HRP-47052

Revision E

Human Research Program Requirements Document

Human Research Program

Revision E

May 2011

National Aeronautics and Space Administration

Johnson Space Center

Houston, Texas

Verify that this is the correct version.

HRP-47052

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Human Research Program
Requirements Document
May 2011

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-47051A, Human Research Program – Program Plan, and is under configuration management control of the Human Research Program Control Board (HRPCB).

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Human Research Program
Requirements Document
May 2011

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REVISION AND HISTORY PAGE

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1. INTRODUCTION

1.1 PURPOSE

This document defines, documents, and allocates the Human Research Program (HRP) requirements to the HRP Program Elements. It also establishes the flow of requirements from the Human Exploration and Operations Mission Directorate (HEOMD) and the Office of the Chief Health and Medical Officer (OCHMO) down to the various HRP Program Elements to ensure that human research and technology countermeasure investments support the delivery of countermeasures and technologies that satisfy HEOMD's and OCHMO's exploration mission requirements.

1.2 SCOPE

Requirements driving 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 following documents:

- ESMD-EARD-08.07 Rev. D, Exploration Architecture Requirements Document;
- NP-2007-07-474-HQ, Section 4.4, ESMD Implementation Plan, pages 12-13;
- NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1: Crew Health; and
- NASA-STD-3001, NASA Space Flight Human System Standard, and Volume 2: Human Factors, Habitability and Environmental Health.

This PRD defines the requirements of the HRP which is composed of the following major Program Elements:

1. Behavioral Health & Performance (BHP),
2. Exploration Medical Capability (ExMC),
3. Human Health Countermeasures (HHC),
4. ISS Medical Project (ISSMP),

5. Space Human Factors & Habitability (SHFH), and
6. Space Radiation (SR).

The requirements are further subdivided into the following three categories:

- Human system standards (section 4),
- Human health and performance risks (section 5), and
- 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 the issuance of change pages or a full re-issue of the document. A review of the PRD will be performed and changes made as necessary to maintain consistency with the evolving HEOMD 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.

Table 1 – Applicable Documents

Document No.	Revision Date	Document Title
NASA-STD-3001 Vol. 1	March 2007	NASA Space Flight Human System Standards, Volume 1: Crew Health
NASA-STD-3001 Vol. 2	February 2011	NASA Space Flight Human System Standards, Volume 2: Human Factors, Habitability and Environmental Health
NASA/SP-2010-3407	January 2010	Human Integration Design Handbook
HRP-47051A	April 2009	Human Research Program – Program Plan
NM 7120-81	September, 2009	NASA Space Flight Program and Project Management Requirements
NPD 1000.0A	August 2008	NASA Governance and Strategic Management Handbook
NPD 8500.1B	December 2007	NASA Environmental Management
NPD 8910.1B	October, 2009	Care and Use of Animals
NPR 1080.1A	May, 2008	Requirements for the Conduct of NASA Research & Technology (R&T)
NPR 2190.1	April 2003	NASA Export Control Program - Revalidated w/changes February 1, 2007
NPR 2810.1A	May 2006	Security of Information Technology
NPR 5800.1E	May 2005	Grant and Cooperative Agreement Handbook
NPR 7100.1	March 2003	Protection of Human Research Subjects w/Change 1 (07/07/08)

Document No.	Revision Date	Document Title
NPR 7120.8	February 2008	NASA Research and Technology Program and Project Management Requirements
NPR 8000.4A	December 2008	Agency Risk Management Procedural Requirements
NPR 7123.1A	March 2007	NASA Systems Engineering Process and Requirements w/Change 1 (11/04/09)

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.

Table 2 – Reference Documents

Document No.	Document Title
ESMD-EARD-08.07D	Exploration Architecture Requirements Document
HRP-47053D	Human Research Program Science Management Plan
HRP-47065B	Human Research Program Integrated Research Plan (electronically available at: http://humanresearchroadmap.nasa.gov/)
JSC 28330D	Space Life Sciences Directorate Configuration Control Management Plan
NASA/SP-2004-6113	Bioastronautics Roadmap
	HRP Evidence Base electronically available at: http://humanresearchroadmap.nasa.gov/evidence/
NPD 1000.3D	The NASA Organization w/Change 9 (June 14, 2010)
NPD 7100.8E	Protection of Human Research Subjects (Revalidated with admin. changes 6/14/2007)
NSPD31	National Security Presidential Directive 31 – The Vision for Space Exploration

Document No.	Document Title
S.1281	National Aeronautics and Space Administration (NASA) Authorization Act of 2005
	NASA Institutional Review Board Website - http://irb.nasa.gov/

3. HRP GOALS

This section reflects the HRP Goals and Objectives described in HRP Program Commitment Agreement and HRP-47051A, Human Research Program – Program Plan.

3.1 THE GOAL OF THE HRP IS TO PROVIDE HUMAN HEALTH AND PERFORMANCE COUNTERMEASURES, KNOWLEDGE, TECHNOLOGIES, AND TOOLS TO ENABLE SAFE, RELIABLE, AND 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 (HRP) SHALL ENABLE THE DEVELOPMENT AND VALIDATION OF NASA'S HEALTH, MEDICAL, HUMAN PERFORMANCE, AND ENVIRONMENTAL STANDARDS IN TIME FOR EXPLORATION MISSION PLANNING AND 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 and performance risks for exploration missions of varying complexity and duration. The NASA Chief Health and Medical Officer (CHMO) has established an initial set of standards that serves to guide the HRP in the expansion of its 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 CHMO and documented in NASA-STD-3001, NASA 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, habitability, and environmental standards to guide the development of spacecraft and systems so as to alleviate human health and performance impacts.

The HRP 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 HHC shall perform the research necessary to enable the development and validation of the Fitness for Duty Aerobic Capacity standard.

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

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

4.1.5 The HHC 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 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 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 shall perform the research and technology development necessary to enable the development of the Extravehicular Activity (EVA) sections of NASA-STD-3001, Space Flight Human Systems Standard, Vol.2.

4.1.9 The BHP 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 shall perform the research necessary to enable the development of the Circadian Entrainment and Workload sections of NASA-STD-3001, Space Flight Human Systems Standard, Vol. 2.

4.1.11 The SR 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 SR shall perform the research and technology developments necessary to enable the development of the Radiation sections of NASA-STD-3001, Space Flight Human Systems Standard, Vol. 2.

4.1.13 The SHFH shall perform the research necessary to enable development and validation of the Permissible Exposure Limit Lunar Dust Inhalation standard.

4.1.14 The ExMC shall perform the research necessary to enable development and validation of Crewmember Selection and Retention Criteria.

4.1.15 The SHFH shall perform the research and technology developments to enable documentation and validation of the environmental and human factors standards within NASA-STD-3001, Space Flight Human Systems Standard, Vol. 2 and the Human Integration Design Handbook.

5. HRP REQUIREMENTS RELATED TO HUMAN HEALTH & PERFORMANCE RISKS

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

Evidence Base

The HRP Evidence Base is a collection of evidence-based risk reports, one for each human health and performance risk listed in this section and for which implementation activities are listed in HRP-47065, HRP Integrated Research Plan. The Evidence Base provides a current record of the state of knowledge, from research and operations, for each of the risks, written for the scientifically educated, non-specialist reader. The risk reports are posted on the Human Research Roadmap Website - http://humanresearchroadmap.nasa.gov/evidence/.

As shown in Figure 1, the development of HRP content has been formulated around the management architecture of:

Figure 1: HRP Management Architecture

Evidence of spaceflight-related issues is used to define risks to crew health and performance. The risks are due to gaps in our knowledgebase. HRP funds tasks to address and close these gaps, and provides deliverables to NASA programs to address identified issues.

Human System Risk Board

The CHMO is the Health & Medical Technical Authority (HMTA) per NPD 1000.3D, The NASA Organization. The CHMO appoints the HMTA Chief Medical Officer (CMO) designee at each NASA center (as appropriate). The JSC CMO established the Human System Risk Board (HSRB) to ensure a consistent, integrated process is established and maintained for managing human system risks.

Per HRP-47051A, HRP Program Plan, the Bioastronautics Roadmap (BR) was used as a starting-point reference document. The BR initially captured the human system risks associated with exploration missions. However, it did not capture the level of detail necessary to prioritize across disciplines or compare strategies for a given risk across mission architectures and resources. The JSC CMO developed the Risk Management Analysis Tool (RMAT) to fill this gap and facilitate discussion and decisions by the HSRB.

The RMAT is used as a communication tool to understand human system risks and compare standards, requirements, mitigation strategies, etc. against known mission architectures and resources. The RMAT collects the appropriate information to allow decision-makers to develop mitigation strategies for the highest priority human risks for each mission architecture. The RMAT format reviews human system risks in terms of consequence, likelihood, uncertainty, contributing factors, and proposals for mitigating the risks and reviews each risk in terms of multiple mission architectures (ISS 6-month mission, ISS 12-month mission, Lunar sortie, Lunar outpost, Asteroid and Mars Mission).

If the HSRB determines there is sufficient evidence for a risk but additional research is required to understand or mitigate the risk, it is assigned to the applicable Program or individual responsible for owning the risk. If assigned to the HRP, the program will complete an analysis of the risk and develop a research plan to further understand the risk, inform the standards, or develop mitigation or monitoring strategies for the risk. The process for changing human health and performance risks is documented in HRP-47069B, Human Research Program Unique Processes, Criteria, and Guidelines (UPCG) document.

Risks in the HRP Portfolio

The table in this section lists the current HRP human health and performance risks and applicable HRP Element assignment. Risk content in the table contains the following information:

1. Risk Title: Top level wording used to describe the risk.
2. Risk Short Title: An abbreviation of the Risk Title
3. Risk Statement: Written to reflect that - Given the [CONDITION], there is a possibility that [CONSEQUENCE] will occur.
4. Risk Context: Written to capture the what, when, where, how, and why of the risk by describing the adverse outcome/event that is to be avoided, the circumstances, contributing factors, and related issues (elaborate on the risk statement).
5. RMAT Verification Status: Has the risk been **Verified** or substantiated by strong evidence either from spaceflight incidents, spaceflight or terrestrial data? If the risk is a concern that cannot be supported or refuted by available information, and for which further evidence to substantiate the risk is required, the risk is **Unverified**.
6. Risk Criticality: Further described below.

Criticality Metric

The HRP utilizes a criticality metric that serves as one of several inputs in the HRP Program Manager’s decision to allocate program resources to determine the priority of each risk.

The criticality metric is based on the level of the current state of knowledge about a risk, whether existing standards are met, and the degree to which the level of understanding of the risk will prompt the HRP Program Manager to recommend, in a forum such as the Human System Risk Board (HSRB), “no-go” for undertaking a mission. Each risk has a separate criticality rating for three mission scenarios: a Lunar Outpost mission (180-days), a Near Earth Asteroid (NEA) mission (1-year), and a Mars mission (3-years). The criticality rating has four possible values: *Unacceptable, Acceptable, Controlled* and *Insufficient Data*. The four ratings are described in detail below.

Rating Level: Unacceptable* (U) *- Red

A risk is deemed to have a rating of ***Unacceptable*** if one or more of its attributes (i.e. consequence, likelihood, uncertainty) are well understood and characterized such that it will not meet existing standards making it ***necessary*** to reduce one or more of these attributes prior to a mission.

Context:

– The current state of data and information on the risk and its mitigation and countermeasures would likely cause the HRP Program Manager to recommend, in a forum such as the HSRB, delaying a mission even if all other elements of the mission were ready (e.g. launch systems, Extravehicular Activity (EVA) systems, landing and life support systems).

– The lack of additional data and/or mitigation would leave NASA with too high of a risk.

Rating Level: Acceptable* (A) *- Yellow

A risk is deemed to have a rating of ***Acceptable*** if one or more of its attributes (i.e. consequence, likelihood, uncertainty) is well understood and characterized such that it meets existing standards but is not fully controlled. This requires an acceptance of the risk and makes it ***important but not necessary*** to reduce one or more of its attributes prior to a mission, but the risk is not expected to preclude a mission.

Context:

– The current state of data and information on the risk and its mitigation and countermeasures would likely not cause the HRP Program Manager to recommend, in a forum such as the HSRB, delaying a mission. However, additional work could further reduce the risk's consequence, likelihood or uncertainty (to the ***Controlled*** category).

Rating Level: Controlled (C) - Green

A risk is deemed to have a rating of ***Controlled*** if one or more of its attributes (i.e. consequence, likelihood, uncertainty) are well understood and characterized, and mitigation exists to control it at an accepted cost. It is still ***helpful but not necessary*** to reduce one or more of these attributes prior to a mission even if the risk will not preclude a mission.

Context:
– The current state of data and information on the risk and its mitigation and countermeasures would not cause the HRP Program Manager to recommend, in a forum such as the HSRB, delaying a mission. However, additional work could (a) further reduce the risk's consequence, likelihood or uncertainty; or (b) increase engineering or operational efficiencies.

Rating Level: Insufficient Data* (I) *- Gray

A risk is deemed to have a rating of ***Insufficient Data*** if one or more of its attributes (i.e. consequence, likelihood, uncertainty) are poorly understood and inadequately characterized to assess whether it has the potential to preclude any mission, and standards do not exist.

Context:
– The current state of data and information on the risk and its mitigation and countermeasures is grossly inadequate to offer the HRP Program Manager any recommendations regarding the impact of the risk to a mission. Additional work is expected to reduce the risk's uncertainty and offer more information to support a recommendation.

The criticality of a risk alone is not sufficient to determine the priority of the risk. Priority is dependent on criticality as well as other factors such as limited availability of certain necessary resources (as in 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. The level of activity (or budget) and timing of research investments reflect the final prioritization of the risks.

Some risks listed below are identified as 'Pending HSRB RMAT Approval' and thus do not adhere to the categories described above. Although most risk wording is a reflection of approved RMATs, there may be instances when the HRP makes a decision to use revised or alternate risk wording. In such cases, the risk will contain a reference to its HSRB approved RMAT.

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
HHC	Risk of Orthostatic Intolerance During Re-Exposure to Gravity (Short Title: OI) Statement: Given that there is cardiovascular adaptation during exposure to microgravity, there is a possibility that crewmembers will suffer from post-flight orthostatic intolerance upon re-exposure to gravity. Context: Post-flight orthostatic intolerance, the inability to maintain blood pressure while in an upright position, is an established, space-related medical problem. Orthostatic intolerance has been shown to progress to presyncope (inability to maintain standing blood pressure) in up to 80% of returning crewmembers tested with a post-flight tilt test. The greatest impact would occur on off-nominal landings, especially for Soyuz and Crew Exploration Vehicle (CEV) returns or when landing on other planetary bodies where there will not be ground support personnel available. Countermeasures have been successfully identified and implemented (fluid loading, re-entry compression garments) or being evaluated (midodrine, post-flight compression garments, etc.). Completion of these efforts will be useful in determining what preventive measures should be used to combat orthostatic intolerance during future mission profiles.	Verified	C	A	A
HHC	Risk of Early Onset Osteoporosis Due to Spaceflight (Short Title: Osteo) Statement: Given some parameters of skeletal adaptation may not be reversible after return to earth, there is the possibility that an early onset of osteoporosis may occur. Context: Osteoporosis is a skeletal syndrome that is characterized by low bone mass and severe structural deterioration. This condition can be due to aging or an extrinsic factor(s). Spaceflight-induced bone loss is classified as the latter (Secondary Osteoporosis) and is not contingent upon age. Bone mineral loss occurs in microgravity due to unloading of the skeletal system, with average	Unverified	C	A	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	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. Likewise, the impact of multiple long-duration missions or of cumulative time in space is not yet established. Space exposure could be a risk factor for long-term health implication of bone mineral loss that could put crewmembers at greater risk of fractures at an earlier age than expected for a terrestrial peer group and as opposed to traumatic fractures that are a result of excessive loading of bone (the biomechanical interaction between bone strength and the applied force vector (magnitude and direction of load)). Greater understanding of the mechanisms for bone atrophy in microgravity, and for recovery after return, is necessary to frame this risk, as well as to understand how current and future osteoporosis treatments may be employed.				
HHC	Risk Factor of Inadequate Nutrition (Short Title: Nutrition) Statement: Given that adequate nutrition is a key factor in all physiological functions, that space flight has been shown to alter many physiological functions in humans, and that countermeasures for individual systems may alter nutritional status, there is a possibility that inadequate nutrition will compromise crew health, including endurance, muscle mass and strength, immune function, bone mass and strength, cardiovascular performance, gastrointestinal function, endocrine function, and ocular, psychological and physical health, and ability to mitigate oxidative damage. Context: In general, nutritional risks increase with duration of exposure to a closed (or semi-closed) food system and when countermeasures are employed. Understanding nutrient requirements in micro- or partial gravity environments and the effect of countermeasures on nutrient requirements is critical to ensure crew health and safety and mission success. Provision of these nutrients in safe amounts (neither high nor low) depends on provision of appropriate, palatable, foods with the stability of nutrients for the duration of the mission, and actual intake of the nutrients, and knowledge that countermeasures are not altering requirements.	Verified	C	A	U
HHC	Risk of Compromised EVA Performance and Crew Health Due to Inadequate EVA Suit Systems (Short Title: EVA) - Pending HSRB RMAT Approval	No Status	A	A	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Statement: Improperly designed Extravehicular Activity (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.				
HHC	Risk of Impaired Performance Due to Reduced Muscle Mass, Strength and Endurance (Short Title: Muscle) Statement: Given that skeletal muscles undergo reduced mass, strength, and endurance in-flight, there is a possibility the crew will be physically unable to perform mission tasks. Context: There is a growing body of research evidence 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 needed for the in-flight exercise program.	Verified	A	A	U
HHC	Risk of Renal Stone Formation (Short Title: Renal) Statement: Given changes in urinary biochemistry during space flight, there is a possibility that symptomatic renal stones may form, resulting in urinary calculi or urolithiasis, renal colic (pain), nausea, vomiting, hematuria, infection, and hydronephrosis.	Verified	C	C	C

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Context: 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 space travel may increase the risk of kidney stone formation, and it is unclear which mitigation strategy would be the most effective in the context of mission operations.				
HHC	Risk of Bone Fracture (Short Title: Fracture) Statement: Given that crewmembers may experience high impact forces and/or decrease in bone strength, there is the possibility that fracture may occur. Context: The Factor of Risk (FOR) for fracture (“Risk of Bone Fracture”) is defined as the ratio between the Applied Force vector to bone and the Fracture Load of bone (vector is used here to indicate that both magnitude and direction of load are critical). Bone fracture load is a reflection of bone strength, but bone fracture load cannot be measured directly without being destructive. A long-established *surrogate* measure for whole bone strength has been the DXA measurement of areal bone mineral density (aBMD). By this measure, skeletal adaptation to microgravity in long-duration (LD) astronauts has been characterized by a ~ 1-2% decline in aBMD per month for normally weight-bearing bones. This rate is an average monthly BMD loss that has been determined over LD missions of 4-6 month duration. This level of BMD loss does not create an unacceptable risk of fractures during ISS missions since the Applied Loads are also reduced in the weightlessness of low Earth orbit. It is unclear whether DXA BMD loss will stabilize at a lower level or continue to diminish beyond 6 months. Thus, the total loss in BMD could be greater with longer missions, and consequently longer missions could increase the FOR. It is also unknown if fractional gravity, present on the moon and Mars, would mitigate the loss. Taken together, it is possible for astronauts, after 6 months of deconditioning, to have an increased FOR for at least one skeletal site in an environment with reduced g forces. The FOR for a given mission	Verified	C	C	C

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	architecture cannot be accurately estimated until the time course of skeletal adaptations (which influences bone strength) and the knowledge of mission activities (which influence applied loads) are identified. With this knowledge, the probabilities of bone overloading during the missions can be assessed. The types of fracture addressed in this risk are those that occur in-mission as opposed to fractures that occur at an earlier age post-flight resulting from osteoporosis due to spaceflight-induced bone loss. Greater understanding of skeletal adaptation to microgravity is necessary to frame this risk, as well as to understand how countermeasures to reduce FOR may be employed.				
HHC	Risk of Intervertebral Disc Damage (Short Title: IVD) Statement: Given the morphological and possible biochemical changes in the intervertebral disc (IVD) during mechanical unloading in space, there is the possibility of IVD damage. Context: Lengthening of the spine in microgravity has been shown to occur during exposure to microgravity (and possibly fractional gravity) and may lead to IVD damage or any detrimental change to the IVD such as protrusion, herniation, degeneration, or tear (more research is required to determine whether biochemical changes occur). Muscle weakness, muscle atrophy, and postural disturbances associated with exposure to microgravity may also be contributors. There has been a relatively high occurrence rate of herniated IVD (5.34 events per 1,000 person-yrs) observed in astronauts post-flight. Although there appears to be a correlation between IVD damage and spaceflight, a causal relationship has yet to be definitively established.	Unverified	C	I	I
HHC	Risk of Cardiac Rhythm Problems (Short Title: Arrhythmia) - Pending HSRB RMAT Approval Statement: Given the condition of microgravity, there is a possibility that cardiac rhythm disturbances may	Unverified	C	I	i

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	occur. Context: Heart rhythm disturbances have been seen among astronauts. Some 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.				
HHC	Risk of Reduced Physical Performance Capabilities Due to Reduced Aerobic Capacity (Short Title: Aerobic) Statement: Given the condition of reduced aerobic capacity as measured by VO2 max, there is a possibility of reduced physical performance. Context: 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.	Verified	A	A	U
HHC	Risk of Crew Adverse Health Event Due to Altered Immune Response (Short Title: Immune) Statement: Given that the spaceflight environment results in an alteration of the immune system and reactivation of latent herpes viruses, there is a possibility that the crew will experience certain	Verified	C	C	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	disease states, including persistent latent viral reactivation, during exploration class missions. Context: 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 and is usually asymptomatic.				
HHC	Risk of Impaired Control of Spacecraft, Associated Systems and Immediate Vehicle Egress due to Vestibular / Sensorimotor Alterations Associated with Space Flight (Short Title: Sensorimotor) Statement: Given that there is an alteration in vestibular/sensorimotor function during and immediately following gravitational transitions manifested as changes in eye-head-hand control, postural and/or locomotor ability, gaze function, and perception, there is a possibility that crew will experience impaired control of the spacecraft during landing along with impaired ability to immediately egress following a landing on a planetary surface (Earth or other) after long-duration spaceflight. Context: It has been shown that long-duration spaceflight alters vestibular/sensorimotor function which is manifested in some, but not all crewmembers (some have only partial symptoms while other show all) as changes in postural and locomotor control, gaze control, degradation of dynamic visual acuity, and perceptual changes. These changes have not specifically been correlated with real time performance decrements. The possible alterations in sensorimotor performance are of interest for Mars missions, performance onboard the ISS and return to Earth from the ISS, flights to and from the ISS, Lunar Sorties, and Lunar Outpost missions with prolonged exposure to Lunar gravitational fields. This risk must be	Verified	C	A	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	better documented, and vestibular/sensorimotor changes must be better correlated with performance issues. Overall, this risk is supported by three factors: • Impaired Manual Control • Space Motion Sickness (SMS) and Gravitational Transition Motion Sickness • Impaired Vehicular Egress (particularly under adverse environmental conditions)				
HHC	Risk of Therapeutic Failure Due to Ineffectiveness of Medication (Short Title: Pharm) - Pending HSRB RMAT Approval Statement: 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.	No Status	C	C	I
HHC	Risk of Microgravity-Induced Visual Impairment/Intracranial Pressure (Short Title: VIIP) - Pending HSRB RMAT Approval Statement: Given that all astronauts are exposed to microgravity and cephalad fluid shift, and given that both symptomatic and asymptomatic patients have both exhibited optic nerve sheath edema on MRI, there is a high probability that all astronauts have idiopathic intracranial hypertension to some degree, and that those susceptible (via eye architecture, anatomy, narrow disc) have a high likelihood of developing either choroidal folds or papilledema, and that the degree of that edema will determine long-term or permanent vision loss, sequelae, or impairment.	Verified	I	I	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Context: Some crewmembers on long duration ISS missions experienced ophthalmic anatomical changes and visual performance decrements of varying degrees which were temporary in some cases and permanent in others. Additionally, future implications for asymptomatic crewmembers that demonstrated anatomical changes via MRI are unknown. It is unknown if exposure to partial gravity will be protective. Visual acuity changes and visual field defects occur at a rate much higher than expected in spaceflight crews. Observed physical findings in long-duration crewmembers include papilledema, choroidal folds, increased optic nerve sheath diameter, and a posterior flattened globe. Persistent increased post-flight intracranial pressure (ICP) has been inferred in several cases, consistent with a root cause of intracranial hypertension (IHT) possibly secondary to microgravity-induced fluid shifts. The mechanisms that cause IHT in microgravity are not known, and the processes by which eye damage occurs as a result of IHT are not understood. Decreased visual acuity, IHT, and other findings are present months and in some cases years after return, indicating that damage may be permanent. Acuity changes have been noted in short-duration crewmembers, indicating that the process starts early in spaceflight, although this group has not been closely examined. It is unknown if fractional gravity would mitigate the hazard, but its persistence after return to Earth suggests not. Likewise, the impact of multiple missions or of cumulative time in space is not yet established. Greater understanding of the mechanisms for eye damage and IHT is necessary to understand and mitigate the hazard and treat the resultant conditions.				
HHC	<u>Risk of Injury from Dynamic Loads (Short Title: Occupant Protection)</u> Statement: Given the range of anticipated dynamic loads transferred to the crew via the vehicle, there is a possibility of loss of crew or crew injury during launch, abort, and landing.	Verified	U	U	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Context: With the retirement of the Shuttle, future spacecraft systems may include launch-abort systems and parachute-assisted, capsule landings. Because of these design features, dynamic loads transmitted to the human may result in higher forces than currently experienced during spaceflight. The current standards and requirements do not adequately document the acceptable limits of forces and/or direction of force vectors which can be transmitted to the human without causing injury. Injuries may impair or prevent a crew-member from unassisted evacuation of the spaceflight vehicle after landing. Development of Agency-level human health and performance standards appropriate to occupant protection from dynamic loads as well as development of the method(s) of meeting those standards in the design, development, and operation of mission systems would reduce the likelihood of this risk so that crew injury or Loss of Crew (LOC) may be avoided or reduced. In addition, the Columbia Crew Survival Investigation Report cited inadequate upper body restraint and protection as a potential lethal event and recommended that future spacecraft suits and seat restraints should use state-of-the-art technology in an integrated solution to minimize crew injury and maximize crew survival in off-nominal acceleration environments (L2-4/L3-4) and should incorporate conformal helmets and neck restraint designs similar to those used in professional auto racing (L2-7).				
SHFH	Risk of Performance Decrement and Crew Illness Due to an Inadequate Food System (Short Title: Food) Statement: Given there is a constrained spaceflight environment with limited-source food supply, there is a possibility of performance decrement, illness, or loss of mission (LOM) due to an inadequate food system. Context: Food must be free from microbiological, chemical, and foreign matter contamination for up to five years of storage to provide a viable food system for the extended duration space missions. Inefficient sanitation, recordkeeping, processes, facilities, and many other factors could cause contamination compromising crew health or survival.	Verified	C	C	U

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Nutrition is essential for the crew by providing nutrients and energy through calories. Adequate nutritional content of the food for up to five years will ensure crew performance and protects the body from deficiencies that may cause disease. Food acceptability, using sensory analysis, measures texture, appearance, flavor, aroma, and temperature of a food item. Acceptable food for up to five years encourages consumption and boosts crew morale by alleviating boredom and stress, and promotes unity amongst the crew during meal time. Inefficient use of resources such as mass, volume, power, crew time, and waste disposal capacity affect mission success. All of these elements influence the safety and quality of flight.				
SHFH	Risk of Inadequate Human-Computer Interaction (Short Title: HCI) - Pending HSRB RMAT Approval Statement: Given that human-computer interaction and information architecture designs must support crew tasks, and given the greater dependence on HCI in the context of long-duration spaceflight operations, there is a risk that critical information systems will not support crew tasks effectively, resulting in flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in crew injuries. Context: Information is presented most effectively when the user's interests, needs, and knowledge are considered. If information displays are not designed with a fully developed operations concept, fine-grained task analysis, and knowledge of human information processing capabilities and limitations, the format, mode, and layout of the information may not optimally support task performance. This may result in users misinterpreting, overlooking, or ignoring the original intent of the information, leading to task completion times that impact the timeline, necessitating costly re-planning and rescheduling, and/or task execution errors, which endanger mission goals, crew	Verified	C	C	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	safety, and mission success.				
SHFH	Risk of Performance Errors Due to Training Deficiencies (Short Title: Train) - Pending HSRB RMAT Approval Statement: Given that training content, timing, intervals, and delivery methods must support crew task performance, and given that training paradigms will be different for long-duration missions with increased crew autonomy, there is a risk that operators will lack the skills or knowledge necessary to complete critical tasks, resulting in flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in crew injuries. Context: Historically, spaceflight operations have mitigated procedure execution errors in at least two ways: specially-trained crew members are assigned to missions and/or rotated into the operational environment when complex, mission-critical tasks must be performed; and, execution of such procedures is closely monitored and supported by flight controllers on the ground who have access to a broader and deeper pool of information and expertise than any individual operator. However, emerging mission architectures include long-duration operations in deep space. Such operations do not allow for assignment of new crew or rotation of crew to ground for training. Further, delays in communication will have a disruptive effect on the ability of earth-based flight controllers to monitor and support space operations in real time. As a result, it is necessary to develop an understanding of how training can be tailored to better support long-duration deep space operations (incl. the extent to which materials, procedures, and schedules of training should be modified).	Verified	C	C	A
SHFH	Risk of Inadequate Design of Human and Automation/Robotic Integration (Short Title: HARI) - Pending HSRB RMAT Approval	Verified	C	C	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Statement: Given that automation and robotics must seamlessly integrate with crew, and given the greater dependence on automation and robotics in the context of long-duration spaceflight operations, there is a risk that systems will be inadequately designed, resulting in flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in crew injuries. Context: The scope of NASA's future missions will involve humans interacting with automated and robotic systems to accomplish mission goals. This will be the case for both near and deep-space exploration missions, as well as Near-Earth-Object and Planetary surface exploration. Varying classes of robotic systems (including dexterous, heavy-lift and mobility systems) will be employed for these missions. Automation will be an integral part of ground and flight systems, in addition to being utilized within Robotic systems. The level of complexity of the operations required to carry out NASA's vision will greatly increase over the paradigm of robotics and automation in use today. Human and Robot teaming will be at the cornerstone of such operations. Systems will have to be designed to support multiple operators, varying time delays and increasing reliance on automation. In addition, robotic systems and their human interfaces must be designed to support all levels of human operation (direct manual control, teleoperation shared control, and supervisory control), while also supporting multiple robot operators in multi-agent team configurations, with those operators separated by time, space or both. Similarly, the integration of automation systems with their human users requires supporting a variety of role divisions: authority and autonomy can be differently allocated between human and automation, and the allocation may change dynamically depending on task or context.				
SHFH	Risk of Poor Critical Task Design (Short Title: Task) - Pending HSRB RMAT Approval Statement:	Verified	C	C	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Given that tasks, schedules, and procedures must accommodate human capabilities and limitations, and given that long-duration crews will experience physical and cognitive changes and increased autonomy, there is a risk that tasks, schedules, and procedures will be developed without considering the human condition, resulting in increased workload, flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in crew injuries. Context: The risk of poor task design relates to the definition and development of mission tasks, task flows, schedules, and procedures. Operations tempo is driven by the scheduling of mission tasks, and can affect workload and situation awareness of crewmembers. Low workload levels have been associated with boredom and decreased attention to task; whereas high workload levels have been associated with increased error rates and the narrowing of attention to the possible detriment of tasks. Tasks are driven by procedures, and when written direction, checklists, graphic depictions, tables, charts or other published guidance is inadequate, misleading or inappropriate, an unsafe situation results. Guidelines for designing task flow, schedules, and procedures are critical for ensuring task and mission success.				
SHFH	Risk of Adverse Health Effects of Exposure to Dust and Volatiles During Exploration of Celestial Bodies (Short Title: Dust) – Pending HSRB RMAT Approval Statement: Given the unique properties of lunar dust and volatiles on celestial bodies such as the moon, asteroids and Mars, minimal data on health effects of contact or airborne exposure, and the lack of a viable exposure standard, there is a possibility that exposure could lead to serious respiratory, cardiopulmonary, ocular, central nervous system, or dermal harm during lunar exploration-class missions, resulting in immediate or long-term health effects. Context:	Verified	A	I	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Current lunar sortie and habitat operations include EVA activities, the collection of lunar rocks and soil, and possibly the use of this material in 'in situ' experiments. While the lunar design architecture is not finalized, current design suggests crew exposure to airborne lunar dust is highly likely. 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 characterization of lunar dust size distribution, grain morphology, chemical reactivity, the mode of activation and passivation of surfaces, toxicity to the respiratory system, ocular irritancy and abrasiveness, and cellular-level toxicity. Health effects from chronic exposure to lunar dust may lead to irreversible compromised pulmonary function and possible organ damage outside the lung through relocation of toxic nano-scale particulates. Acute health effects include ocular irritation and abrasion that might impair crew vision, and dermal abrasion that might impair crew performance. Carbonaceous asteroids have an abundance of volatiles to which crews could be exposed. Martian dust is a major threat at the surface due to global dust storms and seasonal clusters of "dust devils" on the surface. Volatiles are also present at the surface. Asteroid and Martian dust have not been well characterized.				

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	A subset of tests should be performed on “asteroid” dust obtained by grinding meteorites known to originate from asteroid material. Volatiles could pose a health risk during operations on carbonaceous asteroids and at the surface of Mars. This is especially true if industrial-scale operations are employed to extract volatiles for use in production of propellants.				
SHFH	Risk of an Incompatible Vehicle/Habitat Design (Short Title: Hab) - Pending HSRB RMAT Approval Statement: Given that vehicle, habitat, and workspace designs must accommodate variations in human physical characteristics and capabilities, and given that the duration of crew habitation in these space-based environments will be far greater than missions of the past, there is a risk of acute and chronic ergonomic-related disorders, resulting in flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in crew injuries. Context: This risk creates both short-term and long-term negative effects when a crewmember is engaged in performing a task due to problems with aspects of the designed physical working and living environment. Examples of short term effects include overexertion, difficulty in reading a checklist due to spacecraft vibrations or inadequate lighting, high temperatures in a module due to inadequate and excessive co-location of habitability related hardware and activities, difficulty donning a suit due to inadequate habitable volume, difficulties communicating with fellow crewmembers due to high levels of noise in the cabin, diminished mental capacity and discomfort due to high CO_2 levels, or short-term disabilities caused by exposure to environmental contaminants. Inefficiencies may include unnecessary translations between workstations to complete tasks and increased task completion time due to difficulty in accessing equipment. Examples of the long term effects include ergonomic injuries / cumulative trauma disorders that are a result of repetitive motions, sustained maintenance of awkward postures, inadequate	Verified	C	C	A

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	workspace clearances resulting in frequent over-exertions, suit hardware requiring sustained performance at excessively high sub-maximal levels, and poorly designed work practices. Incompatible vehicle/habitat design could force crew members to hold these awkward postures for long periods of time. Interacting with a vehicle/habitat environment which unsatisfactorily accommodates the crew along all anthropometric ranges could also expose crew members to awkward postures and potential contact stress against soft tissue. Mismatched physical task requirements to actual crew's diminished physical capacity (decondition) could lead to the development of repetitive motion injuries, crew frustration, and/or mission failure. The physical well being of the returned crew will be compromised not only temporarily but also permanently as evidenced by the plight of manual laborers in industries with poorly designed ergonomic work conditions and practices.				
SHFH	Risk of Adverse Health Effects Due to Alterations in Host-Microorganism Interactions (Short Title: Microhost) Statement: Given that flight experiment data indicates alterations in microbial virulence and astronaut immune function during spaceflight, the risk of infectious disease may be enhanced during spaceflight missions. Context: While hazard control systems and processes prevent the presence of many medically significant microorganisms during spaceflight missions, potentially pathogenic organisms could be carried by crewmembers, the spacecraft, and its cargo; thus, microbial infection of crewmembers cannot be completely prevented. Recent evidence from spaceflight experiments also suggests alterations in microbial characteristics, including virulence (disease causing potential), in organisms grown during flight. In combination with potential host susceptibility due to dysfunction in the immune system, infectious disease risk may be greater than in the spaceflight environment than in normal workplace settings.	Verified	A	I	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
ExMC	Inability to Adequately Recognize or Treat an Ill or Injured Crew Member (Short Title: ExMC) Statement: Given that there are limited mass, volume, power, and crew training time available for space exploration missions which therefore limits the amount of equipment, consumables, and procedures available to treat medical problems, there is a possibility that certain medical conditions will not be treatable. Context: Mission architecture limits the amount of equipment, consumables, and procedures that will be available to treat medical problems. Mission allocation and technology development must be performed to ensure that the limited mass, volume, power, and crew training time are used efficiently to provide the broadest possible treatment capability. There is a risk that, given the resource limitations, some conditions may go untreated.	Verified	A	A	U
BHP	Risk of Adverse Behavioral Conditions and Psychiatric Disorders (Short Title: Bmed) - Reference RMATs for Risk of Adverse Behavioral Conditions, and Risk of Psychiatric Disorders Statement: Given the extended duration of future missions and the isolated, extreme and confined environments, there is a possibility that (a) adverse behavioral conditions will occur; and (b) mental disorders (DSM-IV –TR) could develop should adverse behavioral conditions be undetected and unmitigated. Context: This risk derives from the occurrence of environmental, social and physical conditions that may occur on a continuum. NASA BHP Ops defines an Adverse Behavioral Condition as: "*Any decrement in mood, cognition, morale or interpersonal interaction that adversely affects operational readiness or performance*." Scientific studies demonstrate that if left unmitigated, personal reactions such as those listed below, can erode individual motivation, morale and	Verified	C	A	U

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	performance. • Worry/anxiety over conditions of mission or on Earth that distracts from mission focus • Anger/resentment toward others that affects cooperation during mission • Insufficient training (Pre, In or Post–Flight) • Depression/loneliness due to isolation from friends and family • Unhappiness over role or treatment by others that leads to social isolation during mission Acute or chronic conditions during spaceflight may also exacerbate the risk of developing a psychiatric disorder from these adverse behavioral conditions. The Diagnostic and Statistical Manual of Mental Disorders IV-TR (DSM-IV-TR), defines a mental disorder as: *"A clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is associated with present distress…or disability…or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom…" (pp.xxxi).*				
BHP	Risk of Performance Errors Due to Fatigue Resulting from Sleep Loss, Circadian Desynchronization, Extended Wakefulness, and Work Overload (Short Title: Sleep) Statement: Given that astronauts experience sleep loss, circadian desynchronization, work overload, and extended wakefulness, there is a possibility a performance decrement will occur, resulting in the crew functioning poorly. Context: Fatigue resulting from sleep loss, circadian desynchronization, extended wakefulness, and work overload occur to some extent for ground and flight crews, prior to and during spaceflight missions. Ground evidence indicates that fatigue, as experienced by ground and flight crews, may lead to performance errors, which could potentially compromise mission objectives, and consequently the mission itself. Efforts are needed to identify the environmental and mission conditions that interfere with sleep quality, as well as individual vulnerabilities to sleep loss and circadian desynchronization. Research areas to mitigate this risk may also include: development of a self-assessment tool for cognitive function and fatigue; light therapy for phase shifting, alertness, and mood disorders; individualized protocols for sleep-wake medication use; sleep	Verified	C	C	C

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	dose-response recovery curves and individualized models for countermeasure implementation and optimal work-rest schedules; and other evidence-based means to improve individual sleep quality and reduce fatigue.				
BHP	Risk of Performance Decrements due to Inadequate Cooperation, Coordination, Communication, and Psychosocial Adaptation within a Team (Short Title: Team) Statement: Given that the conditions of long-duration missions will likely impact behavioral health and functioning of the team, performance decrements may occur that will jeopardize mission success and crew health and safety. Context: Human performance decrements may occur due to problems associated with working in the space environment and to the failure of the crews to cooperate and work effectively with each other and/or with flight controllers and other support staff. Interpersonal conflict, impaired communication, and inadequate teamwork behavior will impact performance and mission success. The history of spaceflight crews regarding important team dynamics including communication, cooperation, and coordination has not been systematically documented. Tools, training, and support methods should be provided to reduce the likelihood of this risk so that optimal crew performance may be realized for exploration missions. Current ISS mission operations for six month durations are sufficient; however, there are ways to improve and optimize current operations regarding teamwork. In addition, lunar missions, while planned for six month durations, will benefit from research addressing monitoring and methods for self-regulating teams living and working in isolated, confined environments.	Verified	C	A	A
SR	Risk of Radiation Carcinogenesis (Short Title: Cancer) Statement: Given that crewmembers are exposed to radiation from the space environment, there is a possibility for increased cancer morbidity or mortality.	Verified	A	U	U

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	Context: In space, astronauts are exposed to ionizing radiation that is quantitatively and qualitatively different from terrestrial radiation. This environment includes protons and high-Z high-energy (HZE) ions together with secondary radiation, including neutrons and recoil nuclei that are produced by nuclear reactions in spacecraft materials or tissue. Astronauts who are on missions to the ISS, the Moon or Mars are exposed to ionizing radiation with effective doses in the range of 50 to 2000 mSv (milli-Sievert) projected for possible mission scenarios. Similar doses from terrestrial radiation sources, such as gamma-rays and X-rays, are associated with an increased risk for development of cancer. Therefore, occupational radiation exposure from the space environment may increase cancer morbidity or mortality risk in astronauts.				

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
SR	<u>Risk of Acute Radiation Syndromes Due to Solar Particle Events (Short Title: ARS)</u> Statement: Given the known occurrence of solar particle events (SPE) and the inability to predict when they might or might not occur, there is a possibility the crew will suffer from acute radiation sickness (ARS), prodromal effects, skin damage and potential hematological/immune changes resulting in LOM. Context: 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 (LEO), the protection of the Earth's magnetosphere 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.	Verified	A	A	A
SR	<u>Risk of Acute or Late Central Nervous System Effects from Radiation Exposure (Short Title: CNS)</u> Statement: Given that the crew is exposed to radiation from the space environment, there is the possibility that they will have CNS damage leading to acute and/or late changes in motor function, behavior, or neurological disorders. Context: Possible acute and late risks to the central nervous system (CNS) from galactic cosmic rays	Unverified	A	I	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	(GCR) and solar particle events (SPE) are a documented concern for human exploration of space. Acute CNS risks include: altered cognitive function, reduced motor function, and behavioral changes, all of which may affect performance and human health. Late CNS risks include neurological disorders such as Alzheimer's disease, dementia or premature aging. Although detrimental CNS changes are observed in humans treated with high dose radiation (e.g., gamma rays and protons) for cancer and are supported by experimental evidence showing neurocognitive and behavioral effects in animal models, the significance of these results on the morbidity to astronauts has not been elucidated. There is a lack of human epidemiology data on which to base CNS risk estimates and therefore risk projection based on scaling to human data, as done for cancer risk, is not possible for CNS risks. Research specific to the spaceflight environment using animal and cell models must be compiled to quantify the magnitude of this risk and to establish validity of the current PEL. In addition, the impact of radiation exposure in combination with individual sensitivity or other space flight factors, as well as assessment of the need for biological/pharmaceutical countermeasures will be considered after further definition of CNS risk occurs.				
SR	Risk of Degenerative Tissue or other Health Effects from Radiation Exposure (Short Title: Degen) Statement: Given that the crew is exposed to radiation from the space environment there is the possibility that they will develop degenerative tissue diseases. Context: Degenerative diseases including cardiac, circulatory, and digestive diseases; and cataracts are documented following exposures to terrestrial sources of ionizing radiation (e.g., gamma rays and x-rays). This provides evidence for possible degenerative tissue effects following exposures to ionizing radiation in the form of galactic cosmic rays or solar particle events expected during long duration space travel, although the mechanisms and the magnitude of influence of radiation leading to these diseases are not well characterized Degenerative disease risks are difficult to	Verified	A	I	I

Table 3 – Exploration Missions Human Health and Performance Risks, Evidence Verification, and Mission Criticality

HRP Element	Risk Title, Short Title, Statement and Context	Evidence Verification Status	Criticality		
			Lunar	NEA	Mars
	assess because multiple factors, including radiation, are believed to play a role in the etiology of the diseases. Data specific to the spaceflight environment must be compiled to quantify the magnitude of this risk, to decrease the uncertainty in current Permissible Exposure Limits (PEL), and to determine if additional protection strategies are required.				

5.1 THE HRP SHALL QUANTIFY THE HUMAN HEALTH AND 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 and software design and mission design.

5.1.1 The HRP Science Management Office (SMO) 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 HRP efforts and ensure proper decision making.

5.1.2 The BHP shall quantify the BHP-applicable Risks identified in Table 3.

5.1.3 The ExMC shall quantify the ExMC-applicable Risks identified in Table 3.

5.1.4 The HHC shall quantify the HHC-applicable Risks identified in Table 3.

5.1.5 The SHFH shall quantify the SHFH-applicable Risks identified in Table 3.

5.1.6 The SR shall quantify the Space Radiation-applicable Risks identified in Table 3.

5.2 THE HRP ELEMENTS SHALL DEVELOP COUNTERMEASURES AND TECHNOLOGIES TO PREVENT OR MITIGATE ADVERSE OUTCOMES OF HUMAN HEALTH AND 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 shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to BHP (see Table 3).

5.2.2 The ExMC shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to ExMC (see Table 3).

5.2.3 The HHC shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to HHC (see Table 3).

5.2.4 The SHFH shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to SHFH (see Table 3).

5.2.5 The SR shall develop countermeasures and technologies to prevent or mitigate adverse outcomes of human health and performance risks relevant to Space Radiation (see Table 3).

5.3 THE HRP ELEMENTS SHALL DEVELOP COUNTERMEASURES AND TECHNOLOGIES TO MONITOR AND TREAT ADVERSE OUTCOMES OF HUMAN HEALTH AND 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 shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to BHP (see Table 3).

5.3.2 The ExMC shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to ExMC (see Table 3).

5.3.3 The HHC shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to HHC (see Table 3).

5.3.4 The SHFH shall develop countermeasures and technologies to monitor and treat adverse outcomes of human health and performance risks relevant to SHFH (see Table 3).

5.3.5 The SR shall develop countermeasures and technologies to monitor indicators of adverse outcomes of human health and performance risks relevant to Space Radiation (see Table 3).

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, NASA Extreme Environment Mission Operation (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 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 [the Space Transportation System (STS), the ISS, and all ISS visiting vehicles that transport crew and/or cargo 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 Sciences Data Archive (LSDA)] and organizing medical and research data to provide proper security levels, allow access by query, and to provide tools to allow analysis of evidence (e.g., Integrated Medical Model).

6.2 THE HRP SHALL ENSURE PRESERVATION AND MAINTENANCE OF CORE TECHNICAL CAPABILITY AND EXPERTISE IN HUMAN RESEARCH AND 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 scientific and management workforce and a robust external scientific community. It also requires an 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 the following:

Strategic planning. Identification and prioritization of the risks to the human system and development of 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.

Acquisition development, planning, and execution. Acquisition of research and technology development is an inherently governmental function that requires core expertise within the civil service to ensure that the U.S. Government remains a “smart buyer” with respect to research and technology development for the human system.

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 Program Elements. As part of the annual Planning, Programming, Budgeting, and Execution (PPBE) process, Program Management will review the core technical capability of the Program Elements and adjust where appropriate.

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

Rationale: The Table of applicable documents includes the NASA Policy Directives (NPD) and NASA Procedural Requirements (NPR) specifically referenced by HRP 47051, HRP Program Plan. This requirement explicitly states which NPR and NPD are applicable to the HRP and ensures that the requirement is flowed down to the Program 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.

6.4 THE HRP ELEMENTS SHALL DEVELOP METHODS AND TECHNOLOGIES TO REDUCE HUMAN SYSTEMS RESOURCE REQUIREMENTS (MASS, VOLUME, POWER, DATA, ETC.).

Rationale: Methods and technologies that reduce the medical systems requirements for mass, volume, power, data, etc. must be developed to reduce the overall Constellation Program resource requirements. Each HRP research element must focus the research on producing countermeasures and technologies that fit within the extremely limited resource envelopes anticipated for the exploration mission. An example is the reduction in time dedicated to exercise prescriptions. Present exercise prescriptions present a large burden on the overall mission timeline.

6.4.1 The HHC shall develop methods and technologies to reduce human systems resource requirements (mass, volume, power, data, etc.).

6.4.2 The BHP shall develop methods and technologies to reduce human systems resource requirements (mass, volume, power, data, etc.).

6.4.3 The SR shall develop methods and technologies to reduce human systems resource requirements (mass, volume, power, data, etc.).

6.4.4 The SHFH shall develop methods and technologies to reduce human systems resource requirements (mass, volume, power, data, etc.).

6.4.5 The ExMC shall develop methods and technologies to reduce human systems resource requirements (mass, volume, power, data, etc.).

APPENDIX A ACRONYMS AND ABBREVIATIONS

aBMD	Areal Bone Mineral Density
ARS	Acute Radiation Sickness
BHP	Behavioral Health & Performance
BMD	Bone Mineral Density
CEV	Crew Exploration Vehicle
CMO	Chief Medical Officer
CHMO	Chief Health & Medical Officer
CNS	Central Nervous System
DNA	Deoxyribonucleic Acid
DSM	Diagnostic and Statistical Manual of Mental Disorders
Degen	Degenerative
e.g.	For Example
ESMD	Exploration Science Mission Directorate
EVA	Extravehicular Activity
ExMC	Exploration Medical Capabilities
Hab	Habitat
HARI	Human & Automation/Robotic Integration
HCI	Human-Computer Interaction
HEOMD	Human Exploration and Operations Mission Directorate
HHC	Human Health Countermeasures
HMTA	Health & Medical Technical Authority
HRP	Human Research Program
HRPCB	Human Research Program Control Board
ISS	International Space Station
ISSMP	ISS Medical Project
IVA	Intravehicular Activity
IVD	Intervertebral Disc
JSC	Johnson Space Center
L.	Lunar
LD	Long Duration
LEO	Low Earth Orbit
LOM	Loss Of Mission
LSDA	Life Sciences Data Archive
Microhost	Host-Microorganism
NASA	National Aeronautics and Space Administration
NEEMO	NASA Extreme Environment Mission Operation
NP	NASA Publication
NPD	NASA Procedural Directive
NPR	NASA Procedural Requirement
NSPD	National Security Presidential Directive
OCHMO	Office of the Chief Health and Medical Office
OI	Orthostatic Intolerance
Osteo	Osteoporosis
PPBE	Planning, Programming, Budgeting, and Execution

PRD	Program Requirements Document
R&T	Research and Technology
RMAT	Risk Mitigation Analysis Tool
SHFH	Space Human Factors & Habitability
SLSD	Space Life Sciences Directorate
SMO	Science Management Office
SMS	Space Motion Sickness
SPE	Solar Particle Event
SR	Space Radiation
SSP	Space Station Program
STS	Space Transportation System
TBD	To Be Determined
U.S.	United States
UPCG	Unique Processes, Criteria, and Guidelines
VIIP	Visual Impairment/Intracranial Pressure