susceptibility modify possible threshold doses for these risks in a significant way?</td>
</tr>
<tr>
<td>Degen – 5:</td>
<td>What quantitative procedures or theoretical models are needed to extrapolate molecular, cellular, or animal results to predict degenerative tissue risks in astronauts? How can human epidemiology data best support these procedures or models?</td>
</tr>
</tbody>
</table>
**Degen – 6:** What are the most effective biomedical or dietary countermeasures to degenerative tissue risks? By what mechanisms are the countermeasures likely to work? Are these CMs additive, synergistic, or antagonistic to other Risks?

**Degen – 7:** Are their significant synergistic effects from other spaceflight factors (microgravity, stress, altered circadian rhythms, changes in immune responses, etc.) that modify the degenerative risk from space radiation?

### Tasks:

**SRPE Directed Study:**

- Epidemiological study of cataract incidence and progression. (Degen 1)

**SRPE Directed Study:**

- NCRP Independent review of degenerative tissue research results including NSCOR, NRA and DOE low-dose. (Degen 1, Degen 3)

**SRPE NRAs and DOE Low Dose Collaboration and European Union Collaboration:**

- Preliminary studies to establish the possibility of differences in mechanisms for stroke and CHD between protons and HZE nuclei and gamma rays. (Degen 2)

**SRPE NRA, NSCOR:**

- Studies on progression rates and latency periods for degenerative risks. (Degen 3)

**SRPE NRA, NSCOR:**

- Studies on individual susceptibility, including heredity to degenerative risks. (Degen 4)

**SRPE NRA, NSCOR:**

- Systems biology approaches to extrapolate molecular, cellular, or animal results to predict degenerative tissue risks in astronauts. (Degen 5) **NOTE:** This systems biology approach overlaps with Cancer 7.

**SRPE NRA, NSCOR:**

- Countermeasure development. (Degen 6) **NOTE:** Combined with Countermeasure tasks in Acute, Carcinogenesis, and CNS risks also.

**SRPE NRA, NSCOR:**

- Assess synergies between other physiological and space flight factors. (Degen 7)

### Deliverables and Required Delivery Milestones:

Products include risk models to quantify the risk of degenerative tissue effects; validated space permissible exposure limits; and countermeasures to mitigate the risk of degenerative tissue effects. Detailed deliverables, as identified in the graphics are listed below:

<table>
<thead>
<tr>
<th>Product</th>
<th>Delivery Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract Risk Projection Model supporting Outpost SRR</td>
<td>2014</td>
</tr>
<tr>
<td>Baseline Heart Risk Projection Model and updates supporting Outpost Operations</td>
<td>2021, 2024</td>
</tr>
<tr>
<td>Space Permissible Exposure Limits supporting Outpost SRR and Operations</td>
<td>2014, 2020</td>
</tr>
<tr>
<td>Countermeasures for SPE supporting Outpost Operations</td>
<td>2023</td>
</tr>
<tr>
<td>Countermeasures for SPE plus GCR supporting Outpost Continuous Presence</td>
<td>2029</td>
</tr>
</tbody>
</table>
Required Platforms:

NASA Space Radiation Lab (NSRL);

NOTE: Next generation TEPC will require ISS validation 2010-2012 but this phase is NOT part of the SRPE scope – handed off to ops with minimal oversight from SRPE)

Project/Organization Responsible for Implementation of Activity:

SRPE -
   Via NRAs, NSCORs, NASA-DoE Collaborative Research
Risk of Degenerative Tissue Effects

Integration of inputs, filling up gaps, moving forward:
1. Updated SRR
2. Lunar Outpost Crew Selection L-4
3. Lunar Outpost L-1
4. Lunar Outpost continuous presence

SRPE-HPR-47: What are the progression rates and latency periods for degenerative risks, and how do progression rates depend on age, gender, radiation type, or other physiological or environmental factors?

SRPE-HPR-47: Independent review of degenerative tissue research results including NESCOR, NRA and DOE Low Dose.

SRPE-HPR-47: What quantitative procedures or theoretical models, including systems biology approaches, are needed to extrapolate molecular, cellular, or animal results to predict degenerative tissue risks in astronauts? How can human epidemiology data best support these procedures or models?
SRPE Research Planning input to HRP IRP - Revision F

**Risk of Degenerative Tissue Effects**

1. Integration of inputs flowing up from gaps
2. Monitoring of Milestones
3. Export Deliverables
4. PEurrets

**SRPE NRA, NSCOR**

Degen - 6: What are the most effective CTFs to degenerative tissue risks? By what mechanisms are the CTFs likely to work? Are these CTFs additive, synergistic or antagonistic to other risks?

Are CM updates required?

**SRPE HHIC NRA**

Do spaceflight factors modify degenerative risk?

Data update on Synergies to RAP
### Agency Mission

<table>
<thead>
<tr>
<th>Lunar Sortie Missions by 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2006–2013</strong></td>
</tr>
<tr>
<td>Perform research on dose-rate effects of protons, develop shielding design tools; apply probabilistic risk assessment to lunar missions</td>
</tr>
<tr>
<td>Use NSRL to simulate space radiation to understand their biological effects; Compete radiation transport codes and design tools</td>
</tr>
<tr>
<td>New risk model that reduces uncertainties in projections to less than 2-fold; Determine if CNS and degenerative risks from GCR will occur</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lunar outpost Missions up to 240 days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2014–2019</strong></td>
</tr>
<tr>
<td>Validate radiation environment and transport models using lunar data; Validate models of proton dose-rate effects</td>
</tr>
<tr>
<td>Continue NSRL research on risks; perform research on biological countermeasures; optimize shielding designs for Mars missions</td>
</tr>
<tr>
<td>Revised risk model with uncertainties in risk projections to less than 50%; lunar-instruments to measure Mars surface environment at solar minimum</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mars Exploration Missions by 2030</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2020–2026</strong></td>
</tr>
<tr>
<td>Develop and deploy operational strategies for managing SPE risks; Apply biomarker methods to samples from lunar crews</td>
</tr>
<tr>
<td>Finish NSRL research on countermeasures; Develop diagnostics of radio-sensitivity and gene therapy for prevention and/or treatment of radiation damage</td>
</tr>
<tr>
<td>Apply knowledge on individual risk assessments and biomarkers; integrate accurate long-term solar weather predictions for Mars assessments</td>
</tr>
</tbody>
</table>

### Contributions to National Priorities

| **2006–2013** |
| Contribute to increased understanding of solar physics; Apply biomarker technologies to problems on Earth |
| Design exploration missions; Apply new knowledge of radiation effects and NASA computational biology models to human diseases on Earth |
| Apply countermeasure knowledge to diagnosis, prevention and treatment of diseases on Earth |

---

**Figure 2:** Timeline for Reducing Uncertainties in Radiation Risks.
RISK OF ADVERSE HEALTH EFFECTS FROM LUNAR DUST EXPOSURE - I X N/A

The toxicological effects of lunar dusts have not been studied in sufficient depth to develop an exposure standard for operations on the lunar surface. Lunar dusts have a high content in the respirable size range, they have a high surface area that is chemically reactive, and elemental iron "nano-particles" are imbedded in the dust grains. These unusual properties may cause the respirable dusts to be at least moderately toxic to the respiratory system, and larger grains to be abrasive to the skin & eye. NASA needs to set an airborne exposure standard based on scientific evidence so that vehicle designs can effectively control exposure.

Under certain conditions on earth, mineral dust can be highly toxic to the human respiratory system, but it is unclear whether exposure to lunar dust will be more or less harmful. Research into the toxicity of lunar dust will provide an evidence base to set exposure standards, which are needed to manage safely exposures in lunar habitats and vehicles.

Context of Risk for Exploration

The nominal toxicity expected from ordinary mineral dust may be increased for lunar dust by the large and reactive surfaces of the dust grains. Human exposures to mineral dusts during industrial operations and from volcanic eruptions give us some sense of lunar dust toxicity, although the earth-based analogs have serious limitations. Animal and cellular studies provide further evidence that mineral dusts can be somewhat toxic. Earth-based research of mineral dust has shown that freshly fractured surfaces are reactive and elicit an increased toxic response. Since lunar dust is formed in space vacuum from highly energetic processes, we expect the grain surfaces to be reactive indefinitely until the dust is brought into a habitable environment.

Lunar dust is characterized as fine, charged and reactive dust capable of entering habitats and vehicle compartments, where it can threaten crewmember health. Testing is critical for the determination of lunar dust toxicity in order to set a permissible exposure limit and risk criteria. Research areas should include identification of lunar dust size, shape, and chemistry, the mode of activation and passivation of lunar dust particles, toxicity to the respiratory system, ocular and dermal toxicity and cellular level toxicity.

Health effects from chronic exposure to lunar dust may be irreversible compromised pulmonary function and possible organ disease through relocation of toxic particulates through the bloodstream. Acute health effects include ocular abrasion that might impair crew vision and dermal abrasion that might compromise function while suited.

Operational Relevance Assessment & Recommendations

The risk of lunar dust exposure was identified during the Apollo missions, when lunar dusts were introduced into the Lunar Lander and command module, resulting in direct exposure and occasional reports of respiratory, dermal, and ocular irritation. NASA’s planning for the return to the Lunar surface has an EVA schedule that is more rigorous than what was experienced during the Apollo era. This increased duration and frequency of exposure to lunar dust requires that NASA set a permissible exposure limit for respirable lunar dust. Dermal and ocular abrasions can occur during spaceflight. These can be minimized by mitigation through operational procedures, i.e., post-EVA clean up in airlocks, temporary breathing apparatus implementation during clean-up exposure periods, and isolation of contaminated suit from respirable environment and appropriate filtering design implementations within ECLSS system.
Strategy for Mitigation

To mitigate the potential health risks and formulate a scientifically sound and defensible permissible exposure limit for exposure to respirable fractions of lunar dust, we have identified several knowledge gaps, and appropriate studies to close these knowledge gaps. The Lunar Airborne Dust Toxicity Assessment Group has been created and utilized to provide expert opinions of NASA proposed gaps and research studies. The proposed research will permit us to gain adequate knowledge to ensure appropriate mitigation strategies.

Gaps

AEH 1: What are the unique properties of lunar dust that affect physiology?

Lunar dust particles are unlike terrestrial dusts. Lunar dusts are known to have a high surface area and other distinctive shape and chemical characteristics.

Tasks: AEH, LADTAG directed study
Dust Factor Study – Dust Size Factor (Physiology) Studies
(Directed Studies – Shape & Chemistry Analysis Study; Forensic analysis of Apollo artifacts)
Activation Factor Study – (Directed Study – Reactivation studies, solar wind impact studies)

Size, Shape, Chemistry Analysis and Lunar Activation Studies
Focused studies will be performed to determine the size distribution, unique shape characteristics and chemical composition of lunar dust particulate. The results will be used to facilitate the management of lunar dust particles in the respirable size range Lunar activation studies will attempt to replicate solar wind, micrometeorite bombardment, and lunar processes that cause surface activation of lunar dust. Understanding the activation and passivation processes and their mode of action in the human system will determine potential health effects and exposure limits during mission related tasks.

Deliverables:
These studies will provide activated dust particles for further toxicity testing.
Determination of size distribution factor for calculation of permissible exposure limit.
Recommendations for operational processes and constraints to minimize exposure to lunar dusts.
Recommendations to be incorporated into Spaceflight Human Systems Standards and MOD planning.
Recommendation for crew scheduling controls to mission designers.

Required Delivery Milestone: PEL required by Lander SDR, FY11

Required Platforms:
The activity will be conducted in various ground laboratory studies.
Validation for planetary Ops is required in Lunar Return Timeframe on the Lunar surface.

AEH 2: What is the toxicity of respired lunar dust in the respiratory system?

During the Apollo missions several crews reported anecdotal respiratory issues with lunar dust. There is no scientifically defensible data to support the toxicity of inhaled lunar dusts. These data are central in determining a permissible exposure limit and risk criteria for lunar dusts.
 Tasks: (AEH, LADTAG – via directed study)
Pulmonary Toxicity Studies (Dose, Species & Activation Factors) – Inhalation Toxicity, Intratracheal &
Intrapharyngeal Instillation Testing
(Directed Studies)
These studies will determine the distribution of inhaled and instilled dust particles throughout the lung and the
overall toxicity in the lung tissue. Gross pathology will be performed as evidence of the degree on lunar dust
toxicity.

Deliverables:
Determination of species, dose and activation factors for calculation of permissible exposure limit.
Implement design features into spacecraft and operational controls post-EVA to minimize crew exposure to dust

Required Delivery Milestone: Provide initial species, dose and activation factors by end of 2009. PEL Required
by Lander SDR in FY11

Required Platforms:
The activity will be conducted in various ground laboratory studies.
Validation for planetary Ops in Lunar Return Timeframe.

AEH 3: What is the mode of action of lunar dust at the respiratory cellular level?
Respirable particles are suspected to be present on the lunar surface; there is no evidence that exists that
would show the toxicity of lunar dust if it penetrates the lungs at the cellular level. The possible
generation of reactive oxygen species (ROS) will aid in the determination of lunar dust toxicity.
Scientifically defensible studies will objectively determine cellular level toxicity. Other relevant
biomarkers of cellular toxicity will be explored if identified.

 Tasks: (AEH, LADTAG – via directed study)
Lunar cell culture toxicity testing (Active vs. Non-Active Dusts)
Human lung cell culture will be tested to determine toxicity of lunar dust particles. The generation of ROS will
be one marker of potential toxicity. Active vs. non-active dust will be tested to determine the differences in
toxicity due to chemical activation.

Deliverables: This information may contribute to the determination of both dose and activation factors for
calculation of permissible exposure limit

Required Delivery Milestone: Provide required data mid 2010.

Required Platforms:
The activity will be conducted in various ground laboratory studies.
Validation for planetary Ops in Lunar Return Timeframe will be necessary.

AEH 4: What is the dermal and ocular toxicity of lunar dust?
During the Apollo missions several crews reported anecdotal dermal and ocular issues with lunar dust
exposure. There is no data to support the dermal and ocular toxicity of lunar dusts. The determination of
the dermal and ocular hazards is necessary to predict and prevent any visual decrement and vapor barrier
loss during lunar operations.
### Dermal Toxicity Studies

Dermal abrasion studies will be performed to determine the degree of dermal toxicity from acute and chronic exposure to lunar dust particles.

**Deliverables:** Research data indicating the degree of dermal toxicity of lunar dusts. Based upon these results a follow on could include an ocular exposure standards, recommended countermeasures, design and operational controls.

**Required Delivery Milestone:** Guidelines and treatment information required for Lunar Lander SDR, FY11.

**Required Platforms:** The activity will be conducted in various ground laboratory studies.

### Ocular Toxicity Studies

Ocular exposure studies will be performed to determine the degree of ocular toxicity from acute and chronic exposure to lunar dust particles.

**Deliverables:** Research data indicating the degree of ocular toxicity of lunar dusts. Based upon these results a follow on could include an ocular exposure standards, recommended countermeasures, design and operational controls.

**Required Delivery Milestone:** Guidelines and treatment information required for Lunar Lander SDR, FY11.

**Required Platforms:** The activity will be conducted in various ground laboratory studies.

### AEH 5: What are the permissible exposure limits for inhalation of lunar dust?

Data collected from AEH Tasks 1-3 will be analyzed for the development of time based exposure limits of lunar dust concentration in air. The standard will cover 6-month episodic exposures, but may include other time based exposure limits (acute and chronic) contingent upon the validity of the data.

**Tasks:** Lunar Dust Toxicity Research Program (LDTRP) will convene the LADTAG for assessment of data from all LDTRP studies. Final recommendation(s) of Lunar Dust Health Standards will be developed.

**Deliverables:**

- Update PEL based upon research (Time based permissible exposure limits for respirable/airborne lunar dust) and studies past 2010.
- Data from AEH4 will be analyzed. Recommendations for countermeasures and protective measures

**Required Delivery Milestone:** Guidelines and treatment information required for Lunar Lander SDR, FY11.

**Required Platforms:** The activity will be conducted in various ground laboratory studies.
AEH Watch Item/NSBRI Research: What are the effects of lunar gravity on permissible exposure limits for inhalation of lunar dust?

| Tasks: (NSBRI – NRA selected task) |  |
|-----------------------------------|  |
| Aerosol Deposition in the Lung in Fractional Gravity |  |
| The hypotheses are that total aerosol deposition in the human lung will be higher in fractional gravity, and that aerosol deposition on the lungs of rats will be more peripheral. The increased deposition and lengthened time before clearance may increase the likelihood of lung injury. |  |
|  |
| Deliverables: Research data on a potential factor to consider in establishing Permissible Exposure Limits; research data on the dynamics of aerosols in the lungs. |  |
| Required Delivery Milestone: Inputs to AEH 5, PEL establishment and updating. |  |
| Required Platforms: The activity will be conducted in various ground laboratory studies including fractional-gravity flights in the NASA Reduced Gravity Aircraft. |  |

Tasks: (NSBRI – NRA selected task)
Clearance of Particles Depositing in the Human Lung in Low Gravity

The deposition of particulate matter in the human lung is known to bring with it both long-term and short-term adverse health consequences. The hypothesis is that clearance rates from the lung of particles deposited in low gravity will be substantially reduced compared to that in normal gravity, resulting in increased residence times in the periphery of the lung, enhancing their potential to cause lung damage.

Deliverables: Inputs to AEH 5, PEL establishment and updating.

Required Delivery Milestone: Inputs to AEH 5, PEL establishment and updating.

Required Platforms: The activity will be conducted in various ground laboratory studies including fractional-gravity flights in the NASA Reduced Gravity Aircraft.
Risk of Adverse Health Affects from Exposure to Lunar Dust Particulate

**AEH1:** What are the unique properties of the lunar dust that affect physiology?

- **Dual Size Factor** (Physiology Studies)
  - Directed Studies – Shape & Chemistry Analysis
  - Forensic analysis of Apollo artifacts

- **AEH:** Activation Factor Studies
  - Directed Study – Reactivation studies, solar wind impact studies

- **AEH2:** What is the toxicity of respired lunar dust in the respiratory system?

**AEH**

- Pulmonary Toxicity Studies
  - Open, Static, & Activation Factor
  - Inhalation Toxicity
  - Intratracheal & Intrahyoidal Instillation Testing

**Determinant Dual Size Distribution Factor – JSC & U Tartan Knoxville Ground Studies**

**Determine Lunar Dust Activation - Factors JSC & U Tartan**

**Develop monitoring requirements**

**Interate with Robotic Missions**

**Determine what experiments to perform?**

**Study methods and mechanisms of Lunar surface deactivation**

**Improve insight into presence of nano-sized Lunar dust particles**

**Examine issues specific to Shuttle**

**Exposure of crew**

**Inputs to AEH5**

**Study variations in toxicity of various types/locations of lunar dust**

**Monitoring requirements needed**

**Standard update required to support development of Lunar Ops Concepts, Requirements, and Hardware (Lander Design is key schedule driver)**

**Constellation**

<table>
<thead>
<tr>
<th>Program Level</th>
<th>SR</th>
<th>CDR-Initial Ops</th>
<th>PDR</th>
<th>CDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orion</td>
<td>PDR</td>
<td>CDR</td>
<td>Full Ops Capability</td>
<td></td>
</tr>
<tr>
<td>EVA Suit</td>
<td>PDR-001</td>
<td>CDR-001</td>
<td>PDR-002</td>
<td>CDR-002</td>
</tr>
<tr>
<td>Lander</td>
<td>ATP</td>
<td>S0R</td>
<td>PDR</td>
<td>CDR</td>
</tr>
<tr>
<td>Mission Operations</td>
<td>PDR-Initial</td>
<td>CDR-Initial</td>
<td>PDR-001</td>
<td>CDR-001</td>
</tr>
</tbody>
</table>

**ISS & Shuttle**

- 6 Crew Capability
- Shuttle Retired
- End of US Commitment

**HRP FRD Requirement:** 5.1, 5.2, 5.3

**Element:** SHFH
Risk of Adverse Health Affects from Exposure to Lunar Dust Particulate

**AEH 3: What is the mode of action of lunar dust at the respiratory cellular level?**

- **Lunar cell culture toxicity testing** - This data may contribute to the dose and activation factors.
- Active vs. non-active dust; reactive oxygen species and other relevant toxic biomarkers tested

**AEH 4: What is the dermal and ocular toxicity of lunar dust?**

- **Dermal toxicity testing**
- **Ocular toxicity testing**

---

288
HRP FRD Requirement: Element

ISS & Shuttle

<table>
<thead>
<tr>
<th>Constellation</th>
<th>6 Crew Capability</th>
<th>Shuttle Retired</th>
<th>End of US Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orion</td>
<td>PDR</td>
<td>CDR</td>
<td>Human Lunar Return</td>
</tr>
<tr>
<td>EVA Suit</td>
<td>PDR-uit1</td>
<td>CDR-uit1</td>
<td>Full Ops Capability</td>
</tr>
<tr>
<td>Lander</td>
<td>SDR</td>
<td>PDR-out2</td>
<td></td>
</tr>
<tr>
<td>Mission Operations</td>
<td>PDR-inf-cap</td>
<td>CDR-inf-cap</td>
<td></td>
</tr>
</tbody>
</table>

AEH Watch Item/NSBRI Research:
What are the effects of lunar gravity on permissible exposure limits for inhalation of lunar dust?

NSBRI
- Aerolec Deposition in the Lung in Fractional Gravity (Ground study, NRA)
- Clearance of Particles Depositing in the Human Lung in Low Gravity (Ground Study, NRA)

Partial G aircraft

Inputs to AEH 5, which sets and updates standards.
RISK OF ACCELERATED OSTEOPOROSIS – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average loss rates of approximately 1% per month. It is unclear whether this bone mineral density will stabilize at a lower level, or continue to diminish. It is unknown if fractional gravity, present on the moon and Mars would mitigate the loss. Mission-related bone loss cannot be corrected by post-mission rehabilitation; crewmembers could be at greater risk of osteoporosis-related fractures in later life. Greater understanding of the mechanisms of bone demineralization in microgravity is necessary to frame this risk, as well as to understand how current and future osteoporosis treatments may be employed.

Operational Relevance and Risk Context

Although it is currently possible 1) to track the course of changes in bone mineral density and bone quality during long duration missions, 2) to determine if bone losses will occur during a Mars visit, and 3) knowing such information to determine the risk of fracture upon return to Earth after a Mars mission, current capabilities are not in any requirement documents for Lunar or Mars missions. However, even after 6-month missions there are indications that bone quality/strength does not recover as quickly as bone mineral density. This may represent a long-term health effect (increased osteoporosis and fracture risk) related to this discordant recovery dynamic. This information is required to assess long-term health risks to returning crew.

Strategy for Mitigation

While demineralization of bone during spaceflight is known and requires mitigation; the time course of in-flight bone changes, the time course of post-flight recovery and individual susceptibilities have not been determined. The 2007 NASA Research Announcement was utilized to solicit and select proposals to gather these space normal data. In addition, work is ongoing with the Space Medicine Division to obtain long-term recovery data. The long-term goals are to deliver countermeasures during the mission, track efficacy, and prevent lifetime health risk. Due to schedule constraints, countermeasure development has been started in parallel with space normal data collection and technology development.

Gaps

B10: What is the time course of bone loss during flights >90 days on ISS and during Lunar Outpost missions? Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore, in-flight monitoring (BMD or other methods) of bone metabolism and density/strength, as new state of the art techniques become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions. It is recommended that additional research on bone loss remain at a low priority until this data is acquired and assessed, and can be used to focus any future efforts.

B1: Is bone strength completely recovered with recovery of BMD? It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?
**Task:** (NxPCM – via NRA)

**Monitoring of Bone Loss Bio-Markers in Human Sweat**

A non-invasive, time efficient means of monitoring bone resorption markers under micro and partial gravity loading conditions.

Validation that the rate and extent of unloading-induced bone loss in humans can be assessed by monitoring the levels of two bone resorption markers in sweat, namely calcium and collagen breakdown products. One of the approaches tested will be a novel, micro-fabricated fluid collection capillary array, known as the micro-fabricated sweat patch (MSP) device, specifically developed for use in microgravity.

**Deliverables:** New technology will be developed to assess bone resorption markers. Assessment of bone markers will allow for an update of information to the bone standard. Data will be shared with ExMC to aid in their work on ExMC Gap 4.06.

**Required Delivery Milestone:** FY2014 – new bone marker technology delivered to mission operations for lunar outpost and Mars planning.

**Required Platforms:**

- Initial work will be performed on the ground for hardware development; the hardware will be evaluated in bed rest campaigns.
- The ISS will be required to validate the hardware.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>10</td>
<td>10 kg/Inc</td>
<td>None</td>
<td>10</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Task:** (NxPCM – via NRA)

**Recovery of Bone Quantity and Quality upon Simulated Space Fight as a Function of Exposure Frequency, Genetics, and Gender.**

This task will examine the consequences of multiple exposures to simulated weightlessness on long-term quantity and quality of trabecular and cortical bone as well as muscle and investigate how recovery periods between periods of weightlessness can be optimized.

**Deliverables:** This study will provide information to aid in closure of the gaps in the FY2011 timeframe.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:**

- This is a ground-based study utilizing a rodent hind-limb unloading model.

**Task:** (NxPCM – via NRA)

**Bone Countermeasure Study – TBD.** This task will examine potential countermeasures for bone.

**Deliverables:** This study will provide a validated countermeasure in the FY2018 timeframe.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:**

- Initial work will be performed on the ground in bed rest campaigns. The ISS will be required to validate the countermeasure.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>31 kg/Inc</td>
<td>4.32 kg/Inc</td>
<td>29.5</td>
<td>8</td>
</tr>
</tbody>
</table>
**Task:** (NxPCM – via NRA)

**Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration Space Flight**

This task will make comparisons between bone densities of crewmembers and the population-based data and use fracture prediction models derived from the cohort to make estimations on fracture risk among crewmembers. It will also explore the data already gathered to date during the US human space program in order to summarize the current state of evidence available on additional risk factors related to bone loss and recovery in microgravity. The ultimate goal of this research proposal is to provide evidence-based information that may assist in guiding the direction of further research required to understand better the risk of bone loss and fracture among crewmembers and the strategies that could be developed to prevent it from occurring.

**Deliverables:** This study will provide information to aid in closure of the gaps and will enable the Bone Discipline Lead to provide information regarding the SFHSS Bone Standard. In addition, information will be shared with the Space Medicine Division for their Conditions List. These products will be delivered in the FY2011 timeframe.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This is a ground-based study data mining-type task.

---

**B1: Is bone strength completely recovered with recovery of BMD?** It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?

**Task:** (NxPCM – via Directed Study)

**Bone Recovery Study – TBD**

This task will examine post-flight changes in bone mineral densities using QCT methodologies. These measurements will occur over a 3-year post-flight period to obtain bone recovery data on crewmembers.

**Deliverables:** This study will provide information regarding the SFHSS Bone Standard; it will be delivered in the FY2011 timeframe.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This task requires long-duration crewmembers and thus requires the ISS.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Task:** (NxPCM – via NRA)

**Contributors to Long-Term Recovery of Bone Strength following Exposure to Microgravity**

This task will characterize: (a) the time course of recovery from simulated microgravity (28d HU), (b) response to a second HU exposure (following an initial HU exposure plus recovery), and (c) the effects of exercise on recovery dynamics. The two exercises will be resistance training and treadmill running. The overall objective is to define the relationships between three different, but crucial, types of bone parameters: bone mass, bone mineral density, and bone quality.

**Deliverables:** This study will provide information to aid in closure of the gaps in the FY2011 timeframe.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This is a ground-based study utilizing a rodent hind-limb unloading model.
N5: Can a single test monitor net bone calcium changes? Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore in-flight monitoring (other than BMD) of bone metabolism and density/strength, as new state of the art techniques become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions.

**Task**: (NxPCM – via NRA)
Rapid measurements of bone loss using tracer-less calcium isotope analysis of blood and urine

This task will develop a method to rapidly detect changes in bone mineral balance by measuring the natural (i.e., tracer-less) isotope composition of calcium in blood and/or urine. This method would provide a way to detect incipient bone loss before changes in bone density are detectable by conventional X-ray methods.

**Deliverables**: New technology will be developed to assess bone resorption markers. Assessment of bone markers will allow for an update of information to the bone standard. Data will be shared with ExMC to aid in their work on ExMC Gap 4.06.

**Required Delivery Milestone**: FY2014 – new bone marker technology delivered to mission operations for lunar outpost and Mars planning.

**Required Platforms**: Initial work will be performed on the ground for hardware development; the hardware will be evaluated in bed rest campaigns. The ISS will be required to validate the hardware.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None – Accounted for with Repository Task</td>
<td>3 kg/Inc</td>
<td>None – Accounted for with Repository Task</td>
<td>0.5</td>
</tr>
</tbody>
</table>

B3: What pharmaceuticals against bone loss are best used and how? MO5: Determine how can osteoporosis treatments be employed? The efficacy of anti-resorptive agents under weightless conditions of spaceflight has not been validated.

**Task**: (NxPCM – via Directed Study)
Bisphosphonates as a countermeasure to space flight induced bone loss, SMO-021

The purpose of this SMO is to determine whether Bisphosphonates, in conjunction with the routine in-flight exercise program, will protect ISS crewmembers from the regional decreases in bone mineral density documented on previous ISS flights. Two dosing regimens will be used: (1) an oral dose of 70 mg of alendronate taken weekly during flight or (2) an IV dose of zoledronic acid 4 mg, administered just once approximately 45 days before flight. Secondary goals will be to document the return to normal bone remodeling post-flight in crewmembers who took Bisphosphonates. If shown to be an effective countermeasure to space flight-induced bone loss, Bisphosphonates could prevent or ameliorate several potential bone-related problems. This study is being conducted in conjunction with the Japan Space Agency.

**Deliverables**: A product will be an effective pharmaceutical countermeasure to mitigate the risk of bone loss. This countermeasure will be delivered in the FY2012 timeframe.

**Required Delivery Milestone**: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms**: The ISS is required to validate the countermeasure.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>16 kg/Inc</td>
<td>2.46 kg + TBD cold stowage/Inc</td>
<td>29.33</td>
<td>16.5</td>
</tr>
</tbody>
</table>
B18: Is vibration a good countermeasure? This gap has been closed, the vibration study conducted did not protect against bone loss.

B3: What pharmaceuticals against bone loss are best used and how? MO5: Determine how can osteoporosis treatments be employed? The efficacy of anti-resorptive agents under weightless conditions of spaceflight has not been validated.

B11: What are the effects of radiation on bone?

**Task:** (NSBRI) Space Radiation and Bone Loss: Lunar Outpost Mission-Critical Scenarios and Countermeasures

Astronauts on long lunar missions will face the adverse affects of microgravity, reduced gravity, and radiation exposure. It is known that microgravity causes bone loss since bones of the lower body do not bear weight in space as they do on Earth. The impact of radiation on bone quality and fracture healing in reduced gravity is unknown. Dr. Ted A Bateman is investigating the effect of different types of space radiation on bone to learn whether radiation increases the rate of loss. His team is also testing the protective effects of pharmacological countermeasures, such as Bisphosphonates, antioxidants and certain proteins.

**Deliverables:** A product will be information regarding bone loss and radiation effects.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This is a ground-based study.

B10: What is the time course of bone demineralization during flights >90 days on ISS and during Lunar Outpost missions? Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore in-flight monitoring (other than BMD) of bone metabolism and density/strength, as new state of the art techniques become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions. It is recommended that additional research on bone loss remain at a low priority until this data is acquired and assessed, and can be used to focus any future efforts.

B1: Is bone strength completely recovered with recovery of BMD? It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?

N14: What nutritional countermeasures can be used to mitigate bone loss?
**Task:** (NxPCM – via NRA)

Dietary intake can predict and protect against changes in bone metabolism during space flight and recovery. This task will document how the ratio of acid to base precursors in the diet is related to directional changes in markers of bone resorption and formation during flight and recovery from flight. There is a high likelihood for success in predicting the extent of bone loss from dietary intake patterns among astronauts during space flight given that this concept is strongly anchored in previous ground-based data from our laboratory and others. The notion of manipulating diet to minimize bone loss could also have significant social and economic impacts for NASA and for the general public – especially given the increasing trends for diets that are high in animal protein and low in fruits and vegetables. The proposed experiments will result in a dietary countermeasure for bone loss that has no associated risks for side effects, no requirement for payload mass, and no additional crew time necessary during flight.

**Deliverables:** This task will deliver a validated nutritional countermeasure that will protect against bone loss.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** The ISS is required to validate the countermeasure.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>31 kg/Inc</td>
<td>4.32 kg + TBD cold stowage/Inc</td>
<td>29.33</td>
<td>8</td>
</tr>
</tbody>
</table>

**N7: What are the potassium, magnesium, and phosphorus changes in relation to cardiovascular issues and bone loss?** The relationship between bone health and the protein/potassium ratio in the diet needs to be further investigated, along with the role of potassium in cardiovascular health during flight. Nominal determinations of phosphorus content of the space food system are required, as well as further investigation of the mechanism and implications of decreased phosphorus excretion after long-duration spaceflight. Nominal determinations of magnesium content of the space food system are required.

**Task:** (NxPCM – via Directed Study)

Nutrition Status Assessment – SMO O16E: Nutrition SMQ

This is a directed study that seeks to expand the Medical Requirement 016L testing in three ways: 1) include in-flight blood and urine collection, 2) expand nominal testing to include makers of normative markers of nutritional assessment, and 3) add an R+30 session to allow evaluation of post flight nutrition and implications for rehabilitation. Additional markers of bone metabolism (helical peptide, OPG, RANKL, IGF-1) will be measured to better monitor bone health and countermeasure efficacy. New markers of oxidative damage will be measured (8-iso-prostaglandin F2a, protein carbonyls, oxidized and reduced glutathione) to better assess the type of oxidative insults during space flight. The array of nutritional assessment parameters will be expanded to include serum folate, plasma pyridoxal 5'-phosphate, and homocysteine to better understand changes in folate, vitamin B6 status, and related cardiovascular risk factors during and after flight. Additionally, stress hormones and hormones that affect bone and muscle metabolism will be also measured (DHEA, DHEA-S, Cortisol, testosterone, estradiol). This additional assessment would allow for better health monitoring, and allow for more accurate recommendations to be made for crew rehabilitation. These additional parameters were added due to the recommendation of an extramural panel that met to define nutritional standards and requirements in 2005. If data indicate countermeasures are necessary for cardiovascular issues and/or bone loss, additional ground-based studies will be initiated. These countermeasures will be validated on board the ISS.

**Deliverables:** The SFHSS nutrition standard will be updated and nutritional requirements will be delivered to AFT. Updates regarding nutritional status in-flight will be delivered to the Human System Risk Forum. All deliverables are scheduled for delivery in the FY2011 timeframe.

**Required Delivery Milestone:** ISS is required to ensure that the data represents space normal.

**Required Platforms:** The ISS is required to validate the countermeasure.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>31 kg/Inc</td>
<td>5.1 kg + TBD cold stowage/Inc</td>
<td>22.5</td>
<td>3.2 (Time shared with Medical Operations Time)</td>
</tr>
</tbody>
</table>
B15: Can exercise hardware and protocol be designed to provide loads necessary to maintain bone health? By directing an exercise protocol to prevent skeletal adaptation to space, we prevent a cascade of subsequent physiological changes that may introduce health risks in and of themselves. For example, bone decalcification can increase the risk for renal stones and can also perturb the body's hormonal system that conserve calcium in the body and absorb calcium from the diet (in Evidence Book). Thus, an optimal exercise prescription could have crosscutting effects that preserves or maintains over all bone health.

Task: (ECP – via Directed Study)
Integrated Countermeasure Study – TBD
This task is referenced under the Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – see gaps M7, M8, M9 and M10

Task: (ECP – via Directed Study)
ISS Prescription Study – TBD
This task is referenced under the Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance – see gaps M7, M8, M9 and M10

Task: (NSBRI)
A Quantitative Test of On-Orbit Exercise Countermeasures for Bone Demineralization Using a Bed Rest Analog
This novel approach involves quantifying typical daily loads to the lower extremities in selected free-living volunteer subjects who are moderate exercisers and planning individual exercise prescriptions based on DLS theory. Subjects were randomized to control or exercise groups and confined to 6-degree head-down bed rest in the General Clinical Research Center (GCRC) at the Cleveland Clinic for 12 weeks. During this time, the exercise group underwent individualized daily exercise programs in the unique Zero Gravity Locomotion Simulator (ZLS) at CCF designed to replace their daily mechanical load stimulus experienced during free living. DXA, MRI, and QCT scans were conducted at the start and end of bed rest to assess variations in bone mineral density, changes in muscle volume, and regional changes (cortical vs. trabecular) in bone. Strength measurements were collected pre- and post-bed rest, and urinary and serum markers of bone resorption and formation were also assessed. Dietary intake sufficient to maintain constant body weight with a balanced intake of macro- and micronutrients was planned and supervised by a registered dietician, and a physician was available 24 hr/day to attend to any medical needs. A rehabilitation program was offered to subjects in the 8 weeks following bed rest. The proposed experiment should provide a categorical answer to the question of whether intermittent load replacement can adequately protect the musculoskeletal system against hypokinetic osteopenia and muscle atrophy and may open a new era in individualized exercise countermeasure planning.

Deliverables: This study will provide data that will help close this gap. At the end of this study a decision must be made whether or not to pursue this exercise model.

Required Delivery Milestone: This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

Required Platforms: This is a bed rest study.
<table>
<thead>
<tr>
<th><strong>Task:</strong> (NSBRI)</th>
<th>Monitoring Bone Health by Daily Load Stimulus Measurement during Lunar Missions</th>
</tr>
</thead>
<tbody>
<tr>
<td>This project will develop and validate a miniaturized accelerometer-based system that could be used during intra- and extravehicular task on the lunar surface to monitor the complete daily load stimulus to the lower extremity and interpret that information in relation to bone health. After validation in the enhanced Zero Gravity Locomotion Simulator (eZLS) at NASA Glenn Research Center and the lunar bed-rest analog at University of Texas Medical Branch, a deliverable of this project will be a system, the Accelerometric Daily Load Sensor (aDLS), including a small shoe-mounted unit that will transmit signals to a BioWATCH that could also be used to collect data on other physiological systems simultaneously. On-board software with visual feedback will determine how much additional exercise is required each day to maintain bone homeostasis.</td>
<td></td>
</tr>
<tr>
<td><strong>Deliverables:</strong> This study will deliver a countermeasure for use on the lunar surface. If the countermeasure will be pursued, it must be validated on the lunar surface</td>
<td></td>
</tr>
<tr>
<td><strong>Required Delivery Milestone:</strong> This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.</td>
<td></td>
</tr>
<tr>
<td><strong>Required Platforms:</strong> This study is being conducted in bed rest.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Task:</strong> (NSBRI)</th>
<th>An Integrated Musculoskeletal Countermeasure Battery for Long-Duration Lunar Missions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The degree to which the musculoskeletal system will maintain its integrity during prolonged sojourns in the reduced gravity of the lunar surface is presently unknown. It is, however, likely that without countermeasures there will be adaptive changes in muscle strength, bone mineral density, bone geometry, and sensorimotor status. When the combined effects of these changes are considered in the context of the construction and exploration tasks that will be performed at the lunar base or at other lunar sites, the risk of injury secondary to a fall is likely to be elevated. To address this fundamental problem, we have constructed a compact platform that integrates a time efficient integrated battery of countermeasures that can be conducted in the confines of the lunar habitat to minimize the risk of musculoskeletal injury. Ultimately, we expect that this battery of countermeasures will be validated using a 10° head-up bed rest simulation of a lunar mission, although it could also be tested in the standard 6 degree head down simulation. The specific objectives of the countermeasure battery are: to preserve muscle strength and cardiovascular fitness; to minimize decrements in postural stability, dynamic balance, and the ability to make corrective actions prior to a fall; to preserve functional performance on mission relevant tasks; and to minimize bone loss in the proximal femur.</td>
<td></td>
</tr>
<tr>
<td><strong>Deliverables:</strong> This study must be reviewed several times before it will deliver a countermeasure. The hardware must be developed and then evaluated in a ground-based study. It will potentially be evaluated in the lunar analog model</td>
<td></td>
</tr>
<tr>
<td><strong>Required Delivery Milestone:</strong> This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.</td>
<td></td>
</tr>
<tr>
<td><strong>Required Platforms:</strong> This is a ground-based study.</td>
<td></td>
</tr>
</tbody>
</table>
**Risk of Accelerated Osteoporosis**

**Risk of Bone Fracture**

$p$: (B1) Is bone strength completely recovered with recovery of BMD?

PCM Bone Recovery Study* (Hogan NRA)

PCM Bone Recovery Study* (LeBlanc/Lang, Directed Study)

$p$: (B1) Is bone strength completely recovered with recovery of BMD? (B10) Time-course of bone degradation during missions?

PCM Bone CM Study TBO* (NRA)

PCM Bone Loss Marker in Sweat* (Clarke NRA)

$p$: (N5) Can a single test monitor net bone Ca+ changes?

PCM Calcium Isotope Study* (Arbar NRA)

---

Note: These activities mitigate a risk to a long-duration Mars mission. The activities are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transition analog.

---

299
Risk of Accelerated Osteoporosis
Risk of Bone Fracture

Gaps: (B1) Is bone strength completely recovered with recovery of BMD? (B10) Time-course of bone degradation during missions?

- Epidemiologic Analysis (Amin NRA)
- Bone Recovery (Judes NRA)

Gaps: (B3) Pharmaceuticals protect bone loss? (MO5) How can osteoporosis treatments be employed?

- Bisphosphonates SMO (LeBlanc Directed Study)
- Nutrition SMO (Smith Directed Study)

Gaps: (N7) What are K+, Mg+, and P+ changes in relation to CV issues and bone loss?

- ISS Study N=12

Gaps: (N14) Nutritional CM for Bone? (B1) Is bone strength completely recovered with recovery of BMD? (B10) Time-course of bone degradation during missions?

- Pro K+ (Smith NRA)

Note: These activities mitigate a risk to a long-duration Mars mission. The activities are conducted in the 2000-2020 timeframe because of the availability of ISS as a Mars transit analog.

* These studies are listed multiple times to answer several gaps.
Risk of Accelerated Osteoporosis

Gap: (B15) Can exercise provide loads to stimulate bone formation?

ECP
- Integrated CM Study* (TED Directed Study)
- ISS Prescription Study* (Directed Study)

NSBRI
- Quantitative Test of On-Orbit Exercise CM for Bone (Cavanagh)
- Integrated Musculoskeletal CM for Lunar Missions (Luna)
- Bone Health Daily Load Stimulate Lunar Missions (Cavanagh)

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.

*These studies are listed multiple times to answer several gaps.
Risk of Accelerated Osteoporosis

Gaps: (B3) Pharmaceuticals protect bone loss? (M05) How can osteoporosis treatments be employed? (B11) Radiation effects on bone?

Space Radiation and Bone Loss: Lunar Outpost Mission Critical Scenarios and Countermeasures (Bratman)

NSBRI

Musculoskeletal Health in Lunar Environment (Bloomfield)

* These studies are listed multiple times to answer several gaps

302
RISK OF BONE FRACTURE – CRITICALITY: LUNAR OUTPOST – D, MARS – D

Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average loss rates of approximately 1% per month. It is unclear whether this bone mineral density will stabilize at a lower level, or continue to diminish. It is also unknown if fractional gravity, present on the moon and Mars would mitigate the loss. This level of bone loss does not create an unacceptable risk of fractures for ISS missions, but longer missions could create higher fracture risk. The risk of fracture during a mission cannot be accurately estimated until mechanisms and probabilities of bone overloading during the missions are understood. Mission-related bone loss cannot be corrected by post-mission rehabilitation; crewmembers could be at greater risk of osteoporosis-related fractures in later life. Greater understanding of the mechanisms of bone demineralization in microgravity is necessary to frame this risk, as well as to understand how current and future osteoporosis treatments may be employed.

Context of Risk for Exploration

Long duration mission DXA scans of astronauts and cosmonauts following long duration missions reveal an average monthly rate of BMD loss at 1-1.5% bone mass in lower limbs, hip, spine and pelvis. QCT further delineates a greater percentage loss in the cancellous bone compartment, relative to loss in cortical bone, as well as geometric changes in the proximal femur. Temporal recovery of preflight bone mass exceeds the duration of spaceflight exposure with a 50% restoration on the order of 200-250 days, based on a mathematical fit of post-flight DXA BMD measurements. Thus, the recovery model, based upon fitted data, suggest that substantial recovery could occur in about 3 years. The fracture risk for bone is related to the ratio of applied load to bone to the fracture load of bone. Thus the increased fracture risk induced by spaceflight is suggested collectively by the accelerated loss of bone mass as an adaptive response, by the weightlessness and reduced gravity fields experienced during missions and by the loads and torques that the skeleton is subjected to during performed tasks of the missions. The most critical work needed for this risk are measures of in-flight changes in bone mass over the course of ISS missions so that temporal changes in bone mass can be predicted during Mars missions. Those data will provide a basis for evaluating whether the expected loads/torques to the bones during human performance on a mission will exceed the failure load of bone (i.e., fracture load). This knowledge will drive mission operations planning.

Strategy for Mitigation

A high risk for fracture is a characteristic of osteoporosis, which is a consequence of the losses in bone mass and in structural deterioration. Therefore, gaps and tasks that fall under the Risk of Accelerated Osteoporosis are also mapped to this risk. The only independent gap for the Risk of Bone Fracture is the unknown incidence of vertebral compression fractures. The task associated with this gap is being completed by the Space Medicine Division.

Gaps

B2: What new technologies are available for in-flight fracture diagnosis? This gap is being worked within the ExMC Program Element. Please refer to ExMC gap 4.02 for further information. HHC is not conducting any work in this area.

B29: What is the risk of vertebral compression fractures? Data needs to be collected for measures of morphological changes to vertebral bodies (for diagnosis of asymptomatic compression fractures) in crews after long-duration spaceflight; characterize morphological changes to vertebral bodies with longitudinal measures in Astronaut population to characterize changes over time.

Task: (Space Medicine)
Assess Vertebral Compression Fractures (MRID)
This task is being conducted as part of Medical Requirement-035L Bone Densitometry

**Deliverables:** One product will be to inform mission operations if the data indicate there are vertebral compression fractures in returning crew. At some point in the data gathering, if indicated, the SFHSS bone standard will be updated.

**Required Delivery Milestone:** Mission operations needs to be informed of data as soon as possible to make any modifications to Orion regarding loads on crew.

**Required Platforms:** ISS is required to collect data on long duration crews.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A Resources encompassed within Space Medicine</td>
<td>N/A Resources encompassed within Space Medicine</td>
<td>N/A Resources encompassed within Space Medicine</td>
<td>N/A Resources encompassed within Space Medicine</td>
<td>N/A Resources encompassed within Space Medicine</td>
<td>N/A Resources encompassed within Space Medicine</td>
</tr>
</tbody>
</table>

**B10: What is the time course of bone demineralization during flights >90 days on ISS and during Lunar Outpost missions?** Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore in-flight monitoring (other than BMD) of bone metabolism and density/strength, as new state of the art techniques become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions. It is recommended that additional research on bone loss remain at a low priority until this data is acquired and assessed, and can be used to focus any future efforts.

**B1: Is bone strength completely recovered with recovery of BMD?** It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gaps B1-B10 in that risk.

- Recovery of Bone Quantity and Quality upon Simulated Space Fight as a Function of Exposure Frequency, Genetics, and Gender
- Bone Countermeasure Study – TBD
- Monitoring of Bone Loss Bio-Markers in Human Sweat a non-invasive, time efficient means of monitoring bone resorption markers under micro and partial gravity loading conditions.
- Epidemiologic Analyses of Risk Factors for Bone Loss and Recovery Related to Long Duration Space Flight

**B1: Is bone strength completely recovered with recovery of BMD?** It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap B1 in that risk.

- Bone Recovery Study – TBD
- Contributors to Long-Term Recovery of Bone Strength following Exposure to Microgravity

**N5: Can a single test monitor net bone calcium changes?** Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore in-flight monitoring (other than BMD) of bone metabolism and density/strength, as new state of the art techniques...
become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions.

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap N5 in that risk.
Rapid measurements of bone loss using tracer-less calcium isotope analysis of blood and urine

B3: What pharmaceuticals against bone loss are best used and how? MO5: Determine how can osteoporosis treatments be employed? The efficacy of anti-resorptive agents under weightless conditions of spaceflight has not been validated.

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap B1 in that risk.
Bisphosphonates as a countermeasure to space flight induced bone loss, SMO-021

B10: **What is the time course of bone demineralization during flights >90 days on ISS and during Lunar Outpost missions?** Although the degree of loss in bone mineral density during the ISS missions is not of great concern, it is not known at what rate losses occur, and it is not currently possible to predict what losses will occur during a Mars mission. Therefore in-flight monitoring (other than BMD) of bone metabolism and density/strength, as new state of the art techniques become available, should be examined on Shuttle, ISS and during Lunar Sortie and Lunar Outpost missions. It is recommended that additional research on bone loss remain at a low priority until this data is acquired and assessed, and can be used to focus any future efforts.

B1: **Is bone strength completely recovered with recovery of BMD?** It is a high priority to determine whether changes occur in bone architecture during long-duration spaceflight that, even with recovery of pre-flight BMD, adversely impacts long-term risk. Is this influenced by multiple flights?

N14: What nutritional countermeasures can be used to mitigate bone loss?

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap B1, B10 and N14 in that risk.
Dietary intake can predict and protect against changes in bone metabolism during space flight and recovery

N7: **What are the potassium, magnesium, and phosphorus changes in relation to cardiovascular issues and bone loss?** The relationship between bone health and the protein/potassium ratio in the diet needs to be further investigated, along with the role of potassium in cardiovascular health during flight. Nominal determinations of phosphorus content of the space food system are required, as well as further investigation of the mechanism and implications of decreased phosphorus excretion after long-duration spaceflight. Nominal determinations of magnesium content of the space food system are required.

**Task:** Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap N7 in that risk.
Nutrition Status Assessment – SMO O16E: Nutrition SMO
Risk of Bone Fracture

p: (B29) Vertebral compression fractures?

(1) Inform mission ops if loads need to be modified

Assess vertebral compression fractures (MRID)

1. Update SPHSS bone loads
2. Lander training program starts
3. Lander training program starts

Outpost Medical Kit

Program Level
- SRP
- CDR: Initial Ops
- PDR
- CDR

End of US Commitment

Onion
- PDR
- CDR: Initial Ops
- Full Ops Capability

EVA Suit
- PDR: out1
- CDR: out1
- PDR: out2
- CDR: out2

Lander
- ATP
- SDR
- PDR
- CDR

Mission Operations
- Full Ops Capability
- CDR: Initial Cap
- Full Ops Capability
- SRP Data
- CDR

FY09 FY10 FY11 FY12 FY13 FY14 FY15 FY16 FY17 FY18 FY19 FY20 FY21 FY22 FY23 FY24 FY25

48 Shuttle

Crew Capacity
- Shuttle Retired
- End of US Commitment

Human Lunar Return
RISK OF RENAL STONE FORMATION – LUNAR OUTPOST – D, MARS – D

Kidney stone formation and passage has the potential to greatly impact mission success and crewmember health for long duration missions. Alterations in hydration state (relative dehydration) and bone metabolism (increased calcium excretion) during exposure to microgravity may increase the risk of kidney stone formation and it is unclear which mitigation strategy would be the most effective.

Context of Risk for Exploration

Countermeasures for renal stone formation must be validated prior to Mars exploration missions because of reduced level of care and prolonged evacuation time. In-flight monitoring must be developed and instituted so that crewmembers will have a means to track their renal stone markers.

Strategy for Mitigation

Space normal must first be defined for this risk; hence data mining tasks are ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed.

Gaps

B5: What is the current state of knowledge regarding renal stone formation? A comprehensive synthesis of all existing data should be compiled, including: the most current clinical knowledge about risk factors and prevention strategies; and all prior and current flight data. The following gaps fall within this group.

B6: What are the contributing factors other than loss of bone mineral density?

B7: Is it necessary to increase crew fluid intake and, if possible, to what extent will it mitigate stone formation?

B8: Do pharmaceuticals work effectively in spaceflight to prevent renal stones?

B9: What is the frequency of post-flight stone formation; the incidence and types of stones; and the time course of stone formation? How does stone formation correlate with food intake and hydration status?

B16: Can inhibitors of stone formation be sufficiently provided through dietary sources? N13: Can renal stone risk be decreased using nutritional countermeasures?
**Task:** (NxPCM – Directed Study)

Data mining for incidence of renal stone formation following spaceflight

The evidence establishing the risk factors and/or the likelihood of risk occurrence for renal stone formation is either known or in-progress. This study will compile data related to the risk of renal stone formation from medical data and raw research data used for previously published reports) and determine primary and other risk factors for renal stone formation, particularly regarding the types of stones formed (to identify the specific risk factor and appropriate countermeasure), the correlation with diet and the time course for formation.

**Deliverables:** Final report of findings will be combined with the Renal Stone flight study and results will be brought to the HSRF in the FY2009 timeframe. If data (combined with Renal Stone study results) indicate that new or additional countermeasures are required, then ground based studies will be solicited to find suitable candidate countermeasures. The best of these countermeasures will then be validated through solicited flight studies and the countermeasure will be delivered in the FY2016 timeframe. All data from this task will be passed to Space Medicine for their Conditions List.

**Required Delivery Milestone:** If data indicate an issue with renal stones, then a validated countermeasure is required as soon as possible

**Required Platforms:** If further countermeasures are needed, the bed rest ground analog is required to demonstrate countermeasure efficacy. ISS is required as the Mars transit analog for countermeasure validation if new countermeasures are developed.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
</tr>
</tbody>
</table>

---

**Task:** (NxPCM – NRA)

Renal Stone Risk During Spaceflight: Assessment and Countermeasure Validation

The studies planned in this investigation will not only provide a better understanding of the stone-forming risk crewmembers experience during and after space flight, but will take the next step to test the efficacy of potassium citrate as a countermeasures to reduce this risk. Based on the known increased risk crewmembers experience, it is imperative that countermeasures to reduce or alleviate this risk are developed and tested.

**Deliverables:** Final report of findings will be combined with the Renal Stone flight study and results will be brought to the HSRF in the FY2009 timeframe. If data (combined with Renal Stone study results) indicate that new or additional countermeasures are required, then ground based studies will be solicited to find suitable candidate countermeasures. The best of these countermeasures will then be validated through solicited flight studies and the countermeasure will be delivered in the FY2016 timeframe. All data from this task will be passed to Space Medicine for their Conditions List.

**Required Delivery Milestone:** If data indicate an issue with renal stones, then a validated countermeasure is required as soon as possible

**Required Platforms:** If further countermeasures are needed, the bed rest ground analog is required to demonstrate countermeasure efficacy. ISS is required as the Mars transit analog for countermeasure validation if new countermeasures are developed.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject (hrs)</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
<td>For Potential CM development, all resources are TBD</td>
</tr>
</tbody>
</table>
**B8: Do pharmaceuticals work effectively in spaceflight to prevent renal stones?**

<table>
<thead>
<tr>
<th>Task: (NSBRI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Multisystem Effect of Exercise Training/Nutritional Support During Prolonged Bed Rest Deconditioning: An Integrative Approach to Countermeasure Development for the Heart, Lungs, Muscles and Bones</td>
</tr>
</tbody>
</table>

Sustained exposure to microgravity leads to adaptive changes in the cardiovascular and musculoskeletal systems that result in substantial morbidity. For example cardiovascular deconditioning may lead to orthostatic hypotension and syncope. Atrophy of skeletal muscle will diminish work capacity and may lead to muscle injury. Bone demineralization increases the risk of kidney stone formation and may reduce bone strength increasing the risk of fracture. Bone resorption may be particularly severe after long duration space flight with uncertain recovery. Despite in depth study, the optimal countermeasure for each system has not been defined. More importantly, previous work has focused predominantly on one organ system at a time, ignoring the interaction among systems, and preventing the development of a specific countermeasure for an individual astronaut that might be effective for the heart, muscles and bones. The global objective of this proposal is to test an integrated countermeasure that will be effective against cardiovascular deconditioning, skeletal muscle atrophy, and bone demineralization, and that ultimately can be applied practically abroad the International Space Station or a mission to Mars.

**Deliverables:** Final report of findings will be delivered to HRP who will decide if the proposed countermeasure from this study should be validated.

**Required Delivery Milestone:** No delivery milestones are required for this task

**Required Platforms:** This is a ground-based study being conducted at the Institute of the Principal Investigator.

---

**N14: What nutritional countermeasures can be used to mitigate bone loss?**

| Task: Tasks to fill this gap are cited under Risk of Accelerated Osteoporosis Risk – See Gap N14 in that risk. |
| Dietary intake can predict and protect against changes in bone metabolism during space flight and recovery |

---
Risk of Renal Stone Formation

Gaps: (B5) Current renal stone formation knowledge. (B6) Contributing factors to renal stone other than loss of BMD? (B7) Increased fluid intake mitigates stone formation? (B8) Pharmaceuticals prevent stone formation? (B9) Frequency of stones, time course of stone formation, stones correlate with food and hydration? (B10) Stone formation inhibited through diet? (N13) Can renal stone risk be decreased using nutritional countermeasures?

NxPCM Renal Stone (Whitev NRA)

NxPCM Data Mining (Sibonga Directed Study)

Gaps: (B8) Pharmaceuticals prevent stone formation?

NSBRI Multisystem Effect of Exercise Integrative CM Development* (Levine)

Gap: (N14) Nutritional CM for Bone?

NxPCM Pre K* (Smith NRA)

* These studies are listed multiple times to answer several gaps.
RISK OF CARDIAC RHYTHM PROBLEMS – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Heart rhythm disturbances have been seen among astronauts. Most of these have been related to cardiovascular disease, but it is not clear whether this was due to pre-existing conditions or effects of space flight. It is hoped that advanced screening for coronary disease has greatly mitigated this risk. Other heart rhythm problems, such as atrial fibrillation, can develop over time, necessitating periodic screening of crewmembers’ heart rhythms. Beyond these terrestrial heart risks, some concern exists that prolonged exposure to microgravity may lead to heart rhythm disturbances. Although this has not been observed to date, further surveillance is warranted.

Context of Risk for Exploration

Missions may be impacted by the occurrence of a clinically significant dysrhythmia. It is important to define “space normal” for this risk so that appropriate countermeasures can be developed if needed.

Strategy for Mitigation

Space normal must first be defined for this risk; hence data mining tasks are ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed.

Gaps

CV1: What are the in-flight alterations in cardiac structure and function? This is a high priority gap for this risk. The task is already underway in collaboration with outside investigators. The studies include in-flight Holter monitoring and ultrasound assessment of cardiac structure and function. Further research into this risk is not recommended until the results from this effort are known.

CV8: Can manifestations of sub-clinical or environmentally induced cardiovascular diseases during spaceflight be predicted? This gap is owned by the Space Medicine Division although it is possible that some data gathered from the Integrated Cardiovascular SMO may be of use.

Task: (NxPCM – directed study)
Integrated Cardiovascular Study

This comprehensive study integrates the objectives of two NRA investigations and a SMO and involves both intramural and extramural investigators. Data will be obtained twice pre-flight, at 2 weeks, 4 weeks, and every 1-2 months during flight, and 3 times post-flight. In-flight testing will require holter monitoring, 2-d echocardiography, and ambulatory blood pressure monitoring. After completion of this study, the clinical expression of cardiac atrophy during long duration spaceflight will be defined clearly, and its significance for cardiac systolic and diastolic function at rest and during gravitational transitions will be elucidated. In addition, preliminary information will be obtained regarding ventricular conduction and repolarization that will provide either strong clinical reassurance, or pathophysiologic insight into the risk for cardiac arrhythmias.

Deliverables: The products are quantification of the extent, time course, and clinical significance of any spaceflight-related cardiac atrophy and identification of its mechanisms and functional consequences. This will be accomplished by updating the HSRF; updating the cardiovascular risk and informing mission operations of requirements to support this risk. All data will be passed to ExMC in support of ExMC gap 4.19. If any countermeasure is required, the Space Medicine Division will be responsible for its development.

Required Delivery Milestone: FY2013 – data required to support mission operations SRR.

Required Platforms: ISS is required for characterization of spaceflight-induced cardiac changes.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None; hardware currently on board the ISS</td>
<td>7.5</td>
<td>None</td>
<td>39.5</td>
<td>12</td>
</tr>
</tbody>
</table>
N7: What are the potassium, magnesium and phosphorus changes in relation to cardiovascular issues and bone loss?

<table>
<thead>
<tr>
<th>Task:</th>
<th>Nutrition Status Assessment – SMO O16E: Nutrition SMO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>See Risk of Accelerated Osteoporosis – Gap N7</td>
</tr>
</tbody>
</table>

CV1: What are the in-flight alterations in cardiac structure and function? This is a high priority gap for this risk. The task is already underway in collaboration with outside investigators. The studies include in-flight Holter monitoring and ultrasound assessment of cardiac structure and function. Further research into this risk is not recommended until the results from this effort are known.

<table>
<thead>
<tr>
<th>Task:</th>
<th>The Multisystem Effect of Exercise Training/Nutritional Support During Prolonged Bed Rest Deconditioning: An Integrative Approach to Countermeasure Development for the Heart, Lungs, Muscles and Bones</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>See Risk of Renal Stones – Gap B8</td>
</tr>
</tbody>
</table>

CV7: How are fluids redistributed in flight? This gap is considered to be a medium priority by HHC; it is not considered necessary to do research on fluid distribution, because the flight surgeons would be able to predict how the body would handle fluid loads. However, alterations in fluid distribution may affect drug distribution and this aspect of the gap should be pursued.

<table>
<thead>
<tr>
<th>Task: (NSBRI) Braslet Investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliverables: TBD</td>
</tr>
<tr>
<td>Required Delivery Milestone: TBD</td>
</tr>
<tr>
<td>Required Platforms: This is a ground-based study.</td>
</tr>
</tbody>
</table>

Task: Braslet

This task is carried under the Risk of Inability to Adequately Treat and III or Injured Crew Member – see ExMC gap 3.02.
Risk of Cardiac Rhythm Problems

Gap: (CV1) Unknown in-flight alterations in cardiac structure and function. (CV8) Inability to predict manifestation of sub-clinical or environmentally-induced cardiovascular disease during spaceflight.

Gap: (N7) What are K+, Mg+, and P+ changes in relation to CV issues and Bone Loss?

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic. These studies are listed multiple times to answer several gaps.
Risk of Cardiac Rhythm Problems

Gap: (CV1) Unknown in-flight alterations in cardiac structure and function.

Gap: (CV7) In-flight fluid distribution is unknown.
RISK OF ADVERSE HEALTH EFFECTS DUE TO ALTERATIONS IN HOST-MICROORGANISM INTERACTIONS – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Preventative measures limit the presence of many medically significant microorganisms during a mission; however, microbial infection of crewmembers cannot be completely prevented. Recent evidence from spaceflight experiments suggest alterations in microbial characteristics, including virulence (disease-causing potential), in organisms grown during flight. The HRP will analyze current spaceflight operational and flight experiment data, develop an infectious disease risk assessment model, and convene risk and requirement reviews to determine if spaceflight poses any unique risk to the crew. Including in this review is a determination of the efficacy of current mitigation strategies and countermeasures given the potential changes in microorganisms and crewmembers and recommendations to current operational or design controls.

Context of Risk for Exploration

Negative impacts from microorganisms during flight are not uncommon; however, major impacts to crew health and performance fortunately do not occur frequently. Unfortunately, the consequences of infectious disease can include loss of mission and loss of crew, and thus the extent of the risk needs clarification. If microbial virulence characteristics do change in a variety of microorganisms during flight, then current mitigation strategies would need to be revisited to ensure crew health and mission success.

Strategy for Mitigation

To mitigate these risks and ensure the use of appropriate microbial health requirements, a requirements review should be accomplished using systematic microbial risk modeling that identifies knowledge gaps, such as the effect of spaceflight on microbial virulence factors. The effect of these gaps should be evaluated, quantified if possible, and investigated if necessary to develop an appropriate knowledge base to model current infectious disease risks and set appropriate microbiological requirements. The knowledge gap concerning limited knowledge of host-microbe interaction during spaceflight will first be addressed by a workshop designed to develop a position on the extent of the risk and need for future investigations, and, if necessary, a systematic pathway to gain adequate knowledge to ensure appropriate mitigation strategies.

Gaps

AEH 6: What are the infectious disease risk factors and how do they affect the risk to crew health during manned spaceflight missions?

Selection of appropriate requirements is based on determination of the best model and assumptions for spaceflight conditions.
### Microbial Risk Assessment Modeling Study

A risk assessment based upon historical microbiological monitoring data is being performed by subject matter experts in quantitative microbial risk assessment and infectious disease to provide a risk model for expected potable water systems in a lunar habitat. Knowledge for this model is provided by data mining of CHeCS operational data, information from the SWAB flight experiment, research data from other ISS experiments, exposure assessments based on ECLSS design specifications, and human immune system data provided by the Integrated Immune SMO (HHC) and previous flight research. Closure of knowledge gaps identified by this model will facilitate review and updates to water requirements and develop a framework from which evaluation of other microbiological requirements can be performed. After completion of the model, a workshop will be convened to review the model, determine any recommended changes to current water requirements, and recommend forward studies if necessary. Successful application of this model to NASA microbial risks would suggest expanding this model to other components of microbiology such as food requirements during a lunar outpost.

### Deliverables:

- A microbial risk model for quantitative assessment of current infectious disease risk and operational procedures
- Microbial Risk Model – 2011
- Recommendations for operational processes and constraints to minimize exposure to microbial contaminants.
- A workshop report detailing the application of the model to spaceflight programs and recommended changes to spaceflight operations and design.
- Workshop review of model and workshop recommendations in 2012.

### Required Delivery Milestone:

| Medical Operations Requirements needed for Mission Operations SRR, FY13 |
| Medical Operations Requirements – Mission Operations PDR, FY14-15 |

### Required Platforms:

Modeling efforts are ground-based reviews.

### SWAB Flight Experiment

During spaceflight, crewmembers are exposed to a wide variety of microorganisms. Extensive monitoring efforts are performed prior to and during flight; however, current methodology is limited and may miss several pathogens that could affect crew health and performance. The SWAB flight experiment uses advanced collection and processing techniques to identify pathogens in the spaceflight environment that could not be identified using current methodology. The information from this experiment is used to decrease uncertainty in the Microbial Risk Assessment Model.

### Deliverables:

Completion of the SWAB flight experiment is expected in 2011. Experiment findings will be incorporated into the Microbial Modeling Study.

### Required Delivery Milestone:

Information needed by Microbial Risk Modeling workshop, FY12.

### Required Platforms:

SWAB flight experiment evaluation requires access to water collection on the ISS.
<table>
<thead>
<tr>
<th><strong>Tasks:</strong> (AEH; Directed Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Mining</strong></td>
</tr>
<tr>
<td>Operational data will be reviewed with the help of the Crew Health Care System manager and with flight surgeons to obtain additional data to inform the Microbial Risk Modeling activity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Deliverables:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data will be incorporated into the Microbial Modeling Study.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Results required for Microbial Risk Modeling, FY10.</strong></th>
</tr>
</thead>
</table>

| **Required Platforms:** This effort is ground based. |

<table>
<thead>
<tr>
<th><strong>Tasks:</strong> (AEH, Directed Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microbial Characteristic Workshop</strong></td>
</tr>
<tr>
<td>A workshop will be held to evaluate current ground and spaceflight data that indicate <em>Salmonella typhimurium</em> changes virulence characteristics during spaceflight, based on the NRA flight experiments, MICROBE and MDRV. The workshop will include NASA and non-NASA scientific experts from the fields of bacterial pathogenesis, immunology, and space microbiology. Key questions discussed in the workshop include the mechanism or inducer that initiates this response, the potential presence of this mechanism in other microorganisms, and the extent of this risk and the necessary forward work.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Deliverables:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Final report on recommendations determined at Workshop.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Results required for Microbial Risk Modeling, FY10.</strong></th>
</tr>
</thead>
</table>

| **Required Platforms:** This effort is ground based. |

<table>
<thead>
<tr>
<th><strong>Tasks:</strong> HHC, NASA flight experiment research contributing to Microbial Risk Modeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results from the NRA flight experiments, MICROBE and MDRV, that were recently completed, and from the HHC / NxPCM Integrated Immune SMO study will be integrated into the workshop and the Microbial Risk Modeling activity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Deliverables:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data to be delivered to the Microbial Risk Modeling activity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Results required for Microbial Risk Modeling, FY10.</strong></th>
</tr>
</thead>
</table>

| **Required Platforms:** These flight experiments use both STS and ISS. Details are described under HHC/ NxPCB, Gap IM 5. |
Risk of Adverse Health Effects due to Alterations in Host-Microorganism Interactions

AEH 6: What are the infectious disease risk factors and how do they affect the risk to crew health during manned spaceflight missions?

- Characterization of Micro-Organisms in Spacecraft Environment (NRA) - SWAB
- Microbial Risk Assessment Model
- Data Mining - CHeCS operational data
- Expert review panel to define risk and research needed to quantify or mitigate host-pathogen risk.
- Studies defined by Panel

NxPCM - IM 5: Lack of knowledge for in-flight illness time course / etiology.
NxPCM Integrated Immune SIM
(Sims - Directed Study)
RISK OF CREW ADVERSE HEALTH EVENT DUE TO ALTERED IMMUNE RESPONSE – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Human immune function is altered in- and post-flight, but it is unclear if this change leads to an increased susceptibility to disease. Reactivation of latent viruses has been documented in crewmembers, though this reactivation has not been directly correlated with the immune changes or with observed disease. Further research may elucidate whether microgravity exposure impairs the immune system, and whether this change represents a health risk to crews.

Context of Risk for Exploration

While there is post-flight evidence to support this risk, in-flight evidence should also be obtained. The necessary in-flight data should be collected and assessed before further determinations of future research direction are undertaken. Ground-based work should be conducted using the Antarctic station space flight analog (best available analog for immunity during >6 months flight) so that ground control data of an appropriate sample size may be obtained. Validation of an analog directly to flight data would be useful for future countermeasures validation. The laboratory findings are to be correlated to clinical findings and follow-up studies are performed to document any latent, long-term effects.

Strategy for Mitigation

Space normal must first be defined for this risk; hence data mining tasks in the form of the Integrated Immune SMO are ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed. In addition, because head down tilt bed rest is not a valuable analog to spaceflight for this discipline, a good analog for immune studies is being sought.

Gaps

IM1: Does spaceflight alter immune function? This is a high priority for HHC. This data is currently unknown.

IM2: Is an improved immune standard needed? Data must be obtained to determine if the standard is accurate and adequate.

IM5: What is the time course and etiology of immune changes? An investigation of individual records of in-flight illness for clarification is needed.

Task: (NxPCM – via NRA)

1) Flight-Induced Changes in Immune Defenses: ‘Immune Function,’ DSO 498/SDBI 1498
   Shuttle-based study investigating the effects of space flight on 1) neutrophil and monocyte functions (phagocytosis, degranulation, oxidative burst capacity, and expression of surface molecules) and 2) natural-killer cell and lymphokine-activated killer cell cytotoxicity against target cells, and cytokine production

   Shuttle-based study investigating the frequency of latent virus reactivation, latent virus shedding, and clinical disease after exposure to the physical, physiological, and psychological stressors associated with space flight

3) Space Flight-Induced Reactivation of Latent Epstein-Barr Virus: ‘Epstein-Barr,’ on Shuttle as DSO 493/SDBI 1493 and ISS as E129
   Shuttle- and ISS-based study investigates the magnitude of immunosuppression as a result of space flight by 1) analysis of stress hormones, 2) quantitative analysis of EBV replication using molecular and serological methods, and 3) determining virus-specific T-cell immune function.
**Deliverables:** Final reports of findings will be delivered in 2009. Data from these Shuttle-based immune studies will be combined with the ISS-based Integrated Immune SMO to update health standards. If these studies together indicate that a countermeasure is needed, then ground-based countermeasure studies will be solicited and performed. Countermeasures developed from these studies will then be validated on ISS.

**Required Delivery Milestone:** These tasks mitigate a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** ISS is required to complete these studies.

---

**Task:** (NxPCM – via directed study)

**Validation of Procedures for Monitoring Crewmember Immune Function: ‘Integrated Immune SMO,’ SMO 015/SDBI 1900**

The objective of this Supplemental Medical Objective (SMO) is to develop and validate an immune monitoring strategy consistent with operational flight requirements and constraints. There are no procedures currently in place to monitor immune function or its effect on crew health. Immune dysregulation has been demonstrated to occur during spaceflight, yet little in-flight immune data has been generated to assess whether or not this may be a clinical problem. This SMO will assess the clinical risks resulting from the adverse effects of spaceflight on the human immune system and will validate a flight-compatible immune monitoring strategy. The correlation between in-flight immunity, physiological stress and a measurable clinical outcome (viral reactivation) will be determined for long- vs. short-duration space flight.

**Deliverables:** Data from this study will be combined with the Shuttle-based immune studies to update health standards. If results indicate that a countermeasure is needed, ground-based countermeasure studies will be solicited and performed. Then these countermeasures will be validated on ISS. In addition, all data will be shared with other Elements to help address related gaps such as (1) ExMC Gap 4.06 – Lack of capability to stabilize and treat bone fractures; (2) ExMC Gap 4.08 – Lack of reusable cold compress and heating pad capability made of suitable spaceflight materials; and (3) SHFH Gap related to new Host-Microbe Interactions Risk.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** ISS is required to ensure that the data represents space normal and for validation of potential countermeasures. A ground analog (Antarctica, NEEMO, and/or Haughton-Mars) may be used to provide additional data.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>None</td>
<td>4kg/Inc</td>
<td>4kg/Inc</td>
<td>5.5</td>
<td>2.27</td>
</tr>
</tbody>
</table>

---

**Task:**

**Host-Microbe Interactions Study**

This task is being conducted by SHFH to address AEH Gap 2.3 under the Risk of Adverse Health Effects Due To Alterations in Host-Microorganism Interactions.

**IM3: Are there suitable analogs for immune dysregulation?** This gap be filled using the Antarctic station analog so that adequate sample sizes may be obtained. Findings using ground-based analogs should be related to clinical findings and follow-up studies should be performed to document any latent, long-term effects.

**Task:** (NxPCM – via directed study)

**NEEMO Rapid Operational Investigation (ROI): Immune function changes during a spaceflight-analog 10-day undersea mission**
This study measures immune functional changes, physiological stress, viral reactivation and viral specific immunity during the NEEMO mission. NEEMO represents a good analog for some aspects of short-duration spaceflight on immunity. This study will provide data to compare this ground-based spaceflight-analog to actual flight data. If immune dysregulation is observed in the NEEMO crews that is similar to that observed in flight crews during/following spaceflight, this analog will be validated for some aspects of spaceflight-associated immune dysregulation. This analog will not supersede the program goal to validate a ground analog for long-duration spaceflight and immunity.

**Deliverables:** Initial product is completion of the NEEMO study and final report of findings. All results will be fed into the Immune SMO data sets.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** NEEMO undersea environment is required to assess the validity of the short-duration space analog.

---

This study is concerned with determining if: VZV is alive, active and has the potential to spread. These data also represent the potential for cases of Shingles and Ramsey Hunt Syndrome to be experienced by flight crews in long duration exploration. VZV may assume increased virulence and/or live virus numbers in microgravity. This study will demonstrate the sensitivity of the model and provide an operational deliverable in the form of a reliable test for live quantifiable virus.

**Deliverables:** The product is completion of the ground-based study and final report of findings.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** Ground-based laboratory is required.

---

Space flight causes lymphopenia, abnormally low mitogen responses, and reduced production of antibodies and cytokines. Space flight-associated factors such as microgravity, lack of load bearing, stress, and radiation are believed to contribute to these effects, but the exact mechanisms are unknown. Ground-based mouse models such as hind limb unloading (HU) and irradiation cause similar effects. We hypothesize that these changes result from lymphocyte apoptosis induced by the cell surface receptor, Fas, in a manner dependent on endogenous opioids. Furthermore, we predict that radiation exposure and HU act synergistically. We have proposed to: 1) elucidate the role of Fas and endogenous opioids in the modulation of the immune system by HU and radiation; and 2) determine the effect of HU and radiation on lymphocyte dynamics and immune responses. In addition, because autoimmune disease is often associated with stress and radiation exposure, we will determine whether HU and radiation promote autoimmunity. The overall goal is to determine the mechanisms underlying apoptosis-related immune modulation using ground-based models.

**Deliverables:** The product is completion of the ground-based study and final report of findings.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** Ground-based laboratory is required.
**Task:** (NxPCM – via directed study)
**Consequences of Long-term Confinement and Hypobaric Hypoxia on Immunity in the Antarctic Concordia Environment (CHOICE – Study)**

In the unique environment of the Concordia station, stress-dependent immune-modulation due to both confinement and hypoxia can be simultaneously investigated with the following goals: 1) Assessment and understanding of stress-associated immune changes that results from confinement living under moderate hypobaric hypoxia comparable to those possible living situations in future lunar habitats where air pressure and oxygen may be lowered for technical and financial reasons and 2) Work out for the rationale for the development of adequate countermeasures to counterbalance the potential risk of confinement and hypoxia-induced immune and health changes.

**Deliverables:** The product is completion of the ground-based study and final report of findings.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This is a ground-based study in the Antarctic.

**IM4:** Can in-flight hardware to evaluate hematology/infection/immunity be developed? This capability must be developed prior to exploration missions. The need for development of this equipment will be further defined when IM1 is filled. It is not clear that work should begin earlier. Simple, reliable means to evaluate immune function and/or infection (e.g., white cell count) is clinically relevant to long-duration space missions.

**Task:** (ISSMP)
**In-flight Flow Cytometer Project**

**Deliverables:** The product is an in-flight flow cytometer capable of various immunology/hematology measurements.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration Mars mission. The tasks are conducted in the 2008-2020 timeframe because of the availability of ISS as a Mars transit analog.

**Required Platforms:** This task is ground-based hardware development.

**Task:** (ExMC)
**Lunar Lab Analysis**

This task is carried under the Risk of Inability to Adequately Treat and Ill or Injured Crew Member – see ExMC gap 4.06

322

HRP-47065

SRPE Research Planning input to HRP IRP- Revision FY09
Risk of Adverse Health Event Due to Altered Immune Response

Gaps: (IM1) Lack of in-flight immune data; (IM2) Improved immunology standard for exploration flight; (IM3) Lack of knowledge for in-flight illness time-course / etiology

Clinical Support

Ground CM Development

Flight Validation

Updates to immune standard

GM does not exist

Pass data to SHF, New Gap

Microgravity CM needed?

NxPCM
Integrated Immune SMO (Same Directed Study)

NxPCM
Latent Virus (Person NRA)

NxPCM
Immune Function (Person NRA)

NxPCM
Epstein-Barr (Straw NRA)

SHF New Risk/Gap
Host microbe interactions Study (Off-Directed)

NOT

YES

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.
Risk of Adverse Health Event Due to Altered Immune Response

Gap: (IM3) Lack of ground analog studies

- NEEMO Immune ROI (Crestron Directed Study)

- Varicella Zoster Virus (Goodwin Directed Study)

- Apoptosis and Immune Homeostasis (Shi)

- CHOICE (ESA Joint Study)

Gap: (IM4) Lack of in-flight hardware to evaluate hematolgy / infection / immunity.

- Flow Cytometer Project

- ExMC (Gap 4.06) Lunar Lab Analysis

Feed data to Immune SMO

Analogue valid?

Find Better Analog

Feed analog information to new CM development

Is device cost effective?

Validate on ISS?

Feed information to others, in-flight.

analystic capability
**RISK OF INVERTEBRAL DISK DAMAGE – CRITICALITY: LUNAR OUTPOST – D, MARS – I**

Extended exposures to microgravity (and possibly fractional gravity) may lead to an increased risk of spinal nerve compression and back pain.

**Context of Risk for Exploration**

Evidence from medical operations indicates that astronauts have a higher incidence of intervertebral disc damage than the general population. Additional work should be done to determine the extent of this problem and guide design of re-entry and post-flight protocols as well as future re-entry spacecraft.

**Strategy for Mitigation**

Space normal must first be defined for this risk; hence data mining tasks are ongoing. Once space normal is defined, the data will be presented to the Human System Risk Forum and it will be decided if countermeasures need to be developed.

**Gaps**

**B4: What is the incidence of intervertebral disk damage following spaceflight?** The evidence provided by the discipline for this risk was the common complaint of back pain by the crewmembers. There is conflicting information from the Space Medicine Division regarding the incidence of disc damage post-flight. An assessment of the current database is needed for supporting evidence for this risk.

**Task:** (NxPCM – directed study)

Data mining for intervertebral disk damage

Additional evidence (research data) needs to be gathered in order to establish whether the lengthening of the spine with space adaptation syndrome exacerbates the risk for IVD damage with loading. The risk for injury may be greater during the performance of mission tasks in hypogravity, with accelerated g forces from piloting spacecrafts, or with return to gravitational loading on Earth.

**Deliverables:** Final report of findings will be brought to the HSRF in the FY2009 timeframe. If data indicate that more data is required are required, then a flight study will be conducted. If the data indicate an issue exists for disk damage, then the bone standard will be updated to include soft tissue damage.

**Required Delivery Milestone:** Updates to the health standard should occur as soon as possible.

**Required Platforms:** Access to Flight Medicine and LSDA databases is necessary for the data mining study.

---

**Task:** (NxPCM – directed study)

Shuttle Pilot Study – TBD

Additional evidence will be gathered in order to establish whether the lengthening of the spine with space adaptation syndrome exacerbates the risk for IVD damage with loading.

**Deliverables:** Final report of findings will be brought to the HSRF in the FY2012 timeframe.

**Required Delivery Milestone:** Mission operations needs to be informed of data as soon as possible to make any modifications to Orion regarding loads on crew. If countermeasure development studies are required, a validated countermeasure will be delivered in FY2016; which is required for long-duration Exploration missions.

**Required Platforms:** This study initially requires Shuttle crew for access to MRI. ISS crews may be required in the future for countermeasure validation.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>None</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD (within R+7)</td>
</tr>
</tbody>
</table>
Task: (NxPCM – directed study)
IVD Mechanical Countermeasure Study – TBD
A back brace may be developed for use during landings to protect against intervertebral disk damage.

**Deliverables:** A mechanical countermeasure will be delivered in the FY2012 timeframe.

**Required Delivery Milestone:** A validated countermeasure is required for long-duration Exploration missions.

**Required Platforms:** This study requires ISS crews for countermeasure validation.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>all long duration crews</td>
<td>None</td>
<td>30</td>
<td>30</td>
<td>0.5 hours</td>
<td>None</td>
</tr>
</tbody>
</table>

**Task:**
Understanding back/neck pain etiology
This task is carried under the Risk of Inability to Adequately Treat and Ill or Injured Crew Member – see ExMC gap 4.03.
Risk of Intervertebral Disk Damage

Gaps: (B4) Incidence of intervertebral disk (IVD) damage following spaceflight?

NxPCM
Shuttle Pilot Study (Shackelford Directed Study)

IVD Mechanical CM Study (TED Directed Study)

Data mining for IVD damage (Directed Study)

ExMC (4.03)
Understand back/neck pain etiology

If IVD damage update SFHSS bone standard for soft tissue required, ASAP

CM required for long duration Exploration Missions

If phy or Pharm CM to mitigate risk validated on lunar surface

These studies can utilize the same crew members, thus reducing the total subjects required as shown by the graphic.
RISK OF ORTHOSTATIC INTOLERANCE DURING RE-EXPOSURE TO GRAVITY – CRITICALITY: LUNAR OUTPOST – D, MARS – I

Post-flight orthostatic intolerance, the inability to maintain blood pressure while in an upright position, is an established, space-related medical problem. Countermeasures have been successfully identified and implemented (fluid loading, compression garments) or being evaluated (Midodrine & others). Completion of these efforts will be useful in determining what preventive measures should be used to combat orthostatic intolerance during future mission profiles.

Context of Risk for Exploration

Twenty percent of Shuttle crewmembers and up to 83% of returning ISS crewmembers suffer hypotension and presyncope or syncope during 10 minutes of upright tilt on landing day. This may constitute a risk when crewmembers experience Earth's gravity after exposure to microgravity. Currently available countermeasures are not effective in all crewmembers; in particular, women are more susceptible than men are. While it is well known that crewmembers can be incapacitated by orthostatic intolerance after six-month missions when they return to Earth’s gravity, it is not known the degree to which this may be ameliorated in the gravity environment on the Martian surface. Early surface operations may require astronauts to be upright and active soon after landing on Mars. A combination of countermeasures, both physical and pharmaceutical, should be pursued for this risk. It is not known if exposure to 1/6 g and 3/8 g will cause orthostatic intolerance or will have mitigating effects on orthostatic intolerance upon return to 1 g.

Strategy for Mitigation

Space normal is defined for this risk; hence current research efforts for this risk are investigations for the efficacy of new countermeasures (i.e., Jobst stockings and pharmacological agents). The new lunar analog currently under development will be utilized to understand the role of the lunar gravity as protection from orthostatic intolerance. In addition, gender effects and the possibility for gender specific countermeasures are also being investigated.

Gaps

CV3: Is orthostatic intolerance a potential hazard? This is considered a high priority for HHC, as it remains an issue for ISS and other long duration flights. It is an egress issue, not a vehicle control issue. It is not known if exposure to 1/6 g and 3/8 g will cause orthostatic intolerance or will have mitigating effects on orthostatic intolerance upon return to 1 g.

<table>
<thead>
<tr>
<th>Task</th>
<th>(NxPCM – directed study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midodrine SMO: Test of Midodrine as a Countermeasure against Post-flight Orthostatic Hypotension, SMO-006</td>
<td></td>
</tr>
<tr>
<td>To date, available countermeasures (e.g., G-suit, fluid load) have not sufficiently reduced post-flight orthostatic hypotension. This study is designed to evaluate a new pharmacological countermeasure for protection from post-flight orthostatic hypotension. This project will measure the efficacy of Midodrine in reducing the incidence and/or severity of orthostatic hypotension in returning astronauts. Efficacy will be evaluated with an expanded operational tilt test. The tilt test is used to assess the effects of prolonged weightlessness on orthostatic tolerance during upright posture, as measured by supine and standing heart rate, blood pressure, stroke volume, cardiac output and total peripheral resistance.</td>
<td></td>
</tr>
</tbody>
</table>

| Deliverables: | Not applicable |
| Required Delivery Milestone: | There is no required delivery milestone for this task. |
| Required Platforms: | Not applicable; this study has been discontinued. |
**Task:** (NxPCM – directed study)

**Hypovolemia as a Model of Space Flight: Cardiovascular Effects and Countermeasures**

A hypovolemia model that reproduces the plasma volume loss seen on landing day has been developed utilizing a regimen of a single dose of IV furosemide, followed by 36 hours of a very low salt diet. In the astronauts, this dehydration regimen reproduces the landing day incidence of orthostatic hypotension and presyncope during tilt tests with 100% fidelity. Future work will include testing the utility of this ground-based model by expanding the measurements to include specific hemodynamic and vascular responses, and compare/contrast them with measurements from bed rest studies. Additional activities include validating the Jobst stocking as a method to mitigate orthostatic intolerance on landing day, and examine alternate pressure garments if the Jobst stocking is not validated as a valid countermeasure against orthostatic intolerance. In addition, alternate medications to mitigate orthostatic intolerance (i.e., octreotide) will be examined using the hypovolemic model. Follow on studies could include validating octreotide in the 6° head-down tilt bed rest model and flight validation of octreotide on ISS. VO2max measurements will also be taken using the hypovolemia model. These data will be combined with the VO2 max SMO occurring on-board the ISS.

**Deliverables:** Data will be shared with the HSRF regarding hypovolemia.

**Required Delivery Milestone:** None

**Required Platforms:** This is a ground-based study utilizing hypovolemia as a model to spaceflight-induced changes in plasma volume.

---

**Task:** (NxPCM – NRA)

**Gender Differences in Bed Rest: Autonomic and Neuroendocrine Changes and Vascular Responses in Lower and Upper Extremities**

Although the reasons are undefined, female astronauts are more susceptible to post-flight orthostatic hypotension and presyncope than are male. Due to the lack of cardiovascular bed rest studies that have female participation, many conclusions about the effects of simulated microgravity on humans are flawed, in that they fail to describe mechanisms in the very people who have the most serious problems. This study focuses on how differences in strategies of arterial pressure control in men and women affect orthostatic tolerance both before and after bed rest. Endothelium-dependent, endothelium-independent and adrenergic receptor responses in both arteries and veins will be evaluated, before and after bed rest. In addition, plasma volumes, and hemodynamic and neuroendocrine responses to arterial and cardiopulmonary baroreceptor inputs will be measured, in women versus men, before and after bed rest. Studies have indicated a differential response of different vascular beds in animal studies where hind limb-suspended rats show hypertrophic remodeling of the vessels in their forelimbs and atrophic remodeling in the vessels of their hind limbs. This is thought to occur because changes in transmural pressures and shear forces with hind limb suspension occur in opposite directions in the upper and lower extremities. These studies have not been repeated in female rats, and nothing like this has been performed in humans of either gender. Since humans are bipedal, bed rest would greatly reduce transmural pressures and shear forces in the legs, but not the arms. If vessel-remodeling follows the patterns in humans as in the rats, large changes could occur; this might contribute to orthostatic hypotension after bed rest. Accordingly, the study will repeat the vascular measurements mentioned above in both upper and lower extremities before and after bed rest and relate the findings to the occurrence of orthostatic hypotension.

**Deliverables:** The initial product is space normal data on gender differences with regards to orthostatic intolerance. This information will be used to update the cardiovascular standard to include orthostatic intolerance. If the results indicate that a gender-specific countermeasure is needed, ground-based countermeasure studies will be solicited. When the development is complete the countermeasure will be validated on the ISS and delivered to mission operations. Data gathered from all activities will be fed into lunar surface studies.

**Required Delivery Milestone:** FY2020 – countermeasure delivery required for long duration exploration missions.

**Required Platforms:** Initially this study requires the bed rest ground analog to microgravity. If a gender-based countermeasure is indicated, the countermeasure will be evaluated in the bed rest microgravity analog and the countermeasure will be validated for flight using the ISS. This is a bed rest study to quantify gender-specific changes in orthostatic intolerance. If a gender-specific countermeasure is required, it will be developed in bed rest and validated on board the ISS. This ISS is required as the Mars transit analog.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>None; this is a ground-based study</td>
<td>None; this is a ground-based study</td>
<td>None; this is a ground-based study</td>
<td>None; this is a ground-based study</td>
<td>None; this is a ground-based study</td>
</tr>
</tbody>
</table>
### Task: (EC)
**Evaluation of Compression Garments as Countermeasures to Orthostatic Intolerance**

The goal of this study is to evaluate the effectiveness of JOBST® custom compression garments to prevent orthostatic intolerance and to compare the JOBST® garment with the Anti-Gravity Suit (AGS) at 1 “click” (0.5 psi). Post-spaceflight plasma volume loss contributes, in part, to the development of orthostatic intolerance. Thus, we are modeling this phenomenon by using a hypovolemia regimen, developed in the Cardiovascular Laboratory, which produces plasma volume losses that are similar to those that occur following spaceflight. This study will compare the outcome of orthostatic challenges (head-up tilt test) conducted in hypovolemic subjects in three conditions: 1) no countermeasure, 2) AGS countermeasure (1-click or ~25mmHg) and 3) JOBST® custom compression garment countermeasure (gradient pressure with a higher amount of compression at feet (~55mmHg) than at thigh (~8mmHg) with an average of 25mmHg over the length of the garment).

**Deliverables:** The product from this task is to provide mission operations of requirements for g-suit design.

**Required Delivery Milestone:** ASAP – requirements for g-suit design.

**Required Platforms:** This is a ground-based study utilizing the hypovolemia model.

### Task: (Space Medicine)
**Evaluation of Jobst Gradient Compression Garments as a Countermeasure to Post-Spaceflight Orthostatic Intolerance**

Five male crewmembers from STS-122 participated in a 10-min, 80° head-up tilt after a 13-day mission. On landing day, February 20, 2008, each crewmember donned a pair of Jobst compression garments prior to tilt. Tilt test data obtained from STS-122 crewmembers (47 ± 2 yrs, 180 ± 2 cm, 86 ± 5 kg) were compared with nine male crewmembers who participated in ten-minute post-spaceflight medical operational tilts since NASA’s Return to Flight mission (STS-114) on July 26, 2005.

**Deliverables:** This task is evaluating Jobst pressure garments on crewmembers.

**Required Delivery Milestone:** FY2020 – countermeasure delivery required for long duration exploration missions.

**Required Platforms:** This study utilized Shuttle crews only.

### Tasks:
**Integrated Cardiovascular Study**

See the Risk of Cardiac Rhythm Problems – Gaps CV1 and CV8

**Vestibular-Cerebrovascular Interaction and their Contribution to Post-Spaceflight Orthostatic Intolerance**

This task has been closed out. It was a heritage NRA that did not provide any deliverables for exploration missions.

### CV4: Is 1/6-g exposure protective of 1-g orthostatic tolerance?**

It is unknown if the partial gravity found on the lunar surface will be protective of orthostatic intolerance. A lunar analog should be developed to determine any protective effects.

### Task:
**Lunar Analog Bed Rest Development**

See HHC Infrastructure Section – Gaps HHC1 and HHC2

**Determination of the magnitude and time course of cardiovascular alterations during a simulated extended stay lunar mission**

See HHC Infrastructure Section – Gaps HHC1 and HHC2
Risk of Orthostatic Intolerance During Re-Exposure to Gravity
Gap: (CV3) Orthostatic intolerance is a potential hazard

CM Studies

Plan: select best CM

Are microgravity CM adequate?

Lunar Study N=12

Lunar CM Studies

CM required for long duration exploration missions

(1) Instruct Mission Ops of gender specific methods to prevent CM

(1) Gender based CM to mitigate risk

(1) Phys CM to mitigate risk validated on Lunar surface

Bed Rest N=34

Gender specific CM needed?

NO

YES

Recommended update to CV standard to include CM

NxPCM

Gender Differences (Platts NRA)

Masedoline SMO (Platts Directed Study)

ISS/STIS Study N=10

* These studies are listed multiple times to answer several gaps
Risk of Orthostatic Intolerance During Re-Exposure to Gravity

Gap: CV3 Orthostatic intolerance is a potential hazard

**Hyperolemia Study**

<table>
<thead>
<tr>
<th>EC</th>
<th>SD</th>
<th>NxPCM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate alternate pressure garments</td>
<td>Joint Flight Eval (Platts/Loke, Directed Study)</td>
<td>Integrated Cardiovascular SVS (Bunge/Loke, Directed Study)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pilot</th>
<th>Pre/Post N=16</th>
</tr>
</thead>
</table>

1. Inform mission ops of pressure garments as design solution for G-suit
2. Inform mission ops regarding risk
3. Update SPHERES CV standard
4. Help ops implement CM

**Clinical Support**

**Pass Task to ExMC Gap 4.20**

**332**
Risk of Orthostatic Intolerance During Re-Exposure to Gravity

Gap: (CV4) Is 1.6-g exposure protective of 1-g orthostatic tolerance?

Select best CM

Lunar Bed Rest CM Studies

Lunar CM needed?

Lunar data required for analogue validation

(1) CMs to mitigate risk validated for lunar surface

Lunar Study N=12

Lunar CM Studies

Are microgravity CM adequate?

* These studies are listed multiple times to answer several gaps
The Risks in this part of the Appendix are aligned with Section 2.5 – Provide Adequate Medical Care for the Crew
INABILITY TO ADEQUATELY TREAT AN ILL OR INJURED CREW MEMBER – CRITICALITY: LUNAR OUTPOST – I, MARS – C

Mission architecture limits the amount of equipment and procedures that will be available to treat medical problems. Resource allocation and technology development must be performed to ensure that the limited mass, volume, power, and crew training time be efficiently utilized to provide the broadest possible treatment capability. This allocation must also consider that not all medical conditions are treatable, given the limited resources, and some cases may go untreated.

Operational Relevance and Risk Context

NPD 8900.3G – The immediate and long-term responsibilities of NASA with regard to the human space flight program require that the Agency provide medical and dental care, observation, and study to astronauts, payload specialists, and other space flight participants while on active duty with NASA. This care, observation (to include health monitoring) and study will be provided, utilizing the best current guidelines for the clinical practice of medicine and dentistry, and will be comprehensive in scope as applicable to the NASA mission. It will encompass all aspects related to the mission, including certification and training, and will include all space flight mission phases (pre-, in-, and post-flight).

Strategy for Addressing Risk and Gaps

To address this broad risk, the ExMC has broken it down into seven categories that correspond with the seven requirements allocated to the ExMC from the HRP Program Requirements Document (PRD). Each of the seven categories is then analyzed individually to determine where gaps exist in satisfying the PRD requirements. Below are the seven categories into which the risk has been separated and an explanation of the strategy for addressing the different categories of gaps.

1.0 Validate Standards: The NASA HQ OCHMO standard that pertain to this risk are Crew Selection and Retention Criteria. The Space Medicine Medical Operations Lead for standards, working with the ExMC Element Scientist, determines gaps in knowledge in the current Crew Selection and Retention Criteria. Tasks are then identified to close those knowledge gaps.

2.0 Quantify the Risk: Because of the limited available operational and research data, incidence rates and outcomes for relevant medical conditions have large uncertainties associated with them. The Space Medicine Exploration Condition List is analyzed to determine gaps in our knowledge about medical conditions’ incidence rates and outcomes in spaceflight. Tasks are then assigned to further study, model and use analog population data to better quantify the medical conditions.

3.0 Mitigate the Risk: Gaps in this section deal with our knowledge about effective training and telementoring programs for Exploration missions. The Space Medicine Medical Operations Lead for training, working with the ExMC Element Scientist, determines gaps in knowledge and techniques for developing future crew, flight surgeon and biomedical ground controller training and telementoring programs. Tasks are then identified to close those knowledge gaps.

4.0 Monitor and Treat the Unmitigated Risk: Based on the Space Medicine Exploration Condition List, each condition is analyzed for each Constellation Design Reference Mission (DRM) for the capabilities required to monitor and treat the condition. An analysis is performed to determine where gaps exist in current technologies or where efficiencies could be realized in the future. Based on when a technology comes online, either a technology watch is implemented or a technology development project is initiated to deliver the technology to enable the mission.
5.0 **Provide Enabling Capabilities:** Provide data integration and management for HRP to ensure proper handling of data (e.g., Life Sciences Data Archive, Mission Extended Medical Enterprise). Gaps exist where these capabilities are either insufficient or incomplete.

6.0 **Comply with Agency Standards:** Follow best practices and programmatic guidelines as levied by the HRP PRD. There are currently no gaps associated with this requirement.

7.0 **Reduce Resource Requirements:** Wherever possible, reduce in-flight and funding resources. There are currently no gaps associated with this requirement.

**Gaps**

**ExMC 1.01:** Inadequate and/or immature information on medical screening technology for the identification of clinical and sub-clinical pathology

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC &amp; NSBRI – Directed Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Science and technology watch for medical screening technology</td>
</tr>
<tr>
<td>Identification of technologies and the medical conditions for which additional preflight medical screening has been validated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables: Updates to Medical Standards Working Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required Delivery Milestone: N/A</td>
</tr>
<tr>
<td>Required Platforms: Ground based</td>
</tr>
</tbody>
</table>

**ExMC 1.02:** Inadequate information on genetic screening technology

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC &amp; NSBRI – Directed Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Science and technology watch for genetic screening methodology to inform future implementation</td>
</tr>
<tr>
<td>The Space Medicine Exploration Condition List will be analyzed to determine if some conditions are suitable candidates to be mitigated preflight by genetic screening.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables: Updates to Medical Standards Working Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required Delivery Milestone: N/A</td>
</tr>
<tr>
<td>Required Platforms: Ground based</td>
</tr>
</tbody>
</table>

**ExMC 1.03:** Inadequate information on the individual susceptibility to hypobaric environments (e.g., 7.2-psi lunar habitat)

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC &amp; NSBRI – Directed Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Mining/Identification of characteristics associated with susceptibility to hypobaric environments</td>
</tr>
<tr>
<td>For Exploration environments where crewmembers will be exposed to months of reduced oxygen partial pressure (e.g., 7.2-psi lunar habitat), this study will search to identify and characterize physiological parameters that indicate susceptibility to hypobaric environments to ideally create a Spaceflight Human Health Standard.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables: Individual Susceptibility to Hypobaric Environments Standard 9/01/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required Platforms: Ground based</td>
</tr>
</tbody>
</table>

**ExMC 2.01:** Lack of knowledge about incidence rates, probabilities and consequences relative to LOC/LOM for the medical conditions on the Exploration Medical Condition List

336
Description: One of the major gaps of knowledge with space medicine is quantification of likelihood and consequence of medical conditions that could occur in spaceflight. Total combined duration of human spaceflight is brief and limited. So the body of medical evidence in which to quantify medical conditions is small when compared to terrestrial medicine body of evidence.

The focus of this gap is to generate a list of medical conditions that are of concern for human spaceflight, and provide quantifiable data and rationale backing why the medical condition is of concern.

Tasks: (NASA JSC – Directed Study)

Integrated Medical Model

Due to limited resource volume constraints of the mission designs (including volume, mass, power, crew time, and crew skills), only the most important medical equipment will be stored onboard the space vehicles to diagnose and treat illnesses or injuries. In addition, crew-training time pre-flight is limited to those medical procedures most likely to occur. Because the astronauts are not likely to be trained medical clinicians, their skill level must be considered in the treatment of medical procedures. The likelihood of patient medical conditions occurring along with the required resources (including those listed above) to diagnose and treat the conditions must be analyzed to determine the level of risk to the astronauts in a quantitative manner. This allows management tradeoffs between resources and acceptable risk levels for various mission scenarios. The Integrated Medical Model (IMM) is a Probabilistic Risk Assessment (PRA) simulation to provide this quantitative risk assessment.

Deliverables: Integrated Medical Model v2.0 9/30/2009

Required Delivery Milestone: N/A

Required Platforms: Ground based

Tasks: (NASA GRC – Directed Study)

Integrated Medical Model (GRC simulations)

To enhance the IMM’s capability to adequately forecast medical events of concern, but where supporting information on the rate of occurrence is lacking, development of external simulation modules is used. The external modules integrate more complete knowledge of external and internal contributors to the event to estimate the rate of event occurrence during the exploration class missions simulated in the IMM. Conditions to be modeled require a higher level of fidelity and include those where insufficient space flight data is available and there is no clear correlation to a terrestrial analog. Additionally, medical events with multiple influencing factors, including gravitationally dependent physics, physiological changes during the mission, specific mission demands, vehicle limitations, crew reaction to critical events and interaction of these factors, can also be included in these models as deemed necessary to produce a simulation with adequate accuracy. The results of this analysis contribute significantly to the IMM’s ability to forecast diagnoses and treatment outcomes of an ill or injured crewmember.

Medical events to be model are selected based on the Exploration Medical Capability (ExMC) Project identified gaps and prioritized through consensus of the IMM team (JSC, Wyle, GRC) with concurrence from the ExMC Element Manager and Element Scientist. The current task includes four specific subject areas:

1. Bone (Hip) Fracture during EVA
2. Sleep Disturbance requiring medical intervention
3. Back pain/Lumbar Disk damage
4. Altitude Sickness requiring medical intervention

Additional subject areas are added as required by the project during regular content reviews.

The diverse nature of the topic areas requires interaction with subject matter experts (SME) at JSC, NSBRI, and the external medical community. As part of this task, at least one SME is identified and consulted within each topic area throughout the development of the model to ensure that the most pertinent data is used in the simulation and that the simulation concept is acceptable to obtain the needed information. Although no direct dependency on work in other projects exists, this modeling scheme does allow for integration of new information as it becomes available from these other projects such as Digital Astronaut.

Deliverables: Probability Density Function modules for IMM 9/30/09

Required Delivery Milestone: N/A

Required Platforms: Ground based
ExMC 3.01: Lack of knowledge about effectiveness of NASA medical training programs including crewmember and ground support

| Tasks: Medical Proficiency Training (SHFE) |
| See activity description under Gap SHFE2 |

| Tasks: (NASA JSC) |
| Post-flight Medical crew debrief data mining |
| This effort will look through past ISS medical and training debriefs to consolidate comments or anecdotes made by crewmembers that would influence how medical training was conducted or could be improved. |

| Deliverables: Final report 3/30/2009 |
| Required Delivery Milestone: |
| Required Platforms: Ground based |

ExMC 3.02: Lack of knowledge about the state of the art in telementoring/telemedicine

Description: Telementoring is the delivery of training and mentoring services across telecommunication networks typically in the format of audio and video. As a subset modality of telemedicine, telementoring is focused on providing a means to train operators with the instructor physically located in a remote location. Based on the type of training content, the presentation format may vary. Various formats include teleconference, video conference, or web exchange. Due to the relative novelty of this form of communication, telementoring has only recently started to gain momentum as a means to guide and train remote operators. As such, effective means to communicate and techniques to convey information are constantly under development. This gap is focused on understanding the latest on telementoring technologies and techniques as well as media platform on which the information is presented.

| Tasks: (NASA JSC:IBMP – Directed) |
| Braslet (Duncan) |
| Methodologies and data will be created by the international team of experts that could result in significant new knowledge and capability, enhancing important areas of operational space medicine such as clinical management of volume shifts induced by altered gravity, clinical diagnostic ultrasound in space flight, and telemedicine. Completion of this project will enable further investigations of steady-state space cardiovascular physiology in long-duration space flight. This investigation will develop and validate appropriate methodology for studying cardiovascular responses to disturbances (for example, gravity change, volume overload, hemorrhage and others) using existing ISS resources. Future use of this methodology will yield valuable physiological and operational data for planning and support of missions to the moon and other remote destinations. |

| Deliverables: Validation of novel volume status measurement techniques, expanded telemedicine processes, and recommendations for forward work 5/31/2009 |
| Final Report 5/31/2010 |
| Required Delivery Milestone: |
| Required Platforms: ISS |
### Tasks: (Henry Ford Health System; NASA JSC-NRA)

**Ultrasound Diagnosis of Fracture (Dulchavsky)**

Crewmembers on long duration space missions are at significant risk of decreased bone strength despite countermeasures. The radiographic capabilities of future spacecraft are unknown; however, ultrasound is currently operational on the ISS. Preliminary investigations have shown that ultrasound can reliably diagnose long bone fractures. This proposal will evaluate the accuracy of ultrasound in the diagnosis of bony fractures and develop “just in time” training methods to allow astronauts to perform and interpret skeletal ultrasound to answer the specific aims:

1. Evaluate the diagnostic accuracy of ultrasound for bony fractures and fracture healing in ground-based studies.
2. Develop CMO training programs to facilitate skeletal ultrasound to exclude fracture.
3. Develop remote guidance training programs for the ground cadre.

### Deliverables:

- Feasibility analysis report 6/15/2009
- Space Medicine Training Programs 7/15/2011

### Required Delivery Milestone:

- N/A
- Outpost Medical Kits SRR (6/01/2017)

### Required Platforms:

None

---

### Tasks: (NASA JSC – NRA)

**Identify medical conditions that require telementoring/telemedicine**

A review of applicable medical conditions that require telementoring/telemedicine capability for diagnosis or treatment. Once identified, this will map against the current telementoring practices and condition-specific telementoring gaps will be developed.

### Deliverables:

- Report and Recommendations 8/01/2010

### Required Delivery Milestone:

N/A

### Required Platforms:

Ground based

---

### Tasks: (NASA JSC – Directed)

**Data mining for telementoring studies and practices**

This literature search will examine past NASA telementoring studies as well as studies done by academia and industry to determine best practices for training. This activity is a technology watch.

### Deliverables:

- Final report 3/31/2009

### Required Delivery Milestone:

- Required Platforms: Ground based

---

**ExMC 4.01: Lack of autonomous medical procedure system that includes decision assistance and integrates with medical hardware**

*Description: The current spaceflight procedure system is a combination of both paper and electronic formats. The procedures themselves are developed and validated on the ground. The burden is placed on the crewmember to be able to collect, analyze, and interpret data to decide which procedure decision pathway to follow. This can be an issue with medical procedures as the crewmembers often are not clinicians. They are given minimal medical training often months prior to the start of their mission.*
This gap focuses on reducing the burden of medical data analysis and decision making on the crewmember. An autonomous medical procedure system would assist the crewmember in analyzing and interpreting the medical data collected so that the proper decision pathways are followed.

**Tasks:** (NASA JSC – Directed)

**Advanced Integrated Clinical System – Guided Medical Procedure System**

Due to the limited medical skills and training of the crew, techniques to help the crewmembers perform medical procedures will be required. This will reduce the time required to perform the procedure, allow the crew to refresh their training skills during the mission, and provide the crew with audio and visual information to guide them through the procedure efficiently. This has the possibility to develop into a decision support system. This directed study will help form the requirements and solicitation for future competed efforts.

**Deliverables:**

- Requirements and IT solutions identified 7/1/2009
- Inform Orion MedKit procedure system 7/1/2010
- Inform Lander MedKit procedure system 5/1/2014
- Inform Outpost MedKit procedure system 4/1/2017

**Required Delivery Milestone:**

- Orion Medical Kits SRR (08/01/2010)
- Orion Medical Kits SRR (08/01/2010)
- Lander Medical Kits SRR (07/01/2014)
- Outpost Medical Kits SRR (06/01/2017)

**Required Platforms:** Ground based

**ExMC 4.02: Lack of non-invasive diagnostic imaging capability and techniques to diagnose identified Exploration Medical Conditions**

**Description:** Exploration Medical Conditions requiring this capability are: Fractures, Dislocations, Back Pain, Constipation, Pneumothorax, Urinary retention, dental conditions, eye abrasions and kidney stones.

Due to the normal constraints of spaceflight, most common clinical diagnostic techniques will not be available during exploration missions. That is especially true for imaging diagnostics. Although physicians commonly use X-rays, Magnetic Resonance Imaging (MRI), ultrasound, and other techniques, perhaps only ultrasound may be compatible with spaceflight. Flight surgeons have also requested improved imaging hardware operating in the visible portion of the electromagnetic spectrum to acquire digital images of skin and body orifices. Work under this gap will initially focus on identifying spaceflight medical conditions where imaging-based diagnosis and/or treatment is required, developing an evidence base for determining which technologies are required, and assessing the spaceflight readiness of the identified technologies.

Once the appropriate technologies are identified and readiness determined, the integration lead will develop a plan to not only integrate the technologies to the greatest extent possible, but also the groups working on those technologies. Those groups include GRC, JSC, and ARC, as well as the NSBRI. The integration lead will also identify relevant work being performed with non-NASA funding and leverage NASA work with those efforts.
<table>
<thead>
<tr>
<th>Tasks: (NASA JSC: NSBRI)</th>
<th>Ultrasound Catalog for Autonomous Medical Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop an intuitive ultrasound image cataloging system, which incorporates ground acquired ultrasound whole body images. The catalog will acquire ground based crewmember images to use for medical diagnosis in space. Develop a mathematical coupling model based on existing ground/in-flight ultrasound data that will allow microgravity associated morphometric and topographic changes to be predicted. Assess the ability of non-physician crew medical officers (CMO) to acquire and interpret complex ultrasound examinations autonomously or with remote guidance.</td>
<td></td>
</tr>
<tr>
<td>Deliverables: Image catalog 3/31/2011</td>
<td></td>
</tr>
<tr>
<td>Required Delivery Milestone: Outpost Medical Kits SRR (06/01/2017)</td>
<td></td>
</tr>
<tr>
<td>Required Platforms: Ground based</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC: NSBRI)</th>
<th>Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop portable, fast, easy-to-use ultrasound-based fracture diagnostic system. Develop low-intensity pulsed ultrasound unit for fracture healing to be incorporated into the diagnostic unit. Evaluate the capabilities of the combined diagnostic and therapeutic system. Evaluate combined diagnostic and therapeutic modalities in an animal model.</td>
<td></td>
</tr>
<tr>
<td>Deliverables: TRL 6 system 10/31/2012</td>
<td></td>
</tr>
<tr>
<td>Required Delivery Milestone: Outpost Medical Kits PDR (04/01/2018)</td>
<td></td>
</tr>
<tr>
<td>Required Platforms: Ground based</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks: (NASA GRC – Directed)</th>
<th>Medical Imaging Integration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ExMC's gap is inability to treat an ill or injured crewmember. To that end, both topical and internal images of the body are frequently required to diagnose pathologies. GRC will serve as the ExMC Imaging Integrator. Tasks include organizing an Imaging Roadmap and Summits as necessary to integrate the different participants and imaging activities including: remote guidance, market surveys/watches, requirements based on the patient condition list, managing solicitations, and providing interfaces to NSBRI, major medical centers such as the Cleveland Clinic, the University of Texas Medical Center, Stanford University Hospital, the National Institute of Biomedical Imaging and Bioengineering, and DoD.</td>
<td></td>
</tr>
<tr>
<td>Required Delivery Milestone: N/A</td>
<td></td>
</tr>
<tr>
<td>Required Platforms: None</td>
<td></td>
</tr>
</tbody>
</table>

ExMC 4.03: Lack of capability to treat back/neck pain/injuries
**Tasks:** (NASA JSC – Directed)

Understand back/neck pain etiology

This task focuses on determining the numerous causes of back or neck pain that could occur in spaceflight. This gap associated with this task describes finding a treatment, however there needs to be an effort to determine all the causes of the injury before finding the best methods for treating those causes.

**Deliverables:** Final report 3/31/2009

**Required Delivery Milestone:** N/A

**Required Platforms:** Ground Based

---

**ExMC 4.04: Lack of smart hardware for ventilation with variable oxygenation capability that mitigates localized oxygen build up.**

**Description:** The proper and adequate operation of a ventilation device and variable oxygen delivery is a skill that takes many hours of training. The Crew Medical Officers (CMO) on CxP missions will more than likely be given very limited medical training overall and even more limited training on ventilation and variable oxygen delivery. The training opportunities to teach the CMO on how to operate a ventilator will not be adequate enough to provide terrestrial standard of care during a medical contingency.

The purpose of this Gap is to develop hardware that can assist the caregiver in decision support involved with operating a ventilator and variable oxygen delivery device. The entire smart system will also need to minimize volume, mass, and power consumption. By developing a smart hardware system, this reduces the cognitive burden on the CMO to operate the ventilator thereby reducing the risk of inadequately trained operator. The smart hardware can manage the ventilation of the patient while the CMO can be freed to perform other medical tasks. This also allows CMO training to focus their limited resources on other aspects of their CMO training for tasks that technology cannot overcome.

---

**Tasks:** (NASA JSC – Directed)

Lightweight Trauma Module (ISSP funded)

There has been an ongoing partnership with military and industry stakeholders to develop autonomous medical capabilities. AICS projects have included the Lightweight Trauma Module (LTM) and O2 concentrator requirements research. The US Army is expected to provide the funding needed to complete the development of a deployable version of the LTM with the delivery of test articles for functional and airworthiness certification the following year. In parallel, the submission to the FDA for 510K clearance for the device and the requirements development and design for a version to support the ISS will also be completed.

**Deliverables:** Lightweight Trauma Module

**Required Delivery Milestone:** N/A

**Required Platforms:** Ground Based

---

**Tasks:** (NASA GRC: NSBRI – Solicitation)

O2 Concentrator Development

Development of TRL 6 system to initially be used with the LTM on ISS and then for Lunar Missions.

**Deliverables:** TRL 6 system 3/1/3013

**Required Delivery Milestone:** Initial Orion to ISS ops

**Required Platforms:** Ground Based
Tasks: (NASA GRC – NSBRI Directed)
Evaluation of O₂ concentrators at altitude
Due to variable vehicle cabin pressures, oxygen concentrator performance can be affected by lower pressures. This task will investigate the performance of COTS oxygen concentrators at altitude to determine their effectiveness.

Deliverables: Final report 9/30/2009

Required Delivery Milestone: Orion Medical Kits SRR (08/01/2010)

Required Platforms: Ground Based

Tasks: (NASA GRC – Directed)
Medical Oxygen Fire Safety
Medical treatment during both ISS and exploration missions may require oxygen therapy. Current hardware increases the oxygen content within the cabin, thus increasing the fire hazard. Therefore, ExMC is partnering with DoD to develop and deploy a device that processes cabin air to increase the local oxygen content. While that makes the cabin safer, the localized concentration may still be a fire hazard, particularly given the lack of convection and weak conduction present in spacecraft. This work will rigorously assess the risk associated with oxygen concentrator therapy in an exploration environment.

Deliverables: Final report 11/1/2009

Required Delivery Milestone: Orion Medical Kits SRR (08/01/2010)

Required Platforms: None

ExMC 4.05 – Lack of minimally invasive in-flight laboratory capabilities with limited consumables required for diagnosing identified Exploration Medical Conditions.

Description: Exploration Medical Conditions requiring this capability are: TBD at a FY09 workshop.

Analyzing bodily fluids (urine, blood, saliva) on the lunar surface will reduce launch/return mass/volume and provide the data near real-time in lieu of post-flight results. A system to perform this analysis in flight is necessary to meet these requirements. NASA has conducted several trade studies analyzing hardware available and developed an Excel-based tool to quantify the ability of hardware to meet mission requirements. To reduce system mass and volume, NASA is investigating developing concepts and hardware for reusable systems of this type.

Such miniaturized systems are dependent upon space medical standards and requirements that will be determined based on expert opinion, risk assessments and evidence bases. These standards and requirements are critical for engineering and medically qualifying the appropriate system for remote space applications. Since no in-situ medical diagnostic device that involves blood or urine fluid analysis is currently operational, it will be important to establish that such a device may be operated routinely. In addition to microfluidic processing systems, non-invasive monitoring devices may also be considered.
**Tasks:** (NASA ARC – NSBRI – NRA: HRP – SBIR)

**Lunar Lab Analysis**

Analyzing bodily fluids (urine, blood, saliva) on the lunar surface will reduce launch/return mass/volume and provide the data near real-time in lieu of post-flight results. A system to perform this analysis in flight is necessary to meet these requirements. NASA has conducted several trade studies analyzing hardware available and developed an Excel-based tool to quantify the ability of hardware to meet mission requirements. To reduce system mass and volume, beginning with the FY 2007 SBIR call and the FY2008 budget year, NASA will begin developing concepts and hardware for reusable systems of this type.

Such miniaturized systems are dependent upon space medical standards and requirements that will be determined based on expert opinion, risk assessments and evidence bases. These standards and requirements are critical for engineering and medically qualifying the appropriate system for remote space applications. Since no in-situ medical diagnostic device that involves blood or urine fluid analysis is currently operational, it will be important to establish that such a device may be operated routinely. In addition to microfluidic processing systems, non-invasive monitoring devices may also be considered.

**Deliverables:**
TRL 6 system (Lander) 9/30/2014
TRL 6 system (Outpost) 10/1/2017

**Required Delivery Milestone:**
Lander Medical Kits PDR (07/01/2015)
Outpost Medical Kits PDR (04/01/2018)

**Required Platforms:** Micro-gravity flights

---

**Tasks:** (NASA GRC: NASA ARC: NSBRI – NRA)

**Reusable Laboratory Capability**

This activity was developed in response to the observation that the size of medical kits for all exploration missions would be extremely limited. When that realization was combined with requirements for medical lab testing found in exploration medical operations documents, the need for reusable capability was apparent. The concept was suggested to the element, and was accepted for development.

This task is performed under the auspices of the general laboratory measurement ability task led by the Ames Research Center (ARC).

**Deliverables:**
Inform Lander Lab Analysis downselect decision 9/30/2010
Inform Outpost Lab Analysis downselect decision 3/30/2013

**Required Delivery Milestone:**
Lander Medical Kits PDR (07/01/2015)
Outpost Medical Kits PDR (04/01/2018)

**Required Platforms:** Ground based; Micro-gravity flights

---

**Tasks:** (NASA GRC: NASA ARC: NSBRI)

**In-flight Blood Analysis Technology for Astronaut Health Monitoring**

Development and demonstration of an automated handheld blood count instrument that is capable of performing white blood cell counts on a nanoliter sized blood sample using MEMS technology and is easy for an astronaut to operate. The system should analyze a minimum of 1,000 RBCs and 200 WBCs that correspond to processing sample volume ~50-100 nL of whole blood. The sample volume should be precisely measured 5%. Ability to provide both blood count and differential will be demonstrated.

**Deliverables:** Engineering prototype 9/30/2011

**Required Delivery Milestone:** N/A

**Required Platforms:** Ground based; Micro-gravity flights
ExMC 4.06: Lack of capability to stabilize and treat bone fractures

Description: Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average loss rates of approximately 1% per month. It is unclear whether this bone mineral density will stabilize at a lower level, or continue to diminish. It is also unknown if fractional gravity, present on the moon and Mars would mitigate the loss. This level of bone loss does not create an unacceptable risk of fractures for ISS missions, but longer missions could create higher fracture risk (excerpt from the IRP).

Current casting methods are problematic for the anticipated operation environment during lunar short and long missions. Modifying existing casting methods or identifying a new technology for casting will be essential to meet this gap.

<table>
<thead>
<tr>
<th>Tasks: (TBD – Solicitation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of methods/technologies for treatment of bone fractures</td>
</tr>
<tr>
<td>Technology development effort to address in-flight bone fractures. Future solicitation will not start until FY11.</td>
</tr>
<tr>
<td>Deliverables: TRL 6 system 3/1/2016</td>
</tr>
<tr>
<td>Required Delivery Milestone: Outpost Medical Kits PDR (04/01/2018)</td>
</tr>
<tr>
<td>Required Platforms: Ground based; Micro-gravity flights</td>
</tr>
</tbody>
</table>

ExMC 4.07: Lack of wound care capability to improve healing following wound closure

<table>
<thead>
<tr>
<th>Tasks: (TBD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of methods/technologies for wound care capability</td>
</tr>
<tr>
<td>Technology development effort to address wound care. Future solicitation will not start until FY11.</td>
</tr>
<tr>
<td>Deliverables: TRL 6 system 3/1/2016</td>
</tr>
<tr>
<td>Required Delivery Milestone: Outpost Medical Kits PDR (04/01/2018)</td>
</tr>
<tr>
<td>Required Platforms: TBD</td>
</tr>
</tbody>
</table>

ExMC 4.08: Lack of reusable cold compress and heating pad capability made of suitable spaceflight materials

Description: With longer missions and more labor-intensive tasks expected in the Constellation Program, the likelihood of musculoskeletal injuries such as sprains and strains are expected to increase. Standard terrestrial therapeutic response to treating sprains and strains is to provide cold compress or heat treatment to the affected area. Cold compress and/or heat treatment is desired that can be stowed in its inactive state in the vehicle’s ambient environment, activated to provide the desired therapeutic relief, recharged using available vehicle resources, and restowed in its inactive state for future use.
### ExMC 4.09: Lack of medical suction and fluid containment capability for chest tube and airway management

**Description:** There is currently no medical suction capability that would work in the space operational environment. Medical suction clears the airway, empties the stomach, decompresses the chest, and keeps the operative field clear.

<table>
<thead>
<tr>
<th>Tasks: (TBD – Solicitation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of methods/technologies for medical suction</td>
</tr>
<tr>
<td>Technology development effort to provide medical suction technology. Future solicitation will not start until FY13.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables: TRL 6 system 10/1/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required Delivery Milestone:</strong> Outpost Medical Kits PDR (04/01/2018)</td>
</tr>
<tr>
<td><strong>Required Platforms:</strong> Ground Based</td>
</tr>
</tbody>
</table>

### ExMC 4.10: Lack of rapid vascular access capability to treat identified Exploration Medical Conditions.

**Description:** Exploration Medical Conditions requiring this capability are: TBD

In a medical contingency, the ability to gain access to the patient’s vascular system to provide medications or fluid can be critical. However, the current techniques for rapidly gaining access require training and skill that cannot be afforded to the Crew Medical Officers (CMO).

This Gap is focused on finding technologies or techniques that can allow a minimally trained care provider to safely and rapidly establish vascular access in a patient.

<table>
<thead>
<tr>
<th>Tasks: (TBD – TBD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of methods/technologies for rapid vascular access</td>
</tr>
<tr>
<td>Technology development effort to provide rapid vascular access technology. Future solicitation will not start until FY13.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables: TRL 6 system 10/1/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required Delivery Milestone:</strong> Outpost Medical Kits PDR (04/01/2018)</td>
</tr>
<tr>
<td><strong>Required Platforms:</strong> Ground Based</td>
</tr>
</tbody>
</table>

### ExMC 4.11 – Lack of dental care capabilities (on hold)

**Description:** With the exception of the legacy Center Director’s Fund task, this gap is a placeholder until it is determined whether or not there is a gap in our current capabilities.
**Tasks:** (NASA JSC – JSC Innovative Partnership Program)

Innovative Treatments of Dental Emergencies for Lunar and Exploration Missions

This project is a spinoff of a previously funded JSC Center Director’ Discretionary Fund effort involving microwave interactions with nerve-derived cells, myoblasts, and bacteria. It is currently funded by the JSC Innovative Partnership Program office. It was not selected or reviewed by ExMC or HRP, but does address a gap for the Lunar Outpost DRM.

The lightweight, handheld microwave device to be developed will consist of a focusing antenna capable of killing bacteria implicated in tooth decay, curing proprietary composites for tooth repair and reconstruction as well as killing diseased pulpal tissue (root canal) without harming the healthy tooth and surrounding gum tissue. This technology uses either C-band or Ka-band microwave energy radiated through a specifically designed antenna to sharply focus the beam. Previous studies done at JSC demonstrated that this energy can ablate nerve-derived cells similar to those inside a tooth and, simultaneously, kill any surrounding caries (tooth bacteria).

**Deliverables:** Final Report 3/1/2009

**Required Delivery Milestone:** Outpost Medical Kits PDR (04/01/2018)

**Required Platforms:** Ground Based

---

**Tasks:** (TBD – TBD)

Development of methods/technologies for dental conditions

Technology development effort to provide dental care technology. Future solicitation will not start until FY13.

**Deliverables:** TRL 6 system – 10/1/2017

**Required Delivery Milestone:** Outpost Medical Kits PDR (04/01/2018)

**Required Platforms:** Ground Based

---

**ExMC 4.12: Lack of in situ intravenous (IV) fluid generation capability**

*Description:* Medical operations concepts for both International Space Station (ISS) missions and exploration missions include pharmaceuticals that can only be given intravenously. Additionally, several conditions may require intravenous fluid to maintain hydration and electrolyte balance. Because of the volume and mass that would be required to treat all conditions specified, NASA prefers to generate sterile water for injection in situ on an ad hoc basis. Currently, no proven technology exists that can do this in a spaceflight environment.

*The IntraVenous fluid GENeration (IVGEN) for exploration experiment will develop and conduct a microgravity test of a system capable of generating Sterile Water for Injection (SWIS) and mixing that water with salt to form normal saline according to the standards set by the United States Pharmacopeia.*

**Tasks:** (NASA GRC – HRP)

Medical Water Generation & IV Drug Mixing (IVGen)

Medical operations concepts for both International Space Station (ISS) missions and exploration missions include pharmaceuticals that can only be given intravenously. Additionally, several conditions may require intravenous fluid to maintain hydration and electrolyte balance. Because of the volume and mass that would be required to treat all conditions specified, NASA prefers to generate sterile water for injection in situ on an ad hoc basis. Currently, no proven technology exists that can do this in a spaceflight environment.

The IntraVenous fluid GENeration (IVGEN) for exploration experiment will develop and conduct a microgravity test of a system capable of generating Sterile Water for Injection (SWIS) and mixing that water with salt to form normal saline according to the standards set by the United States Pharmacopeia.
### Medical Water Generation & IV Drug Mixing (IVGen) (cont’d)

**Tasks:** (NASA GRC – HRP)

<table>
<thead>
<tr>
<th>Deliverables:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IVGEN Launch</td>
<td>2/11/2010</td>
</tr>
<tr>
<td>IVGEN Final Report</td>
<td>2/28/2011</td>
</tr>
</tbody>
</table>

**Required Delivery Milestone:**

| N/A |
| Outpost Medical Kits PDR | 04/01/2018 |

**Required Platforms:** ISS

---

**ExMC 4.13:** Lack of lithotripsy or other capability to treat a renal stone

*Description:* *Kidney stone formation and passage has the potential to greatly impact mission success and crewmember health for long duration missions. Alterations in hydration state (relative dehydration) and bone metabolism (increased calcium excretion) during exposure to microgravity may increase the risk of kidney stone formation and it is unclear which mitigation strategy would be the most effective (excerpt from IRP).*

*Given the high probability of kidney stone formation in crewmembers during long duration missions the capability to perform Lithotripsy is highly desirable. Lithotripsy is a medical procedure that uses shock waves to break up stones that form in the kidney, bladder, ureters, or gallbladder.*

---

**Tasks:** (NASA JSC:NSBRI – NRA)

<table>
<thead>
<tr>
<th>Smart therapeutic ultrasound device for mission critical care</th>
</tr>
</thead>
<tbody>
<tr>
<td>The principal, long-term objective of this proposed effort is to develop a smart medical device that would be lightweight, portable, FDA-approved, commercially produced, and capable of addressing a variety of risks described in the Bioastronautics Roadmap. This device would be based upon the platform technology of ultrasound, would potentially incorporate other imaging and therapy modalities, and would not require high skill levels from the user.</td>
</tr>
</tbody>
</table>

| Deliverables: | Engineering prototype 7/31/2012 |
|---------------|---------------------------------
| Required Delivery Milestone: | Outpost Medical Kits PDR (04/01/2018) |
| Required Platforms: | Ground based |

---

**ExMC 4.14:** Lack of efficient medical consumable inventory tracking system that provides data on overall usage and usage rate and integrates securely with vehicle inventory management system

**AND**

**ExMC 4.15:** Lack of medication usage tracking system that includes automatic time stamping and crew identification

*Description:* *When shuttle and ISS medical kits are returned to earth, fewer medical consumables remain in the medical kits than would be expected based on reported use by the astronauts. This gap is significant because the possibility exists that exploration missions could be undersupplied and run the risk of being able to treat an ill or injured crewmember, particularly given the small volume available for the medical kits.*

*Work under this gap will identify current practices, develop controls, processes, and technical solutions to accurately track the inventory of medical consumables including pharmaceuticals*
**Tasks:** (NASA GRC – Directed)

**Consumable Tracking**

When shuttle and ISS medical kits are returned to earth, fewer medical consumables remain in the medical kits than would be expected based on reported use by the astronauts. This is significant because the possibility exists that exploration missions could be undersupplied and run the risk of being able to treat an ill or injured crewmember, particularly given the small volume available for the medical kits.

This task will identify current practices, develop controls, processes, and technical solutions to accurately track the inventory of medical consumables. It is a sister task to the Consumable Tracking Task in gap ExMC 4.16, which tracks the inventory and consumption of medications.

**Deliverables:** TRL 6 system 4/1/2012

**Required Delivery Milestone:** Orion Medical Kits CDR (04/01/2012)

**Required Platforms:** Ground based

---

**ExMC 4.16: Lack of technique or procedure to draw injectable medication into a syringe without bubble formation and deliver medication**

**Description:** Given the possibility that vehicle failures could result in crew needing to remain in Extra-Vehicular Activity (EVA) suits for up to 144 hours, and given that medical operations may need to provide medications via injection during that time, NASA must develop reliable methods for delivering such medications through the EVA suit.

**Key assumptions as part of this effort are that if the crew is in their EVA suits, the cabin atmosphere is likely to be absent, or at a greatly reduced pressure. Such a condition could lead to bubbles in the medication and pharmaceutical freezing.**

**Tasks:** (NASA GRC – Directed, SBIR)

**Injectables**

Given the possibility that vehicle failures could result in crew needing to remain in Extra-Vehicular Activity (EVA) suits for up to 144 hours, and given that medical operations may need to provide medications via injection during that time, NASA must develop reliable methods for delivering such medications through the EVA suit.

Key assumptions as part of this effort are that if the crew is in their EVA suits, the cabin atmosphere is likely to be absent, or at a greatly reduced pressure. Such a condition could lead to bubbles in the medication and pharmaceutical freezing.

**Deliverables:** TRL 6 system 6/1/2011

**Required Delivery Milestone:** Orion Medical Kits PDR (06/01/2011)

**Required Platforms:** Ground based; Micro-gravity flights; ISS

---

**ExMC 4.17: Lack of adequate protection for medications to preserve stability and shelf life**

**Tasks:** (NASA JSC – Directed)

**ISS injectable medication study for Medical Kit Redesign**

ISS funded activity looking at efficient methods for medication injections.

**Deliverables:** Redesigned ISS Medical Kit with new procedures for injectable medications. 9/30/09

**Required Delivery Milestone:** Orion Medical Kits PDR (06/01/2011)

**Required Platforms:** Ground based; Micro-gravity flights; ISS
Description: It is currently unknown how effective the packaging of medications preserves the stability and shelf life of the contents from the effects of spaceflight. Spaceflight adds the elements of microgravity and radiation that are not applicable on the surface of Earth. This Gap seeks to address materials or products that can mitigate spaceflight effects and assist in preservation of medications.

Tasks:
NxPCM: Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)
See description under HRP IRP Gap PH9

ExMC 4.18: Lack of adequate biomedical monitoring capability for Constellation EVA Suits

Description: The crewmembers’ physiological data, if monitored regularly, can indicate to the flight surgeons if there is a medical problem. During EVAs and periodic IVA activities, the flight surgeons need the ability to monitor key physiological signals that indicate the crew’s workload and other physiologic parameters. The current system for donning the sensors is time consuming and inconvenient, requiring shaving, application of electrodes, and signal checks. A more efficient system will save crew time and reduce the overhead of stowing additional supplies. This system will be achieved through the integration of small, easy to use biomedical sensors that will have the ability to measure, store and transmit physiologic parameters during operational and ambulatory scenarios. Such a system would also provide a wealth of data for the medical and research communities. Coordination with the HHC element for an overall medical and research biomedical sensing plan will occur.

Tasks: (NASA ARC – Directed, SBIR)
Biomedical Sensors (EVA)
The crewmembers’ physiological data, if monitored regularly, can indicate to the flight surgeons if there is a medical problem. During EVAs and periodic IVA activities, the flight surgeons need the ability to monitor key physiological signals that indicate the crew’s workload and other physiologic parameters. The current system for donning the sensors is time consuming and inconvenient, requiring shaving, application of electrodes, and signal checks. A more efficient system will save crew time and reduce the overhead of stowing additional supplies. This system will be achieved through the integration of small, easy to use biomedical sensors that will have the ability to measure, store and transmit physiologic parameters during operational and ambulatory scenarios. Such a system would also provide a wealth of data for the medical and research communities. Coordination with the HHC element for an overall medical and research biomedical sensing plan will occur.

Deliverables: Final requirements for EVA suits 10/1/2010
Required Delivery Milestone: EVA Suit 2 SRR (03/01/2011)
Required Platforms: Ground based

Tasks: (NASA JSC: NASA ARC: NSBRI)
Noninvasive Biosensor Algorithms for Continuous Metabolic Rate Determination
Develop and validate algorithms to accurately calculate VO2 from NIR spectra collected from muscle
Develop and validate algorithms to simultaneously calculate muscle temperature
Support incorporation of the sensor algorithms into the EVA suit testing for noninvasive continuous metabolic rate assessment during lunar EVA.

Deliverables: TRL 6 system 9/30/2011
Required Delivery Milestone: EVA Suit 2 PDR (08/01/2012)
Required Platforms: Ground based
ExMC 4.19: Lack of definition of biomedical monitoring requirements for performing periodic clinical status evaluations

<table>
<thead>
<tr>
<th>Tasks: (NASA ARC – Directed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical Sensors (IVA)</td>
</tr>
<tr>
<td>The crewmembers’ physiological data, if monitored regularly, can indicate to the flight surgeons if there is a medical problem. During periodic IVA activities, the flight surgeons need the ability to monitor key physiological signals that indicate the crew’s workload and other physiologic parameters. The current system for donning the sensors is time consuming and inconvenient, requiring shaving, application of electrodes, and signal checks. A more efficient system will save crew time and reduce the overhead of stowing additional supplies. This system will be achieved through the integration of small, easy to use biomedical sensors that will have the ability to measure, store and transmit physiologic parameters during operational and ambulatory scenarios. Such a system would also provide a wealth of data for the medical and research communities. Coordination with the HHC element for an overall medical and research biomedical sensing plan will occur.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverables:</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRL 6 system (Lander) 3/1/2015</td>
</tr>
<tr>
<td>TRL 6 system (Outpost) 12/1/2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Delivery Milestone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lander Medical Kits PDR (07/01/2015)</td>
</tr>
<tr>
<td>Outpost Medical Kits PDR (04/01/2018)</td>
</tr>
</tbody>
</table>

| Required Platforms: Ground based, NEEMO |

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC, NASA ARC – SBIR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunar Health Monitor: A Wearable System to Monitor Astronaut Health Status (Orbital)</td>
</tr>
<tr>
<td>Deliverables: Prototype 6/1/2010</td>
</tr>
</tbody>
</table>

| Required Delivery Milestone: Lander Medical Kits PDR (07/01/2015) |

| Required Platforms: Ground based |

<table>
<thead>
<tr>
<th>Tasks: (NASA JSC, NASA ARC – SBIR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lightweight, Wearable Metal Rubber-Textile Sensor for In-Situ Lunar autonomous Health Monitoring (NanoSonic)</td>
</tr>
<tr>
<td>Deliverables: Prototype 6/1/2010</td>
</tr>
</tbody>
</table>

| Required Delivery Milestone: Lander Medical Kits PDR (07/01/2015) |

| Required Platforms: Ground based |
Tasks: (NASA JSC, NASA ARC – SBIR0)
Wearable Health Monitoring Systems (Nyx)

To build a working prototype of the wearable health monitoring system that will demonstrate:
- the integration of medical sensors, electrodes, electrical connections, circuits, and power supply into a single wearable assembly to simplify donning and doffing
- the distribution of electrical circuits around the human torso to reduce bulk and enable it to be worn underneath an LCVG
- the facility to easily replace electrodes used to attach to the skin
- the ability to measure biological sensor data and transmit it to an external computing device
- the simplicity of adding medical sensors to the system through use of a digital data-bus to reduce overall wiring count.

Deliverables: Prototype 6/1/2010

Required Delivery Milestone: Lander Medical Kits PDR (07/01/2015)

Required Platforms: Ground based

ExMC 5.01: Lack of medical data management infrastructure for Exploration Missions

Description: In spaceflight, there is a large amount of data generated to understand and monitor the health and safety of the crewmember. Because of the large volume of data, a data management infrastructure needs to be deployed to allow users access to the data. The system needs to be available, secure, and ensure data integrity. This way users can gain valuable insight into health and safety of the crew to maintain their health status and ensure mission success.

Tasks: (NASA JSC – Directed/Infrastructure)
Mission Medical Information System

Incorporate medically relevant information into a database system for use in operations as well as for research support. The data sources to be incorporated include MRID’s as well as other mission data. Currently the data resides on an FTP server, in flight surgeon files, some in the Electronic Medical Record (EMR), and some in the Longitudinal Study of Astronaut Health (LSAH) database. Structured data sources such as the EMR and LSAH will not be duplicated, but rather joined. Effort refocused to get data into structured form first and then work on data entry at the point of collection. Effort is co-funded 50/50 with Crew Health and Safety.

Deliverables: Operational system 9/30/09

Required Delivery Milestone: N/A

Required Platforms: Ground based

Tasks: (NASA JSC – Directed/Infrastructure)
Life Sciences Data Archive (JSC)

NASA's Life Sciences Data Archive (LSDA) is a web-based, active archive that is continually updated with information and data from space flight experiments funded by the NASA. The archive includes investigations from 1961 (Mercury Project) through current missions (ISS and Shuttle) involving human, plant and animal subjects. Effort includes a process to streamline access while protecting confidentiality.

Deliverables: Information and data provided via the LSDA public and restricted web-based databases

Required Delivery Milestone: N/A

Required Platforms: Ground based
<table>
<thead>
<tr>
<th><strong>Tasks:</strong></th>
<th>(NASA ASC – Directed/Infrastructure)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Life Sciences Data Archive (JSC)</strong></td>
<td>NASA’s Life Sciences Data Archive (LSDA) is a web-based, active archive that is continually updated with information and data from space flight experiments funded by the NASA. The archive includes investigations from 1961 (Mercury Project) through current missions (ISS and Shuttle) involving human, plant and animal subjects. Effort includes a process to streamline access while protecting confidentiality.</td>
</tr>
<tr>
<td><strong>Deliverables:</strong></td>
<td>Information and data provided via the LSDA public and restricted web-based databases</td>
</tr>
<tr>
<td><strong>Required Delivery Milestone:</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Required Platforms:</strong></td>
<td>Ground based</td>
</tr>
</tbody>
</table>
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

1.0 Inform Crew Selection and Retention Criteria

Gap: (ExMC 1.01) Inadequate and/or immature information on medical screening technology for the identification of clinical and sub-clinical pathology

ExMC Science and Technology watch for medical screening technology

Coordination with HHC, BHP, and SRP on evidence for selection criteria

Gap: (ExMC 1.02) Inadequate information on genetic screening technology

ExMC Science and Technology watch for genetic screening methodology to inform future implementation
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- Identification of TBED characteristics associated with hypobiotic environments
- Selection of hypobiotic environments

Decision Tree:
- Minimize dose to environment
- NO
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
- YES
-YES
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

2.0 Quantify Risk

Gap: (ExMC 2.01) Lack of knowledge about incidence rates, probabilities and consequences relative to LOGLOM for the medical conditions on the Exploration Medical Condition List

ExMC/Integrated Medical Model

ExMC/Integrated Medical Model

GRC Simulations

Statistical & Clinical Validation

Validated Model available for MedOps planning

Additional models to reduce uncertainty in HMM incidence rates
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

1. Mitigate Risk

1. CEV Training Program development starts

2. Lander Training Program development starts

1. (1) Inform CEV Medical training

2. (2) Inform Lander Medical training

Develop integrated procedure and training process to optimize emergency medical response.

Inform SHFE study

Provide report to HRP Elements
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

0 Mitigate Risk

- ExMC3.02 Lack of Knowledge about the state of the art in telementoring/telemedicine

- Ultrasound Diagnosis of Fracture (Ducharsky)

- Identify medical conditions that require telementoring/telemedicine

- ExMO/Data Mining for Telementoring studies and practices
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- Monitor and Treat
- Mitigated Risk

ExMC: (ExMC 4.01) Lack of autonomous medical procedure system that includes decision assistance and integrates with medical hardware

ExMC/Advanced Integrated Clinical System - Guided Medical Procedure System
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- (ExMC 4.03) Lack of capability to treat back/neck injuries
- ExMC/Understand back/neck pain etiology

Is it a problem that requires a technology solution?

HHC/E4
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- (ExMC 4.04) Lack of smart hardware for ventilation with variable oxygenation capability that mitigates carbon dioxide and oxygen build up.

- ISS/Lightweight Trauma Module (ISS funded)

- NSERI or SBIR/O2 Concentrator Development

- NSERI/Evaluation of O2 concentrators at altitude (Johannesburg)

- ExMO/Medical Oxygen Fire Safety
### Shuttle Capability

<table>
<thead>
<tr>
<th>Program Level</th>
<th>SR</th>
<th>CDR - Initial Ops</th>
<th>PDR</th>
<th>CDR</th>
<th>Full Ops Capability</th>
<th>Human Lunar Return</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orion</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVA Suit</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lander</td>
<td>ATP</td>
<td>SRR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mission Operations</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Risk of Inability to Adequately Treat an Ill or Injured Crew Member

1. **(ExMC 4.06) Lack of capability to stabilize and treat bone fractures**

   - ExMC/Development of methods/technologies for treatment of bone fractures
   - NSBRI/Combined Scanning
   - Confocal Ultrasonic Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing (Cir)

2. **(ExMC 4.07) Lack of wound care capability to improve healing following wound closure**

   - ExMC/Development of methods/technologies for wound closure
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- \( \text{(ExMC 4.08) Lack of reusable cold compress and heating pad capability made of suitable spaceflight materials} \)
  - ExMC/Development of methods/technologies for providing cold compress and heating pad capability

- \( \text{(ExMC 4.09) Lack of medical suction and fluid containment capability for chest and airway management} \)
  - ExMC/Development of methods/technologies for medical suction

- \( \text{(ExMC 4.10) Lack of rapid vascular access capability to treat identified exploration medical conditions} \)
  - ExMC/Development of methods/technologies for rapid vascular access

---

365
### 8 Shuttle

<table>
<thead>
<tr>
<th>8 Crew Capability</th>
<th>A</th>
<th>A</th>
<th>Shuttle Retired</th>
<th>A</th>
<th>End of US Commitment</th>
</tr>
</thead>
</table>

#### Program Level
- **SRR**: Initial Ops
- **PDR**: CDR
- **CDR**: Full Ops Capability

#### Orion
- **PDR**: Out1
- **CDR**: Out1

#### EVA Suit
- **PDR**: Out2
- **CDR**: Out2

#### Lander
- **ATP**:
- **PDR**: CDR

#### Mission Operations
- **PDR**: Int Cap
- **CDR**: Int Cap

#### Medical Kits/Systems
- **SRR**: CDR
- **PDR**: CDR
- **Outpost**: CDR

---

**Risk of Inability to Adequately Treat an Ill or Injured Crew Member**

- **ExMC 4.11**: Lack of dental care capabilities (on hold)
- **ExMC/Development of**: Innovative treatments of dental emergencies for Lunar and Exploration Missions
- **ExMC/Development of**: Methods and technologies for dental conditions

---

**Final Report**

**Outpost Medical Kit PDR**

**Ongoing Tech Watch**: Solicit

**HW devt**: (1) Technology at TRL 6
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- (ExMC 4.12) Lack of in situ venous (IV) fluid generation capability
- (ExMC 4.13) Lack of lithotripsy or other capability to treat a renal stone

ExMOMedical Water Generation & IV Drug Mixing (IVGen)

NSDR/Smart therapeutic ultrasound device for mission critical care (Crum)

HRP-47

367
### Risk of Inability to Adequately Treat an Ill or Injured Crew Member

- **(ExMC 4.14)** Lack of efficient medical consumable inventory tracking system that provides data on overall usage and usage rate and integrates securely with vehicle inventory management system.
- **(ExMC 4.15)** Lack of medication usage tracking system that includes automatic time stamping and identification.

#### ExMC/Consumables Tracking

- HHC/PH1, PH2
- BHP/Sleep5, Sleep7

#### Orion Medical Kit

- PDR

#### Mission Operations

- PDR-outcap
- CDR-outcap

#### Shuttle Retired

- Full Ops Capability

#### End of US Commitment

<table>
<thead>
<tr>
<th>Program Level</th>
<th>SRR</th>
<th>CDR: Initial Ops</th>
<th>PDR</th>
<th>CDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orion</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVA Suit</td>
<td>PDR</td>
<td>CDR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lander</td>
<td>ATP</td>
<td>SDR</td>
<td>PDR</td>
<td>CDR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Medical Kits/Systems

- Orion Med Kit
- PDR
- (1) Technology at TRL 5
- Inform Solution for ISS

---

368
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

p: (ExMC 4.16) Lack of technique or procedure to draw injectable medication into a syringe without bubble formation and deliver medication

ExMC/Injectables

ISSP/Injectable medication study for ISS Medical Kit
Redesign

p: (ExMC 4.17) Lack of adequate protection for medications to preserve stability and shelf-life

ExMC/Development of methods/technologies for medication stability and shelf-life

MPC/S/Pharmacotherapeutics and Nutritional Compounds: Stability and Shelf Life

Does spaceflight affect stability and shelf-life?

Tech watches, downselect studies and/or provide TRL 6 technology to meet Space Medicine Requirements.
Risk of Inability to Adequately Treat an Ill or Injured Crew Member

p: (ExMC 4.19) Lack of definition of biomedical monitoring requirements for performing periodic medical status evaluations

ExMC/Biomedical Sensors (IVA)

SBIR/Lunar Health Monitor: A Wearable System to Monitor Astronaut Health Status (Orbital)

SBIR/Lightweight, Wearable Metal Rubber Textile Sensor for In-Situ Lunar Autonomous Health Monitoring (NamSonic)

SBIR/Wearable Health Monitoring Systems (Nyx)

Utilize ISSP to certify or continue to pursue III for more development
**RISK OF THERAPEUTIC FAILURE DUE TO INEFFECTIVENESS OF MEDICATION – CRITICALITY: LUNAR OUTPOST – D, MARS – I**

Based on subjective reports, drugs are effective during space flight. Better record keeping of medication use, efficacy, and side effects will be instituted and those records will provide evidence for or against this risk. If medications are found to be ineffective, research will be performed to determine if drug metabolism is affected by space flight. Studies to determine if space flight affects drug stability are currently underway.

**Context of Risk for Exploration**

Better recordkeeping of medication use, efficacy, and side effects should be instituted. This will provide evidence for or and should be a precursor to a formal assessment of PK/PD on orbit. It is thought that the reduction in gastrointestinal (GI) motility and function, offered as the first piece of evidence for this gap, is not an issue after the first few days of flight. In general, SD avoids prescribing oral medications during this period of the mission. It is not known to what extent different volumes of distribution might be a factor in flight. Drugs selected for the PK/PD studies should be commonly used, have few side effects, and different metabolic pathways. External consultants should be used to determine which drugs to test and to design testing protocols. SD needs to develop a process and procedures to track systematically crew medication use, including subjective comments on efficacy and side effects, particularly for ISS. It is particularly important to know what pharmaceuticals are taken prior to in-flight tasks.

**Strategy for Mitigation**

The overarching strategy for this risk is to obtain better record keeping of medication use, efficacy, and side effects. This includes several data mining tasks that will provide evidence for or against this risk. If there is evidence indicating ineffectiveness of medications, a pharmacokinetics/pharmacodynamics study will be performed in flight to obtain further information.

**Gaps**

**PH6: Can a standard procedure for prospective analyses of drugs to be considered for flight and periodic analyses of drugs that are used for flight be developed?** A Pharmacy and Therapeutics Committee should be formed.

**PH10: What are the performance effects of in-flight drugs on exercise, orthostatic tolerance, motor control, cognitive function, etc?** Much of this information is available in the literature and should be synthesized. New studies should be undertaken only when there is no existing data or the existing information is not relevant. This effort should be cross-disciplinary and should employ the simplest monitoring techniques possible to identify performance issues.

**CV6: What influence does in-flight medication use have on physical and cognitive performance?**

This has not systematically documented. Much of this information is available in the literature and should be synthesized. New studies should be undertaken only when there is no existing data or the existing information is not relevant. This effort should be cross-disciplinary and should employ the simplest monitoring techniques possible to identify performance issues.
**Task:** (NxPCM – via directed study)
**Terrestrial Drug Database Review – Data Mining TBD**

**Deliverables:** The product from this task will be to recommend changes in medication tracking to Flight Medicine.

**Required Delivery Milestone:** There are no required delivery milestones for this task.

**Required Platforms:** Access to necessary pharmacological and Space Medicine databases is required.

**PH7: What are the effects of spaceflight on pharmacokinetics/pharmacodynamics?** Subjective reporting indicates that many drugs are effective in flight. There has been little documentation of the ineffectiveness of drugs. Better recordkeeping of medication use, efficacy and side effects should be instituted. This will provide evidence for or against this gap, and should be a precursor to a formal assessment of PK/PD on orbit. It was thought that the reduction in gastrointestinal (GI) motility and function, offered as the first piece of evidence for this gap, was not an issue after the first few days of flight. In general, Flight Medicine avoids oral medications during this period of the mission. It was not known to what extent different volumes of distribution might be a factor in flight. Drugs selected for the PK/PD studies should be commonly used, have few side effects, and different metabolic pathways. External consultants should be used to determine the test and to design testing protocol.

**Task:** (NxPCM – via NRA)
**Bioavailability and Performance effects of Promethazine (PMZ) during spaceflight**
Promethazine is currently given to treat motion sickness during Shuttle missions. The side effects associated with PMZ include dizziness, drowsiness, sedation, and impaired psychomotor performance. Anecdotal reports from crewmembers indicate that these central nervous system side effects of PMZ are absent or greatly attenuated in microgravity. Recent reviews of medical debriefs indicate that, at least in some crewmembers, there are significant central nervous system depressant effects. In addition, the pharmacokinetics and bioavailability of medications administered in microgravity may be different from on Earth, which could significantly alter drug efficacy, as well as, the severity of side effects for a given dosage. This study will systematically evaluate PMZ bioavailability, effects on performance, side effects, and efficacy in the treatment of motion sickness to determine optimal dosage and best route of administration of PMZ in flight.

**Deliverables:** The product is a completed study and report findings.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** Space Shuttle is required for assessing spaceflight effects of PMZ.

**Task:** (NxPCM – via directed study)
**Drug Efficacy Data Mining**
This task will review the available pharmacokinetic/pharmacodynamic data from previous missions to develop and understanding of the bioavailability and uptake of pharmaceuticals in a microgravity environment. If results indicate drugs are ineffective, flight studies will be initiated to examine PK/PD.

**Deliverables:** Initial product is a final report of findings. If results indicate that drug effectiveness is diminished in flight, ISS pharmaceutical PK/PD studies will be solicited and performed.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** Access to Flight Medicine, JSC Biomedical Research Laboratory data, and LSDA databases is necessary for the data mining study. ISS is required as the Mars transit analog for in-flight PK/PD studies and for countermeasure validation.
**Task:** (NxPCM – via NRA)

Methods for the Assessment of Gastrointestinal Physiology and Function in a Lunar Analog Environment (Smart Pill)

New capsule endoscopy technology provides a direct measurement of GI transit time as well as GI pH, monomotry and temperature. The effects of altered GI function on the behavior of ingested content have also never been studied. Disposition profiles of drugs like acetaminophen (APAP) serve as effective markers for gastric emptying and absorption. We propose to evaluate influence of reduced gravity on GI function using the SmartPill® technology.

**Deliverables:** Initial product is a final report of findings. If results indicate that drug effectiveness is diminished in flight, ISS pharmaceutical PK/PD studies will be solicited and performed.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** In order to measure GI transit time in microgravity; this task requires head down tilt bed rest. It is an add-on to ongoing bed rest campaigns.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Task:** (NxPCM – via NRA)

Stability of Pharmacotherapeutic and Nutritional Compounds: Stability SMO (Flight)

The experiment design consists of a protocol that involves investigative physical/chemical analyses of both medications and food items returned from STS and ISS along with corresponding lot-matched controls stored on ground in a controlled environment. This experiment has 2 sub-payloads attached to it. See the Risk of Inadequate Nutrition for the nutrition sub-payload information. The Pharmacology Sub-Payload will identify pharmaceutical preparations at risk for degradation that are used by astronauts during space missions; characterize degradation profiles of the unstable formulations after exposure to ISS environment; and compare and contrast stability of ISS flown medications to their matching controls from the same lot and commercial packing conditions. This study will provide critical information about the susceptibility of vitamins in the space food system to adverse environmental factors and storage encountered during space missions.

**Deliverables:** Results from this task will be delivered to the HSRF to discuss altered gravity’s effect on GI transit time.

**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** In order to measure GI transit time in lunar gravity; this task requires a lunar analog. It is an add-on to ongoing lunar bed rest campaigns.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**PH9:** What is the effect of long-term spaceflight on drug stability and what measures can be employed to extend the duration of drug efficacy?

**Task:** (NxPCM – via directed study)

Methods for the Assessment of Gastrointestinal Physiology and Function in a Lunar Analog Environment (Smart Pill)

New capsule endoscopy technology provides a direct measurement of GI transit time as well as GI pH, monomotry and temperature. The effects of altered GI function on the behavior of ingested content have also never been studied. Disposition profiles of drugs like acetaminophen (APAP) serve as effective markers for gastric emptying and absorption. We propose to evaluate influence of reduced gravity on GI function using the SmartPill® technology.

**Deliverables:** Data for this task will be delivered to the Flight Medicine. In addition, data will be shared with ExMC for their gap 4.18.
**Required Delivery Milestone:** There is no required delivery milestone for this task.

**Required Platforms:** ISS required for proper radiation doses on pharmaceutical samples.

---

**Task:**

*Development of methods/technologies for medication stability and shelf-life*

This task is being conducted by ExMC; see the Risk of Inability to Adequately Treat and Ill or Injured Crew Member gap ExMC 4.18 for details.

---

**PH1: Inadequate tracking of medication use, indication, efficacy, and side effects**

**PH3:** What training methods and reference documents should be employed for training the crew and medical team to identify and mitigate side effects and interactions of commonly used medications? These two gaps have been transferred to ExMC; see the Risk of Inability to Adequately Treat and Ill or Injured Crew Member gap ExMC 4.15, 4.16 for further information.
Risk of Therapeutic Failure Due to Ineffectiveness of Medication

Gaps: (PH7) What are the effects of spaceflight on pharmacokinetics/pharmacodynamics?

NXPCM PMZ (Putcha, NRA)
NXPCM Smart Pill (Putcha, NRA)
NXPCM Smart Pill (Putcha, NRA)

Gap: (PH9) Stability of drug during long-duration spaceflight

ExMC Gap 4.18 Development of methods/techniques for medication stability and shelf-life

ISS Study

Lunar on
bed rest on

YES

NO

Drugs ineffective?

In-flight PK/PD Study

Provide info to BHP gaps 2.2.2, 2.2.3

(1) Recommended changes to Flight Medicine

Stability SMO (Putcha, Directed Study)

Ongoing Tech Watch, Solid, HAN devt

(1) Technology at TRL 6

(1) Recommended changes to Flight Medicine

PMZ (Putcha, NRA)
**Risk of Therapeutic Failure Due to Ineffectiveness of Medication**

Gaps: (PH6) Develop standard procedure for prospective analysis for proposed drugs for flight; (CV6) Influence of in-flight medication use on physical and cognitive performance is not systematically documented; (PH10) What are the performance effects of in-flight drugs on exercise, orthostatic intolerance, motor control, cognitive function, etc?

**Data Mining: Terrestrial Drug Database review**

- **Dev Proc:**
  - (1) Recommended changes to Flight Medicine
HUMAN HEALTH COUNTERMEASURES INFRASTRUCTURE

**HHC1: Can partial gravity be simulated on Earth?** In order to begin determining the lunar gravity’s effects on human physiology, a ground-based analog should be developed.

**HHC2: How does 1/6-g and 3/8-g influence countermeasures?** It is unknown how the lunar and Martian gravities will affect current spaceflight countermeasures. Utilizing a ground analog for different gravities, the gravitational effects can be measured.

**Tasks:** (FAP – via directed study)

**Lunar Analog Bed Rest Development**

This study is for the development of a lunar analog. These lunar mission simulations may or may not include (~3 day) transit phases between Earth and Moon. While it may be useful to simulate some impacts of (7-14 day) sortie missions, the primary focus will be on longer, outpost missions; thus, simulation durations will generally range up to 90 days.

**Deliverables:** Lunar analog

**Required Delivery Milestone:** This task mitigates a risk to a long-duration lunar and Mars missions.

**Required Platforms:** This effort is ground-based analog development, developing a lunar analog model. The model will not be validated until lunar surface mission ops begin the in the 2020 timeframe.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Tasks:** (ECP – via directed study)

**Lunar EVA Study – TBD**

ECP with input from EPSP will develop a lunar analog simulation paradigm that will be an add-on to the FAP lunar bed rest research platform. This simulator will take into consideration EVA operations scenarios as well as the aerobic and resistive stress induced by lunar EVA. This study will evaluate the role that EVA will have, if any, in protecting muscle function, bone health and aerobic capacity. There after ECP will sponsor studies that aim to identify exercise countermeasures that are required in addition to lunar EVA in order to maintain astronaut health and mission performance.

**Deliverables:** This task will determine if proposed lunar EVA activities are protective for muscle and cardiovascular performance. If it is determined that lunar EVA tasks are not protective further lunar countermeasures studies will be conducted.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration lunar and Mars missions.

**Required Platforms:** Lunar Bed Rest add-on

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Tasks: (NxPCM – via NRA)

**Determination of the magnitude and time course of cardiovascular alterations during a simulated extended stay lunar mission**

The effects of this level of hypovolemia on cardiac function and orthostatic tolerance are not clear. We propose to study the time course of the fluid shifts and plasma volume losses experienced during a simulated trip to, and extended habitation on, the Moon. Additionally, we propose to evaluate the effect of this volume change on cardiac function using newer preload-independent echocardiographic techniques. By acquiring daily measurements during the transitional phases of changing gravitational levels, we plan to validate the current computational model and further quantify the crew health and performance risks associated with extended duration missions to the Moon and other partial Earth gravity environments.

**Deliverables:** The deliverable from this task will be to inform the Human System Risk Forum of any protective effects from lunar gravity on the cardiovascular system. If the data indicate lunar gravity is not protective, then additional countermeasure development studies may be pursued.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration lunar and Mars missions.

**Required Platforms:** This is an add-on task to the Lunar Analog Pilot Study.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Tasks: (ECP – via NRA)

**Thermoregulatory Capacity and Exercise Responses Following Prolonged Lunar Analog Bed Rest**

The studies proposed in this application will examine the effect of a Lunar Analog Bed Rest (LABR) model on exercise capacity, thermoregulatory function during exercise and the effects of combined thermal and exercise challenge on cardiovascular responses during prolonged sub-maximal exercise. In addition, the effectiveness of an exercise-countermeasure throughout bed rest, on expected thermal and cardiovascular alterations, will be investigated. The following hypotheses will be tested: 1) prolonged LABR impairs exercise-thermoregulation, 2) prolonged LABR reduces exercise capacity and augments cardiovascular strain during exercise-heat stress, and 3) an exercise-countermeasure throughout LABR will preserve thermoregulatory responses and exercise capacity associated with LABR. These data will provide valuable insight into the effects of partial gravity associated with lunar living and the potential impact on safety and success of exploratory missions, with focus on both the short-duration (2 week) Lunar sortie and long-duration Lunar Outpost.

**Deliverables:** The deliverable from this task will be to inform the Human System Risk Forum of any protective effects from lunar gravity on the cardiovascular system.

**Required Delivery Milestone:** This task mitigates a risk to a long-duration lunar and Mars missions.

**Required Platforms:** This is an add-on task to the Lunar Analog Pilot Study.

<table>
<thead>
<tr>
<th># of Subjects</th>
<th>Initial Upmass (kg)</th>
<th>Upmass (kg/subject)</th>
<th>Downmass (kg/subject)</th>
<th>Crew Time/Subject</th>
<th>Post-Flight BDC Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
APPENDIX B:

TECHNICAL READINESS LEVELS (TRL)
Definition of Technical Readiness Levels (TRL)

**TRL-1** Basic principles observed

**TRL-2** Technology concept and/or application formulated

**TRL-3** Analytical and experimental critical function/proof-of-concept

**TRL-4** Component and/or breadboard validation in lab

**TRL-5** Component and/or breadboard in relevant environment

**TRL-6** System/subsystem model or prototype demonstration in relevant environment

**TRL-7** Subsystem prototype in a space environment

**TRL-8** System completed and flight qualified through demonstration

**TRL-9** System flight proven through mission operations