NASA’s Human System Risk Assessment Process

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Integrated Human System Risk Management Structure

Policy, Operations, and Research → Human Health/Performance Risk Framework

- **HQ - Office of the Chief Health and Medical Officer (OCHMO)** – Health and Medical Authority (HMTA) – Level I
  - Medical Policy, Health and Performance Standards, and Bioethics
  - Risk Assessment and Mitigation - via the JSC Chief Medical Officer (JSC CMO) – Level II

- **Crew Health and Safety (CHS)**
  - Medical Operations & Occupational Health (career health care/post career monitoring)

- **Human Research Program (HRP)**
  - Perform scientific research necessary to understand & reduce health & performance risks for space exploration

- **AES & STMD** – Technology/Protocol Development

- **International Space Station (ISS), Orion, Commercial Crew Programs**
  - Implementation of Medical Operations
    - Medical Requirements, Tests and hardware
NASA Human Health and Performance

Goal: Enable Successful Space Exploration by Minimizing the Risks of Spaceflight Hazards

Spaceflight/Design Reference Missions

- Hostile Spaceflight Environment
- Altered Gravity
- Radiation
- Isolation
- Hostile/Closed Environment
- Distance from Earth

Hazard: Human Risks
- Bone & Muscle loss
- Radiation Exposure
- Toxic Exposure

Evidence

Standards

Risks

Standards to Requirements

Mitigations

Deliverables:
- Technologies
- Countermeasures (prevention & treatment)

Medical Ops
- Occupational Surveillance
- Environmental Research
All of the Human System Risks are evaluated against the following DRMs:

<table>
<thead>
<tr>
<th>DRM Categories</th>
<th>Mission Duration</th>
<th>Gravity Environment</th>
<th>Radiation Environment</th>
<th>Earth Return</th>
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</thead>
<tbody>
<tr>
<td>Low Earth Orbit</td>
<td>6 months</td>
<td>Microgravity</td>
<td>LEO - Van Allen</td>
<td>1 day or less</td>
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<tr>
<td></td>
<td>1 year</td>
<td>Microgravity</td>
<td>LEO - Van Allen</td>
<td>1 day or less</td>
</tr>
<tr>
<td>Deep Space Sortie</td>
<td>1 month</td>
<td>Microgravity</td>
<td>Deep Space</td>
<td>&lt; 5 days</td>
</tr>
<tr>
<td>Lunar Visit/Habitation</td>
<td>1 year</td>
<td>1/6g</td>
<td>Lunar</td>
<td>5 Days</td>
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<tr>
<td>Deep Space Journey/ Habitation</td>
<td>1 year</td>
<td>Microgravity</td>
<td>Deep Space</td>
<td>Weeks to Months</td>
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<tr>
<td>Planetary Visit/Habitation</td>
<td>3 years</td>
<td>Fractional/ Microgravity</td>
<td>Planetary*</td>
<td>Months</td>
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</tbody>
</table>

*Planet has no magnetic poles, limited atmosphere

Examples of Missions that would fall into the DRM Categories:

**Low Earth Orbit** – ISS6, ISS12, Commercial Suborbital, Commercial Visits to ISS, future commercial platforms in LEO

**Deep Space Sortie**: MPCV test flights, moon fly around or landing, visits to L1/L2, deep space excursion

**Lunar Habitation**: Staying on the surface more than 30 Days (less than 30 days would be similar)

**Deep Space Habitation**: L1/L2 Habitation, Asteroid visit, journey to planets

**Planetary Habitation**: Living on a planetary surface, MARs & extended journey in microgravity to and from
Hazards of Spaceflight
Hazards Drive Human Spaceflight Risks

- **Altered Gravity - Physiological Changes**
  - Balance Disorders
  - Fluid Shifts
  - Cardiovascular Deconditioning
  - Muscle Atrophy
  - Bone Loss

- **Distance from Earth**
  - Drives the need for additional "autonomous" medical care capacity – cannot come home for treatment

- **Space Radiation**
  - Acute In-flight effects
  - Long term cancer risk

- **Hostile/Closed Environment**
  - Vehicle Design
  - Environmental – CO₂ Levels, Toxic Exposures, Water, Food
  - Decreased Immune Function

- **Isolation & Confinement**
  - Behavioral aspect of isolation
  - Sleep disorders
Evidence is gathered from in-flight medical and research operations, spaceflight analogs, terrestrial analogs, and/or animal data. Data must be correlated from NASA medical (LSAH), research (LSDA), environmental & terrestrial data bases.

**NASA/HMTA Human Risks Evidence Base**

**Medical Data** *(mandatory)*
- Medical data generally does not require informed consent and may only be used for:
  - Medical care by clinician
  - Occupational Surveillance

**Environmental & Operational Data**
- Data gathered to understand the occupational environment, such as:
  - CO2 levels, acoustic, landing loads, radiations levels, mission operations

**Research Data** *(voluntary)*
- Research data requires informed consent by the subject & the data.
  - Ground analogs
  - Includes animal research

**Terrestrial Data**
- Related terrestrial incidence, treatment and research

¾ of Risk Evidence from Operational Medical/Environmental/ Occupational Surveillance Programs

¼ of Risk Evidence from Research Programs *(Focus on Human System Risks understanding and countermeasure development)*

Correlation of data by subject matter experts & physicians.

Generation of Metrics to assess Human System Risks
### Summary of Human Risks of Spaceflight
Grouped by Hazards – 30 Human Risks

#### Altered Gravity Field
1. Spaceflight-Induced Intracranial Hypertension/Vision Alterations
2. Renal Stone Formation
3. Impaired Control of Spacecraft/Associated Systems and Decreased Mobility Due to Vestibular/Sensorimotor Alterations Associated with Space Flight
4. Bone Fracture due to spaceflight induced changes to bone
5. Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance
6. Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity
7. Adverse Health Effects Due to Host-Microorganism Interactions
8. Urinary Retention
9. Orthostatic Intolerance During Re-Exposure to Gravity
10. Cardiac Rhythm Problems
11. Space Adaptation Back Pain

#### Radiation
1. Space Radiation Exposure on Human Health (cancer, cardio and CNS)

#### Distance from Earth
1. Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions
2. Ineffective or Toxic Medications due to Long Term Storage

#### Isolation
1. Adverse Cognitive or Behavioral Conditions & Psychiatric Disorders
2. Performance & Behavioral health Decrements Due to Inadequate Cooperation, Coordination, Communication, & Psychosocial Adaptation within a Team

#### Hostile/Closed Environment-Spacecraft Design
1. Acute and Chronic Carbon Dioxide Exposure
2. Performance decrement and crew illness due to inadequate food and nutrition
3. Reduced Crew Performance and of Injury Due to Inadequate Human-System Interaction Design (HSID)
4. Injury from Dynamic Loads
5. Injury and Compromised Performance due to EVA Operations
6. Adverse Health & Performance Effects of Celestial Dust Exposure
7. Adverse Health Event Due to Altered Immune Response
8. Reduced Crew Health and Performance Due to Hypobaric Hypoxia
9. Performance Decrements & Adverse Health Outcomes Resulting from Sleep Loss, Circadian Desynchronization, & Work Overload
10. Decompression Sickness
11. Toxic Exposure
12. Hearing Loss Related to Spaceflight
13. Injury from Sunlight Exposure
14. Crew Health Due to Electrical Shock

#### Concerns
1. Clinically Relevant Unpredicted Effects of Meds
2. Intervertebral Disc Damage upon & immediately after re-exposure to Gravity
Factors that Influence Human Risk – by Mission Phase

**Pre-Mission**
- **Generic Factors**
  - Screening Criteria
  - Pre-flight treatment(s)
  - Pre-flight training
  - Flight Assignments
  - Age, sex, physiological

**In-Mission**
- **Generic Factors**
  - Mission Duration
  - Mission location
  - LEO, BLEO
  - Countermeasures

**Post-Mission**
- **Generic Factors**
  - Reconditioning
  - Post mission Screening
  - Occupational Health Care for Astronauts
  - Duty/lifestyle constraints
  - Treatments

Determines/Reduces Total Risk Posture

**Radiation Example**
- **Radiation Factors**
  - Individual Sensitivity – Biomarkers*
  - Selection – age, sex
  - Model Projection of Risk

**Radiation Factors**
- Shielding
- Mission Duration
- LEO vs. BLEO
- Solar Min vs. Max
- Operational Planning
- Risk Assessment
- Dosimetry

**Radiation Factors**
- Personalized Cancer Screening*
- Cancer Treatment

*In development

HMTA considers pre, in and post mission factors/countermeasures to evaluate risks and ensure crew health.
Sample Risk – Human System Risk Board (HSRB) Assessment Performed for all 30 Risks

Risk Title: Risk of Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance*

Risk Statement: Given that exposure to a microgravity environment causes skeletal muscles to undergo reduced mass, strength, and endurance, there is a possibility that mission task performance would be impaired or tasks could not be performed.

Primary Hazard: μ-gravity  Secondary Hazard: Closed Environment (spacecraft design), radiation

Contributing Factors: Mission Design, Microgravity, Cardiovascular Changes, Diet, Hydration, Radiation, Closed Environment

State of Knowledge: Fitness for duty standard; maintain 80% shall be within normal values for age & sex of the astronaut population (see metric). No capability for direct strength measurements on microgravity environment unquantifiable, but considered to be contributing cardiovascular effects and vestibular/sensorimotor alterations associated with space flight (reference).

DRM Categories | Mission Duration | LxC OPS | Risk Disposition | LxC LTH | Risk Disposition
--- | --- | --- | --- | --- | ---
Low Earth Orbit | 6 Months | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted
| 1 Year | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted

Deep Space Sortie | 1 Month | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted

Lunar Visit/ Habitation | 1 Year | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted

Deep Space Journey/Hab | 1 Year | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted

Planetary | 3 Years | 1 x 4/ 3 x 3* | Requires Mitigation | 3 x 2 | Requires Mitigation

Countermeasures: Risk title and statement are generated. Primary hazard (only one) and then secondary hazards (can be multiple) are determined. Any contributing factors are listed.

Drivers: The assumption is that “ISS-like” countermeasures will be available for all future exploration DRMs. Ops Likelihood: ALL DRMs: Activities with the highest impact are emergency egress & rescue of an incapacitated crew member. Probability of these occurrences is ≤ 0.1%. Additionally, (*) Planetary: Surface EVA (freq./type) would also be impacted and the probability is >1% due to transit duration effect on muscle strength/endurance. Ops Consequence, All DRMs: Death if unable to emergency egress or rescue an incapacitated crew member. In addition, (*) Planetary: Significant Reduction of Performance (shorter duration EVA, less strenuous activities) for surface operations.

LTH Likelihood: All DRMs: ~25% of crew do NOT maintain 80% of preflight values during a 6 month ISS mission with CEVIS, ARED & T2. LTH Consequence: All DRMs ex. Planetary: Crew return to baseline within 3 months with limited intervention. Planetary: Anticipate taking longer to return to baseline - 1 year recovery.

Risk Disposition Rationale: For all missions except Planetary, the risk is acceptable but optimization of countermeasure is desired (particularly inflight exercise hardware). For Planetary: Mitigation is required to provide effective countermeasures with less mass and volume.
Sample Risk – Human System Risk Board (HSRB) Assessment Performed for all 30 Risks

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Risk Statement: Given that exposure to a microgravity environment causes skeletal muscles to undergo reduced mass, strength, and endurance, there is a possibility that mission task performance would be impaired or tasks could not be performed.

Primary Hazard: μ-gravity
Secondary Hazard: Closed Environment (spacecraft design), radiation
Contributing Factors: Mission Design, Microgravity, Cardiovascular Changes, Diet, Hydration, Radiation, Closed Environment
Countermeasure: Prevention: Pre-flight training, inflight exercise, diet, aerobic & resistive hardware. Treatment: Post flight reconditioning

State of Knowledge: Fitness for duty standard; maintain 80% of baseline muscle strength. Pre-flight standard: Pre-flight muscle strength & function shall be within normal values for age & sex of the astronaut population. Ample data from shuttle and ISS document pre & post flight strength assessment (see metric). No capability for direct strength measurements on ISS. Limited in flight time course of change in muscle strength. Impact of radiation environment unquantifiable, but considered to be contributing cardiovascular factor (reference radiation risk). Capability for emergency egress is also tightly coupled with vestibular/sensorimotor alterations associated with space flight (reference sensorimotor risk).

DRM Categories | Mission Duration | LxHC OPS | Risk Disposition | LxHC LTH | Risk Disposition |
--- | --- | --- | --- | --- | ---
Low Earth Orbit | 6 Months | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted |
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Deep Space Journey/Hab | 1 Year | 1 x 4 | Accepted/ Optimize | 3 x 1 | Accepted |
Planetary | 3 Years | 1 x 4/ 3 x 3* | Requires Mitigation | 3 x 2 | Requires Mitigation |

Risk Disposition Rationale: For all missions except Planetary, the risk is accepted but optimization of countermeasure is desired (particularly inflight exercise hardware). For Planetary: Mitigation is required to provide effective countermeasures with less mass and volume.

State of Knowledge is a summary of the evidence. Detailed evidence is listed in the presentation package of each risk and a summary is added as a metric (see next page).
Metric for Risk of Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance

% of Crew with Muscle loss greater than standard

Data based on LSAH/Exercise Lab data assessment, MRIDs and Sprint Research Data 7/2013
% Crew that do NOT meet Health and Fitness Muscle Standard
< 20% loss of pre-flight baseline Knee Flex Strength

ISS 6 months N=22
36%

ISS 6 months N=25
25%

ISS 6 months N=5
20%

ISS 12 months TBD

Countermeasure(s)

iRED TVIS, CEVIS Non-Standard* Exercise Prescription

ARED T2, CEVIS Non-Standard* Exercise Prescription

ARED T2, CEVIS SPRINT Research Exercise Prescription

ARED T2, CEVIS Non-Standard* Exercise Prescription

(*) "Non-Standard" indicates customized exercise prescriptions
### Projectized Approach to Human System Risk Mgmt

Each risk matures as it follows the CRM Process.

#### Deliverables Required

<table>
<thead>
<tr>
<th>Knowledge/Research:</th>
<th>Responsible Program/Mechanism</th>
<th>Budget ($M) - FY 2014-18</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARED Kinematics</td>
<td>HRP</td>
<td>$0.5M</td>
</tr>
<tr>
<td>ISS SPRINT</td>
<td>HRP</td>
<td>$1.5M</td>
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<td>Other Risk Task (Active/Planned)</td>
<td>HRP/ISS/EA</td>
<td>$600K/2015</td>
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<td>Technology:</td>
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<tr>
<td>Portable Load Sensing Evals.</td>
<td>HRP</td>
<td>$1.5M</td>
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<td>Adv. Exercise Concept Evals. ISS</td>
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<td>MPCV Exercise Concept Dev.</td>
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<td>Adv Exercise Risk Mitigation</td>
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<tr>
<td>ISS Ops – Sustaining, Log, Main.</td>
<td>ISS</td>
<td>$3.3M</td>
</tr>
</tbody>
</table>

#### Operational Protocols:

| - ASCR Std - Exercise Prescriptions | ISS/CHS | $4M |
| - MedB 5.1-3 (Fn Fit., IsoTestingCMS) | ISS | $3.3M |
| - ISS Ex. HW – Sustaining, Log, Main. | ISS/CHS/HRP/NSBRI | $0.5M |

#### Guidelines/Requirements/Standards:

| - Standard Updates | ISS/CHS/HRP/NSBRI | $0.5M |
| - Requirements for MPCV | ISS/CHS/HRP/NSBRI | $0.5M |

#### Note:

All tasks costs are shared with the Aerobic risk except for MedB5.1-3.

*Italics indicates desired work for which a Program sponsor has not been identified (not included in totals).

Each risk matures as it follows the CRM Process.

Deliverables required to mitigate the risk are tracked at a high level. Detailed tracking maintained by funding programs.

**Total Budget 2014-18 = $54M**

- **CHS**, $0.5 M
- **ISS**, $19.5 M
- **HRP**, $34.0 M

Countermeasure Optimization Mars Concept Devices

= Risk Evaluation Assessment

Countermeasure implementation
## Risks to Standard - Requirement Flow

### Risks
- Bone Fracture due to Spaceflight-induced Changes to Bone
- Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity
- Impaired Performance Due to Reduced Muscle Mass, Strength & Endurance

### Standard(s)
- **Space Flight Health Standard**
  - NASA-STD-3001, VOLUME 1, CREW HEALTH
  - March 2007, In process of update
  - 4.2.8 Permissible Outcome Limit for Muscle Strength Standard
  - 4.2.8.2 Countermeasures shall maintain in-flight skeletal muscle strength at or above 80% of baseline values.

- **Space Flight Health Standard**
  - NASA-STD-3001, VOLUME 2, HUMAN FACTORS,...
  - January 2011
  - 7.4.1 The system shall provide countermeasures to meet crew bone, muscle, sensory-motor, and cardiovascular standards defined in NASA-STD-3001, Volume 1.

### Requirements

#### ISS
- SSP 50260 International Space Station Medical Operations Requirements Document - MORD
- **8.5.2.2 CREW PARTICIPATION IN DAILY PHYSICAL EXERCISE**
  - ISS crewmembers shall participate in physical exercise, consisting of aerobic, anaerobic and resistive exercise as prescribed by medical specialists.

#### Commercial Crew
- CCT-REQ-1130 ISS Crew Transportation Requirements Document
- N/A – due to limited duration of mission

#### MPCV
- MPCV Human System Integration Requirements - HSIR
- **3.5.4.1 Exercise Capability [HS6032]**
  - The system shall provide the capability for aerobic and resistive exercise training for 30 continuous minutes each day per crewmember for missions greater than 8 days.

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**Risks to Standards**

**Standards to Program Requirements**
Human Risks Disposition for all DRMs

### Human System Risks 04/22/15

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<tbody>
<tr>
<td>VIIP</td>
<td>6 Months</td>
<td>12 Months</td>
<td>30 Days</td>
<td>1 year</td>
<td>1 Year</td>
<td>3 years</td>
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<td>Renal Stone Formation</td>
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<td>A</td>
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**Legend:**
- **A** – Accepted
- **RM** – Requires Mitigation
- **Green** – low/very low consequence
- **Yellow** – low to medium consequence
- **Red** – high consequence

### In Mission Risk - Operations

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### Post Mission Risk - Long Term Health

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Summary

- **Human Health/Performance Risk Framework** – Level I (Policy) & Level II (Operations & Research)

- **Risk Assessments for Space Exploration** are based on DRM **Categories** as actual DRMs are not available (conceptual) – These categories were designed to envelope the different DRMs

- 5 hazards of Spaceflight engender the 30 identified HS risks

- All factors that influence human risk pre/in/post-flight are evaluated together to ensure crew health

- **Systematic development of individual risk crew summaries** with risk statements, hazards, state of knowledge, metrics, LxC ratings, deliverables, etc. **evolve via the Continuous Risk Management (CRM) process**

- **The individual risk plans are “Projectized”** via high-level budget pie charts and high-level schedules via Gantt charts

- **Portfolio Management approach** will take advantage of risk dispositions and common elements identified within individual risks to develop priorities and broad range mitigation strategies

Thank you!
Backup