HRP-47052

Revision A

# Human Research Program Requirements Document

# Human Research Program

## Revision A

**July 2007**

National Aeronautics and Space Administration

Johnson Space Center

Houston, Texas

Verify that this is the correct version.

# Human Research Program Requirements Document July 2007

## PREFACE

## HUMAN RESEARCH PROGRAM REQUIREMENTS DOCUMENT

This document is the Human Research Program Requirements Document. The purpose of this document is to define, document, and allocate HRP requirements. The need to produce a Program Requirements Document (PRD) 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:

| | |
|---|---|
| *Original signature on file.* | *7/16/07* |
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HRP-47052

Revision A

# Human Research Program
# Requirements Document
# July 2007

## CONCURRENCE

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## REVISION AND HISTORY PAGE

| REV. | DESCRIPTION | PUB. DATE |
|---|---|---|
| Baseline | Initial Release (Reference per SLSDCR-HRPCB-07-006, EFF. 05-15-07) approved by the HRPCB | 05-15-07 |
| Rev A | Revision (Reference per SLSDCR-HRPCB-07-033, EFF. 07-03-07) approved outside-of-board by the HRPCB chair. | 07-03-07 |
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# 1. INTRODUCTION

## 1.1 PURPOSE

The purpose of this document is to define, document, and allocate the Human Research Program (HRP) requirements to the HRP Program elements. It establishes the flow-down of requirements from Exploration Systems Mission Directorate (ESMD) and Office of the Chief Health and Medical Officer (OCHMO) to the various Program Elements of the HRP to ensure that human research and technology countermeasure investments are made to insure the delivery of countermeasures and technologies that satisfy ESMD's and OCHMO's exploration mission requirements.

## 1.2 SCOPE

Requirements driving the HRP work and deliverables are derived from the exploration architecture, as well as Agency standards regarding the maintenance of human health and performance. Agency human health and performance standards will define acceptable risk for each type and duration of exploration mission. It is critical to have the best available scientific and clinical evidence in setting and validating these standards. In addition, it is imperative that the best available evidence on preventing and mitigating human health and performance risks is incorporated into exploration mission and vehicle designs. These elements form the basis of the HRP research and technology development requirements and highlight the importance of HRP investments in enabling NASA's exploration missions.

HRP requirements are derived from the Exploration Architecture Requirements Document – Section TBD, ESMD Implementation Plan – Page 18 1$^{st}$ paragraph (NP-2006-11-448-HQ), NASA Space Flight Human Systems Standards, Volume I: Crew Health (SFHSS Vol. 1), and NASA Space Flight Human Systems Standards, Volume II: Habitability and Environmental Health (SFHSS Vol. 2).

This PRD defines the requirements of the HRP which is comprised of the following major Program Elements: Behavioral Health and Performance, Exploration Medical Capability, Human Health Countermeasures, ISS Medical Project, Space Human Factors and Habitability, and Space Radiation. The requirements are divided into the following three categories: 1) human system standards (section 4), 2) human health & performance risks (section 5) and 3) provisions of enabling capabilities (section 6).

HRP requirements, as defined in this document, are allocated to the Program Office and its Program Elements. Where appropriate, the Program Elements further allocate requirements to their research and technology development projects. These allocations are documented in the Element/Project plans.

Project plans describe specific endpoint deliverables that are linked to Project requirements.

### 1.3 CHANGE AUTHORITY

This document is under Configuration Management control of the Human Research Program Control Board (HRPCB). Changes to this document will result in issuance of change pages or a full re-issue of the document. Review of the PRD will be performed and changes made as necessary to maintain consistency with the evolving ESMD strategies, goals, and objectives.

## 2. DOCUMENTS

### 2.1 APPLICABLE DOCUMENTS

The following documents of the specified revision or the latest revision if not identified, are applicable to the extent specified herein. Inclusion of applicable documents herein does not in any way imply any order of precedence.

| Document No. | Revision | Document Title |
|---|---|---|
| SFHSS Vol. 1 | | NASA Space Flight Human Systems Standards, Volume I: Crew Health |
| SFHSS Vol. 2 | | NASA Space Flight Human Systems Standards, Volume II: Habitability and Environmental Health |
| HRP 47051 | | Human Research Program – Program Plan |
| NPD 1000.0 | August 2005 | NASA Strategic Management and Governance Handbook |
| NPD 8500.1 | Revision A | NASA Environmental Management |
| NPD 8910.1 | Revision A | Care and Use of Animals |
| NPR 1080.1 | February 2, 2005 | NASA Science Management |
| NPR 2190.1 | April 10, 2003 | NASA Export Control Program |
| NPR 2810.1 | August 26, 1999 | Security of Information Technology |
| NPR 5800.1 | May 19, 2005 | NASA Grant and Cooperative Agreement Handbook |
| NPR 7100.1 | March 28, 2003 | Protection of Human Research Subjects |
| NPR 7120.5 | Revision C & D | NASA Program and Project Management Processes and Requirements |
| NPR 8000.4 | April 25, 2002 | Risk Management Procedural Requirements |
| NPR 7123.1A | March 26, 2007 | NASA Systems Engineering Process and Requirements |

### 2.2 REFERENCE DOCUMENTS

The following documents contain supplemental information to guide the user in the application of this document. These reference documents may or may not be specifically cited within the text of the document.

| | |
|---|---|
| HRP-TBD # | HRP Integrated Research Plan |
| NASA/SP-2004-6113 | Bioastronautics Roadmap |
| S.1281 | National Aeronautics and Space Administration (NASA) Authorization Act of 2005 |
| NSPD31 | National Security Presidential Directive 31 – The Vision for Space Exploration |
| ESMD-TBD # | Exploration Architecture Requirements Document |
| NP-2006-11-448-HQ | ESMD Implementation Plan |
| HRP 47053 | HRP Science Management Plan |
| JSC 28330 | SLSD Configuration Control Management Plan |
| NPD 7100.8 | Protection of Human Research Subjects |

## 3. HRP GOALS

This section reflects the HRP Goals and Objectives described in the HRP Program Commitment Agreement and the HRP Program Plan (HRP 47051).

### 3.1 THE GOAL OF THE HRP IS TO PROVIDE HUMAN HEALTH & PERFORMANCE COUNTERMEASURES, KNOWLEDGE, TECHNOLOGIES, & TOOLS TO ENABLE SAFE, RELIABLE, & PRODUCTIVE HUMAN SPACE EXPLORATION. THE SPECIFIC OBJECTIVES OF THE HRP ARE:

3.1.1 Develop capabilities, necessary countermeasures, and technologies in support of human space exploration, focusing on mitigating the highest risks to crew health and performance. Enable the definition and improvement of human spaceflight medical, environmental and human factors standards.

3.1.2 Develop technologies that serve to reduce medical and environmental risks, to reduce human systems resource requirements (mass, volume, power, data, etc.) and to ensure effective human-system integration across exploration mission systems.

3.1.3 Ensure maintenance of Agency core competencies necessary to enable risk reduction in the following areas: space medicine, physiological and behavioral effects of long duration spaceflight on the human body, space environmental effects, including radiation, on human health and performance and space human factors.

# 4. HRP REQUIREMENTS RELATED TO HUMAN SYSTEM STANDARDS

## 4.1 THE HUMAN RESEARCH PROGRAM SHALL ENABLE THE DEVELOPMENT AND VALIDATION OF NASA's HEALTH, MEDICAL, HUMAN PERFORMANCE, & ENVIRONMENTAL STANDARDS IN TIME FOR EXPLORATION MISSION PLANNING & DESIGN.

*Rationale:* A first step in mitigation of human health and performance risks is the establishment of human spaceflight health standards. These standards are designed to address acceptable levels of human health risk for exploration missions of varying complexity and duration. The NASA Chief Health and Medical Officer has established an initial set of standards that serve to guide the Human Research Program in the expansion of evidence base regarding human spaceflight health and performance risks. HRP sponsors research and technology development enabling modification or development of OCHMO maintained standards.

Several different types of standards have been established by the Chief Health and Medical Officer, and documented in Space Flight Human Systems Standards, Vol. 1 and Vol. 2. Specifically, the standards sets are listed below.

- Fitness-for-duty standards for maintaining the physiological and behavioral parameters necessary to perform the required tasks;
- Permissible outcome limits for the changes in health outcomes that are potentially affected by long-term exposure to the space environment;
- Permissible exposure limits for managing risks by controlling human exposure;
- Levels of care standards for guiding medical capabilities needed to respond to a medical contingency during exploration missions; and
- Human factors and environmental standards to guide the development of spacecraft and systems so as to alleviate human health and performance impacts.

The Human Research Program requirements necessary to ensure the best possible evidence base in order to enable the development of standards are included in this section:

4.1.1 The Human Health Countermeasures (HHC) Program Element shall perform the research necessary to enable the development and validation of the Fitness for Duty Aerobic Capacity standard.

4.1.2 The HHC Program Element shall perform the research necessary to enable the development and validation of the Fitness for Duty Sensorimotor standard.

4.1.3 The HHC Program Element shall perform the research necessary to enable the development and validation of the Fitness for Duty Hematology and Immunology standard.

4.1.4 The HHC Program Element shall perform the research necessary to enable the development and validation of the Permissible Outcome Limit for Nutrition standard.

4.1.5 The HHC Program Element shall perform the research necessary to enable the development and validation of the Permissible Outcome Limit for Muscle Strength standard.

4.1.6 The HHC Program Element shall perform the research necessary to enable the development and validation of the Permissible Outcome Limit for Microgravity Induced Bone Mineral Loss Performance standard.

4.1.7 The HHC Program Element shall perform the research and ensure the technology availability to ensure the Levels of Care standards in pharmacology can be met for each exploration mission.

4.1.8 The HHC Program Element shall perform the research and technology development necessary to enable the development of the Extravehicular Activity sections of the Spaceflight Human Systems Standard, Vol.2.

4.1.9 The Behavioral Health and Performance (BHP) Program Element shall perform the research necessary to enable the development and validation of the Fitness for Duty Behavioral Health and Cognition standard.

4.1.10 The BHP Program Element shall perform the research necessary to enable the development of the Circadian Entrainment and Workload sections of the Spaceflight Human Systems Standard, Vol. 2.

4.1.11 The Space Radiation Program Element shall perform the research necessary to enable development and validation of the Space Permissible Exposure Limit for Space Flight Radiation Exposure standard.

4.1.12 The Space Radiation Program Element shall perform the research and technology developments necessary to enable the development of the Radiation sections of the Spaceflight Human Systems Standard, Vol. 2.

4.1.13 The Space Human Factors and Habitability (SHFH) Program Element shall perform the research necessary to enable development and validation of the Permissible Exposure Limit Lunar Dust Inhalation standard.

4.1.14 The Exploration Medical Capability (ExMC) Program Element shall perform the research and ensure technology availability in order to ensure that Levels of Care standards can be met for each exploration mission.

4.1.15 The SHFH Program Element shall perform the research and technology developments necessary to enable the development of the Spaceflight Human Systems Standard, Vol. 2.

# 5. HRP REQUIREMENTS RELATED TO HUMAN HEALTH & PERFORMANCE RISKS

The primary objective of the Human Research Program is to enable prevention and mitigation of human health and performance risks to enable successful completion of exploration missions, and preservation of astronaut health over the long-term.

A key component of the HRP risk mitigation strategy is adoption of an occupational health model of managing astronaut health in the hazardous environment of space. In this model, NASA seeks the most comprehensive evidence base possible, including medical data obtained over 40 years of space operations, and data obtained via research protocols.

The HRP also seeks to strengthen its partnerships with international space agencies, NSBRI, ground based research clinicians in major medical centers, and the emerging commercial space transportation industry in order to provide the most extensive evidence base possible. In this way, we will maximize our ability to understand and reduce health and performance risks.

Per the HRP Program Plan, the Bioastronautics Roadmap (BR) was used as a starting-point reference document. The BR identifies risks, potential risks and areas of concerns, but it does not capture the level of detail necessary to prioritize across discipline or compare strategies for a given risk across mission architectures. Therefore, the Space Life Sciences Directorate developed the risk mitigation analysis tool (RMAT).

The RMAT format reviews medical risks in terms of probability, impact, and proposals for mitigating the risks, and reviews each risk in terms of multiple mission architectures (short-duration Earth-orbital mission, ISS 6-month mission, ISS 12-month mission, short-duration Lunar sortie, long-duration Lunar mission, and Mars Mission). Costs and risks are weighed against the probabilities of success of investing in developing a given risk mitigation proposal. This approach facilitates analysis of the risk across the different mission architectures and across underlying risk factors for a given architecture and will assist with resource allocation to address these risks.

The HRP conducted an extensive review of medical research findings that led to the identification of a series of risks and contributing risk factors. Table 1 contains items for which substantial evidence exists, while Table 2 contains items of concern that cannot be supported or refuted by available information. These risks and contributing factors are dynamic. New risks may be identified with further mission experience, while some risks/contributing factors may be retired, if evidence is gathered that refutes their importance. The HRP shall periodically review available information and revise these risks/contributing factors as appropriate.

As an example, future research may determine that microgravity exposure does not lead to heart rhythm disturbances, which would allow that risk to be retired. To facilitate such reviews, the HRP will compile spaceflight medical research data in a centralized, well-cataloged and retrievable database. The HRP will also strengthen partnerships with international space agencies, ground-based research clinicians in academic medical centers, and the commercial space transportation industry, to ensure that the spaceflight medical database is as complete and robust as possible.

**Table 1, Exploration Missions Human Health and Performance Risks Substantiated by a Strong Evidence Base**

| **Applicable HRP Element** | **Risk and Risk Definition** |
|---|---|
| HHC | <u>Risk of Accelerated Osteoporosis</u><br><br>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. |
| HHC | <u>Risk of Orthostatic Intolerance During Re-Exposure to Gravity</u><br>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. |

| Applicable HRP Element | Risk and Risk Definition |
|---|---|
| HHC | <u>Risk of Unnecessary Operational Limitations due to Inaccurate Assessment of Cardiovascular Performance</u><br>Current inflight indicators of cardiac performance may not accurately reflect astronauts cardiovascular performance. Making operational decisions based on inaccurate cardiac performance measures may unnecessarily restrict crewmembers for critical activities or, more seriously, could subject crewmembers to activities for which they are not physically prepared. Accurate measurement of crewmember aerobic capacity can eliminate this risk. |
| HHC | <u>Risk Factor of Inadequate Nutrition</u><br>It is critical that crew members 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. |
| SHFH | <u>Risk Factor of Inadequate Food System</u><br>If the food system does not adequately provide for food safety, nutrition and taste, then crew health and performance and the overall mission may be adversely affected. |
| SHFH | <u>Risk Factor of an Inefficient Food System</u><br>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. |
| ExMC | <u>Risk of Inability to Adequately Treat an Ill or Injured Crew Member</u><br>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. |
| HHC | <u>Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems</u><br>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. |

| Applicable HRP Element | Risk and Risk Definition |
|---|---|
| HHC | Risk of Urinary Tract Dysfunction<br>Multiple cases of urinary retention and subsequent urinary tract infections have been observed during short duration spaceflight, chiefly among females. It is not clear why exposure to microgravity adversely affects the functioning of the urinary tract. Further research into this area could explain this phenomenon, and assist with the clinical management of these cases. |
| HHC | Risk of Impaired Vision due to Refractive Visual Changes During Long Duration Spaceflight<br>Significant changes in visual refraction have been documented among ISS crewmembers. These changes appear to be due to senescent accommodative changes that may be exacerbated by the small volume of spacecraft cabins. Vascular engorgement of retinal support layers also appear to play a role. Not all crewmembers suffer from this problem. Identification of associated risk factors, underlying pathophysiology, and mitigation strategies are necessary for maintaining crew vision during long duration missions. |
| SHFH | Risk of Error Due to Inadequate Information<br>Operator errors are common in all work environments. Task errors during human spaceflight missions could have drastic consequences. Errors can be due to lack of information which in turn may be due to any of the following: (a) lack of situational awareness, which can be due to poorly designed interfaces, poorly designed tasks, or cognitive decrements due to, e.g., fatigue or exposure to toxic environments; (b) forgetting, which can be due to inadequate training, poorly designed procedures, or to cognitive decrements due to, e.g., fatigue or exposure to toxic environment; (c) inability to access appropriate data and procedures due to poorly designed interfaces, poorly designed tasks, or to cognitive decrements due to, e.g., fatigue or exposure to toxic environments; or (d) failure of judgment due to incorrectly perceived or interpreted cues, inappropriately estimated results of decisions, or inadequate data. The risk is currently based on extensive data from commercial aviation, from nuclear power plant operations, and from other activities with high dependence on technology under sustained operations. The HRP must provide standards for reducing operator errors in spaceflight through adequate understanding of causes and mitigations of operator errors. |
| BHP | Risk of Behavioral and Psychiatric Conditions<br>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 crew on a 3-year mission to determine that there is a significant likelihood of psychiatric conditions emerging. |

| Applicable HRP Element | Risk and Risk Definition |
|---|---|
| | 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. |
| BHP | <u>Risk of Performance Errors Due to Sleep Loss, Circadian Desynchronization, Fatigue, and Work Overload</u><br>Fatigue occurs during spaceflight and will 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. |
| Space Radiation | <u>Risk of Radiation Carcinogenesis</u><br>Occupational radiation exposure from the space environment may increase cancer morbidity or mortality risk in astronauts. This risk may be influenced by other space flight factors including microgravity and environmental contaminants. A Mars mission will not be feasible unless improved shielding is developed or transit time is decreased. |
| Space Radiation | <u>Risk of Acute Radiation Syndromes Due to Solar Particle Events</u><br>Radiation and synergistic effects of radiation may place the crew at significant risk for acute radiation sickness from a major solar event or artificial event, such that the mission or crew survival may be placed in jeopardy. Crew health and performance may be impacted by acute solar events. Beyond Low Earth Orbit, the protection of the Earth's atmosphere is no longer available, such that increased shielding and protective mechanisms are necessary in order to prevent acute radiation sickness and impacts to mission success or crew survival. The primary data available at present are derived from analysis of medical patients and persons accidentally exposed to high doses of radiation. Data more specific to the spaceflight environment must be compiled to quantify the magnitude of increase of this risk and to develop appropriate protection strategies. |
| SHFH | <u>Risk Associated with Poor Task Design</u><br>Errors are often related to poor task design. Critical tasks must be designed to minimize operator error. Automation, feedback and other task design elements may be used in these cases. Multiple actors, including robots, present a unique risk. |

| Applicable HRP Element | Risk and Risk Definition |
|---|---|
| HHC | Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance<br><br>There is a growing research database which suggests that skeletal muscles, particularly postural muscles of the lower limb, undergo atrophy and structural and metabolic alterations during spaceflight. 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. |
| HHC | Risk of Operational Impact of Prolonged Daily Required Exercise<br><br>Muscle atrophies in microgravity and strength decreases. Currently, significant daily time is scheduled to crew exercise. Making the exercise more efficient may allow similar beneficial effects to be achieved more simply, and in shorter time, which would provide more crew time for operational support. Benchmarking crew strength requirements, and testing exercise equipment and regimens against these benchmarks, will promote the development of more efficient, yet equally safe, exercise regimens. |

**Table 2, Exploration Missions Human Health and Performance Risks Requiring Further Evidence to Substantiate the Risk/Risk Factor**

| Applicable HRP Element | Risk and Risk Definition |
|---|---|
| HHC | Risk of Bone Fracture<br><br>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. |

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|---|---|
| HHC | <u>Risk of Intervertebral Disc Damage</u><br>Extended exposures to microgravity (and possibly fractional gravity) may lead to an increased risk of spinal nerve compression and back pain. |
| HHC | <u>Risk of Renal Stone Formation</u><br>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. |
| HHC | <u>Risk of Cardiac Rhythm Problems</u><br>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 spaceflight. 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. |
| HHC | <u>Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity</u><br>Astronauts' physical performance during a mission, including activity 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. |
| HHC | <u>Risk of Adverse Health Effects due to Exposure to Hypoxic Environments</u><br>Spacecraft designers strive to maintain a normal terrestrial atmosphere for crewmembers; however, frequent EVA's necessitate decreasing the atmospheric nitrogen levels to decrease the risk of decompression sickness. Decreasing nitrogen partial pressure without decreasing oxygen partial pressure creates a significant fire risk. Concerns exist whether crew performance could be adversely affected if cabin oxygen pressures are decreased. Research into human performance at lower oxygen partial pressures could lead significant safety improvements in the design of future vehicles and missions. |
| HHC | <u>Risk of Adverse Health Effects due to Prolonged Exposure to Elevated Carbon Dioxide Levels</u><br>Available scrubbing technologies cannot lower cabin carbon dioxide levels to terrestrial atmospheric concentrations. Frequent repairs of complex scrubbing equipment have led to elevated $CO_2$ levels on multiple occasions. Crews often complain of symptoms that could relate to elevated $CO_2$ levels. It is unclear how chronic exposure to elevated $CO_2$ levels affect human health. More research is necessary. |

| | |
|---|---|
| SHFH | Risk of Adverse Health Affects from Lunar Dust Exposure<br><br>It is clear that prolonged exposure to rock dust is harmful, but it is not clear if exposure to regolith dust is more or less harmful that terrestrial rock dust. Research into this area may determine if exposure limits need be changed, and/or if additional medical treatment capability is required. |
| HHC | Risk of Crew Adverse Health Event Due To Altered Immune Response<br><br>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 nor with observed disease. Further research may elucidate whether microgravity exposure impairs the immune system, and whether this change represents a health risk to crews. |
| HHC | Risk of Impaired Ability to Maintain Control of Vehicles and Other Complex Systems<br><br>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. |
| HHC | Risk of Therapeutic Failure Due to Ineffectiveness of Medication<br><br>Based on subjective reports, drugs are effective during spaceflight. Better recordkeeping 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 spaceflight. Studies to determine if spaceflight affects drug stability are currently underway. |
| BHP | Risk of Performance Errors Due to Poor team Cohesion and Performance, Inadequate Selection/Team Composition, Inadequate Training, and Poor Psychosocial Adaptation<br><br>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 will impact performance and mission success. The history of spaceflight crews regarding team cohesion, training and performance has not been systematically documented. Tools, training and support methods should be provided to reduce the likelihood of this risk and improve crew performance. |

| | |
|---|---|
| Space Radiation | Risk of Acute or Late Central Nervous System Affects from Radiation Exposure<br>Acute and late radiation damage to the central nervous system (CNS) may lead to changes in motor function and behavior, or neurological disorders. Radiation and synergistic effects of radiation with other space flight factors may affect neural tissues, which in turn may lead to changes in function or behavior. Data specific to the spaceflight environment must be compiled to quantify the magnitude of this risk. If this is identified as a risk of high enough magnitude then appropriate protection strategies should be employed. |
| Space Radiation | Risk of Degenerative Tissue or other Health Affects from Radiation Exposure<br>Occupational radiation exposure from the space environment may result in degenerative tissue diseases (non-cancer or non-CNS) such as cardiac, circulatory, or digestive diseases, as well as cataracts, although the mechanisms and the magnitude of influence of radiation leading to these diseases are not well characterized. Radiation and synergistic effects of radiation cause increased DNA strand and tissue degeneration, which may lead to acute or chronic disease of susceptible organ tissues. Data specific to the spaceflight environment must be compiled to quantify the magnitude of this risk to determine if additional protection strategies are required. |
| SHFH | Risk of Reduced Safety and Efficiency Due to Poor Human Factors Design<br>Inadequate human factors design in the physical work environments (e.g. vehicles, tools and tasks) will result in reduced human performance and increase the likelihood of errors. Research is needed to provide spaceflight human factors design data and design tools in microgravity and partial gravity. |

## 5.1 THE HRP SHALL QUANTIFY THE HUMAN HEALTH & PERFORMANCE RISKS ASSOCIATED WITH HUMAN SPACEFLIGHT FOR EXPLORATION MISSIONS.

*Rationale:* In many cases, there is a large uncertainty associated with the risk due to lack of controlled spaceflight (or ground analog) experimental evidence. This HRP requirement is to quantifiably describe the likelihood and consequences of the risks. The uncertainties associated with these quantities should be narrowed to the target values identified by each standard or to the greatest extent practical to facilitate proper decisions for exploration hardware design and mission design.

**5.1.1** The HRP Science Management Office shall develop ways to improve estimates of the integrated human health and performance risk associated with human spaceflight for exploration missions.

*Rationale:* The overall risk assessment extends beyond a “list” of risks. The risks often have inter-relationships and interdependencies. The SMO must evaluate the risks to identify and quantify these inter-relationships and interdependencies, and provide an assessment of the total risk to the human system for spaceflight. This will help focus the HRP effort and ensure proper decision making.

**5.1.2** The BHP Element shall quantify the BHP-applicable Risks identified in Tables 1 & 2.

**5.1.3** The ExMC Element shall quantify the ExMC-applicable Risks identified in Tables 1 & 2.

**5.1.4** The HHC Element shall quantify the HHC-applicable Risks identified in Tables 1 & 2.

**5.1.5** The SHFH Element shall quantify the SHFH-applicable Risks identified in Tables 1 & 2.

**5.1.6** The Space Radiation Element shall quantify the Space Radiation-applicable Risks identified in Tables 1 & 2.

## 5.2 THE HRP ELEMENTS SHALL DEVELOP COUNTERMEASURES & TECHNOLOGIES TO PREVENT OR MITIGATE ADVERSE OUTCOMES OF HUMAN HEALTH & PERFORMANCE RISKS.

*Rationale:* Each risk is written with respect to an adverse outcome. The intent of the HRP is to prevent the adverse outcome from occurring. If that cannot be done, the intent is to develop and validate novel countermeasures (devices, drugs, procedures, etc) that will mitigate the adverse outcome. In this context, “mitigate” means “reduce the severity or reduce the probability of the adverse outcome.”

**5.2.1** The BHP Element shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to BHP (see Tables 1 & 2).

**5.2.2** The ExMC Element shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to ExMC (see Tables 1 & 2).

**5.2.3** The HHC Element shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to HHC (see Tables 1 & 2).

**5.2.4** The SHFH Element shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to SHFH (see Tables 1 & 2).

**5.2.5** The Space Radiation Element shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to Space Radiation (see Tables 1 & 2).

### 5.3 THE HRP ELEMENTS SHALL DEVELOP COUNTERMEASURES & TECHNOLOGIES TO MONITOR & TREAT ADVERSE OUTCOMES OF HUMAN HEALTH & PERFORMANCE RISKS.

*Rationale:* If a risk cannot be mitigated adequately, the human must be monitored for indicators of an adverse outcome, and treatment and or countermeasures should be developed.

**5.3.1** The BHP Element shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to BHP (see Tables 1 & 2).

**5.3.2** The ExMC Element shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to ExMC (see Tables 1 & 2).

**5.3.3** The HHC Element shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to HHC (see Tables 1 & 2).

**5.3.4** The SHFH Element shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to SHFH (see Tables 1 & 2).

**5.3.5** The Space Radiation Element shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to Space Radiation (see Tables 1& 2).

## 6. HRP REQUIREMENTS RELATED TO PROVISION OF ENABLING CAPABILITIES

### 6.1 THE HRP SHALL PROVIDE THE ENABLING CAPABILITY TO FACILITATE HUMAN SPACE EXPLORATION WITH RESPECT TO THE HUMAN SYSTEM.

*Rationale:* Ensuring Human exploration requires some infrastructure or activities that do not readily fall into a specific research and technology development category. The requirements below are intended to provide NASA with the necessary infrastructure or capabilities to implement the research and technology work required to update inform and validate standards and to address the risks relevant to human exploration.

In the course of research and technology development, each HRP Element may encounter the need to perform studies in a ground-based space analog environment (e.g. bed-rest facility, Antarctica, NEEMO). Each Element is responsible for the selection and/or validation of the appropriate analogs and the necessary planning, integration and execution. Large resource commitments to analog facilities must be reflected in the Element Research Plan so that the cost-benefit to the HRP is clear.

**6.1.1** The ISS Medical Project (ISSMP) shall plan, integrate, and execute HRP research tasks requiring access to space to address standards or reduce or eliminate human health and performance risks.

*Rationale:* Access to space research platforms, namely the Space Transportation System (STS), the ISS and the Crew Exploration Vehicle (CEV) (transport to and from the ISS) is required to study and/or validate many of the items in sections 4.1 and 5.0. The ISSMP serves as the service to integrate, across all other HRP Elements, and optimize the research plans requiring access to space. The ISSMP provides the interface to the spaceflight programs to ensure that the research is properly planned, integrated and executed with the required data returned to the investigator.

**6.1.2** The ExMC shall provide data integration and management function to ensure proper handling of and access to HRP data.

*Rationale*: Access to data is critically important to advancing the state of knowledge of the human system in space. A data integration and management function includes the proper archiving of historical research data (e.g. The Life Science Data Archive), and organizing medical and research data to provide proper security levels, allow queriable access, and to provide tools to allow analysis of evidence (e.g. Integrated Medical Model).

## 6.2 THE HRP SHALL ENSURE PRESERVATION & MAINTENANCE OF CORE TECHNICAL CAPABILITY & EXPERTISE IN HUMAN RESEARCH & TECHNOLOGY DEVELOPMENT.

*Rationale:* The core competencies are those which are necessary to maintain and nurture an understanding of the existing evidence base regarding risks and adverse outcomes to humans due to spaceflight. This core competency involves sustaining and maintaining a dedicated workforce and a robust external scientific community. It also requires adequate testing laboratory physical plant capability. Preservation and maintenance of this capability is necessary to provide stability over the multi-decadal implementation of the vision for space exploration. This core competency is necessary to facilitate:

1) Strategic Planning. Identifying, prioritizing the risks to the human system and developing long-range plans to quantify, prevent, mitigate, and treat the adverse outcomes requires competency of both the internal and external community to ensure proper direction to the research community for focusing their effort.

2) Acquisition development, planning and execution. Acquisition of research and technology development is an inherently government function that requires core expertise within the civil service to ensure that the US Government remains a “smart buyer” with respect to research and technology development for the human system.
3) Operations support for near-real time and real-time operational decisions involving the human system and environment. Laboratory facilities and the expertise to run them and interpret results are necessary to support an ongoing evaluation of the human system response to the space environment, and to support the medical operations function during a mission. This involves the internal community, and to some extent the external community where uniquely specialized expertise must be sought.

The requirement is written at the HRP level and not specifically allocated to the Elements. The Program Manager will periodically review the core technical capability of the Program Elements and adjust where appropriate.

## 6.3 EACH HRP ELEMENT SHALL ENSURE THAT THEIR PROCESSES & PRODUCTS COMPLY WITH THE NASA POLICY DIRECTIVES & NASA PROCEDURAL REQUIREMENTS LISTED IN THE TABLE OF APPLICABLE DOCUMENTS IN SECTION 2.1.

*Rationale:* The Table of applicable documents includes the NPDs and NPRs specifically referenced by the HRP Program Plan (HRP 47051). This requirement explicitly states which NPRs and NPDs are applicable to the HRP, and ensures that the requirement is flowed down to the element level. Identification of specific NPR/NPD applicability falls upon each individual Element/Project when the Project Plan is defined. The intent of this requirement is to ensure HRP compliance with these documents within the normal processes and product development ongoing in the HRP.

# 7. APPENDIX A ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| BHP | Behavioral Health & Performance |
| BMD | Bone Mineral Density |
| CEV | Crew Exploration Vehicle |
| CM | Configuration Management |
| CMS | Competency Management System |
| Cx | Constellation |
| E.G. | For Example |
| ELEM | Element(s) |
| ESMD | Exploration Science Mission Directorate |
| EVA | Extravehicular Activity |
| HHC | Human Health Countermeasures |
| HRP | Human Research Program |
| HRPCB | Human Research Program Control Board |
| HRPRD | Human Research Program Requirements Document |
| IOM | Institute of Medicine |
| IRP | Integrated Research Plan |
| ISS | International Space Station |
| ISSMP | ISS Medical Project |
| IVA | Intravehicular Activity |
| JSC | Johnson Space Center |
| Lab | Laboratory |
| NASA | National Aeronautics and Space Administration |
| NEEMO | NASA Extreme Environment Mission Operations |
| NGO | Needs, Goals, Objectives |
| NP | NASA Publication |
| NPD | NASA Procedural Directive |
| NPR | NASA Procedural Requirements |
| NSPD | National Security Presidential Directive |
| NSTS | National Space Transportation System |
| OCHMO | Office of the Chief Health and Medical Office |
| PIO | Program Integration Office |
| PRD | Program Requirements Document |
| RMAT | Risk Mitigation Analysis Tool |
| SA | Space Life Sciences Directorate |
| SAT | Small Assessment Team |
| SD | Space Medicine Division |
| SHFH | Space Human Factors & Habitability |
| SFHCS | Space Flight Health Care Standard |
| SFHSS | Space Flight Human System Standard |
| SLSD | Space Life Sciences Directorate |
| SMO | Science Management Office |
| SMP | Science Management Plan |
| SSP | Space Station Program |
| STS | Space Transportation System |
| TBD | To Be Determined |
| U.S. | United States |