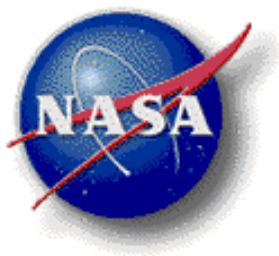


Human Research Program Program Plan

Revision D, PCN-2

November 5, 2018



**National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas 77058**

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Human Research Program

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It is the responsibility of each of the signing parties on this page to notify the other in the event that a plan cannot be met and to initiate the timely renegotiations of the terms of this agreement.

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Human Research Program

Program Plan

November 5, 2018

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REVISION AND HISTORY PAGE

REV.	DESCRIPTION	PUB. DATE
Baseline	Baseline approved by Kathleen C. Laurini/Manager HRP and Scott J. Horowitz, Associate Administrator, Exploration Systems Mission Directorate per SLSDCR-HRPCB-06-002 (4/19/2006)	5/31/2006
Rev A	Revised by HRPCB per SLSDCR-HRPCB-08-019 (12/11/08) and DPMC approval (4/13/09)	4/13/2009
Rev B	Adjusted for NASA Headquarters (HQ) reorganization merging ESMD with HEOMD and for the addition of the International Science Office to HRP per SLSDCR-HRPCB-12-008 (4/23/2012)	2/5/2013
Rev B PCN-1	Revised by HRPCB per SLSDCR-HRPCB-14-010 (3/14/2014) Added document number to the header of the document Update Figure 1-1 Updated Figure 3-1 Adjusted document to reflect the transition from SLSD to HHPC Changed CPHS references to IRB Updated Appendix C with WBS additions Updated Appendix F with new Domestic and International Agreements and completed or extended agreements Updated Applicable Documents Added information on the Mishap Preparedness and Contingency Plan Process Added information on the Risk Management Plan and current processes	3/27/2014
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Rev D	Revised by HRPCB per HHPDCR-HRPCB-17-001 Updated HRP Element structure, WBS and acronyms list Updated Figures 1-1, 1-2. Update the Associate Chief Scientist description. Revised Appendix B to updated Risk Management practices and revise Appendix C to include the HRP Schedule Management Plan	2/28/2017
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1 HUMAN RESEARCH PROGRAM OVERVIEW

1.1 INTRODUCTION

Crew health and performance is critical to successful human exploration beyond low-Earth orbit. The Human Research Program (HRP) investigates and mitigates the highest risks to human health and performance, providing essential countermeasures and technologies for human space exploration. Risks include physiological effects from radiation, hypogravity, and planetary environments, as well as unique challenges in medical treatment, human factors, and behavioral health support. Without HRP results, National Aeronautics and Space Administration (NASA) will face unknown and unacceptable risks for mission success and post mission crew health.

The HRP was established in October 2005 at the Johnson Space Center (JSC) in response to the NASA decision to focus its research investment on investigating and mitigating the highest risks to astronaut health and performance in support of exploration missions. Strategically, the HRP conducts research and technology (R&T) development that:

1. Enables the development or modification of Agency-level human health and performance standards by the Office of the Chief Health and Medical Officer (OCHMO) and
2. Provides the Human Exploration and Operations Mission Directorate (HEOMD) with methods of meeting those standards in the design, development, and operation of mission systems.

1.2 PROGRAM GOALS, OBJECTIVES AND METRICS

1.2.1 Goals and Objectives

The HRP is an applied R&T program that contributes to the NPD 1001.0C, 2018 NASA Strategic Plan, through:

Strategic Goal 2: Extend Human Presence Deeper into Space and to the Moon for Sustainable Long-Term Exploration and Utilization

Objective 2.2: Conduct Human Exploration in Deep Space, Including the Surface of the Moon.

The HRP is responsible for understanding and mitigating the highest risks to astronaut health and performance to ensure that crew remain healthy and productive during long-duration missions beyond low Earth orbit. The HRP leverages the talents of researchers within NASA, across U.S. academia and associated with International Partners to implement a detailed plan for risk reduction, with much of this work taking place onboard the ISS. The specific objectives of the HRP are:

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;
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. 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.

1.2.2 Metrics

Since the HRP provides key information on human health and performance risks to ensure exploration program success, the measure of success is defined by providing high-quality products that meet customer requirements and are delivered to support exploration milestones.

The HRP products include:

1. Reduction or elimination of human health and performance risks,
2. Reduction in uncertainty surrounding human health and performance risks,
3. Countermeasures translated to medical operations practice,
4. Technologies for monitoring and treatment of adverse outcomes, and
5. Information to update the human health and performance standards.

The HRP monitors and tracks the progress of tasks to ensure timely inputs to the OCHMO space flight health standards, exploration programs, medical operations, mission procedures, and flight rule requirements development. The HRP, in conjunction with stakeholders, annually reviews the research progress in closing gaps in technology or knowledge. As gaps are closed, risks are reassessed to verify progress toward meeting the spaceflight health standards for exploration missions. Progress is indicated by changes in the likelihood, consequence, or uncertainty of human health and performance risks. As this data matures, it allows OCHMO and HEOMD managers to accept, mitigate, transfer, or retire the risks.

The Government Performance and Results Modernization Act (GPRMA) of 2010 provides for the establishment of strategic planning and performance measurement in the Federal Government. NPR 1080.1A, Requirements for the Conduct of NASA Research and Technology (R&T), Section 4.3, Performance Management, is the Agency's response to the GPRMA.

1.3 CUSTOMER-SUPPLIER AND STAKEHOLDER DEFINITION AND ADVOCACY

1.3.1 Customers and Stakeholders

A customer is the primary recipient and ultimate owner of any resultant deliverables. Two organizations are the primary recipients of HRP outcomes and products: OCHMO and HEOMD. HRP research focuses on reducing crew health and performance risks for exploration missions. In addition, HRP research gathers the data necessary to understand and mitigate the long-term health risks to the crew, to allow the update of specific crew health standards for each mission scenario, to support crew selection, and to address any rehabilitation requirements. HRP technology development enables the advancement of medical care and countermeasure systems.

The program also develops and matures operations concepts that will inform requirements for the design and operation of space vehicles and habitats needed for exploration missions. HRP products will be incorporated into OCHMO standards, exploration program requirement documents, vehicle designs, and operational processes and documents.

A stakeholder is any entity with an interest in the deliverables. Since 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, a key stakeholder is the Astronaut Office at JSC. Flight crewmembers are the equivalent risk takers per NPD 8700.1E, NASA Policy for Safety and Mission Success. The HRP consults with representatives from the Astronaut Office and involves crew personnel in decision making as members of the HRP control boards.

Additional HRP stakeholders are the Office of Chief Technologist (OCT) and Office of Chief Scientist (OCS) at NASA Headquarters (HQ). The HRP will work with the OCT and OCS to prevent duplication of technology development and coordinate efforts where appropriate. In addition, the HRP will provide human systems expertise to assist with their hardware and software development.

1.3.2 Customer and Stakeholder Advocacy

Customers and stakeholders must be active participants in the process of planning, reviewing, and assessing the direction and results of HRP activities. Frequent communication with the customer will ensure HRP products remain relevant to exploration needs and goals. Customers and stakeholders will provide inputs to the products by reviewing the proposed standards, requirements, countermeasures, and systems solutions to ensure that products are usable, crew health is maintained, operating efficiency is improved, and vehicle and habitat designs are conducive to safe and efficient crew performance. HRP R&T development is conducted to satisfy customer requirements, therefore, the HRP will establish formal customer-supplier agreements (CSA) to ensure deliverables meet those requirements. These agreements are essential for defining anticipated use, operational concepts, and expectations and for identifying requirements for the R&T development (HRP-47069, Human Research Program Unique Processes, Criteria, and Guidelines [UPCG]). CSAs will also describe the responsibilities for transitioning and infusing the product into the customer's program.

1.4 PROGRAM AUTHORITY AND MANAGEMENT STRUCTURE

1.4.1 Program Authority, Organizational Structure, and Reporting

In October 2005, the NASA Exploration Systems Missions Directorate (ESMD) established the HRP and assigned management of the HRP to JSC. The HRP Program Commitment Agreement, (PCA) identifies HRP as a Research & Technology Development Program that is governed by NPR 7120.8, NASA Research and Technology Development Program and Project Management Requirements.

In 2012, the ESMD and Space Operations Mission Directorate were merged to form HEOMD. The HRP Program resides within the Space Life and Physical Sciences Research Applications (SLPSRA) Division of HEOMD, but the Program Director reports to the HEOMD Associate

Administrator (AA). The governing Program Management Council for the HRP is the Agency Program Management Council (APMC). The HEOMD AA delegates the project decision authority to the HRP Program Director. The “project” description in NPR 7120.8, equates to the “Element” description for the HRP. Thus, the HRP Program Director authorizes Element implementation with approval of the Element plan. The reporting and management structure, including the program control boards, for the HRP is shown in Figure 1-1.

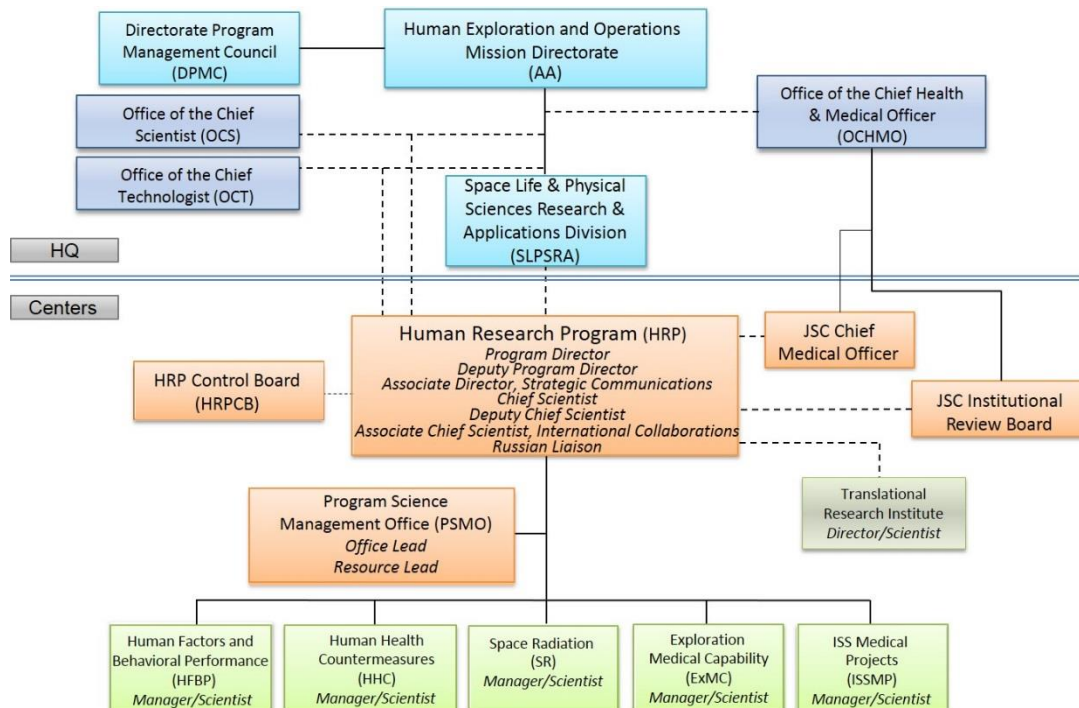


Figure 1-1: HRP Management and Reporting Structure

The HRP is an Agency Program with a Program Office that resides within the Human Health and Performance Directorate (HHPD) at JSC to facilitate effective integration with other human health programs (Crew Health & Safety and ISS Medical Operations). HRP research implementation plans will be coordinated with Crew Health and Safety and ISS Medical Operations plans to ensure overall effective use of resources to address top human health and performance risks. The HHPD is responsible for ensuring successful transition of HRP products to operational use.

The SLPSRA Division within the HEOMD provides the necessary advocacy, monitoring of program progress, and compliance of the HRP to Agency needs, goals, and objectives. The OCHMO plays a key role as the NASA Health and Medical Technical Authority (HMTA), providing health standards for the development of exploration requirements and by approving HRP countermeasure deliverables for operational use.

The HRP organization is designed to support and accomplish the goals of the HEOMD and OCHMO. The Program Director and Deputy Program Director lead all aspects of the program. The HRP Chief Scientist and Deputy Chief Scientist lead the science management and coordination. The Associate Chief Scientist for International Collaboration leads all HRP international R&T interactions. Any references in this document to the Program Director and

Chief Scientist apply to the deputy positions as well, unless specifically identified for the Deputy Program Director or Deputy Chief Scientist. The Program Science Management Office (PSMO) supports program and science management and provides program-level integration across the Elements. Five program Elements comprise the HRP and are focused to accomplish specific goals for investigating and mitigating the highest risks to astronaut health and performance. An HRP Element may elect to establish portfolios and projects within its Element in order to focus management and resources across related tasks.

The HRP is a multicenter program that utilizes expertise at JSC, Ames Research Center (ARC), Glenn Research Center (GRC), Langley Research Center (LaRC), and Kennedy Space Center (KSC) to accomplish its objectives. Each supporting center establishes institutional capabilities and processes to meet HRP objectives. HRP leadership is a collaboration of program/portfolio management and science management at the program, Element, and portfolio levels. Both management and science skills are required at each level to implement the program and successfully meet objectives. Personnel collaboration is critical to the success of the HRP. Roles and responsibilities of key management personnel are identified in Section 1.4.5. Roles and responsibilities of key science management personnel are identified in the HRP-47053, Human Research Program Science Management Plan.

With program management located at JSC, the HRP utilizes existing JSC tools and processes as much as possible to facilitate program implementation and efficiently use program resources. Since HRP support at JSC is largely matrixed from the HHPD, the HRP uses many HHPD tools and processes, such as for configuration management, Information Technology (IT) and administrative support. Details on the use of JSC and HHPD tools and processes are contained throughout this document.

1.4.2 Management Processes and Documents

The HRP was formulated and initially implemented as an applied research program in accordance with NPR 7120.5C, NASA Program and Project Management Processes and Requirements. In February 2008, HRP was identified as an R&T program per NPR 7120.8. Revision A of the HRP PCA and this Program Plan implemented the transition from NPR 7120.5C to NPR 7120.8.

NPR 7120.8 applies at the program level as well as all of the HRP Elements, except for the ISS Medical Projects (ISSMP). The ISSMP is the HRP Element associated with spaceflight hardware and software development. Thus, the ISSMP shall be managed in accordance with NPR 7120.5E, NASA Space Flight Program and Project Management Requirements. The remaining HRP Elements are assigned responsibility to investigate and mitigate the highest human health and performance risks composed of gaps and associated tasks. Most tasks are applied research, but some technology development is completed in concert with those research tasks. This parallel flow of activity within an Element correlates to the R&T Portfolio Project per NPR 7120.8. The Elements use the management processes identified for an R&T Portfolio Project as well as any additional content levied per this document.

HRP Element Plans were baselined using NPR 7120.5C templates. The HRP assessed the NPR templates and concluded all NPR 7120.8 template requirements are met within the NPR 7120.5C templates. The HRP elected to maintain the NPR 7120.5C templates to provide more specific information on R&T strategy, Safety and Mission Assurance (S&MA), environmental impact, institutional and logistics, physical and information technology security, verification and validation,

education and public outreach, and termination review criteria. This content is addressed in this Program Plan as well as the Element Plans. Although documentation may not be formatted per the NPR 7120.8 templates, any content specifically required per NPR 7120.8 is included in the program and Element plans.

HRP-47054, Human Research Program Documentation Tree (Figure 1-2), identifies the principal program documents and associated hierarchy.

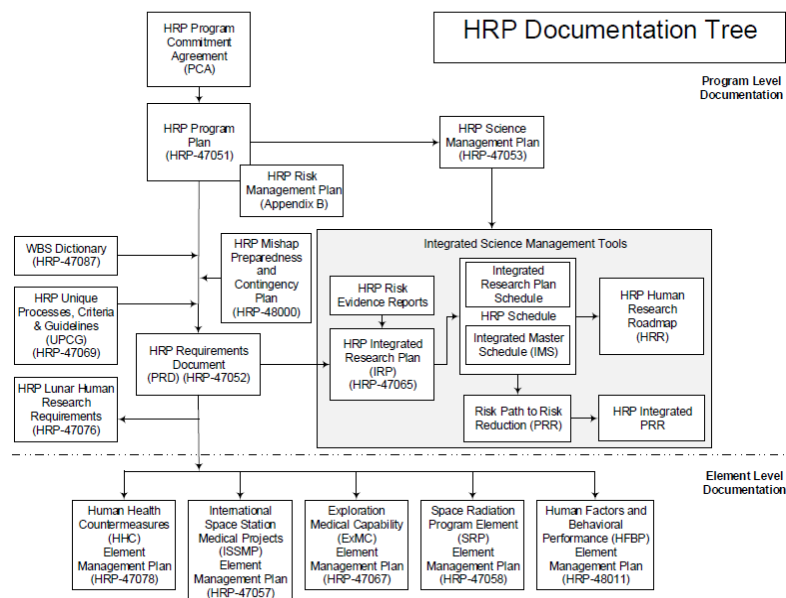


Figure 1-2: The HRP Documentation Tree

The HRP Program Plan and budget are approved by the HEOMD AA. All other HRP documents are controlled by the HRP Control Board (HRPCB). The HRP utilizes standard documents for program management, such as HRP-47052, Human Research Program Requirements Document and the Integrated Master Schedule (IMS). In addition, HRP utilizes unique documents to facilitate management of the science and research content, which include the HRP-47053, HRP Science Management Plan, and the HRP-47065, HRP Integrated Research Plan (IRP), and the HRP Evidence Reports.

The HRP Science Management Plan describes the policies and processes utilized in the science management of the HRP. The HRP IRP, is a comprehensive document that defines projected R&T required for both flight and ground experiments and facilities. The Evidence Reports are a collection of evidence-based review articles that provide a current record of the state of knowledge from research and operations for each of the identified human health and performance risks within the HRP. These three documents are key management tools for resource allocation across the program and product delivery to customers.

The HRP IRP, is electronically available as a database via the Human Research Roadmap (HRR): <http://humanresearchroadmap.nasa.gov/>. In the HRR database, the user can easily search for such items as gaps associated with a risk, the tasks associated with a given gap, the cross-integration of a task across multiple gaps or risks, and deliverables associated with a gap or task.

1.4.3 Program Work Breakdown Structure

The top-level Work Breakdown Structure (WBS) for the HRP is shown in Figure 1-3. The complete WBS, and associated definitions, can be found in the HRP-47087, Human Research Program Work Breakdown Structure Dictionary.

Each WBS item corresponds to one of five HRP Program Elements, the HRP Program Science Management Office or the Cross-Cutting WBS, which includes the Translational Research Institute for Space Health; these WBS elements are described in Section 1.4.4. The tasks within the Program Science Management WBS are described in Section 1.4.5.

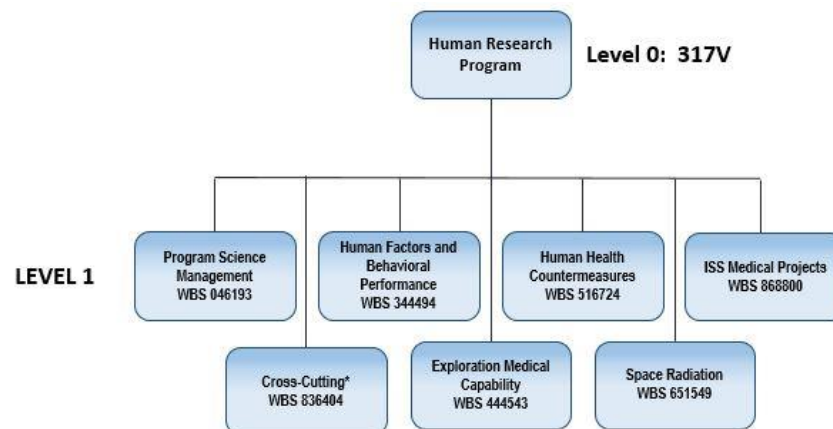


Figure 1-3: HRP Work Breakdown Structure

*Note: The Translational Research Institute for Space Health (TRISH) cooperative agreement is funded within the Cross-Cutting WBS.

1.4.4 HRP WBS Definition

1.4.4.0 WBS Level 0, Human Research Program

Program Code 317V: Human Research Program

This WBS element encompasses all the work required to organize, plan, lead, and control the activities assigned to HRP. Activities include establishing team norms, values, and leadership philosophies, as well as advocating within, and external to, the program for resources to achieve HRP goals. Activities also include working with customers to set HRP goals and communicating these goals to the program.

This WBS element shall provide the necessary program controls to ensure proper oversight of HRP operations. This shall include business and performance measurement systems and analysis. This WBS element shall also account for all work required to provide periodic reviews of the activities within HRP, which includes both internal reviews across the program as well as external reviews of HRP activities for adequacy and compliance.

1.4.4.1 WBS Level 1, Program Elements

The program is divided into five major Elements (Figure 1-2), the Program Science Management

Office and Cross-Cutting projects, which are described in the following subsections. The Program Elements provide the knowledge and capabilities to conduct research to address the human health and performance risks as well as advance the readiness levels of technology and countermeasures to the point of transfer to the customer programs and organizations. An Element consists of the aggregation of related portfolios and research tasks focused toward developing products that reduce risks to the crew. As previously stated, an Element is managed as an R&T portfolio project, but may elect to establish formal projects within its Element. A project is characterized as an integrated set of tasks undertaken to deliver a product or set of products to a designated customer on a specified date.

Each Element is managed at JSC, with R&T development expertise provided by JSC, ARC, GRC, LaRC, KSC, academic institutions, and other Agencies or organizations identified in the Element Plans. Management and technical resources at each center supporting the Element are included in each Element WBS.

WBS 4286.046193: Program Science Management

The Program Science Management (PSM) WBS element accounts for the personnel and operations of the HRP Program Offices. This WBS is responsible for program planning, integration and coordination of activities across the HRP in support of the Program Director, Deputy Director, Chief Scientist, Deputy Chief Scientist, and Associate Chief Scientist for International Collaborations. This WBS includes program control and resource management, as well as science and risk management. This WBS also includes the coordination, integration and oversight of all HRP research and technology development projects, as well as cultivating strategic research partnerships with other domestic and international agencies.

WBS 4286.836404: Cross-Cutting

The Cross-Cutting WBS element is responsible for performing integrated analysis and support across all Elements for Biomarker Identification, Model Translation & Space Biology Integration, Computational Modeling, and Standard Measures.

Additionally, the HRP partners with the TRISH to perform translational research, an interdisciplinary model of research that focuses on translating fundamental research concepts into practice, with appreciable health outcomes. The TRISH will implement a “bench-to-spaceflight” model, moving results or methods from laboratory experiments or clinical trials to point-of-care astronaut health and performance applications. The goal of the research is to produce promising new approaches, treatments, countermeasures or technologies that have practical application to spaceflight.

WBS 4286.344494: Human Factors and Behavioral Performance (HFBP)

This WBS element is responsible for identifying and characterizing the human factors and behavioral performance risks associated with training, living and working in space, and returning to Earth while focusing on the human system in space environments. The HFBP Element develops strategies, concepts, standards, tools, and technologies to mitigate these risks.

The major deliverables for the HFBP Element include inputs to health and medical standards, the NASA Space Flight Human System Standards (NASA-STD-3001 Volumes 1 & 2), requirements for behavioral health maintenance and human performance, and operational tools.

The HFBP Element is supported by ARC, GRC, JSC and KSC as well as national and international agencies cooperating on joint research studies.

WBS 4286.444543: Exploration Medical Capabilities (ExMC)

This WBS element is responsible for establishing requirements for crew health maintenance during exploration missions, developing treatment scenarios, extrapolating from the scenarios to health management modalities, and evaluating the feasibility of those modalities for use during exploration missions. The ExMC Element is also responsible for the technology and informatics development that will enable the availability of medical care and decision systems for exploration missions.

Exploration objectives present significant new challenges to crew health care capabilities. These challenges include the hazards created by the terrain of lunar or planetary surfaces that may be difficult to traverse during exploration, the effects of gravity transitions, low-gravity environments, and limited communications with ground-based personnel for diagnosis and consultation. Each challenge has associated medical implications and medical requirements and technologies to ensure safety and success.

The major deliverables for the ExMC Element are inputs to medical standards for crew selection and retention criteria; requirements for medical equipment, clinical care capabilities, medical equipment technology development; and medical informatics.

The GRC, ARC, LaRC and JSC contribute technology development, medical risk assessment and clinical care expertise to the ExMC Element.

WBS 4286.516724: Human Health Countermeasure (HHC)

The WBS element is responsible for understanding the physiological effects of spaceflight and developing countermeasure strategies and procedures. The Element provides the biomedical expertise for the development and assessment of medical standards and vehicle and spacesuit requirements dictated by human physiological needs. In addition, the HHC Element develops a validated and integrated suite of countermeasures for exploration missions to ensure the maintenance of crew health during all mission phases.

Countermeasures target human physiology and performance capabilities at risk from spaceflight missions at each stage of mission performance. Preflight countermeasures involve crew selection, physical fitness and exercise, physiological adaptation training, and health stabilization. In-flight countermeasures cover physiological and nutritional health, physical fitness, and mission performance. Post-flight countermeasures target rehabilitation strategies.

The major deliverables for the HHC Element are input for the refinement of health and medical standards, validated human health prescriptions, validated exercise system requirements, extravehicular activity (EVA) pre-breathe protocols and physiological requirements for suit development, integrated physiological countermeasures, partial gravity human performance predictions and requirements, and criteria for the agency fitness for duty and crew selection/retention standards. Core competencies provide the biomedical expertise that enables the development of medical standards, the assessment of the risks to crew health and performance, and the validation of countermeasures.

The ARC, GRC, and KSC contribute to the HHC Element, as do international agencies

cooperating on joint flight proposals, reduced gravity studies, and collaborative bedrest studies.

WBS 4286.651549: Space Radiation (SR)

This WBS element performs investigations to develop the scientific basis to accurately project and mitigate health risks from the space radiation environment. This knowledge yields recommendations for Permissible Exposure Limits (PEL), assessment/projection tools/models of crew risk from radiation exposure, and models/tools to assess vehicle design for radiation protection.

The major deliverables for the SR Element include inputs to standards for radiation health, habitability, and environments; requirements for radiation protection; models and tools to assess and predict risks due to space radiation exposure as well as vehicle design; and strategies to mitigate or treat exposure effects. Although information exists to recommend crew exposure limits and spacecraft design requirements for missions in low-Earth orbit, there is insufficient knowledge of the health effects of radiation, the space radiation environment, and countermeasure efficacy to provide recommendations on crew exposure limits and design requirements for extended lunar and future exploration missions. Therefore, a major focus of the SR Element is basic and fundamental research to expand the knowledge base and reduce the uncertainty inherent in current exposure limits and design requirements.

The SR Element conducts research using accelerator-based simulation of space radiation at the NASA Space Radiation Laboratory (NSRL). The LaRC and JSC contribute to the SR Element.

WBS 4286.868800: International Space Station Medical Projects (ISSMP)

This WBS element is responsible for managing all ISS and ground analog human research activities, including those integrated with operational medical support of the crews, to ensure research tasks are completed. The ISSMP is responsible for all planning, integration, and implementation services for HRP research tasks and evaluation activities requiring access to space, ground analogs, or related resources on the ISS, Soyuz, Progress, H-II Transfer Vehicle (HTV), commercial vehicles, Multi-Purpose Crew Vehicle (MPCV), and domestic and international ground analogs. This includes support to related pre-flight mission and post-flight mission activities.

The ISSMP provides and manages the Human Research Facility, enabling generic test and monitoring capabilities for HRP flight studies on the ISS. ISSMP services include operations and sustaining engineering for flight hardware; experiment integration and operation, including individual research tasks and on-orbit validation of next generation on-orbit equipment; medical operations; procedures; crew training concepts; and operation and sustaining engineering for the Telescience Support Center, which provides real-time operations and data services to all HRP flight and the Human Exploration Research Analog (HERA) experiments. This Element integrates the HRP-approved flight and ground analog activity complements and interfaces with external implementing organizations, such as the ISS Research Integration Office and International Partners, and analog owner/operators to accomplish HRP objectives.

1.4.5 Program Science Management Office

Responsibility for implementation of program planning, integration, and coordination efforts, including science management and program management, international science coordination,

and strategic communications, is delegated to the HRP PSMO. The PSMO ensures close coordination of exploration customer needs and program deliverables to meet those needs. In these activities, PSMO supports the HRP Program Directors, the Chief Scientist, Deputy Chief Scientist and the Associate Chief Scientist for International Collaborations.

The PSMO:

- a. Coordinates budget formulation and the integrated HRP input to the annual HEOMD planning, programming, budgeting, and execution (PPBE) process;
- b. Develops and maintains the HRP baseline technical requirements with allocations to the Element level, as well as all Program-level documentation;
- c. Collects and communicates the programmatic risk posture per the HRP Risk Management Plan (HRP Program Plan, Appendix B). The PSMO assures thorough risk assessment is conducted for all program activities and provides recommendations for elevating and rating of program risks;
- d. Establishes and coordinates technical and programmatic trade studies that involve more than one HRP Element;
- e. Supports the identification and prioritization of the research objectives that reduce the operationally relevant human health and performance risks associated with exploration missions. Develops tools and analyses of the program portfolio to help assure proper balance of content and priorities, including the HRR development and maintenance. The IRP/HRR documents prioritized research needs, goals, and objectives. The plan guides allocation of HRP resources to manage the portfolio of ground and flight research;
- f. Leads the acquisition process for procurement of program support tasks that include coordinating procurement of HRP scientific R&T development tasks through appropriate acquisition mechanisms via development of NASA Research Announcements (NRA), Small Business Innovative Research (SBIR), Announcements of Opportunity (AO) or Broad Agency Announcements (BAA);
- g. Coordinates and integrates HRP program-level reports and products for delivery to external stakeholders in their required format;
- h. Ensures HRP product and process quality control by developing and tracking execution of HRP internal processes and facilitating process improvement activities;
- i. Supports the development of external relationships with domestic and international agencies and institutions that either reinforce HRP core competencies or develop products that help the HRP meet its goals and objectives. Domestic agencies and institutions include other U.S. Government agencies, academic institutions, and commercial entities. Provides a formal conduit to the Office of the Chief Technologist, the Advanced Exploration Systems, and other exploration programs;
- j. Coordinates with the Office of International and Interagency Relations (OIIR) at NASA HQ for development and approval of international research agreements;
- k. Supports logistics management and documentation for the Multilateral Human Research Panel for Exploration (MHRPE) to include development and implementation of MHRPE Data Sharing Principles and interfaces with member research organizations and clinical and space medicine entities;

- l. Supports the development of programmatic processes and tools to enable effective program insight;
- m. Conveys the mission of the HRP to the general public by chronicling on-going research findings and supporting NASA public outreach efforts.

1.4.6 HRP Program Office Key Personnel Roles and Responsibilities

Program management covers the HRP Program Management Office personnel and operations, including the Program Director, Deputy Program Director, Associate Director of Strategic Communications, Chief Scientist, Deputy Chief Scientist, and the Associate Chief Scientist for International Collaborations. Program management and its supporting office, PSMO, provide the overall management of the Program and its external interfaces.

1.4.6.1 HRP Program Director

The HRP Program Director is accountable to the HEOMD AA for the performance of the program against established HEOMD objectives. The Program Director is responsible for program safety, security, cost, schedule, technical performance, and risk. The HRP Program Director is also responsible for integration, oversight, and assistance to the constituent Program Elements. The HRP Program Director coordinates program content with the HEOMD, provides leadership, and is responsible for the successful accomplishment of the program that meets the needs of the customers. The Program Director informs the HEOMD of the establishment or termination of Program Elements.

In addition to the responsibilities defined in NPR 7120.8, the Program Director:

- a. Manages and implements the HRP, including activities performed at participating NASA centers;
- b. Supports HEOMD by providing necessary program support to strategic management functions;
- c. Approves and presents the program budget submission during the annual HRP PPBE process;
- d. Allocates and manages program resources;
- e. Oversees and approves program outreach activities;
- f. Establishes Elements and approves Element Plans, communicating organizational changes to the HEOMD;
- g. Acts as the Selection Official for all research solicitations;
- h. Approves international agreements;
- i. Approves human research utilizing Astronaut subjects both in flight and on the ground;
- j. Manages program metrics assessments and reporting;
- k. Approves intergovernmental agreements such as those with the National Institute of Health (NIH) and the U.S. Department of Energy (DOE);
- l. Oversees the programmatic mishap preparedness and contingency plan process (Section 3.7.3);
- m. Manages a programmatic risk management process (Section 3.8.);

- n. Coordinates HRP center-level implementation activities with supporting center management;
- o. Generates an annual assessment of HRP progress in meeting metrics, delivering products, and risk mitigation and closure; and,
- p. Assures communication of HRP results and their relevancy to the operations community, as well as transition of HRP deliverables to the appropriate customers.

The HRP Director may delegate responsibilities to the HRP Deputy Director.

1.4.6.2 HRP Chief Scientist

The Chief Scientist, and the Deputy, are responsible for science management, planning, coordination and integration as well as maintaining the scientific integrity of the HRP through peer review. The Chief Scientists work closely with the Program Directors to formulate the Program vision, ensuring operational relevance of research for transition of HRP research products into flight operations.

The Chief Scientist has delegated the primary interface for establishing agreements and processes for conducting international bi- and multi-lateral research to the Associate Chief Scientist for International Collaborations.

HRP-47053 details the specific roles and responsibilities of all science positions and the policies and processes utilized for science management within the HRP. Collaboration is critical between management and science personnel utilizing the content of this plan and the HRP Science Management Plan to successfully implement the HRP to meet its objectives.

The Chief Scientist:

- a. Guides development of the Program research portfolio, ensuring overall balance across Elements, adequacy of planned research, appropriate utilization of ground and space-based platforms, and appropriate research prioritization;
- b. Leads the planning and coordination of HRP science, including development of new, innovative research and technology investment strategies;
- c. Approves Element research plans and solicitation topics, communicating content and status to the Program Director;
- d. Oversees external reviews of scientific content and merit of the Program from peer review of individual proposals through National Academy reviews of overall Programmatic content;
- e. Approves Element recommendations for research selections and presents an integrated selection recommendation to the Program Director;
- f. Approves scientific content of intergovernmental agreements and international agreements;
- g. Recommends approval for human research utilizing Astronaut subjects both in flight and on the ground;

- h. Serves as the primary Program advocate for science, representing program research within and external to NASA, interfacing with Agency, Program and Center Chief Scientists, external domestic and international scientists and partners to develop and ensure effective coordination and execution of joint research activities;
- i. Manages research results and reporting;
- j. Represents the Program science to scientific society members, scientists, students, the general public, and the press;
- k. Establishes data and specimen policies, advocating for adequate funding for data sharing, processing and analysis, as appropriate, to encourage and facilitate broad scientific access to NASA data and specimens, assuring timely release of data, publicity for and publication of results;
- l. Advises the Program Director on the scientific value of proposed new or reduced content; and,
- m. Serves as Contracting Officers Representative for HRP funded research institute(s).

1.4.6.3 PSMO Manager

The PSMO Manager leads the integration and support functions described in Section 1.4.5.1. The PSMO Manager is responsible for managing the staff, infrastructure, and resources necessary to support the senior program management team (Program Director, Deputy Director, Chief Scientist, Deputy Chief Scientist and Associate Chief Scientist for International Collaborations) in executing their duties. The PSMO Manager:

- a. Develops and maintains the baseline HRP PSMO budget, schedule and technical content;
- b. Leads budget formulation and the PSMO input to the annual HRP PPBE process;
- c. Ensures the development, documentation, configuration management and implementation of HRP plans, policies, commitments, processes and guidelines, ensuring compliance with NPR 7120.8;
- d. Manages the HRP board, panel, and working group activities;
- e. Establishes and tracks science management activities, risk reduction plans and progress, Program control milestones and deliverables;
- f. Develops products that represent an integrated, cross-Center program position;
- g. Coordinates external and internal Program-level reviews and meetings, including the annual Investigators' Workshop;
- h. Coordinates the release of scientific solicitations and merit reviews;
- i. Integrates programmatic and science activities across the HRP, including the Human Research Roadmap and integrated tool development and maintenance; and,
- j. Develops programmatic reporting tools to include interfaces with other NASA Programs and technology pipelines, and research engagement and communication.

1.4.6.4 Element Leadership

Element leadership is a collaboration between Element Management and Element Science. Both management and science skills are required at each level to implement the Program and successfully meet objectives. The HRP Program Director delegates the responsibility for the implementation, management, and oversight of the constituent portfolios to the Element Managers. The Chief Scientist delegates the development and direction of the scientific research and technical approach to the Element Scientists. Although each have specific responsibilities, neither has a subordinate role and the shared leadership model for HRP Elements requires many shared responsibilities. The Element Manager must collaborate with the Element Scientist to integrate the best possible research into the resource, platform and schedule constraints imposed on the Element. The Element Scientist must collaborate with the Element Manager to ensure recommended research fits within Element constraints to produce the appropriate deliverable. Many negotiations and agreements require both parties, however, once negotiations are complete, each will have separate responsibilities in implementing resultant agreements.

1.4.6.4.1 Element Manager

The Element Manager:

- a. Manages the integration of technical cost and schedule performance across portfolios within the Element based on the scientific research or technical content developed by the Element Scientist and the direction provided by the Program Director (i.e., allocated requirements, resources, goals, objectives);
- b. Works closely with the Element Scientist to ensure all Element scientific or technological activities are synchronized with the Element schedule, procurement plans, cost, and milestones and all Element reviews are properly supported;
- c. In conjunction with the Element Scientist, provides technical, cost, and schedule status reports to the Program Director;
- d. Ensures timely and effective grants management per NPR 9680.1B, NASA's Management of Grants and Cooperative Agreements;
- e. In conjunction with the Element Scientist, coordinates Element activities across the Agency;
- f. Supports the Element Scientist in recommending updates to HRP-47065, HRP Integrated Research Plan (IRP);
- g. Maintains communication with other Element Managers to ensure solutions are integrated;
- h. Provides budget, schedule, and performance direction to the Portfolio or Project Managers as appropriate;
- i. Develops and manages contracts and agreements, as appropriate, for Element support and tasks;
- j. Manages the implementation of appropriate international agreements and other Agency-approved agreements, based on content negotiated with the Element Scientist;
- k. Participates in the HRP programmatic risk management process (including that with respect to strategic acquisitions, if applicable);

- l. Maintains an Element-level schedule that integrates lower-level portfolio or project schedules and feeds key milestones in the HRP IMS;
- m. Develops an Element acquisition plan, incorporating recommendations from the Element Scientist, and portfolios/projects within the Element, where applicable;
- n. In conjunction with the Element Scientist, analyzes and evaluates performance against plans - monitoring data, identifying agency-wide trends, concerns, and policy implications. Performance monitoring data relates to reduction of the human system risks assigned to the Element, as defined in the Human Research Roadmap; and,
- o. In conjunction with the Element Scientist, manages issues of conflict-of-interest, bias, and confidentiality to ensure fairness and credibility of all stages of Federal awards - proposal, evaluation, selection, award, and administration.

1.4.6.4.2 Element Scientist

The Element Scientist:

- a. As per HRP-47053, HRP Science Management Plan, and consistent with the vision of the HRP Program Director and Chief Scientist, develops, directs, and manages the scientific and technical content of the Element-specific research plan, clearly demonstrating integration and coordination of the scientific research program across portfolios within the Element, with other HRP Elements, other NASA organizations, and fitting within Element constraints;
- b. Manages the development, maintenance and integration of the Integrated Research Plan (IRP) for the Element, clearly demonstrating integration and coordination of the various projects within the Element, other HRP Elements, the HRP Translational Research Institute for Space Health (TRISH) or with other NASA organizations as necessary;
- c. Works closely with the Element Manager to ensure all Element scientific or technological activities are synchronized with the Element schedule, procurement plans, cost, and milestones and all Element reviews are properly supported;
- d. In conjunction with the Element Manager, provides technical, cost, and schedule status reports to the Program Director and Chief Scientist;
- e. Develops, coordinates and submits scientific solicitation input, evaluates new proposals (i.e., solicited, unsolicited, directed task) and directed research for merit and relevance, and provides relevance and feasibility recommendations to the HRP Chief Scientist;
- f. Ensures that the Element's scientific research portfolio, including all scientific components, is organized and executed to enable mitigation of operationally-relevant risks and to design and develop countermeasures and/or technologies that support exploration missions;
- g. Ensures timely and effective performance of Element-sponsored scientific research content implemented (e.g., grants, contracts, or Cooperative Agreements);
- h. Identifies the content and helps negotiate technical requirements for appropriate international agreements and other Agency-approved agreements;
- i. Participates in the HRP Element risk management process to identify and manage technical risks;

- j. Ensures technical content is appropriately represented in the Element-level schedule, integrates lower-level portfolio or project schedules (where applicable), and feeds key milestones in the HRP IMS;
- k. Directs and integrates the science performed within the element, portfolios, projects, and teams at JSC and other NASA Centers as appropriate;
- l. In conjunction with the Element Manager, develops a recommended Element science procurement plan taking into account the needs of the Projects, Portfolios and Risks within the Element;
- m. In conjunction with the Element Manager, analyzes and evaluates performance monitoring data, identifying agency-wide trends, concerns, and policy implications; Performance monitoring data relates to reduction of the human system risks assigned to the Element, as defined in the Human Research Roadmap; and,
- n. In conjunction with the Element Manager, manages issues of conflict-of-interest, bias, and confidentiality to ensure fairness and credibility of the proposal, evaluation, selection, award, and administration of Federal award.

1.4.6.5 Center Point of Contact

The Center POC performs management functions at those NASA centers that participate in the HRP. These functions are in addition to the support provided to the individual program Elements. The Center POC directly interfaces with HRP management. The Center POC:

- a. Provides overall coordination of center activities in support of the HRP including center programmatic content, budget, resource assessment and allocation, and staffing;
- b. Ensures its NASA Center meets all of its commitments to the HRP; and,
- c. Assists the HRP management team in strategic planning, implementation, and advocacy.

2 HUMAN RESEARCH PROGRAM BASELINE

2.1 PROGRAM REQUIREMENTS/OBJECTIVES

The HRP, in consultation with customers and stakeholders, is responsive to OCHMO and HEOMD needs, goals, and objectives for maintaining crew health and performance during exploration missions. Exploration program documents provide the mission architecture definitions, mission concepts of operations, vehicle, habitat, and spacesuit performance requirements, and other technical information needed to focus the HRP efforts for specific exploration missions. As a program within the HEOMD, HRP objectives are identified in the HRP PCA. Per NASA NPR 7120.8, programs shall follow the established Technical Authority (TA) process which provides independent oversight in support of safety and mission success. The HRP implements the use of TAs from Engineering, Safety and Mission Assurance (S&MA), and Health and Medical Technical Authority (HMTA) per the agreement detailed in memo SA-16-017 issued and approved in February 2016 (Appendix E).

The Chief Health and Medical Officer (CHMO) is the Health and Medical Technical Authority (HMTA) per NPD 1000.3, 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 as guided by the Continuous Risk Management principles; Section 3.1.3 for contains additional descriptions of the HMTA and HSRB.

The HSRB evaluates evidence to identify human health and performance risks and concerns. If research is required to understand or mitigate the risk, it is assigned to the HRP. HRP presents its assessment of the risks including anticipated mitigations and deliverables which are documented and approved in the HSRB Risk Summary. The HRP then develops and executes a research plan to further understand the risk and inform associated standards, or develops mitigation or monitoring strategies for the assigned risk. Evidence resulting from HRP research is presented to the HSRB to update the status of a risk.

Exploration program requirements are merged with applicable HSRB human system risks to form the requirements of the HRP documented in HRP-47052. The requirements are further decomposed in the Element Plans. HRP-47052 is updated as needed per exploration program revisions and HSRB decisions regarding HRP-applicable human system risks. Performance against requirements is a function of progress in mitigating or eliminating human system risks that is achieved via R&T development tasks and assessed by independent review, approved through the HMTA, and implemented by the OCHMO and HEOMD.

The HRP conducts research, develops countermeasures, and undertakes technology development to inform and support compliance with NASA's health, medical, human performance, and environmental standards. HRP R&T development results in:

- Identification and quantification of the risks associated with human spaceflight for the various exploration missions,
- Delivery of data to support development of, and updates to, applicable human health and performance standards for the various exploration missions,
- Development of countermeasures to provide mission planners and system developers with strategies for mitigating crew health and performance risks,
- Development of technologies to provide mission planners and system developers with strategies for monitoring and mitigating crew health and performance risks,
- Maintenance of NASA's core competency in human health and performance.

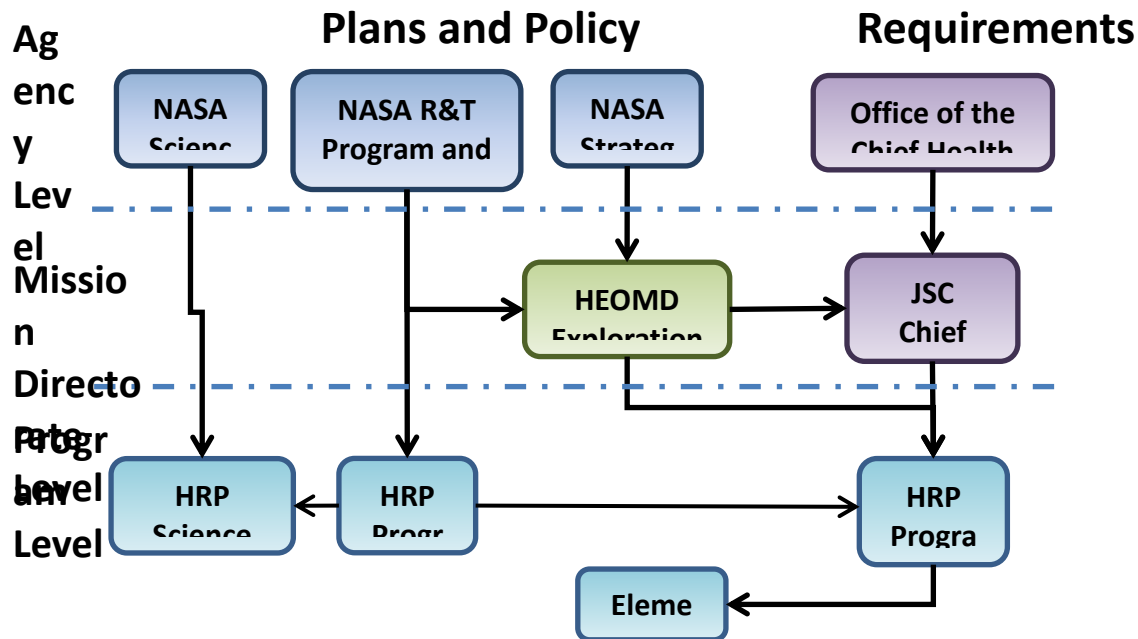


Figure 2-1: HRP Requirements Flow

2.2 PROGRAM SCHEDULE

The key target milestones for the HRP are defined in the HRP PCA and reflected in the HRP Integrated Path to Risk Reduction (iPRR) Appendix C.

In support of the Program’s evidence and risk-based management approach, HRP developed the Path to Risk Reduction (PRR) using data obtained from several sources. The PRR combines the list of HSRB-approved human health and performance risks assigned to HRP as listed in HRP-47052, HRP Program Requirements Document (PRD) with the current likelihood and consequence (LxC) in the HSRB risk record system. To better plan research, some risks are broken down into sub-risks by HRP; these LxC scores are estimated by the Elements. The PRR also utilizes information from HRP-47065, HRP Integrated Research Plan (IRP) which contains the comprehensive set of research gaps and tasks. Lastly, the PRR displays chronological data from the IMS which contains the expected timeline for accomplishing the HRP research plan and detailed definition of key target milestones. The PRR aligns directly with the requirements and priorities identified by the HSRB to ensure that all stakeholders have a common understanding of the risk priorities involved in human exploration.

Currently, the PRR shows the critical milestones, knowledge, and deliverables needed to reduce the likelihood and consequence drivers for each associated risk for design reference missions defined by the HSRB; this is the research strategy, logical sequence and timing of tasks and significant milestones and can be found in the schedule section of the HRP IRP. The information contained in the PRR is generated directly from the project schedules for each risk. HRP management reviews the PRRs with the Elements on a quarterly basis. Following each quarterly review, the IMS is updated and approved by the HRPCB.

Continuous evaluation of risk posture and priorities is also done annually by the HSRB and is supported by HRP leadership as well as evidence and research progress submitted by discipline experts. Significant changes and updates to a risk research plan (e.g., new milestone evidence and deliverables, gap closures, PRR changes) are key inputs to the annual PPBE cycle.

The iPRR serves as a graphical display of the long-range, strategic research plan and schedule (i.e., the integrated master schedule) and contains all the HSRB risks assigned to HRP. The iPRR is used to communicate the top-level schedule and plan for reducing the risk-associated LxC.

2.3 PROGRAM RESOURCES

HRP resources are defined in the HRP PCA. The HRP Program Director makes formal recommendations to HEOMD to establish resource commitments with annual updates as part of the PPBE process defined in NPR 7120.8 and NPD 1000.0B, NASA Governance and Strategic Management Handbook. The HRP Program Director coordinates center-level resources with the Center POCs.

The Program Director manages program resources to maintain focus on program goals and objectives and to control program costs. The Program Director implements a budget control process to support Agency full-cost accounting objectives. The HRP Program Director holds reserves for discretionary use within the program.

The budgets for each contributing field center cover the full cost of the assigned responsibilities from the HRP and include ground-based R&T endeavors and flight definition, implementation, and operations activities. Each Element integrates and reports field center budgets as part of its submittal during the annual PPBE process. Budget agreements between contributing centers are documented using Internal Task Agreements (ITA). The Element PPBE submittal also addresses specific resources necessary to fulfill applicable commitments from international agreements. Changes to budgets are tracked and authorized using Budget Change Directives (BCD).

3 SUBPLANS

3.1 CONTROLS AND COMPLIANCE

The HRP uses existing HHPD processes and tools for the management and control of the program in order to maintain operating efficiency and reduce costs.

Program management monitors changes affecting the HRP that warrant modifications to the PCA and Program Plan. The Program Director will prepare modifications and document in the change log, as required. The HEOMD coordinates approval of the PCA and Program Plan through HQ.

3.1.1 Requirements Monitoring and Control

Requirements from a number of sources drive the content and direction of the HRP. The HRP Program Director is responsible for ensuring that requirements monitoring and change control activities are consistent with agency policies, practices, and procedures and support HEOMD needs, goals, and objectives.

Program reviews will be conducted, as defined in Section 3.13, to ensure that program goals and objectives, as well as research and development activities, remain consistent with current HEOMD research and mission needs. Each task will be reviewed to assess the status and continuing relevance of HRP content against the evolving HEOMD research and mission requirements. These reviews may result in adjustments to HRP content to align with updated HEOMD R&T development requirements.

The results of the research conducted within the HRP, as well as evolving exploration requirements and mission definitions, may identify the need for a new task to further understand and mitigate the effects and risks associated with human spaceflight. The HRP will work with the HEOMD and customers and stakeholders to fully define the scope of these tasks, obtain funding, and gain authorization to proceed.

3.1.2 Program Configuration Management

Configuration management of program-level documents, milestones, and Element Plans identified in HRP-47051 shall be in accordance with JSC 28330, Human Health and Performance Directorate Configuration Control Management Plan. Configuration Management (CM) of these items will be controlled through the HRPCB. Configuration control of internal Element implementation documents, schedules and products is delegated to the appropriate Element.

3.1.3 Configuration Control Boards

The HRP uses a set of boards to provide configuration management and review of HRP content (Figure 3-1); primary control is through the HRPCB. HRP Elements may choose to constitute an Element-level board, as needed, to CM Element-controlled products. In lieu of an Element-level board, the HRPCB can be used with an augmentation of the membership (i.e., ad hoc members) to ensure the appropriate expertise for decisional items. The Element Science Working Group is chartered by the HRPCB to integrate science across Elements and formulate research content and priority recommendations for HRPCB decision.

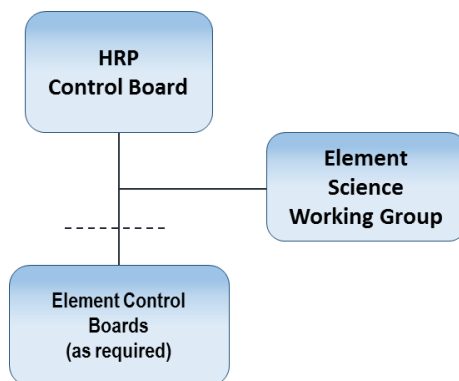


Figure 3-1: Control Boards for the HRP

3.1.1.1 Human Research Program Control Board

The HRPCB is chaired by the Program Director and serves as the configuration management and decision-making forum for the HRP. The HRPCB provides a cross-Element forum for approval

of the HRP technical, management, operations, user and integration requirements, science priorities, as well as program schedules and resources. Detailed responsibilities and duties are defined in the HRPB charter.

3.1.1.2 Element Science Working Group

The Element Science Working Group (ESWG) is the HRPB-chartered forum chaired by the HRP Chief Scientist to facilitate the science management functions. Detailed responsibilities and duties are defined in the ESWG charter.

3.1.1.3 Health and Medical Technical Authority

The JSC CMO is responsible for implementing the HMTA process for programs managed at JSC. The JSC CMO is an independent entity responsible for assuring compliance and approving deviations to program health and medical technical requirements, processes, and policies. Results from the HMTA process inform JSC, other center, and agency level reviews of program and project progress, including concurrence or non-concurrence on technical issues.

The JSC CMO has the responsibility to review appeals of standards and requirements that are not met in a specific program based on the analysis of their respective owners (program and division configuration and control boards). Appeals of HMTA decisions are reported through independent chains, i.e., program and project managers to the HEOMD AA and the HMTA to the NASA CHMO. The HEOMD AA and CHMO will work resolution of the appeal. If an agreement cannot be reached, then the issue will be escalated to the NASA Administrator for resolution.

3.1.1.4 Human System Risk Board

Human system risks encompass environmental exposures, crew performance issues, biomedical stressors/susceptibilities, the ability to provide medical care, and any other challenges that affect the human as a system. The JSC CMO established the HSRB to ensure a consistent, integrated process is established and maintained for managing human system risks using Continuous Risk Management (CRM) principles. The HSRB advises the JSC CMO, HMTA delegates, HHPD management, and key HHPD boards concerning the identification, status, coordination, integration, mitigation, and research strategy of all human system risks. The HSRB is the primary board for establishing official recommendations and positions regarding human system risks.

The HSRB is delegated responsibility by the HMTA for two categories of activities:

- Documenting and tracking all risks to the human system associated with spaceflight activities.
- Managing all human system risks and specifying actions to be taken with respect to the risks such as accept, mitigate, transfer, watch, close or research.
- For the HRP, the HSRB establishes what human system risks require research and determines if research results sufficiently reduce, mitigate, or retire a human system risk. The HSRB advises the ISS Program and exploration programs on status and recommendations to disposition human system risks applicable to their programs and/or missions.

3.1.3.5 Engineering and Safety and Mission Assurance Technical Authorities

As an R&T development program focused on investigating and mitigating human health and performance risks, the HRP more directly and frequently interfaces with the HMTA. However, the HRP also interfaces with the Engineering and S&MA Technical Authorities established per the governance model.

The Office of the Chief Engineer (OCE) ensures that missions are planned and conducted with sound engineering practices and with proper controls and management. OCE requirements are contained within NASA Policy Directives (NPD), NASA Procedural Requirements (NPRs) and technical standards. The Office of Safety and Mission Assurance (OSMA) assures the safety and enhances the success of all NASA activities through the development, implementation, and oversight of Agency wide safety, reliability, maintainability, and quality assurance policies and procedures.

Engineering and S&MA Technical Authority are individuals funded independent of programs and projects with formally delegated Technical Authority traceable to the Administrator through the NASA Chief Engineer and Chief, S&MA, respectively. These individuals are identified in center Technical Authority implementation documents.

The HRP interfaces with the technical authorities primarily through development of flight hardware systems, ground facilities for testing, and associated reviews and boards established at the center, HEOMD, and Agency levels. HRP also interfaces with the Engineering and S&MA Technical Authorities when recommending updates to the NASA-STD-3001, Volume 2. Appeals of Technical Authority decisions are reported through independent chains, i.e., HRP Program Director to the HEOMD AA and the Technical Authority through the OCE or OSMA. The HEOMD AA and OCE or OSMA, as applicable, will work resolution of the appeal. If agreement cannot be reached, then the issue will be escalated to the NASA Administrator for resolution.

3.1.4 Cost and Schedule Controls

The HRP uses regular cost and schedule reporting, as coordinated through the PSMO, to measure performance of the Elements against the program baseline. Individual Elements report status at quarterly technical, cost, and schedule reviews (TCSR). The HRP uses BCDs to re-allocate funding at the Element levels. Changes to control milestones must be approved by the HRP Program Director.

3.1.5 Communication Plan

Formal communication includes all deliverables as well as management and technical information related to the technical, cost, schedule, and risk performance of the HRP. All formal program communication with the HEOMD, exploration programs, and OCHMO is controlled through the HRP Program Office (including the PSMO) and is approved by the Program Director or designee.

The communication paths for the HRP are depicted in Figure 3-2.

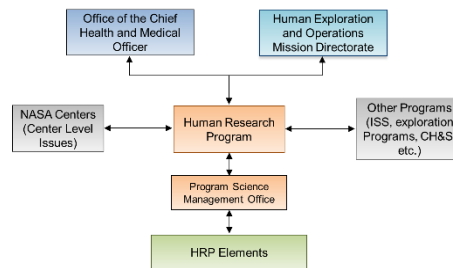


Figure 3-2: HRP Communication Paths

HRP management fosters an environment for open and timely communication by providing regularly scheduled forums, such as the ESWG and HRPCB, as well as access for special topic meetings. A weekly meeting is conducted with program and Element managers to convey status across the program. The HRP program offices also flow information and requirements to and from the external organizations to the Elements as necessary. Program and Element management facilitate communication between Elements to ensure HRP objectives are met. This communication provides integration of the output from the various research and development tasks. The HRP program offices and Elements conduct all day-to-day communication with internal and external researchers and support organizations with respect to meeting program objectives. This communication is with principal investigators, research facilities, academia, international support teams, supporting NASA Centers, and other research organizations as well as other program offices. Any issues that may affect cost or schedule or that cannot be resolved at the Element level will be forwarded to the program offices for resolution.

3.2 RELATIONSHIPS TO OTHER PROGRAMS AND ORGANIZATIONS

3.2.1 Internal Relationships and Agreements

Internal relationships and agreements are those that exist within NASA between the various programs and centers. Internal agreements that may be concluded with the authority of the HRP Program Director include those with organizations at the NASA Centers, including other program offices. These agreements shall be formally documented either through the use of Memoranda of Agreement (MOA), Memoranda of Understanding (MOU), CSA, the PPBE process, ITA and BCD.

Internal agreements that must be developed under the authority of the HEOMD include agreements with other NASA organizations that require reprogramming of funds. The HRP is not dependent on any NASA activities outside of the HEOMD and OCHMO to fulfill its objectives.

In order to manage conflict of interest, and consistent with internal support to NASA Programs, Internal Task Agreements (ITA) are developed to clearly identify Program tasks to be performed by Line Organization personnel and the funding to be transferred to the specified organization. ITAs enable the Program to manage conflict of interest (actual or perceived) for key Program personnel and provides autonomy for an Organization performing ITA work. The Program also utilizes Memoranda of Understanding (MOU) with Line Organizations in order to manage conflict of interest and the Program's role in evaluating the work performed by the Organization.

3.2.2 External Relationships and Agreements

External relationships and agreements are those that exist with organizations outside NASA. External agreements that may be concluded under the authority of the Program Director include partnering opportunities as solicited through internal calls for proposals, directed research projects, AOs, and BAAs. External agreements that must be developed under the authority of the NASA HQ include agreements with International entities for the purpose of sharing research facilities, multi-user hardware, and collaboration on research activities of mutual interest. The HEOMD may authorize agreements with other federal agencies for the purpose of sharing research facilities, multi-user hardware, and collaboration on research activities of mutual interest. The current list of external agreements is located in the HRP Share Point site.

3.3 BUDGET AND ACQUISITION STRATEGY

The HRP Elements use the NASA PPBE process to generate baseline budgets.

The HRP uses available NASA and HEOMD acquisition methods, such as AOs, BAAs, NRAs, Cooperative Agreement Notices (CAN), SBIR solicitations, open innovation calls, internal calls for proposals, Requests for Proposals (RFP), Requests for Quotes (RFQ), and Requests for Information (RFI) to acquire R&T development support. In addition, acting in partnership with NASA, the TRISH provides access to the external research community by supporting research via national solicitations.

Directed research is another acceptable acquisition method. Directed research can involve in-house, external, or a combination of both researchers. The HRP uses directed research as an acquisition method for obtaining selected research data and technology development when:

- a. There is insufficient time for solicitation. In certain cases, NASA must define scientific activities in a short time (e.g., because of the emergence of new opportunities to carry out activities in space). When this is the case, use of a directed study may be the only practical way to respond.
- b. The research is highly constrained. In this case, the Element or project requires constrained data gathering and analysis that is more appropriately obtained through a well-defined solicitation using a RFP or by a non-competitively developed proposal (e.g., the research task may involve extensive operational practices and associated operational personnel who must be heavily involved in the development of the study design).

Participating NASA Centers also utilize competitive contracts for procurement of support to intramural project tasks. The centers have multiple options for procurements and select the optimal procurement method based on the Agency policy of the widest possible use of competitive processes.

Regardless of the acquisition method, the review and selection of science is in accordance with NASA policies, which include incorporation of a risk-informed decision process of identification, analysis, and management of programmatic, institutional, technical, cost, schedule, environmental, safety, management, industry, and external policy risks that might jeopardize the success with which NASA executes its acquisition strategies. Furthermore, the selection of science is merit reviewed per HRP-47053.

3.4 RESEARCH AND TECHNOLOGY STRATEGY

3.4.1 Basic and Applied Research

The HRP performs research tasks that focus on the reduction of the most significant risks to crew health and performance to enable exploration missions and that increase the knowledge base to inform the development of human health standards and human support systems. Tasks include basic and applied research to inform crew health and medical standards, develop human-system integration, and guide the development of human health countermeasures.

Basic and applied research includes the test and validation of hypotheses, formulation of countermeasure concepts and initial demonstration of efficacy, clinical trials/testing, and finally, validation and delivery for operational implementation.

The OCHMO transition to medical practice process, as defined in NPR 8900.1A, NASA Health and Medical Requirements for Human Space Exploration - Appendix D - Transition to Operations Review Process, Transition to Medical Practice, the HSC HMTA Transition to Operations (TtO) process (JSC 66705, JSC Human System Risk Management Plan) and the HRP TtO process, as defined in HRP-47069, HRP Unique Processes, Criteria and Guidelines, shall be used to review and approve Element deliverable countermeasures and technologies prior to their operational use.

3.4.2 Countermeasure Development

The HRP nominally begins a countermeasure development at Countermeasure Readiness Level-4 (CRL-4) and develops the selected countermeasure to CRL-7 or -8. At this point, the HRP transfers the countermeasure to the implementing organization for incorporation. For some Elements, Space Radiation for example, countermeasure development must begin at much lower CRLs and are thus developed to CRL-6 prior to transition (Figure 3-3).

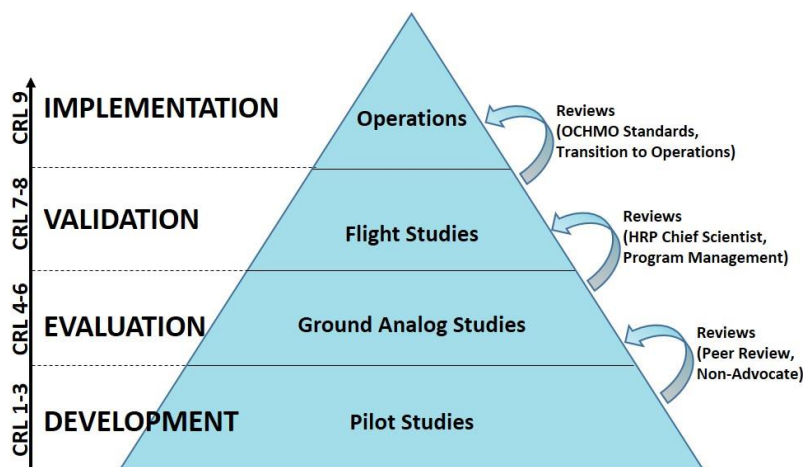


Figure 3-3: Countermeasure Development Process

3.4.3 Technology Development

The HRP nominally develops critical human system technologies to Technology Readiness

Level-6 (TRL-6) by the time of the applicable Preliminary Design Review. See Figure 3-4. However, in cases where the individual technology requires demonstration in the spaceflight environment, it may be developed to TRL-7 or 8. The final TRL delivered will be determined in the CSA. Technology development may include those tasks needed to mature countermeasures as defined in Section 3.4.2. The HRP utilizes the ISS and ground test beds to integrate and demonstrate technologies. Technology deliverables will be transitioned to the customer for final maturation, development, and insertion into the flight program. The HRP works with the Space Technology Mission Directorate (STMD) to ensure that human health technology development activities are complementary and avoid duplication across HRP and STMD portfolios.

Before technologies are delivered, the HRP completes an infusion process, which includes assessment of TRLs and successful completion of development control gates. This includes an independent technical review with the participation of the intended customer. This review will provide early visibility of technology capabilities to the program and stakeholders, enabling the identification of preferred technology insertion paths. An internal review of the technology development status will be conducted to assess its readiness for delivery to the targeted customers.

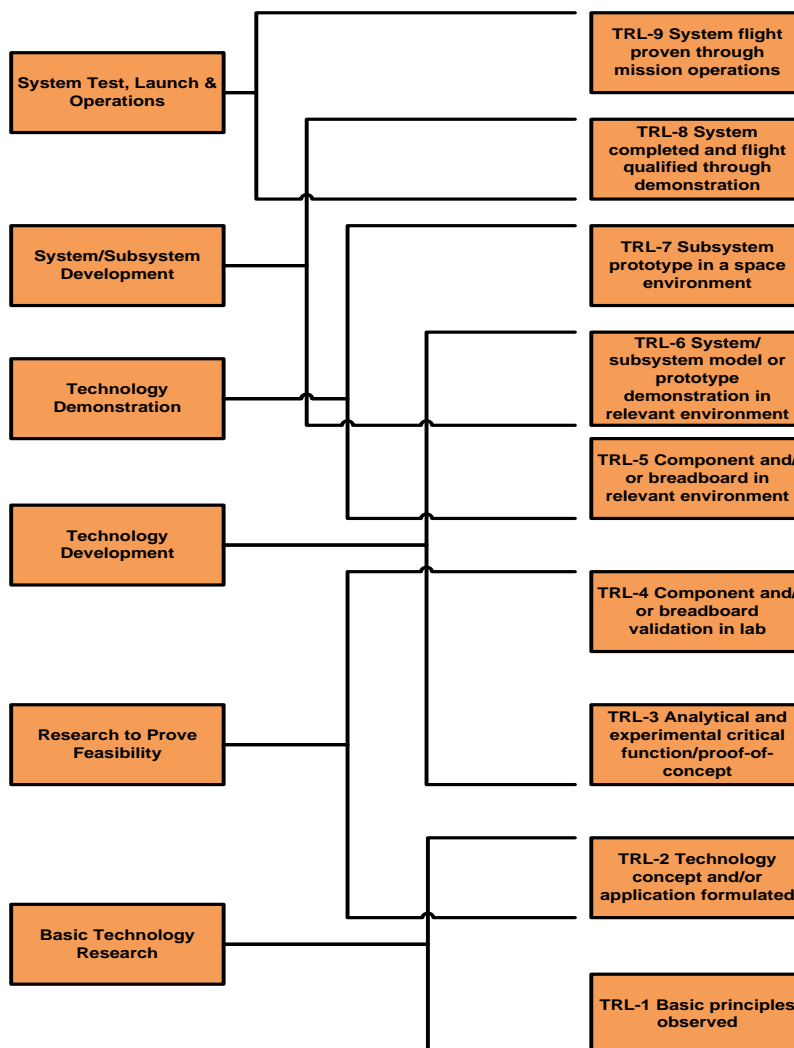


Figure 3-4: Definition of Technology Readiness Levels

3.5 COOPERATION AND COMMERCIALIZATION

The JSC Strategic Opportunities and Partnership Development (SOPD) Office will support the HRP to identify and evaluate commercial opportunity options. As applicable, the JSC SOPD Office works with the HRP to develop specific commercialization partnership and/or technology transfer opportunities. The SOPD Office support of partnership development includes industry market analysis, search for and connection to potential partners, and partnership due diligence and evaluation. Agreement negotiation and definition are performed within the JSC Directorate by the delegated representative of the agreement's sponsoring organization. Similarly, the supporting NASA Centers use their own commercialization and technology transfer organization, as appropriate, in support of their content.

3.6 DATA MANAGEMENT AND DISTRIBUTION

The documents developed under the HRP are stored in HRP managed databases for

configuration management and are available to the general public in accordance with JSC policy. For cross-center integration, the HRP utilizes a SharePoint website and an HEOMD-provided storage location and tools for review documents and schedules.

A goal within the HRP is to maximize the availability and access to data by appropriate users within fiscal constraints. The HRP complies with NPD7100.8E Protection of Human Research Subjects and NPR 7100.1. The HRP follows the procedures and requirements established for protecting the privacy of data collected during voluntary medical research involving active, inactive, or retired spaceflight crewmembers and for ground-based and in-flight data collection. No data attributable to an individual will be publicly released without the permission of the subject. This concept encompasses non-disclosure of an individual's name and requires sufficient pooling of data to preclude determining an individual's identity by combining or cross-referencing data (e.g., height, weight, sex, and flight number may identify a specific individual).

The Life Sciences Data Archive (LSDA) contains research descriptions, publication citations, results, and data generated from NASA-sponsored spaceflight, flight analog, and ground investigations. JSC Institutional Review Board (IRB) has established a repository function for LSDA, which allows dissemination of this data for purposes beyond its original collection. Data management and distribution capabilities are available within the LSDA system and may be used to collect structured data for experiments, distribute that data, and archive experiment data for future use.

Astronaut data collected for clinical purposes are available for research through NASA's medical data repository, the Lifetime Surveillance of Astronaut Health (LSAH).

A request for research and/or clinical data must be submitted via the Data Request tab on the LSDA home page located at <http://lsda.jsc.nasa.gov/>. The request is reviewed by the Evidence Base Working Group, which may approve the request, identify additional information needed, or elevate the request to the LSAH Advisory Board for additional discussion. The Board may approve requests, disapprove, or approve with conditions. Requestors will be contacted by a POC from the Working Group who will keep the requestor apprised of the status of their request.

HRP documents also include published journal articles, conference papers, and/or technical presentations generated by extramural and/or intramural researchers. HRP deliverables are archived using approved database applications.

3.7 SAFETY AND MISSION ASSURANCE

3.7.1 Research S&MA

3.7.1.1 Human Test Subjects

For NASA-funded investigations involving human subjects, the Element shall comply with NPD 7100.8E, Protection of Human Research Subjects, and NPR 7100.1 to ensure the health, safety, and privacy of the subjects are protected. All human research funded, sponsored, conducted, or supported by NASA, is reviewed by an IRB approved by NASA or the Office of Human Research Protection at the Department of Health and Human Services. IRBs are established at NASA Centers to review all ground-based and aeronautical flight research involving human subjects conducted at the centers or utilizing center equipment or personnel.

All research performed on NASA spacecraft involving crewmembers is reviewed by the JSC IRB. The HRP requires all HRP research to be reviewed by the IRB. The IRB has the authority to approve, disapprove, or require changes in the proposed human research protocols and procedures and to suspend or terminate its approval of research activities that are not conducted in accordance with the approved protocol or that have been associated with serious harm to subjects. For international projects, Element strategies will be submitted for additional review by the Human Research Multilateral Review Board.

3.7.1.2 Animal Test Subjects

For tasks involving animal subjects, the Element will obtain prior approval from the Institutional Animal Care and Use Committee for the appropriate testing location and shall comply with

- Code Fed. Reg. Title 9, NRC Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act,
- NPD 8910.1B, Care and Use of Animals, and
- NPR 8910.1C, Care and Use of Animals.

3.7.1.3 Ground Research

Ground-based research will be conducted at multiple NASA Centers and non-NASA facilities. The HRP will comply with the approved safety, environmental, and quality standards for the performing center and facility.

3.7.1.4 Flight Research

For flight research, the Element shall comply with the applicable standards and procedures governing flight payloads including SSP 50021, Safety Requirements Document. The ISSMP Project Manager and the funding Element Manager will ensure that S&MA processes are properly established and implemented within the task.

Hardware will be presented to the JSC Payload Safety Review Panel (PSRP). Safety engineers participate in all phases of the hardware and software design process and develop Phase 0, I, II, and III Flight and Phase 0/I/II and III Ground Safety Data Packages for hardware items and act as a liaisons to the PSRP. Safety engineers review flight and ground procedures for compliance with safety requirements and identify hazard controls during the procedure development process prior to baseline. Compliance will be verified during the safety reviews as well as the Certification of Flight Readiness (CoFR) review process.

3.7.2 Technology Development

Technology development projects will comply with S&MA requirements at the relevant centers.

3.7.3 Mishap Preparedness and Contingency Plan Process

The PSMO develops plans to be used by the HRP in the event of a contingency that falls under its jurisdiction. HRP-48000, Human Research Program Mishap Preparedness and Contingency Plan, defines appropriate responsibilities imposed on HRP organizations that comply with NPR 8621.1C, NASA Procedural Requirements for Mishap and Close Call Reporting, Investigating

and Recordkeeping. The HRP responsibility continues until the investigation's correction action plan is implemented. HRP-48000 applies to all HRP sponsored or funded ground and flight R&T development activities, whether those activities take place on-orbit at the ISS, at NASA Field Centers, at universities and non-profit research institutes, or at for-profit industries, and may involve human research subjects.

3.8 RISK MANAGEMENT STRATEGY

The HRP Program Director implements risk-informed decision making (RIDM) and continuous risk management (CRM) principles and processes in accordance with NPR 8000.4/NID 8000-108, Risk Management Procedural Requirements. HRP-47051, HRP Program Plan Appendix B, Program Risk Management Plan, contains further details of the programmatic risk management process.

The HRP uses the JSC Integrated Risk Management Application (IRMA) as the common tool for documenting and tracking all programmatic risks. All ISS-unique risks are entered into the ISS IRMA. HRP risks which are related to ISS-unique risks are associated in IRMA.

3.9 ENVIRONMENTAL IMPACT

The HRP complies with the responsibilities defined in NPD 8500.1C, NASA Environmental Management. The HRP requires each Element to evaluate the environmental risks and liabilities associated with each task. The Element or Project Manager is responsible for compliance with environmental requirements and development of documentation associated with environmental compliance considerations, as needed.

3.10 INSTITUTIONAL AND LOGISTICS

Institutional facilities and equipment exist at various NASA Centers to support HRP tasks, including ARC, GRC, JSC, and KSC.

External to NASA, the TRISH provides facilities and equipment to support cutting-edge, innovative R&T development aimed at preventing or addressing health problems related to long-duration space travel and prolonged exposure to microgravity.

In addition, the HRP utilizes bed rest and other spaceflight analog facilities through partnering agreements with international and other agencies. The program will utilize parabolic aircraft as needed to support its research projects.

The HRP makes use of the NASA Space Radiation Laboratory (NSRL) at the U.S. DOE Brookhaven National Laboratory, as well as other DOE laboratories and international laboratories. The HRP also utilizes radiation research facilities at the Loma Linda University Medical Center.

3.11 PHYSICAL AND INFORMATION TECHNOLOGY SECURITY

To ensure export controlled data, human subject privacy data, and NASA internal data are protected appropriately, the HRP manages its information in accordance with NASA information

technology security policy, including export control per NPR 2190.1, NASA Export Control Program, and information security per NPR 2810.1, Security of Information Technology.

3.12 VERIFICATION AND VALIDATION

As an applied research program, the HRP will ensure verification and validation of all HRP R&T development deliverables, such as standards updates, new technologies, countermeasures, design models, and risk projection models. Verification and validation of HRP products will be completed prior to delivery and will adhere to applicable NASA standards.

The Elements will subject hardware and software used in flight experiments and tests to functional verification and safety reviews as required by the appropriate U.S. and International vehicle programs. The Elements will document these requirements in associated plans as required by these programs.

Validation of research tasks includes scientific merit review. Therefore, where possible, results from the research used in developing a deliverable will be published in peer-reviewed journals, using the appropriate refereed journal publication processes. Deliverables developed from the integration or research results will be validated through merit review and verified, where applicable, through independent procedure, hardware, or software verification processes.

The verification and validation of HRP deliverables are Element unique and will be documented in their management plans. Verification and validation are driven by the customer or stakeholder requirements and will be identified in associated CSA.

3.13 REVIEWS AND KEY DECISION POINTS

3.13.1 Program Reviews and Reporting

The HRP will conduct management and technical reviews to maintain cognizance of current status and risks and to discuss progress toward accomplishment of goals and objectives for the program. The HRP will provide monthly, quarterly, and annual reports and status briefings to HEOMD as listed in Table 3-1 to keep the directorate apprised of current status, cost, schedule, and risks.

As an R&T Program under NPR 7120.8, Program Status Reviews (PSR) are conducted in accordance with NPR 7120.8 and every two years, unless waived by the APMC. This independent assessment is coordinated and led by the Independent Program Assessment Office (IPAO). Results are briefed to the HEOMD Directorate Program Management Council (DPMC) and the APMC.

Quarterly technical, cost, schedule, and risk reviews of each multi-center program Element, and applicable projects, are conducted at the program level with representation from each participating Center. The Element or project obtains status from the Centers and presents an integrated status of the R&T development tasks across the Element or project. In addition, HRP management and the Center POCs have a separate session during the review to address center-specific issues. The key metric in the quarterly timeframe is how well the planned activities adhere to schedules and whether or not expected results were achieved.

3.13.2 Research Reviews

The quality of basic and applied research efforts within the HRP is assured by competition and merit review, where merit review means independent evaluation by internal or external subject matter experts who do not have a conflict of interest. For all investigations/tasks (science and technology) funded by the HRP, merit reviews are conducted in accordance with HRP-47053, and implemented in accordance with NPR 1080.1A. The merit review determines the quality, relevance, and value of the work.

3.13.3 Other Reviews

The HRP Program Director will recommend use of advisory boards when external advice is required. Any advisory board usage will be approved and managed by the HEOMD. Examples of advisory boards relevant to the HRP include the National Research Council (NRC), National Academy of Sciences (NAS) and the National Academy of Engineering (NAE). Elements and projects will use focused advisory boards or working groups when external advice specific to Element or project objectives are required.

The HRP Elements and projects shall support CoFR Reviews per JSC 28225, Certification of Flight Readiness Implementation Plan, for missions involving HRP research objectives or flight experiments. This document addresses specific reporting to the vehicle programs, such as SSP 52054, ISS Program Payloads CoFR Implementation Plan, Generic.

The HRP supports independent assessments, external audits, and other program evaluations as required by NPR 7120.8.

TABLE 3-1: HRP PROGRAM REPORTING AND REVIEWS

Review / Report	Frequency	Customer Organization	Input Responsibility
HEOMD Level			
HRP Quarterly Review	Quarterly	HEOMD	HRP Program Office
HRP Annual Report	Annual	HEOMD	HRP Program Office
Planning, Programming, Budgeting, and Execution (PPBE)	Annual	HEOMD/HRP	Elements and Projects
Program Status Review (PSR)	At least every three years after the PIR	APMC/HEOMD designated independent review team	HRP Program Office and IPAO
Cancellation Reviews	As required	HEOMD/HRP	Elements and Projects
Program Level			
HRP Quarterly Review (TCSR)	Quarterly	HRP Program Office	Elements and Projects
HRP Programmatic Risk Review	Quarterly	HRP Program Office	Elements, Projects, Risk Custodians, HRP Risk Manager
Certification of Flight Readiness (CoFR) Review	Prior to related launch	Flight Vehicle Program Office	JSC/HHPD and Elements and Projects

3.15 TERMINATION REVIEW CRITERIA

The HRP will review the status of each Element and project annually and assess the ability to meet its objectives. HRP Elements and projects are subject to termination as authorized by the HRP Program Director. Criteria for termination includes:

- Strategic: inconsistent with the exploration vision; inconsistent with the program/mission objectives; overlap with another funded activity; or low priority ranking for the HRP given funding constraints;
- Technical/Scientific: performance measures indicate that the technology will not achieve the required technical results by the scheduled need date; performance measures indicate degradation in projected performance versus performance commitments; product delivered is of insufficient quality and/or does not meet performance requirements;
- Cost: over budget by five percent per year for an Element; over budget by 15 % per year for a project;
- Schedule: missed milestone(s) or key decision points; missed due dates for major activities, projected delay in the operational readiness review greater than 6 months from the committed date;

- Noncompliance with Agency or HEOMD policy;
- Knowledge sought is obtained through means other than the current HRP-funded activities.

3.16 WAIVERS

There are no known deviations or waivers against NASA policies, directives or external requirements, either in existence within the HRP or to be obtained by the HRP.

APPENDIX A: APPLICABLE AND REFERENCE DOCUMENTS

The following documents of the specified revision or the latest revision if not identified, form a part of this plan to the extent defined herein.

Table A.1 Applicable Documents

Document No.	Revision	Document Title
	July 2012	HRP Program Commitment Agreement, Rev B
HRP-47052, Rev G, PCN-1	May 2017	Human Research Program Requirements Document
JSC 28225, Rev H	May 2015	Certification of Flight Readiness (CoFR) Implementation Plan
NASA-STD-7009	July 2008	Standards for Models and Simulations
NPD 1000.0B	November 2014	NASA Governance and Strategic Management Handbook
NPD 1000.5B	December 2013	Policy for NASA Acquisition
NPD 1001.0C	February 2018	2018 NASA Strategic Plan
NPD 2190.1B	June 2010, 2012	NASA Export Control Program
NPD 2810.1E	July 2015	NASA Information Security Policy
NPD 7100.8E	May 2002	Protection of Human Research Subjects (Revalidated with admin. changes 12/18/2012)
NPD 8500.1C	December 2013	NASA Environmental Management
NPD 8700.1E	October 2008	NASA Policy for Safety and Mission Success (Revalidated 12/6/2013)
NPD 8910.1B	May 2008	Care and Use of Animals (Revalidated 6/25/2013)
NPR 1080.1C	November 2016	Requirements for the Conduct of NASA Research and Technology (R&T)
NPR 2190.1B	December 2011	NASA Export Control Program
NPR 2800.2	January 2011	Electronic and Information Technology Accessibility
NPR 2810.1E	July 2015	Security of Information Technology

Document No.	Revision	Document Title
NPR 7100.1A	February 2018	Protection of Human Research Subjects
NPR 7120.5E	August 2012	NASA Space Flight Program and Project Management Requirements w/changes 1-12
NPR 7120.8	February 2008	NASA Research and Technology Program and Project Management Requirements (w/change 4 dated 01/04/2017)
NPR 7150.2B	November 2014	NASA Software Engineering Requirements
NPR 8000.4B	December 2017	Agency Risk Management Procedural Requirements
NPR 8900.1B	December 2016	Health and Medical Requirements for Human Space Exploration
NPR 8621.1C	May 2016	NASA Procedural Requirements for Mishap and Close Call Reporting, Investigating, and Recordkeeping
NPR 8910.1C	December 2011	Care and Use of Animals (updated w/change 2 on 3/20/14)
NPR 9680.1B	August 2015	NASA's Management of Grants and Cooperative Agreements
NSTS 1700.7B ISS Addendum	December 1995	Safety Policy and Requirements for Payloads Using the International Space Station – ISS Addendum (Safety Package)
SSP 50021, Rev B	February 2000	Safety Requirements Document, International Space Station
JPR 1281.5B	June 2012	Document and Data Control (Revalidated 6/5/2017)

Table A.2 Reference Documents

Document No.	Revision	Document Title
HRP-47053, Rev E PCN-2	October 2017	Human Research Program Science Management Plan
HRP-47065, Rev J	July 2018	Human Research Program Integrated Research Plan
HRP-47069, Rev G	January 2018	Human Research Program Unique Processes, Criteria, and Guidelines (UPCG)
HRP-47087, Rev C, PCN-1	May 2018	Human Research Program Work Breakdown Structure Dictionary
HRP-48000, PCN-1	April 2015	Human Research Program Mishap Preparedness and Contingency Plan

Document No.	Revision	Document Title
JSC 28330, Rev G	March 2015	Human Health and Performance Directorate Configuration Control Management Plan
JSC 66705	May 2014	Human System Risk Management Plan
NASA-STD-3001, Volume 1 Rev A	February 2015	NASA Space Flight Human System Standard - Volume 1: Crew Health
NASA-STD-3001, Volume 2	February 2015	NASA Space Flight Human System Standard - Volume 2: Human Factors, Habitability, and Environmental Health
	January 2009	NRC Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act (Code Fed. Reg. Title 9)

APPENDIX B: HRP RISK MANAGEMENT PLAN

B1. INTRODUCTION

B1.1 Purpose

The purpose of this plan is to document the process by which the Human Research Program (HRP) identifies, assesses, plans for and makes decisions on risks to the Program. It provides personnel across the Elements and projects with a description of how the HRP manages its programmatic risks. This plan meets the intent of requirements stating NPR 7120.8 and NPR 8000.4/NID 8000.108.

B1.2 Scope

This plan addresses the management of programmatic risks related to achieving the Program's baseline schedule, budget, and deliverable products and is applicable to the PSMO, Elements, and projects that comprise the HRP, including associated contractor support.

Although the purpose of the HRP is to reduce human health and performance risks for exploration missions, the process for managing these risks is not addressed in this plan but rather in the Human System Risk Management Plan (JSC-66705) which governs the Human System Risk Board (HSRB) risk process. The Human Research Program Science Management Plan (HRP-47053) is the document that contains the policies utilized in the management of the HRP work performed to address those human system risks delegated to the Program by the HSRB and designated as requiring research.

B2. DOCUMENTS

B.2.1 Applicable Documents

NID 80000.108	October 2016	Agency Risk Management Procedural Requirements
JSC-66705	May 2015	JSC Human System Risk Management Plan
JPR 8000.4	December 2016	JSC Risk Management Plan
NPD 1000.5B	February 2017	Policy for NASA Acquisition
NPR 7120.8	February 2008	NASA Research and Technology Program and Project Management Requirements
NPR 8000.4B	December 2017	Agency Risk Management Procedural Requirements

B3. RISK MANAGEMENT PROCESS AND TOOLS

B3.1 Risk-Informed Decision Making (RIDM) and Continuous Risk Management (CRM)

NPR 8000.4B/NID 80000.108, Agency Risk Management Procedural Requirements, requires the integration of Risk Informed Decision Making (RIDM) and Continuous Risk Management (CRM) into a coherent framework to inform decision making through better use of risk information. HRP utilizes this construct wherein research and planning decisions are made with

regard to outcomes of the decision alternatives, taking into account applicable risks and uncertainties.

As prescribed by NPR 8000.4B, when a threat is identified or when a potential performance shortfall has been identified, the risk management process is initiated using the following RIDM steps:

- 1) Identify decision alternatives: Consider challenges and opportunities based on stated objectives.
- 2) Analyze alternatives: Apply subject matter expertise across disciplines as needed to bound risk scenarios; integrate all key drivers and impacts, and consider performance measures.
- 3) Select an option: After a deliberative review informed by risk analysis results, select a decision alternative and develop risk mitigation strategies.

This approach is particularly useful when a threat entails high stakes, complexity, uncertainty, multiple attributes or competing objectives, or a diverse range of stakeholders. It also improves deliberation during consideration of the performance requirement through use of the program's experience base and tacit knowledge.

The HRP primarily uses the CRM process to manage programmatic risks related to the management of research that supports achievement of human performance requirements and safety for space operations. The CRM paradigm wheel, depicted in Figure B-1, illustrates a continuous and iterative process based on six phases: Identify, Analyze, Plan, Track, Control, and Communicate and Document. HRP's implementation of this process is described in Section B3.4.



Figure B-1: Continuous Risk Management Process

B3.3 Roles and Responsibilities

Each risk has a Risk Owner who is responsible for developing and implementing the mitigation plan for the risk (*note: the HSRB risk process utilizes a different term for the same role – Risk Custodian*). A Risk Owner may delegate specific tasks within the mitigation plan to other personnel as needed but remains the primary overseer.

The Program Director, who serves as the HRP Control Board (HRPCB) Chair, makes decisions regarding the establishment, and acceptance or closure of program risks, and authorizes and allocates resources to reduce them. The Program Director may delegate authority for these functions to the Deputy Program Director as necessary. The PSMO Manager and Element Managers authorize and allocate resources to reduce Program- and Element/project-level risks,

respectively, and make decisions on whether the risks ought to be elevated to the Program-level. A project manager who controls resources also functions in a similar manner.

A Risk Manager is dedicated to overseeing the implementation of CRM principles and has the overall responsibility to ensure facilitation and implementation of the risk management process for programmatic risks as well as the HSRB risk process as it relates to health and performance risks addressed by HRP research. The Risk Manager works with appropriate personnel from the HRP Program Office and Elements to develop content for the appropriate definition of risks. The PSMO Manager has responsibility for the technical, cost and schedule review of risk management for the Program.

B3.4 HRP Risk Management Process (based on CRM)

The activities involved in the execution of the CRM process in the management of HRP programmatic risks are summarized in Figure B-2; the details follow.

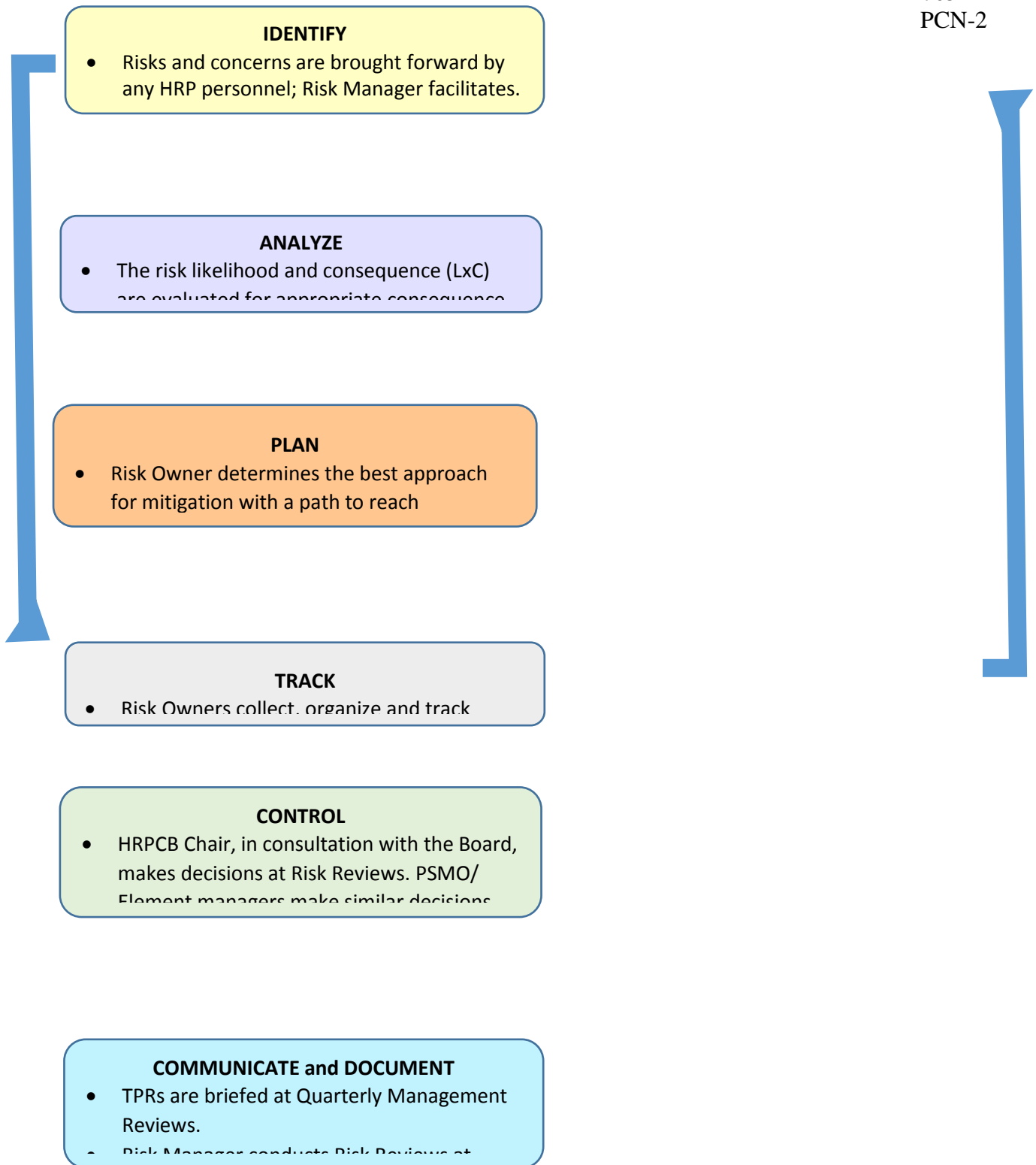


Figure B-2: CRM Process Flow

B3.4.1 Risk Identification

A RISK is an item of interest that has a clear consequence and attendant likelihood supported by evidence. HRP programmatic risks are driven by technical risks, budget constraints, safety and schedule. These risks are identified from various sources and forums such as budgetary reviews, engineering trade studies, test results, historical data, close call reports, and lessons learned meetings as well as during daily activities of personnel. A CONCERN or EMERGING RISK is an item of interest that is brought forward for discussion as potentially being defined as a risk. These concerns may also be brought forward by any HRP personnel and the decision on their validation is made at the appropriate risk level.

Risk Levels

The HRP classifies risks at various levels according to their scope, the level of resources warranted to track and mitigate them, and the approval authority needed. Risks for which the scope of impact extends across program-level functions and goals are called PROGRAM RISKS. Resources for their mitigation and tracking come from the HRP Program Office. Program risks are approved by the HRPCB Chair. The Chair may designate certain program risks as TOP PROGRAM RISKS if their significance warrants their communication by the HRP Program Director to Headquarters.

Risks for which the scope of impact only covers the internal functions of the PSMO and the Element are called PSM RISKS and ELEMENT RISKS, respectively. Their mitigation and tracking are managed using PSMO and Element resources as approved by the PSMO and Element Managers, and do not require additional approval by the HRPCB Chair. Element Managers may also identify lower level PROJECT RISKS associated with specific projects managed by their Elements. These risk levels are illustrated in Figure B-3.

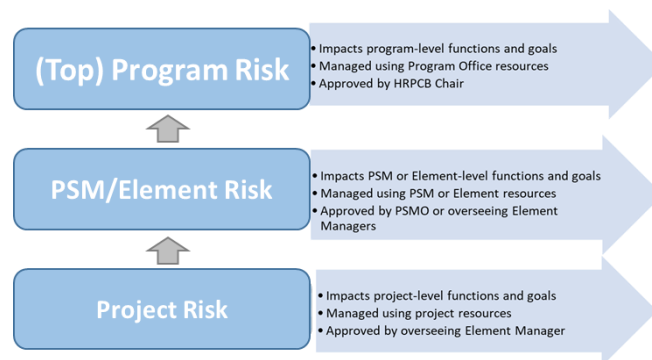


Figure B-3: HRP Risk Levels

Risk Information

Each risk will have a Risk Statement to capture a concise description of the risk that will be written using the following format:

Given the CONDITION, there is a possibility that CONSEQUENCE(S) will occur.

CONDITION – a single phrase that describes a current key circumstance or situation that is causing concern, doubt or anxiety.

CONSEQUENCE – a single phrase that describes the undesired outcome(s) of the current condition that could occur if no additional actions are taken.

Clarity in Risk Statement has a significant effect on the accuracy of both the risk analysis and the risk communication. It is important that the defined risk suggests a scope and level for which a feasible mitigation plan can be developed. An accompanying Risk Context captures additional information beyond what is in the Risk Statement and provides the what, how, when, where, and why of the risk. The Risk Status contains a description of the latest key developments that impact the progress of completion of the mitigation strategy.

To determine if a concern could be validated as a risk, the following questions can be used:

- Does the individual risk adequately communicate the possible sequence of events leading from the CONDITION through the CONSEQUENCE?
- Is the risk based on evidence, documentation or individual/group knowledge?
- Does the risk involve a change from the program/project/activity baseline plan for which an adequate contingency plan does not exist?
- Does the risk impact at least one agency/program/project/activity requirement that can be objectively measured, described, and characterized?

B3.4.2 Risk Analysis

The purpose of risk analysis is to characterize the significance of risks once they have been identified and validated. An evaluation of risk probability and impact/severity is used to establish the significance relative to other risks. The likelihood and consequence (LxC) score for an HRP programmatic risk is qualitatively assessed based on the assumption that available countermeasures and mitigations are taken. A scale of 1 to 5 is used, where 1 represents the lowest likelihood or least consequence, and 5 represents the highest likelihood or consequence.

For each risk, the Risk Owner clearly defines the consequence, determines the criterion (Safety, Schedule, Cost and Technical) to which it belongs and assigns a score based on the definitions for that category (Table B-1). If a risk is applicable to multiple criteria, the Risk Owner chooses the highest consequence score assigned. Next, the Risk Owner evaluates the likelihood of the selected consequence and applies a score based on the likelihood scale definitions (Table B-2). The rationale and the drivers behind the selected scores are documented, and the uncertainty noted as appropriate.

TABLE B-1: CONSEQUENCE CRITERIA AND SCALE

		Consequence Criteria			
		Safety	Schedule	Cost	Technical
5 Very High	Condition may lead to death or permanent disabling injury or facility destruction, or loss of major systems	Slip in delivery of one or more major PRR risk buy-down milestones that impacts the customer's schedule or requires the Agency to accept more/higher risk.	Increase to budget allocation exceeds reserves, with a significant impact on higher-level reserves	Major unmet science objectives due to inability to access suitable testing platforms, analytical capabilities, or skilled experts	
4 High	Condition may cause severe injury or occupational illness, or major property damage to facilities, systems, equipment or flight hardware.	Delay in planned technical or research tasks that impacts one or more major PRR risk buy-down milestone, but alternate strategies can be implemented that may allow milestones to be realized.	Increase to budget allocation exceeds reserves, with minimal impact to higher-level reserves	Loss of critical function or science objective(s) due to the inability to access suitable testing platforms, analytical capabilities, or skilled experts	
3 Moderate	Condition may cause minor injury or occupational illness, or minor property damage to facilities, systems, equipment or flight hardware.	Delay in planned technical or research tasks that impacts one or more major PRR risk buy-down milestone, but alternate strategies can be implemented that allow milestones to likely be realized.	Increase to budget allocation is covered by reserves, with none left	Major science objectives not likely to be fully met due to the inability to access suitable testing platforms, analytical capabilities, or skilled experts	
2 Low	Condition may result in minor first aid though would not adversely affect personal safety or health. Subjects facilities, equipment or flight hardware to more than normal wear and tear.	Delay in planned technical or research tasks that impacts one or more major PRR risk buy-down milestone, but alternate strategies can be implemented that result in minimal schedule impact that is fully recoverable.	Increase to budget allocation is covered by reserves, leaving some reserves	Some desired science objectives and/or technical performance not likely to be completely met due to the inability to access suitable testing platforms, analytical capabilities, or skilled experts	
1 Very Low	No impact to personnel or facilities.	Delay in planned technical or research tasks that impacts one or more major PRR risk buy-down milestone, but alternate strategies can be implemented that result in no impact to these or subsequent milestones.	Minor impact to budget allocations – can easily be addressed within reserves.	Inability to access suitable testing platforms, analytical capabilities, or skilled experts, with minimal impact to meeting research objectives	

TABLE B-2: LIKELIHOOD SCALE

Likelihood of Occurrence	
5 Very High	Occurrence is very likely and cannot be prevented by existing processes, procedures, and plans; no alternative approaches or processes are available.
4 High	The existing processes, procedures, and plans cannot prevent this event, but a different approach or process may prevent the event.
3 Moderate	The existing processes, procedures and plans may prevent this event, but additional actions shall be required.
2 Low	The existing processes, procedures, and plans are usually sufficient to prevent this type of event.
1 Very Low	The existing processes, procedures, and plans are sufficient to prevent this event.

The resulting LxC score is then plotted on a 5 x 5 risk matrix shown in Figure B-4. The LxC score is associated with the color of the cell within which it falls.

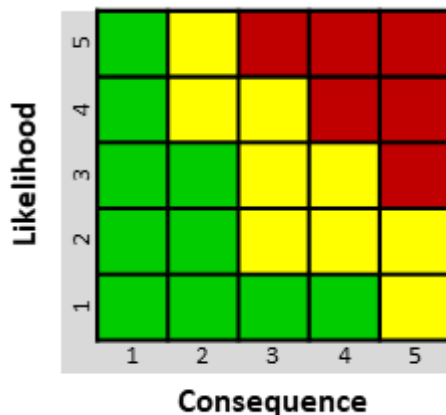


Figure B-4: Risk LxC Matrix

Risk records are maintained in a tool identified by the PSMO Manager and jointly managed by the Risk Manager and Risk Owners.

In certain instances as determined by the HRPCB Chair, it may be necessary to analyze a set of risks as an aggregate risk. This type of risk is a view of the set of risks as they contribute to a broader consequence outcome. The same LxC scales apply to its assessment.

B3.4.3 Risk Planning

As a new risk is identified, approved, and analyzed, the Risk Owner considers available resources and recommends a mitigation plan that includes a clear path to acceptance or closure. The mitigation plan specifies activities to reduce the risk in order to minimize the probability of occurrence and/or severity of the consequence. Within the strategy, each mitigation step or set of steps may have an LxC score that traces the path to an LxC goal that makes the risk acceptable to the program. The criteria by which to evaluate the success of each mitigation step are identified. A brief description of the resources required for implementing each mitigation step is also documented as appropriate.

Developing the mitigation strategy for a risk should consider relationships with other risks that are defined in terms of scope or potential shared activities or issues. These relationships are clearly noted in the risk record and factored in the evaluation of the progress of risk reduction. This evaluation may also identify cross-cutting risks, which are risks generally applicable to multiple HRP efforts, with attributes and impacts found in multiple levels of the organization or in multiple organizations within the same level.

Contingency plans are made when necessary to reduce the severity of impact should the adverse event, as identified by the risk, occur.

B3.4.4. Risk Tracking

The goal of tracking risks is to collect, update, organize, and analyze risk to have accurate status updates, and to support decisions to be made by the Risk Owners and the HRPCB Chair (for program risks). The Risk Owner is responsible for the execution of the mitigation plan as scheduled and the monitoring of risk metrics. Having the right metrics enables the assessment of the impact of the mitigation plan or the effectiveness of specific actions against established performance metrics. Thresholds and triggers are defined at which further actions may be taken as decided upon by the HRPCB Chair for program risks, and the PSMO and Element Managers for PSM and Element risks, respectively. The tracking phase can yield information that identifies

new risks. Risk records in the risk tool are updated with tracked information.

B3.4.5 Controlling Risks

During Risk Reviews and meetings dedicated to discuss risk issues, the HRPCB Chair, in consultation with the Board, makes decisions on new, existing, closed and emerging program risks as well as concerns.

Decisions on new program risks

- Approve: The HRPCB Chair makes a decision by considering the supporting risk information and mitigation plan brought forward by the proposer. The proposed risk will have been pre-coordinated with the Risk Manager prior to presentation.
- Elevate: The PSMO Manager or any Element Manager may propose the elevation of a risk from their respective levels to program level when resources within their organizational units are no longer available to successfully execute the mitigation plan. Upon approval by the HRPCB Chair, the new program risk may be rescoped to better reflect the program-level concern, and may be assigned a new risk identifier.

Although a rare situation, a risk may also be de-elevated from program level when circumstances downgrade the scope of a program risk to the PSM or Element level.

Decisions on existing program risks

During regular status updates of program-level risks, the HRPCB Chair decides on the appropriate path forward for active program risks based on status updates and agreed upon triggers or new evidence presented in the tracking phase. The following are the paths available for each risk:

- Continue: If the existing plan is still adequate to address to the risk, the HRPCB Chair directs the Risk Owner to continue its implementation until the next status update to the HRPCB.
- Replan/Modify: In the event that developments impact the applicability of the current plan for the risk, the HRPCB Chair may direct the Risk Owner to modify the plan or invoke any existing contingency plan to refocus the mitigation efforts for the risk.

Accept: The HRPCB Chair may decide that the Program is willing to accept the consequences and the associated likelihood of a risk, and that resources are no longer to be allocated for managing it. The assumptions and conditions for the basis of the acceptance are documented.

A risk may be accepted if one of the following criteria is satisfied: (1) available resources are not sufficient to buy down either the likelihood or consequence of the risk; (2) it is no longer cost-effective to invest resources in reducing the likelihood or consequence; or (3) limited resources are being allocated elsewhere based on priorities of the program. Accepted risks will be reviewed periodically to ensure that the acceptance rationale remains valid. The review cycle will be noted in the acceptance rationale.

If the risk pertains to safety of HRP personnel or has implications on mission objectives, the HRPCB Chair shall additionally obtain the signature of the applicable Engineering and Safety and Mission Assurance Technical Authorities and the Risk Taker(s) concurring with the decision. Such additional risk acceptance information will be captured on a HRP Risk Acceptance Form.

- Close: The HRPCB Chair may decide to close a risk if one of the following criteria is satisfied: (1) the risk has been mitigated to where it is in the green portion of the risk matrix; or (2) a major circumstance for the risk has changed making the risk no longer appropriate. Closed risks are no longer reported at Risk Reviews but are revisited on a periodic basis.
- Transfer: The HRPCB Chair may decide to transfer a risk to another organization if it is determined that the change in responsibility is more suitable. The transfer should be coordinated with the organization taking responsibility.
- Escalate: The HRPCB Chair may decide to escalate risk management decisions to the next higher level of the NASA hierarchy when the risk can no longer be effectively managed within HRP. This is done (1) when coordination and/or visibility of a risk is needed with other organizations/stakeholders; (2) to call attention to adverse changes in consequence or likelihood; or (3) to request resources that are not available to handle the risk at the present organizational unit.

These actions are also implemented by the PSMO and Element Managers for their level of risks and are communicated at the Risk Reviews. All decisions and accompanying rationale are recorded in the risk record tool.

Decision on closed risks

Program risks that have been closed are revisited on a periodic basis.

- Reopen: The HRPCB Chair may decide to reopen a previously closed risk if the circumstances by which the acceptance rationale supported the decision have changed or are no longer valid.

Decisions on emerging program risks

- Drop - The topic is determined no longer valid for discussion at any future Risk Reviews.
- Watch - The topic is revisited at the next Risk Review to assess any changes to the state of the issue that might compel a focused investigation.
- Investigate - Resources are expended to determine the appropriateness for proposing the concern as a risk to be entered into the risk system.
- Propose - The concern is supported by a reasonable set of evidence that could be basis for proposing it to be approved as a risk at the next Risk Review.

B.3.4.6 Communicating and Documenting Risk

Successful risk management relies upon:

- Open communication at, and among all, organizational levels within HRP and HRP stakeholders (including NASA Headquarters);
- Continuously identifying and addressing areas that may potentially cause future problems; and,
- Continuously assessing risks and strategies to mitigate those risks.

In preparation for any risk meeting, the Risk Manager coordinates with the Risk Owners and risk stakeholders including Program Management. A brief presentation of TPR updates may be made during Quarterly Management Reviews by the PSMO Manager while detailed discussions and

decisions occur at the Quarterly Risk Reviews.

Risk Reviews

The Risk Review is a forum conducted at the HRPCB dedicated solely for the purpose of an open and respectful discussion of existing and emerging risks with the goal of facilitating the risk management process. It is specifically aimed at providing the Board with information and status updates on program, PSM and Element risks (no project risks), and obtaining the HRPCB Chair’s decisions on program risks and concerns. Risk Reviews are ideally held within four weeks of Quarterly Management Reviews but may be included in any HRPCB agenda depending on the urgency of risk topics and required decisions. The Risk Manager leads the Risk Review and moderates the discussion while PSMO and Element Managers or Risk Owners present their respective information to receive feedback from the Board.

The Risk Manager follows up on actions and facilitates resolution of issues that come out of the Risk Reviews and risk discussions, and continues to facilitate risk identification and development. Risk Owners track their mitigation plans and keep risk records updated in the risk tool in preparation for Risk Reviews and meetings with the Program Director as requested. The Risk Manager ensures that information in the risk tool is current. TPR updates are presented by the Program Director at HEOMD Quarterly Reviews and by the Risk Manager at the JSC Risk Working Group Meetings as applicable.

The overall process for communicating HRP programmatic risks is shown in Figure B-5.

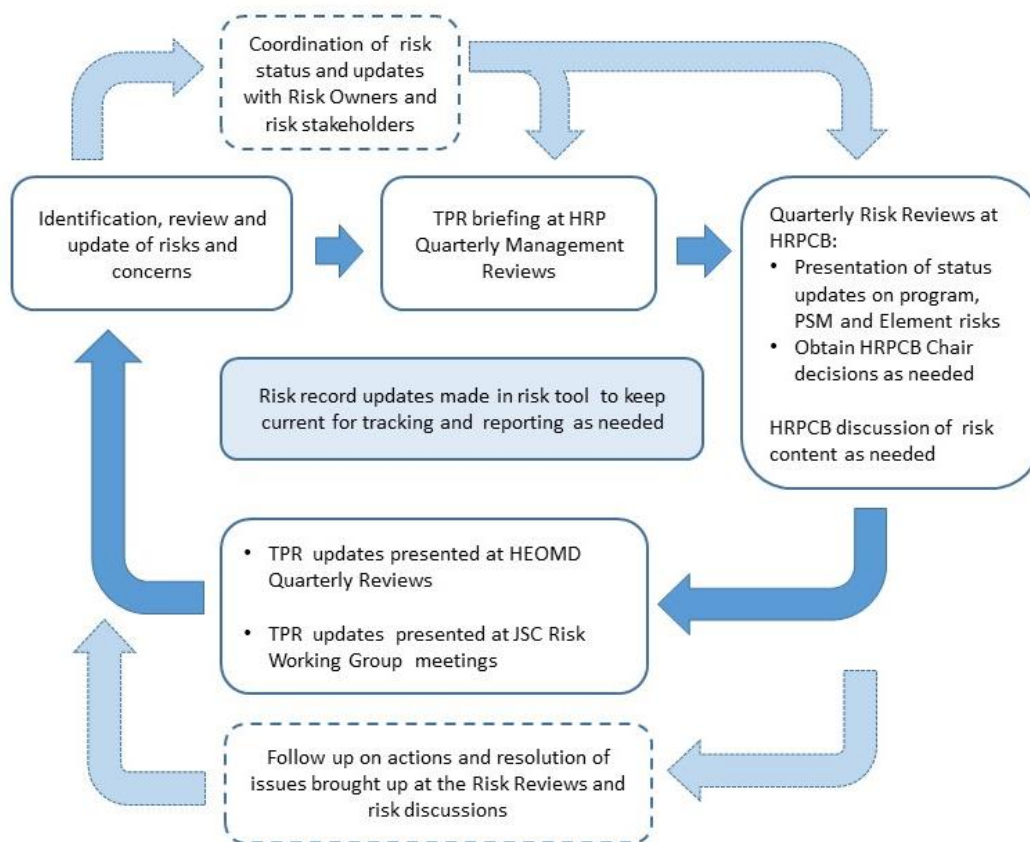


Figure B-5: Risk Communication Flow

APPENDIX C: HRP SCHEDULE MANAGEMENT PLAN

C1. INTRODUCTION

C1.1 OVERVIEW AND PURPOSE

Sound schedule management involves the establishment, utilization, and control of a baseline master schedule. Schedule management at the project level entails the creation of an Integrated Master Schedule (IMS) that contains a logic network made up of tasks and milestones, interdependency relationships, task durations, and valid date constraints. The IMS provides the framework for time phasing and coordinating Human Research Program (HRP) research tasks into a master plan to ensure that exploration objectives are accomplished within project or program commitments.

With the IMS playing such a critical role in achieving project success, it is crucial for project schedules to provide accurate and meaningful planning data for all levels of management oversight within both NASA and its contractor community. Regardless of the project type being implemented, it is essential that the IMS contains credible schedule data that addresses the total scope of work at a level of detail to allow for discrete progress measurement, management visibility, and critical path identification and control. This approach provides management with greater schedule visibility and the capability to accurately plan necessary resources when needed to accomplish the work.

This document describes the generation and management of schedules to plan the HRP research in order to reduce human health and exploration risks in a timely manner.

C1.2 REFERENCE DOCUMENTS

NASA/SP-2010-3403	January 2010	NASA Schedule Management Handbook
GAO-15-89G	December 2015	GAO Schedule Assessment Guide
NPR 7120.8	February 2008	NASA Research and Technology Program and Project Management Requirements
HRP-47051	May 2017	HRP Program Plan
HRP-47065	March 2018	HRP Integrated Research Plan
HRP-47069	January 2018	HRP Unique Processes, Criteria, and Guidelines
n/a	July 2012	NASA Schedule Test and Assessment Tool (STAT) User's Guide 4.0.0.X_01232013
n/a		HRP Admin Guide [EPIC]
n/a	Draft	HRP Project Server Users Guide [EPIC]

C2.PROJECT SCHEDULE MANAGEMENT ORGANIZATION

C2.1 ROLES AND RESPONSIBILITIES

The HRP research goals are organized by human health and performance risks that are managed by the HRP Elements. The HRP Element Managers work in concert with the HRP Element Scientists and subject matter experts to design a sound research plan to reduce the likelihood or consequence of those risks. The Human System Risk Board (HSRB) approves the mitigation strategies. The HRP also utilizes a Schedule Team to provide the Elements with expertise in Microsoft (MS) Project and KIDASA's Milestones Professional.

HRP Roles and Responsibilities are further detailed in HRP-47051, HRP Program Plan.

C2.2 SCHEDULE PROCESS MANAGEMENT

C2.2.1 Process Improvement and Lessons Learned

The HRP Scheduling Team conducts regular coordination meetings and maintains informal lessons learned via email, desktop instructions, and the HRP SharePoint page. Processes and training are evaluated by the HRP Scheduling Team, HRP Management, and external evaluators to identify areas of need.

C2.2.2 Internal Process Documentation and Instructions

The HRP Scheduling Team members maintain process documentation to communicate scheduling practices unique to the applicable schedules, to allow for ease of training backup schedulers, and to allow for the evaluation of schedule quality. This includes Element/Portfolio-specific schedule management approaches, unique reporting structure or symbology, Element/Portfolio contact personnel, and other pertinent information. This documentation may also be used to capture and review scheduling notes, assumptions, and direction from Element management.

C3.INTEGRATED MASTER SCHEDULE (IMS) APPROACH

C3.1 PATH TO RISK REDUCTION

The HRP research plan consists of human health and performance risks for space exploration. Each research plan details the gaps in our knowledge about characterizing or mitigating these risks, and the tasks to be carried out in order to produce the deliverables needed to close the gaps. Due to the integrated nature of risks to the human system, these risk research plans are compiled and documented in HRP-47065, HRP Integrated Research Plan, with the detailed content being managed through a web-based repository called the Human Research Roadmap (HRR) (<http://humanresearchroadmap.nasa.gov/>). The Integrated Research Plan (IRP) ensures that synergistic relationships between research content components are captured.

Each risk research plan describes the strategy and logic to provide critical knowledge and deliverables to execute the research portion of the mitigation strategy. Once the research strategy is defined for each risk, the logical sequence and timing of tasks and significant milestones, such

as completion of major deliverables, interim assessment points, or gap closure, are laid out in a project schedule. The schedule contains the key milestones that impact a risk’s likelihood or consequence; these milestones are used to create the Path to Risk Reduction (PRR), a tool that reflects a risk’s research plan for a given Design Reference Mission (DRM). The top-level schedules associated with each risk are then compiled into an integrated master schedule and reflected as the Integrated PRR (iPRR), Figure C-1. The most recent version can be found on the [HRP Document Tree](#).

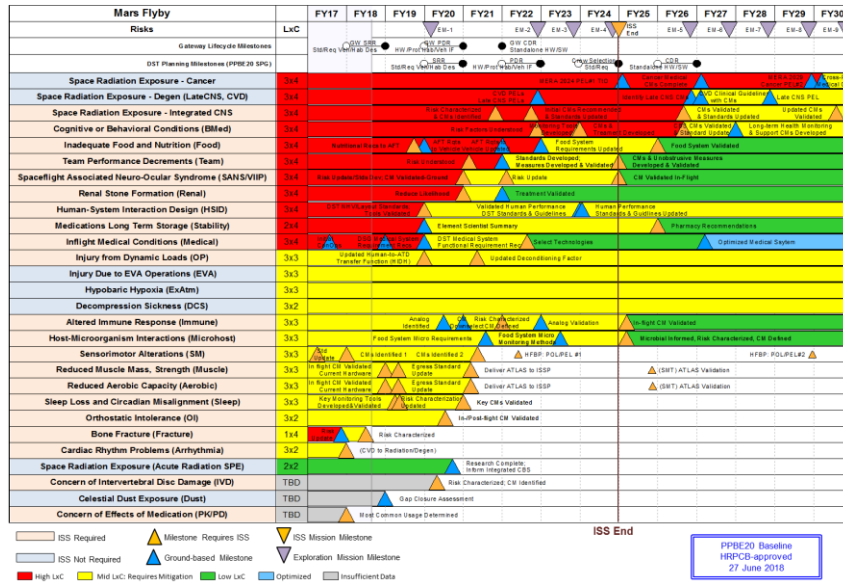


Figure C-1: The HRP Integrated Path to Risk Reduction

New PRRs and status updates are brought by the Element to be reviewed by HRP Management at any one of the following forums: (1) the HRP Quarterly review; (2) Planning, Programming, Budgeting, and Execution (PPBE); or (3) the Element monthly tag with the HRP Management. Periodic assessments of the progress made toward reducing the likelihood or consequence of a risk is necessary to determine whether the research plan is on track or whether updates are needed.

C3.2 SCHEDULE TYPES

The HRP utilizes three types of schedules for planning of program and Element tasks, as well as HRP-relevant plan information supplied by external organizations. There are schedules that contain critical paths (research plan) and those that do not (infrastructure/management and external organizations).

C3.2.1 Research Plan Schedules

The HRP risk schedules are the basis for the PRR and are also integrated with the HRR Content Management System (HRCMS). The HRP risk schedules have dependency logic applied as appropriate, with activity chains ultimately supporting completion of the PRR-level research milestones. The HRP PRRs address criticality from both schedule and technical merit perspectives. Critical paths within the project schedule have the highest fidelity when using the timeframe between PRR milestones as the analysis range.

Research plans tend to be volatile, with variations from expected results affecting future planning. Similarly, the space environment provides unique programmatic challenges that are not in the control of the HRP, such as vehicle launch and landing schedules, and on-orbit crew time availability, which may delay activities or levy constraints on schedules. The PRR approach allows for Elements to adjust to changing research needs and constraints by providing a context for planning information as well as a basis for creating dependencies and relationships. Schedule logic may not provide a network from project start to project completion through each task or study, but the HRP tasks provide deliverables (i.e., countermeasures, knowledge, technology, medical standards) that result in HRP recommendations to the HSRB for reductions in risk likelihood and consequence (LxC) ratings; these are represented by the PRR milestones.

Detailed research schedules for each risk can be found in HRP-47065, HRP Integrated Research Plan, Section 6. HRP Elements utilizing research schedules include:

ExMC – Exploration Medical Capability

HFBP – Human Factors and Behavioral Performance

HHC – Human Health Countermeasures

SR – Space Radiation

C3.2.2 Infrastructure/Management Schedules

The HRP Management schedules are used by the program and Elements to capture high level planning that supports the detailed technical plans of the risk schedules. Items in the management schedules include, but are not limited to, various reviews, conferences, workshops, contract management activities, facility configuration changes, documentation update cycles, and annual status meetings.

These management schedules are linked to the risk schedules as appropriate, providing the risk schedules awareness of upcoming event dependencies, document releases, and facility availability. Because of the event-list nature of the information in these schedules, dependency logic is generally less mature than in the risk schedules. Dependencies are applied where appropriate (e.g., release cycles, upgrade processes, contract activity stages). Critical paths are also not applicable to the management schedules because of the independent nature of the activities.

In some cases, the HRP Elements may integrate some of the management information into risk schedules to clarify dependency applicability and reduce schedule management complexity.

HRP infrastructure/management schedules include:

PSM – Program Science Management

ExMC – Exploration Medical Capability Management

HHC – Human Health Countermeasures Management

C3.2.3 External Organization Schedules

Organizations supporting the HRP research provide HRP-relevant planning information to allow the HRP Element risk schedules to create proper dependencies. These organizations maintain

more extensive schedules outside of the HRP scheduling environment and provide a subset of their planning information for HRP planning purposes.

Similarly to management schedules, these external organization schedules are generally structured to provide support information and are not expected to have mature logic connections and are not structured to support critical path analysis.

HRP external organization schedules include:

ISSMP – International Space Station Medical Projects

FAP – Flight Analogs Project

C3.3 SCHEDULE BASELINE CONTROL

C3.3.1 Baseline Approval

HRP schedule baselines are established to coincide with the HRP PPBE revisions. The PPBE revision is indicated as “PPBE Rev” in HRP schedules and reports. PPBE baselines for the forthcoming execution period are set at PPBE and are valid through the execution period, or until designated for rebaselining by HRP Management. Schedules created or submitted between PPBE cycles are baselined pending review and approval of the associated research plan by HRP Management.

C3.3.2 Baseline Revisions and Replanning

Nominally, schedule baselines are not revised between PPBE cycles. In cases requiring significant replanning (budget reductions, vehicle failures, government shutdowns, etc.), baselines may be designated for rebaselining outside of the normal PPBE timeframe. Other baseline changes are assessed on an individual basis by HRP Management.

C3.4 SCHEDULE REPORTING

C3.4.1 Reporting Format

The primary reporting format for the HRP is the PRR, as defined in HRP-47065, Human Research Program Integrated Research Plan, Section 6.

The PRR is a representation of a risk’s research plan, driven by the latest schedule content. PRR report structure and content will differ between risks based on the reporting needs of the Element. HRP schedulers maintain points of consistency to promote readability. An example of the common PRR template is shown on the attached Reference Card.

C3.4.2 Reporting Frequency

HRP Reviews are detailed in HRP-47051, HRP Program Plan, Section 3.13. The primary schedule-related reviews are as follows:

- HRP Quarterly Review
- Planning, Programming, Budgeting, and Execution (PPBE)
- Program Status Review (PSR)
- Human Exploration and Operations Mission Directorate (HEOMD)

- Directorate Program Management Council (DPMC) Quarterly Review
- HEOMD Quarterly Program Management Review (QPMR)

C3.5 HRP SCHEDULING WORKFLOW

C3.5.1 Key Scheduling Dates (Notional)

The nominal HRP Scheduling cycle incorporates the HRP schedule reviews and a series of internal activities to ensure schedule integrity and quality. Off-nominal activities may cause these activities to be reprioritized and replanned in coordination with HRP Management guidance.

- Oct 01 Fiscal Year Begins
- HRP Q1 Review [January]
- HRP Q2 Review/PPBE [April/May]
 - PPBE Submittal
 - Change request (CR) for Integrated PRR baseline with slips/accelerations accepted
 - Annual pre-baselining schedule archival
 - Annual PPBE reference baseline set
 - Annual Health Check
 - Annual Server performance review
- HRP Q3 Review [July/August]
 - Post-PPBE lessons learned and process revisions
- Office of Management and Budget (OMB) Milestone Solicitation for FY+2
 - Solicit Elements for proposed OMB Milestones [August]
 - Initiate OMB Milestone CR [September]
 - Disposition comments, request approval of OMB Milestone CR
 - HRP Deadline for approval of OMB Milestone CR [October]
- Sept 30 Fiscal Year Ends
- HRP Q4 Review [October]

C3.5.2 HRP Quarterly Preparation Timeline (Notional)

Each HRP Element and scheduler is responsible for working together to determine the proper timeline for that Element and scheduler to prepare for an upcoming quarterly. The following dates represent a notional workflow to support cross-Element coordination and allow proper time for development of schedule products to support Element quarterly reports.

- HRP Scheduling Tags
 - Qtrly -4wk: Quarterly Preparation kickoff
 - Identify any unique requirements for upcoming Quarterly and adjust nominal timeline appropriately
 - Begin coordination with Element personnel to incorporate new reporting requirements
 - Qtrly -3wk: Quarterly Preparation checkpoint
 - Identify cross-Element coordination needs
 - Identify scheduling issues/difficulties

- Check progress of draft charts for risk/portfolio and management review
- Qtrly -2wk: PRR Delivery checkpoint
 - Identify any unresolved issues
 - Provide assistance to meet chart review/drop deadlines
- Activities/Deliveries
 - Qtrly --15d Draft charts for risk/portfolio personnel and management review
 - Qtrly --12d: Final updates of External Organization schedules (ISSMP, FAP, etc.)
 - Qtrly -10d: Final chart refresh to schedule and delivery to Element management
 - Qtrly -7d: Element chart review for HRP Quarterly
 - Qtrly -2d: Element chart drop for HRP Quarterly
 - Qtrly -0d: HRP Quarterly

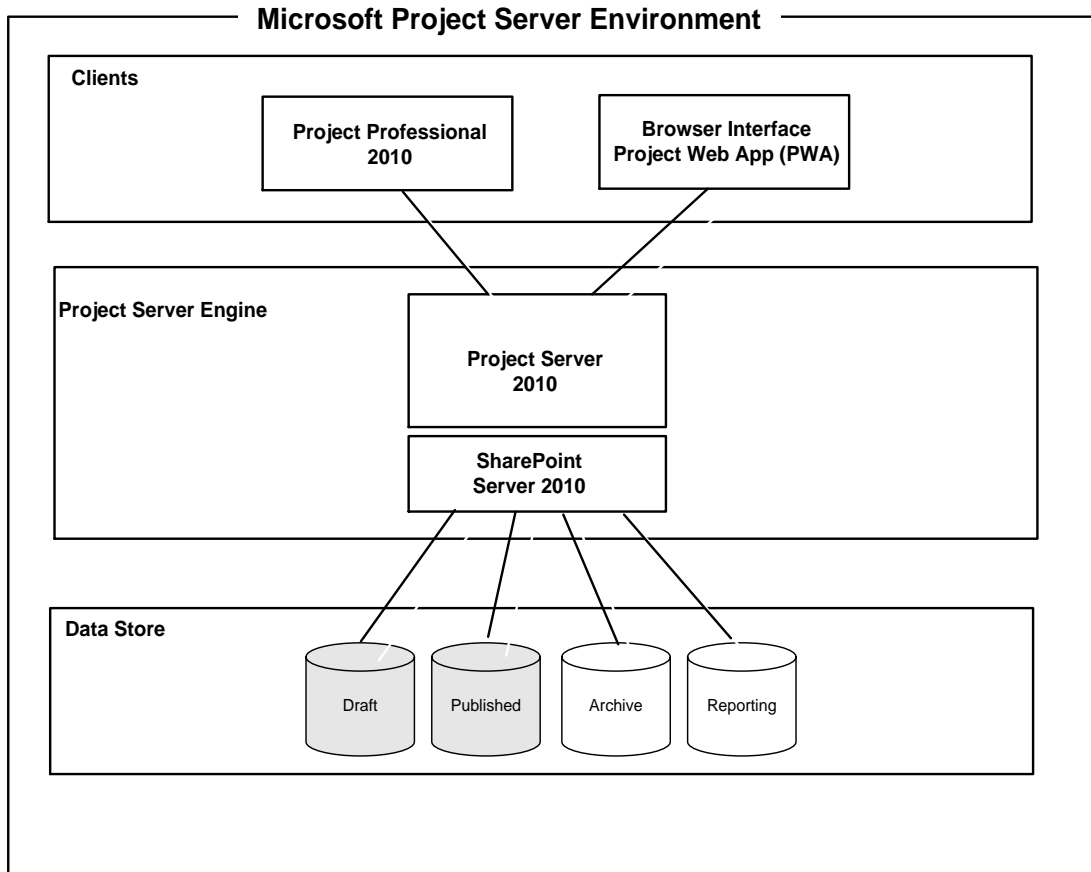
C4.SCHEDULE MANAGEMENT AND ANALYSIS

C4.1 SCHEDULE MANAGEMENT TOOLS

C4.1.1 Scheduling Tools

As shown in Figure C-2, HRP Schedules are hosted in an MS Office environment.

- MS Office Project Server 2010 (Project Server): This is an Enterprise Project Management solution system that enables coordinated and integrated management of multiple projects and resources to deliver benefits not available if projects were managed individually at the desktop level. It allows schedule management in conjunction with integrated SharePoint data exchange and workflow functionality to create a comprehensive, integrated solution. Project Server is used to create the IMS and centralize project information online so that it is available across the organization. Schedules are stored and shared through Project Server in a similar way that documents are shared in SharePoint.
- MS Office Project Professional 2010: This is the workstation application that is used to create, maintain, and publish project schedules. The application resides on a desktop or laptop and is very similar to MS Project 2007. Like other MS applications, the 2010 version of MS Project uses the ribbon bar as the primary interface. Most schedule editing work will use this interface.
- Project Web Application (PWA) is the web front-end application (app) that allows users to do some basic viewing and editing of schedules through a browser-only interface. The main PWA screen looks much like a typical SharePoint page and has additional functions such as timesheets and other services that are not used by HRP.



Source: HRP Project Server User's Guide

Figure C-2: Microsoft Project Server Environment

C4.1.2 Reporting Tools

PRRs are generated using KIDASA's Milestones Professional, with task data automated to synchronize with the Project Server schedules.

Milestones Professional allows the HRP to implement integrated and highly customizable reports. These reports are primarily used to represent the HRP Risk PRR's and iPRR.

C4.1.3 Schedule Management and Analysis Tools

The HRP schedules are developed to include a high level of fidelity and detail near-term, and a notional representation of long-term plans. The HRP schedule analysis is performed using the NASA Schedule Test and Assessment Tool (STAT). As such, the STAT analyses for near-term periods of time (current PRR milestone timeframe) are the most representative indicators of schedule quality.

The STAT assists the scheduling community in the identification, measurement, and rating of key credibility indicators contained within a project IMS. By monitoring key indicators and incorporating necessary corrections, the STAT aids in the development of accurate project schedules.

This analysis is performed once per year coinciding with PPBE. Results of the HRP Schedule quality analyses are reviewed with the HRP Management during the PPBE review timeframe.

C4.1.4 Data Integrity

The HRP uses Friedrich, Klatt, and Associates' Project Master Consolidator to scan the scheduling environment for issues, diagnose errors, clean scheduling logic anomalies, and visualize the logic relationship network. The tool scans for issues such as circular references, orphaned linkages, duplicated linkages, missing/invalid link references, data corruption, and misaligned project settings, and provides capabilities to assist with repairing and reporting found issues.

Data integrity scans are run weekly during periods of new schedule creation or heavy schedule logic development, and monthly during periods of normal development.

C4.2 SCHEDULE DESIGN CHARACTERISTICS AND BEST PRACTICES ASSESSMENT

C4.2.1 Government Accounting Office (GAO) Assessment Guide Scheduling Best Practices Guidance

Figure C-3 below, as described in GAO-12-120G, GAO Schedule Assessment Guide, identifies schedule design characteristics with respect to the GAO best practices used for schedule evaluation.

The Four Characteristics of a Reliable Schedule	
Schedule characteristic	Schedule best practice
<p>Comprehensive, reflecting</p> <ul style="list-style-type: none"> all activities as defined in the project's WBS the labor, materials, and overhead needed to do the work and whether those resources will be available when needed how long each activity will take, allowing for discrete progress measurement with specific start and finish dates 	<p>1 Capturing all activities 3 Assigning Resources to all activities 4 Establishing the durations of all activities</p>
<p>Well constructed, with</p> <ul style="list-style-type: none"> all activities logically sequenced with predecessor and successor logic limited amounts of unusual or complicated logic techniques that are justified in the schedule documentation. a critical path that determines which activities drive the project's earliest completion date total float that accurately determines the schedule's flexibility 	<p>2 Sequencing all activities 6 Confirming that the critical path is valid 7 Ensuring reasonable total float</p>
<p>Credible, reflecting</p> <ul style="list-style-type: none"> the order of events necessary to achieve aggregated products or outcomes varying levels of activities, supporting activities, and subtasks key dates that can be used to present status updates to management a level of confidence in meeting a project's completion date based on data about risks and opportunities for the project. necessary schedule contingency and high priority risks based on conducting a robust schedule risk analysis 	<p>5 Verifying that the schedule is traceable horizontally and vertically 8 Conducting a schedule risk analysis</p>
<p>Controlled, being</p> <ul style="list-style-type: none"> updated periodically by schedulers trained in critical path method scheduling statused using actual progress and logic to realistically forecast dates for program activities compared against a documented baseline schedule to determine variances from the plan accompanied by a corresponding baseline document that explains the overall approach to the project, defines assumptions, and describes unique features of the schedule subject to a configuration management control process 	<p>9 Updating the schedule with actual progress and logic 10 Maintaining a baseline schedule</p>

Source: GAO.

GAO-12-120G Schedule Assessment

Figure C-3: GAO Assessment Guide: Schedule Best Practices Guide

C4.2.2 HRP Schedule Mapping to GAO Schedule Best Practices

The HRP schedules are designed to implement characteristics of a reliable schedule by addressing the GAO best practices through the detailed schedules and PRR Reports. Management of research criticality allows Element management to tailor budget and personnel allocations to essential research as necessary, allowing the HRP to appropriately manage resources in an effective and agile manner consistent with the intent of the Critical Path Method detailed in GAO-12-120G.

Below is a mapping of the HRP schedule approach to GAO schedule best practices.

- a. Capturing all activities
 - Tasks are reflected in both the Master Task List (MTL) and HRR and are added to the schedule through the HRRCMS task creation process.

- Tasks are organized by the HRP Risk/Gap/Task/Deliverable structure per the Risk Research Management Process as defined in HRP-47069, HRP Unique Processes, Criteria, and Guidelines (UPCG).
- b. Sequencing all activities
 - Risk schedules have been designed with predecessor/successor logic to forecast activities as appropriate.
- c. Assigning resources to all activities
 - The HRP does not maintain resource-loaded schedules.
 - Study personnel are indicated for most HRP tasks in both the detailed schedules and the HRRCMS.
- d. Establishing the duration of all activities
 - Detailed activity durations are consistent with actual task lengths.
 - Many studies require lengthy periods of external research or development. These tasks are estimated as closely as possible based on funding, deliverable need-dates, and historical performance of similar tasks.
 - The HRP tracks certain milestones and deliverables per the definitions in Section C5.
- e. Verifying that the schedule can be traced horizontally and vertically
 - Logic between tasks is traceable in schedules and through the HRP PRR reports.
 - Schedules are organized to facilitate Element management, including rollup and logical linking of supporting tasks to activities such as reviews, documentation cycles, and the PRR milestones.
- f. Confirming that the critical path is valid
 - The HRP PRR Reports are designed to represent the research criticality, research logic, flow, and Element planning approaches through the lifecycle of the program risk area. HRP resource management depends on an assessment of research criticality, budget availability, and logic of the PRR and detailed schedule, meeting the resource management intent of the Critical Path Method.
- g. Identifying reasonable float between activities
 - Float is not actively managed in HRP schedules. Due to the nature of HRP's activities, tasks may be constrained by events outside of the schedule logic flow. Flexibility of contract awards, International Space Station (ISS) and research analog availability, and investigator delivery extensions are built into lags/leads and durations. Management of float is performed via Element processes throughout the task lifecycle. Optimization of float utilizes the PRR, funding profile, and Element research plan detailing accumulation of essential knowledge.
- h. Conducting a schedule risk analysis
 - The HRP schedule risk is managed internally at the PRR level, through the reviews listed in Section C3.4, Schedule Reporting.
- i. Updating the schedule using logic and durations to determine the dates
 - Schedule coordination and status updating is described in Section C4.3, Schedule Management Approach. The management approach described provides the ability

for schedulers and Element personnel to continually refine the logic and build historical reference data for lags, leads, and task durations.

- j. Maintaining a baseline schedule
 - The HRP Baseline control is described in Section C3.3, Schedule Baseline Control.

C4.3 SCHEDULE MANAGEMENT APPROACH

C4.3.1 Schedule Automation and Coordination

HRP management, technical, and support personnel collaborate extensively to ensure that goals, plans, and implementations are efficiently integrated among teams. To further enable this collaboration, the HRP scheduling environment utilizes MS Project Server's cross-project dependency capability to allow for coordination of plans between teams within Elements, across Elements, and between Program and Element management. Changes to predecessor dates flow down to their successor tasks, improving the ability of Element teams to respond quickly to replanned or delayed predecessor tasks.

C4.3.2 Status Updates

Status update frequency is delegated to the Element Manager, to be coordinated with Element personnel and the primary scheduler for that Element. Element requirements for schedule update frequency are determined by Element planning activities that require current schedules, as well as HRP Quarterly reviews and program level planning needs. The best practice guideline for status frequency is monthly (minimum) to bi-weekly (desired).

C4.3.3 Schedule Configuration Management and Integrity

In addition to using the NASA STAT to analyze schedule quality, HRP implements configuration management methods to ensure schedule integrity. Schedule access accounts are permission limited, and permissions are managed to ensure that editing privileges are granted on an as-needed basis. Schedule reports and documentation products are maintained in an access-controlled HRP SharePoint library. HRP schedule baselines are set at the beginning of the yearly PPBE cycle and archived prior to being reset at the beginning of the next PPBE cycle.

Element management and scheduling personnel are responsible for coordinating any additional schedule baselines required to support Element processes and for storage/archival of intermediate (monthly/quarterly) scheduling artifacts.

Schedules are also reviewed and coordinated between members of the HRP Scheduling team periodically. The HRP Schedule team also reviews the PRR Template, risk PRRs, and other team products to identify inconsistencies and potential improvements.

C4.3.4 Schedule Data Archive

Schedules are automatically backed up daily and manually archived prior to yearly reset of reference dates (PPBE Revision). Schedules are also manually archived by Project Server admins prior to forecasting activities or as requested by schedulers.

C5.DEFINITIONS

Task: Defined project activity with a specified duration

Milestone: Defined project event that has no duration

Dependency: Predecessor/successor logic relationships

Path to Risk Reduction (PRR) milestone: A milestone that indicates when a risk research plan expects to improve risk posture and/or LxC rating. This includes color changes (i.e., rating thresholds of gray, red, yellow, green, and blue), but also includes changes within the same color rating (i.e., 3 x 4 changes to 2 x 4, remaining red in color, but lower in likelihood). These milestones should be based on deliverables or groups of deliverables (i.e., Knowledge, Guidelines, Countermeasures, Requirements and Standards) that contribute to knowledge accumulation affecting the mitigation of the risk and changing the risk posture. PRR milestones are presented on the top line of the PRR graphic and in the Integrated PRR (iPRR).

Research Path milestone: A milestone or task finish date in a risk research path directly linked as a predecessor to a PRR Milestone. This can include deliverables received from another HRP Element, research or gap assessment points, external or OMB milestones, etc.

External milestone: A milestone for an externally delivered product that has or is anticipated to have a Customer Supplier Agreement (CSA). Examples of external deliverables are Element deliveries to ISS, other NASA programs, or other customers external to HRP.

Office of Management and Budget (OMB) milestone: A milestone, as proposed by the Elements and approved by the Program, whose status is reported to the NASA OMB.

OMB Milestone selection criteria per HRP Management:

- The OMB Title should be easy to understand by NASA HQ or OMB personnel that have limited knowledge of HRP.
- The OMB Title should be specific on what the deliverable is and who it is delivered to.
- The OMB Milestones should be consistent with the verb at the beginning (e.g., conduct, complete, deliver, etc.)
- The OMB milestone date should be one month after the actual planned completion date.
- The dates should not include the time for personnel outside of HRP to use the delivery. For example, if we propose a new standard to HMTA, the date should be when we provide that standard to HMTA, not when HMTA includes it in the next document.

PPBE Revision (PPBE Rev) reference point: Agreed upon and approved schedule content that serves as the basis for performance and progress measurement during Program implementation. The HRP PPBE Rev reference dates are set at the conclusion of PPBE and are used for the PPBE cycle as the performance baseline of the PRR.

HRP SCHEDULE MANAGEMENT REFERENCE CARD

Introduction

HRP Elements and HRP Program Science Management Office (PSMO) maintain detailed Microsoft Project schedules for program/Element management and Element research risk management. These schedules are the basis for schedule reporting products utilized by the HRP to plan, direct, and control the program and ensure timely completion of tasks.

The primary HRP schedule reporting product is the Path to Risk Reduction (PRR). The PRR is generated at two levels, one for an individual risk and one Integrated master schedule, the Integrated PRR (iPRR) roll up that reflects the HSRB risks assigned to the HRP. PRRs focus on the deliverables and timeline for a research plan to improve risk status. Deliverables and progress reporting (e.g. planned vs. actual) for the HRP schedules are presented at the HRP Quarterly Reviews and during Program Planning Budget Execution (PPBE) reviews.

HRP Scheduling References

HRP Management and Tools

- [HRP Control Board \(HRPCB\)](#)
- [HRP Management SharePoint](#)
- [HRP Scheduling SharePoint](#)
- [HRP Project Server Web App](#)
- [Unique Processes, Criteria, and Guidelines \(UPCG\)](#)
- [Human Research Roadmap \(HRR\)](#)
- [HRP HRR Content Management System \(HRRCMS\)](#)

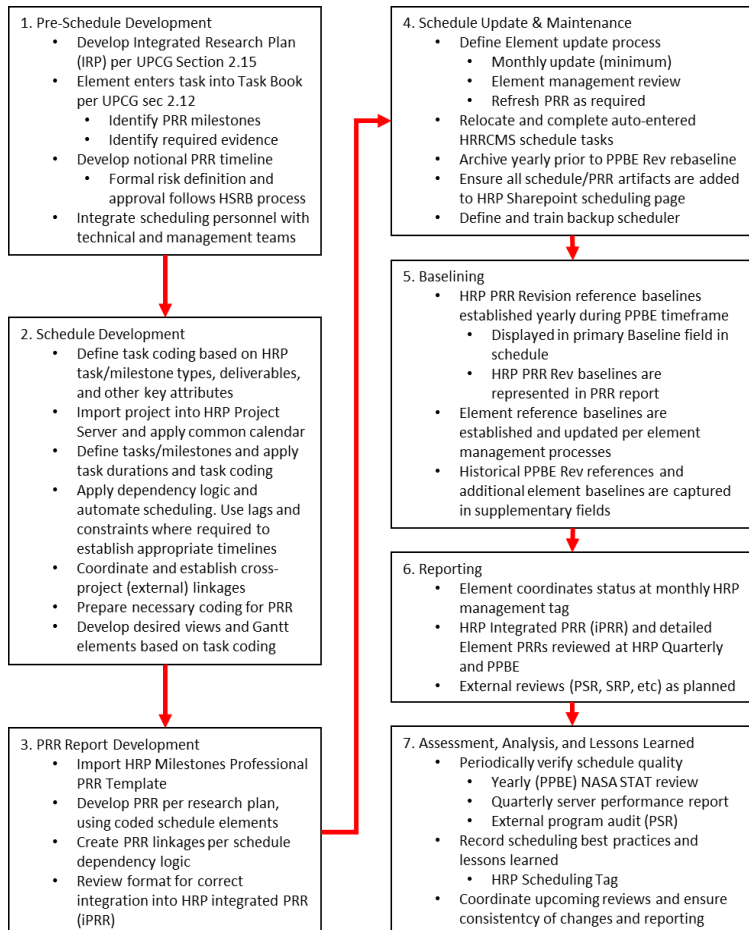
JSC/NASA Resources

- [NASA NPR 7120.8](#)
- [Human System Risk Board \(HSRB\)](#)
- [NASA Schedule Management Handbook](#)
- [JSC Planning and Scheduling CoP](#)

Other Resources

- [GAO Schedule Assessment Guide](#)
- [NDIA Planning & Scheduling Excellence Guide \(PASEG\)](#)

HRP Schedule Management Life Cycle



HRP Key Scheduling Terms and Concepts

HRP scheduling terms and concepts

Task: Defined project activity with a specified duration

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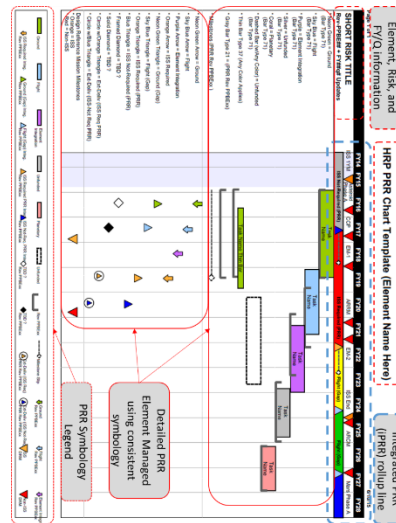
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HRP Path to Risk Reduction Report



APPENDIX D: ABBREVIATIONS AND ACRONYMS

AA	Associate Administrator
AO	Announcement of Opportunity
APMC	Agency Program Management Council
ARC	Ames Research Center
BAA	Broad Agency Announcement
BCD	Budget Change Directive
CAN	Cooperative Agreement Notice
CCP	Commercial Crew Program
CHMO	Chief Health and Medical Officer
CH&S	Crew Health and Safety
CM	Configuration Management
CMO	Chief Medical Officer
CoFR	Certification of Flight Readiness
CoP	Community of Practice
CR	Change Request
CRL	Countermeasure Readiness Level
CRM	Continuous Risk Management
CSA	Customer-Supplier Agreement
CSRR	Center for Space Radiation Research
DOE	Department of Energy
DPMC	HEOMD Program Management Council
DRM	Design Reference Mission
EM	Exploration Mission
EPIC	Engineering Products Integration Contract
ESMD	Exploration Systems Mission Directorate
ESWG	Element Science Working Group
EVA	Extravehicular Activity
ExMC	Exploration Medical Capabilities
FAP	Flight Analogs Project
FY	Fiscal Year
GAO	Government Accountability Office
GPRMA	Government Performance and Results Modernization Act
GRC	Glenn Research Center
HEOMD	Human Exploration and Operations Mission Directorate (HQ)
HERA	Human Exploration Research Analog
HFBP	Human Factors and Behavioral Performance
HHC	Human Health and Countermeasures

HHPD	Human Health and Performance Directorate
HMTA	Health and Medical Technical Authority
HQ	Headquarters (NASA)
HRMRB	Human Research Multilateral Review Board
HRP	Human Research Program
HRR	Human Research Roadmap
HRRCMS	Human Research Roadmap Content Management System
HRPCB	HRP Control Board
HSRB	Human System Risk Board
HTV	H-II Transfer Vehicle
IMS	Integrated Master Schedule
IRP	Integrated Research Plan
IOM	Institute of Medicine
IPAO	Independent Program Assessment Office
iPRR	Integrated Path to Risk Reduction
IRB	Institutional Review Board
IRP	Integrated Research Plan
IRMA	Integrated Risk Management Application
ISS	International Space Station
ISSMP	ISS Medical Projects
IT	Information Technology
ITA	Internal Task Agreement
JPD	JSC Policy Directive
JPR	JSC Procedural Requirements
JSC	Johnson Space Center
KSC	Kennedy Space Center
LxC	Likelihood by Consequence
LaRC	Langley Research Center
LSAH	Lifetime Surveillance of Astronaut Health
LSDA	Life Sciences Data Archive
MAR	Monthly Activity Report
MHRPE	Multilateral Human Research Panel for Exploration
MPCV	Multi-purpose Crew Vehicle
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MS	Microsoft
MSFC	Marshall Space Flight Center
NAE	National Academy of Engineering
NAS	National Academy of Science
NASA	National Aeronautics and Space Administration

NDIA	National Defense Industrial Association
NIH	National Institute of Health
NPD	NASA Policy Directive
NPR	NASA Procedural Requirements
NRA	NASA Research Announcement
NRC	National Research Council
NSRL	NASA Space Radiation Laboratory
NSTS	National Space Transportation System
OCE	Office of the Chief Engineer
OCHMO	Office of the Chief Health and Medical Officer (HQ)
OCS	Office of Chief Scientist
OCT	Office of Chief Technologist
OIIR	Office of International and Interagency Research
OMB	Office of Management and Budget
OSMA	Office of Safety and Mission Assurance
PASEG	Planning and Scheduling Excellence Guidance
PCA	Program Commitment Agreement
PCN	Page Change Notice
PEL	Permissible Exposure Limit
PIR	Program Implementation Review
POC	Point of Contact
PPBE	Planning, Programming, Budgeting, and Execution
PRD	Program Requirements Document
PRR	Path to Risk Reduction
PSM	Program Science Management
PSMO	Program Science Management Office
PSR	Program Status Review
PSRP	Payload Safety Review Panel
PWA	Project Web Application
QPMR	Quarterly Program Management Review
Qtrly	Quarterly
R&T	Research and Technology
Rev	Revision
RFI	Request for Information
RFP	Request for Proposal
RFQ	Request for Quotes
RIDM	Risk-Informed Decision Making
S&MA	Safety and Mission Assurance
SBIR	Small Business Innovation Research
SLPSRA	Space Life and Physical Science Research Applications

SOPD	Strategic Opportunity and Partnership Development
SR	Space Radiation
SSP	Space Station Program
STAT	Schedule Test and Assessment Tool
STD	Standard
STMD	Science Technology Mission Directorate
STEM	Science, Technology, Engineering, and Mathematics
TA	Technical Authority
TCSR	Technical, Cost, and Schedule Review
TMR	Technical Monitor's Representative
TPR	Top Program Risk
TRISH	Translational Research Institute for Space Health
TRL	Technology Readiness Level
TtO	Transition to Operations
UPCG	Unique Process, Criteria, and Guidelines
WBS	Work Breakdown Structure

APPENDIX E: INTENT TO MEET 7120.5E REQUIREMENT FOR TECHNICAL AUTHORITIES

National Aeronautics and
Space Administration

Lyndon B. Johnson Space Center
2101 NASA Parkway
Houston, Texas 77058-3696



February 5, 2016

Reply to Attn of: SA-16-017

TO: NASA Headquarters
Attn: Associate Administrator for Human Exploration and Operations
Mission Directorate
Chief Engineer Officer
Chief Safety and Mission Assurance Officer
Chief Health and Medical Officer

FROM: SA2/Director, Human Research Program

SUBJECT: Request for Concurrence with the Human Research Program (HRP)
Approach to Meet the Intent of NASA Procedural Requirement (NPR)
7120.5E

The recent Program Status Review of the HRP was held at the Johnson Space Center (JSC) on August 17-19, 2015. As documented in NPR 7120.5E, Table 2-3, *Expected Maturity State Through the Life Cycle of Uncoupled and Loosely Coupled Programs*, the objective of the review was to evaluate the Program's continuing relevance to the Agency's Strategic Plan, assess performance with respect to expectations, and determine the Program's ability to execute the implementation plan with acceptable risk within cost and schedule constraints. One of the findings from the Standing Review Board (SRB) specifically addressed the non-compliance of the HRP with NPR 7120.5E in the area of the involvement of the Technical Authorities (TA) from Engineering, Safety and Mission Assurance (S&MA), and Health and Medical Technical Authority (HMTA).

While the HRP concurred with the SRB's recommendation to address this non-compliance (either through the formal appointment of a Chief Engineer, a Chief S&MA Officer, and a Health and Medical TA, or a waiver to the NPR) there was perhaps some confusion as to the applicability of the specific NPR to the HRP. After further investigation with experts in the implementation of TA, we fully realize that as a loosely coupled Program, the HRP is subject to the requirements within the referenced NPR. However, due to the unique nature of our Program, we feel that we can meet the intent of the specific requirements through this letter of interpretation without the need for formal appointment of the identified TA.

The six elements of the HRP include both flight and ground-based testing. For the flight case, we feel that the relevant TA input to the process is incorporated through the normal

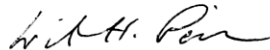
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Program review process, since the Chief Engineer and Chief S&MA Officer are voting members of the respective Flight Program Control Boards. So for example, a flight experiment, developed under the International Space Station Medical Project (one of the six elements of the HRP), will be processed through the ISS Payload Safety Review Panel, and will eventually be approved (including any waivers, exceptions or deviations) at the Space Station Program Control Board. Future flight vehicles, developed under current Agency Programs, also have the requisite Program Control Boards (with the requisite TA involvement) as an approval step prior to flight.

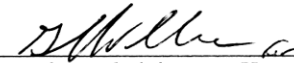
For the case of HRP developed ground-based studies involving human subjects (flight crews or test subjects), the JSC Institutional Review Board (IRB), established under the authority of the Office of the Chief Health and Medical Officer, reviews and approves these studies and has the required TA engagement. The IRB requisite S&MA, Engineering, and Health representatives are assigned by their respective TA with funding independent of the HRP and access to the independent TA pathway.

Consequently, it is our belief that the intent of the program requirement within NPR 7120.5E is being met without the need to appoint a formal Chief Engineer, Chief S&MA Officer or Chief Medical Officer, and we request your concurrence on this approach.



William H. Paloski, Ph.D.
Director, Human Research Program

Concurrence:



Associate Administrator, Human Exploration
and Operations Directorate

23 MARCH 2016
Date

see attached

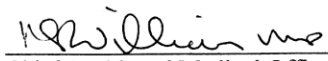
Chief Engineer Officer

March 7, 2016
Date



Chief Safety and Mission Assurance Officer

Feb 25, 2016
Date



Chief Health and Medical Officer

17 Feb. 2016
Date

SA-16-017

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William H. Paloski, Ph.D.
Director, Human Research Programs

Concurrence:

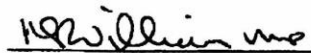
Associate Administrator, Human Exploration
and Operations Directorate



Chief Engineer Officer



Chief Safety and Mission Assurance Officer



Chief Health and Medical Officer

Date

March 7, 2014

Date

Feb 25, 2014

Date

17 Feb. 2016

Date