Human Research Program
Science Management Plan

October 24, 2007

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

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Human Research Program
Science Management Plan
October 24, 2007

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# Human Research Program
## Science Management Plan

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Human Research Program
Science Management Plan

1.0 INTRODUCTION

1.1 PURPOSE
The purpose of this document is to describe the policies and processes utilized in the science management of the Human Research Program (HRP) within the Exploration Systems Mission Directorate (ESMD). The Human Research Program is an applied research and technology program that addresses NASA needs for human health and performance risk mitigation strategies in support of the Vision for Space Exploration. HRP research and technology development is focused on the highest priority risks to crew health and safety with the goal of ensuring mission success and maintaining long-term crew health. The intent of the HRP Science Management Plan is to provide guidelines, rather than prescriptive processes, for managing the science component of the Human Research Program.

The Vision for Space Exploration includes both lunar missions and missions to Mars. Although both mission types involve some of the same human health and performance challenges, each also includes specific challenges that depend on the nature of the mission and the mission development schedule. HRP research and technology development is being phased to supply appropriate deliverables in time to meet the challenges of each mission as it occurs. An important component of the HRP involves research on the International Space Station (ISS), a unique laboratory environment in space that enables the collection of critical inflight data necessary for exploration mission risk reduction. The HRP must ensure that the ISS is utilized to the maximum extent possible to perform the essential research and technology development tasks that can only be done inflight.

NASA has defined a “standards to deliverables” risk mitigation approach for exploration. Crew health and performance standards will be defined by the NASA Chief Health and Medical Officer (see 1.4) to set the acceptable risk for exploration missions. These standards will then define the need for deliverables that allow crew health to be maintained within acceptable limits based on the levels of care required for the mission scenario. The role of the HRP is to conduct research and develop technology that underlies standards development as well as enables deliverables which ensure that standards can be met.

1.2 SCOPE
The policies and processes referenced in this plan apply to all ground and flight scientific research and development activities of the HRP, whether those activities take place at NASA Field Centers, at universities and non-profit research institutes, or at for-profit industries. Further information concerning the goals, objectives, customers, stakeholders, general organization and management of the Human Research Program may be found in the Human Research Program Plan (HRP-47051). Note that although the descriptive information contained within the HRP Science Management Plan may differ slightly from similar information contained in the Human Research Program Plan, the differences are not substantial.
1.3 AUTHORITY
The Human Research Program Plan (HRP-47051) defines the need to document the Human Research Program science management policies and processes in the Science Management Plan. If the Human Research Program Plan and the Science Management Plan differ on any substantial matters, the Human Research Program Plan takes precedence.


All authority and responsibility to develop and manage the Human Research Program resides at Johnson Space Center. However, the ESMD has established an Advanced Capabilities Division (ACD) within the Directorate at NASA Headquarters to provide the necessary advocacy, monitor program progress, and assure compliance of the HRP to Agency needs, goals, and objectives. The Director for the ACD and the associated HRP Executives within the ACD are responsible for developing opportunities for leveraging non-NASA HRP-related research to enhance mission requirements and for assessing the applicability of internal and external research and technology development activities to address ESMD requirements.

1.4 SPACE FLIGHT STANDARDS FOR HUMAN PERFORMANCE
The NASA Chief Health and Medical Officer is responsible for the development, implementation and maintenance of standards for levels of medical care and the health status of crewmembers during space flight. The Space Flight Health Standards for Human Performance (Volume 1 (Crew Health) approved 13 November 2006; Volume II under review) define the degree of physiological change that can be safely tolerated during space missions without negatively impacting the health of crews or their ability to perform their duties, and will assist in guiding NASA's biomedical research to target specific medical countermeasures for the deleterious effects of space flight.

The Human Research Program uses these Space Flight Health Standards for Human Performance as one of the major rationales for the initiation and development of the research necessary for the high priority applied research/technology development deliverables, and to focus the research on the results needed in the formulation of new standards or the modification of established standards.

2.0 PROGRAM RESEARCH CONTENT OVERVIEW
The Human Research Program's content is divided into unique program Elements, each of which is focused on critical areas of research and technology development that address the highest priority crew health and safety risks, or on core service activities, or a mixture thereof, that maximize the utilization of a common research platform. As depicted in Figure 1, some program Elements consist of a single project and some contain multiple projects. In the case where multiple projects exist within a program Element, cross-discipline dependencies and interactions are important and thus the projects must be integrated at the Element level.
Figure 1. Elements and Projects within the HRP.
While funding for the NSBRI cooperative agreement is centralized through NSBRI management, NSBRI researchers will communicate and coordinate with their NASA counterparts to ensure that research is complementary (see 2.7).

Figure 1 also shows that the nature of HRP research content falls into three categories; applied research and development activities, technology development activities and core service activities. Such categorization facilitates the definition of science management processes and allows for maximum efficiency in managing associated research activities. A definition of the categories can be found in Appendix E. The HRP research program Elements are described below.

2.1 SPACE RADIATION
The Space Radiation program Element performs investigations to assure the crews can safely live and work in the space radiation environment without exceeding the acceptable accumulation limits during and after the missions. 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 definitive recommendations on crew exposure limits and design requirements for extended lunar and Mars missions. Therefore, a major focus of the Space Radiation Project will be basic and fundamental research to expand the knowledge base and reduce the uncertainty inherent in current exposure limits and design requirements.

The major deliverables for the Space Radiation program Element include inputs to standards for radiation health, habitability, and environments; requirements for radiation protection, early technology development for monitoring equipment, caution and warning, models and tools to assess and predict risks due to space radiation exposure, and strategies to mitigate exposure effects.

2.2 HUMAN HEALTH COUNTERMEASURES
The Human Health Countermeasures (HHC) program Element contains four key projects that perform research that underlies human health and physiological standards development and one Core Service project. It also performs research to enable deliverables such as a validated and integrated suite of countermeasures for exploration missions that ensure the maintenance of crew health and performance during all phases of these missions. Countermeasures target human physiology and performance capabilities at risk from space flight missions at each stage of mission performance. Pre-flight 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 reconditioning strategies.

The EVA Physiology Systems and Performance Project performs human research necessary to support EVA suit and mission design for exploration. The Exercise Countermeasures Project performs research to develop optimum exercise protocols to protect against deleterious effects of spaceflight, as well as provide more reliable exercise hardware capabilities. The Non-Exercise Countermeasures Project performs research necessary to inform the development of crew health standards, as well as research to identify and validate non-exercise countermeasures. The Flight Analogs Project is a core service activity within this program element providing a ground-based analog for use by any project within HRP. The Fractional Gravity Project is tasked with
evaluating the efficacy of artificial gravity as a general countermeasure, with a special focus on bone and muscle loss, cardiovascular deconditioning and other multidisciplinary changes.

2.3 EXPLORATION MEDICAL CAPABILITY
The Exploration Medical Capability (ExMC) program Element sponsors research and analysis leading to the development of advanced technologies and medical equipment, clinical care capability, medical equipment technology and medical informatics. The ExMC performs the appropriate critical technology development to meet the medical requirements based on the level of care for the given mission scenario. It also develops the data systems containing the evidence base of NASA life sciences experimental data. As part of that effort, ExMC conducts analyses to quantify the risk associated with exploration tasks and missions. These data systems are some of the basic inputs to a medical decision support system for exploration missions.

2.4 BEHAVIORAL HEALTH AND PERFORMANCE
The Behavioral Health and Performance (BHP) program Element performs risk reduction research to inform medical standards and habitability requirements, and to enable development of targeted countermeasures in three key areas: sleep loss, circadian desynchronization and workload and fatigue; crew cohesion, training, and psychosocial adaptation; and behavioral medicine and clinical cognition. It focuses on deliverables such as evidence-based practices and monitoring tools and technologies that enable performance of mission operations and that prevent or mitigate, through early detection and assessment strategies, the occurrence of behavioral health problems during space missions.

2.5 SPACE HUMAN FACTORS AND HABITABILITY
The Space Human Factors and Habitability program Element contains three projects: Space Human Factors Engineering project, Advanced Environmental Health project and the Advanced Food Technology project. The Space Human Factors Engineering project focuses on challenges that are fundamental to design and development of the next generation crewed space vehicles, including: understanding individual and team human physical and cognitive capabilities in the context of the space environment and the engineering system design; carrying out research that underlies standards and requirements for human-system interfaces; and developing technology and tools that enable human performance consistent with mission success.

The Advanced Environmental Health project assesses the acute and long-term health impacts of targeted pollutants in the environment, including lunar dust, microorganisms, and atmospheric contaminants and assists other elements of the Exploration Systems Mission Directorate develop the latest technologies for environmental monitors that identify and quantify significant environmental contaminants.

The Advanced Food Technology project focuses on the development of extended shelf life foods with improved nutritional content and quality and reduced packaging volume and mass to provide easier trash management. Thus, this area addresses nutritional, psychological, safety, and acceptability requirements while minimizing mass, volume, waste, power, and trace gas emissions.
2.6 **ISS MEDICAL PROJECT**

The ISS Medical Project (ISSMP) is a core service activity that provides the planning, integration, and implementation activities necessary to enable projects throughout the HRP to carry out activities in space. Such activities may utilize flight resources on the ISS, Shuttle, Soyuz, Progress, or other spaceflight vehicles and platforms, and may require preflight, inflight and postflight resources. The ISSMP team must be well coordinated with the medical operations teams to ensure efficient use of resources before, during and just after a mission.

2.7 **THE NATIONAL SPACE BIOMEDICAL RESEARCH INSTITUTE (NSBRI)**

The NSBRI is a significant research component of the HRP. Operating under a cooperative agreement with NASA, the NSBRI was formed in 1997 and is an important partner in defining, selecting and conducting research associated with exploration risks. A consortium of 12 member institutions, the NSBRI represents a unique partnership between the academic biomedical community and NASA. NSBRI researchers are working on advancing countermeasures and technologies in all the major discipline areas required to support space exploration.

NSBRI investigators are an important part of the HRP. The NSBRI contributes to defining risk areas, identifying and demonstrating candidate countermeasures, development of medical technologies and maintenance of discipline-level expertise. These connections and the dialog that occurs because of the cooperative agreement allow the NSBRI to develop an important, synergistic component of the HRP research program. The NSBRI plans yearly solicitations of research, coordinated with the rest of the program and targeted at reducing human-related exploration risks. NSBRI solicitations may be issued jointly with NASA or, at a minimum, these solicitations will be complementary to NASA-direct funded research. NASA and NSBRI are committed to maximizing the return on research investments through open communication and dialog concerning human health and performance risks.

2.8 **THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM**

The Small Business Innovation Research (SBIR) Program was established by Congress in 1982 to provide increased opportunities for small businesses to participate in research and development. The SBIR and STTR (Small Business Technology Transfer) programs are ways to supplement HRP’s technology development. Through participation in the definition and selection process for SBIR and STTR programs, the HRP can ensure that the selected projects are aligned with strategic needs for human exploration.

The SBIR program is administered by NASA Headquarters to meet research and technology development requirements. Topic and subtopic solicitations are developed across all NASA centers. HRP Element managers recommend specific subtopics related to their area of expertise for the annual solicitation, and the specific subtopics are approved by the HRPCB. The NASA HQ Program Management Office reviews and finalizes all the NASA topics and subtopics. A request (solicitation) for innovative technology proposals relating to a topic/subtopic is released to the public. Upon closure of the solicitation for proposals from small businesses, the proposals are reviewed by HQ Procurement and Legal Offices then forwarded back to the subtopic managers for technical review and recommended selections to the HRPCB. Element managers ensure coordination of subtopic proposal reviews across all participating Centers and prepare a recommendation for selection, which prioritizes the proposals within its subtopics and identifies the appropriate Center for the contract. Ranked proposals are forwarded to HQ for final approval.
HQ then releases the selection statement of SBIR awards by NASA. (For further information please refer to Directive SSPS 2006-1, Roles and Responsibilities in the NASA Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs)

3.0 SCIENCE MANAGEMENT ROLES AND RESPONSIBILITIES

As described in the Human Research Program Plan (HRP-47051), responsibility for HRP science management, planning, and coordination is delegated to the HRP Science Management Office (SMO). The SMO is managed by the Program Scientist who performs and coordinates all program-level science management activities.

In order to ensure HRP deliverables can be ready in time to support NASA’s exploration mission needs, the HRP applies project management principles to the management of all HRP science activities. Element and Project Scientists are responsible for the scientific content and direction within their element/project. Element/Project Managers are responsible for overall performance of the element/project as well as performing the tasks necessary to enable the research within their areas. Element/Project Managers and Element/Project Scientists must work as a team to manage all of the various activities in an effective manner. Element/Project Scientists will provide recommendations to the Element/Project Managers regarding selection and performance of research studies and technology development projects that meet HRP requirements that address Agency needs, goals and objectives.

The HRP research seeks an integrated and validated countermeasure suite to meet standards and provide deliverables that manage human health and performance risks. Science integration across the program Elements is the responsibility of the Program Scientist. Integration within a program Element is the responsibility of the Element Scientist. For example, the Human Health Countermeasures Element Scientist must integrate research across the various projects in order to deliver an integrated set of deliverables focused on risk management and countermeasure development. Project Scientists are responsible for scientific direction within their projects.

NASA’s core capabilities associated with understanding the effects of spaceflight on the human body are aligned by discipline. In order to translate this knowledge into operationally relevant research, Discipline Integrated Product Teams (see 4.3) have been formed to identify and maintain our critical path for research within a given discipline. The teams contain science expertise (NASA and external researchers) and operations personnel, and meet as required by the Program to review the evolving evidence base and ensure that research is constantly focused on operationally relevant topics. In short, Discipline Integrated Product Teams identify research gaps in their area of expertise, while Program Elements use this information in developing and executing their research plans.

At each level, key science management positions provide the sound backbone to the program that enables strategies and options to be informed by expert knowledge and evidence. Figure 2 illustrates the general relationships among these science management positions for the HRP. This figure includes additional information concerning scientific coordination panels (defined in Section 4 of this document) and research plans (defined in Section 5 of this document). The present section describes the roles and responsibilities of the different types of science management positions.
3.1 PROGRAM SCIENTIST

The Program Scientist is the senior science management official within the HRP and is the person delegated the responsibility for internal science management and coordination. The Program Scientist shall be a senior scientist with an advanced biomedical or biological degree or the equivalent experience, and shall possess extensive experience in designing and conducting experiments and in managing space-flight related investigations and projects.

The Program Scientist shall:

- Identify and cultivate strategic partnerships to leverage HRP capabilities in support of the Vision for Space Exploration;
- Serve as the primary scientific representative for the HRP with other NASA offices and programs external to the HRP, collaborating Federal programs and the general scientific community;

Figure 2. The general relationships among the various parts of the HRP Program Science infrastructure, as defined in this Plan.
• Work with other domestic and international agencies to assure effective integration between their research activities and those of the HRP;
• Present HRP’s scientific program to ESMD, other governmental entities and others, as appropriate;
• Serve as the Contracting Officer’s Technical Representative (COTR) for the NSBRI cooperative agreement;
• Develop, with designated NSBRI representatives and Element Scientists, plans for the full coordination of research activities between NASA and the NSBRI;
• Ensure that an appropriate interface is established between the HRP and the Constellation Program regarding scientific issues affecting health and performance;
• Participate, as appropriate, in the International Space Life Sciences Working Group and all other formal bilateral or multilateral international working groups working collaboratively with the HRP;
• Develop and maintain the HRP Cooperative Activities Profile, documenting the strategy and tactics related to joint programs and projects with other Federal agencies, with international space agency partners and other entities;
• Integrate among all HRP program Elements to ensure that science activities are focused on the highest risks to crew health and performance in support of exploration missions;
• Develop and maintain the Integrated Research Plan and the process used to create and update it and present it to the HRP Control Board for approval;
• Review the research and technology development content of the Element and Project Plans, ensuring that this content is sound, integrated across the Elements and Projects as appropriate and reflects all of the HRP’s scientific needs;
• Chair annual reviews of science progress;
• Prepare an annual report on the science activities of the HRP, to be used as a part of the HRP Annual Report;
• Compile and publish an annual publication report containing the list of HRP-sponsored research papers that have appeared in peer-reviewed journals;
• Support and coordinate, as needed, the presentation of HRP-sponsored research findings at appropriate national and international scientific and technological meetings;
• Chair the Science Management Panel composed of the Element Scientists and other designated members;
• Maintain a list of technologies and their associated TRL levels in active development in addition to a list of technology gaps related to risk reduction;
• Develop, with the advice of the Science Management Panel, a prioritized list of scientific experiments to be conducted on Shuttle and the International Space Station;
• Approve the science component of the Element procurement plans, coordinating common procurement approaches across the various Program Elements;
• Coordinate the Discipline Integrated Product Team activities, including the development and maintenance of the Discipline Proposed Research Profile;
• Develop a plan to maintain and periodically update the Bioastronautics Roadmap;
• Coordinate the maintenance of the HRP Task Book, an open, web-based description of all of the funded activities of the HRP;
• Coordinate the schedule for the HRP science management reviews;
• Manage the Program’s peer review system;
• Receive reports regarding real or perceived conflicts of interest from Element and Project Scientists and others and determine the action to be taken in each case;
• Determine which Program Element should disposition any unsolicited proposals related to this Program that are submitted to NASA (if no Program Element is appropriate, the Program Scientist dispositions the proposal);
• Develop, in consultation with the Element Scientists, the Charter for the Standing Review Panels (see 7.2.1), the membership profile for each NAR Panel, a list of candidate members, and, in consultation with the Panel chair, a membership roster and service term for members;
• Manage and coordinate the schedule for Standing Review Panel review activities and meetings and forward proposals to the NAR panels for merit review, as needed;
• Manage the Clinical and Operational Research Working Group (see 6.3.1);
• Coordinate, with recommendations from the appropriate Element and Project Scientists, the preparation and release of any scientific solicitations necessary to carry out the Program Science approved procurement plan, and coordinate the reviews of submitted proposals;
• Based on the Project and Element Scientists and Managers recommendations, provide the Program Manager with a Program selection position on all scientific proposals that have completed the appropriate reviews;
• Solicit and coordinate inputs from other NASA Field Centers, as appropriate, in the execution of all of the above functions; and
• Coordinate with the appropriate NASA legislative affairs offices the release of selection information.

Although the Program Scientist may not function as a scientific investigator within the HRP, he/she may serve as an investigator within scientific projects that are funded or managed by other Agencies or NASA Programs.

3.2 ELEMENT SCIENTIST

The Element Scientist is responsible for the scientific components within the Element. The Element Scientist shall be a senior scientist with an advanced biomedical or biological degree or the equivalent experience in the Element research area, and shall possess appropriate experience in designing and conducting experiments and in managing space-flight related investigations and projects. The Element Scientist position described in this document is referred to as the "Element Principal Coordinating Scientist" in the HRP Program Plan.
The Element Scientist is responsible for the following:

- Ensure that the research carried out by the Element is organized to mitigate the high-priority, operationally-relevant risks and develop countermeasures and/or technologies that support NASA's Vision for Space Exploration;

- Develop and maintain the Element Research Plan, the research component of the Element Plan (see 5.2), clearly demonstrating the integration, coordination and convergence of the various projects within the Element, or with other NASA organizations, as necessary;

- Work closely with the Element Manager to ensure that all Element scientific or technological activities are synchronized with the Element schedule, cost and milestones as reflected in the Element Management Plan and that the Element reviews are properly supported;

- Chair the Element Science Panel, where one exists, (see 4.2) composed of the Project Scientists within the Element;

- Review and approve the Project Research Plans;

- Recommend to the Program Scientist whether any unsolicited proposals submitted to NASA are strongly relevant and, thus, should be formally reviewed for merit;

- Provide approval for individual unsolicited or Project Directed Study proposals to be formally reviewed for merit and forward such approved proposals to the Program Scientist;

- Support the Element Manager in developing a recommended Element science procurement plan taking into account the needs of the various Projects within the Element;

- Review the Project’s proposed selection recommendations and forward approved recommendations to the Program Scientist for selection by the Program Manager;

- If the Element does not have Project Scientists, ensure that all of the responsibilities of the Project Scientist are fulfilled; and

- Serve as the Element representative to the Science Management Panel.

The Element Scientist may not serve as an investigator within scientific projects funded or managed through the HRP. The HRP Manager may, on the recommendation of the Program Scientist, grant an exception if the Element comprises a single project or if the investigation is funded or managed by a different Element.
3.3 PROJECT SCIENTIST

The Project Scientist is the key person managing and directing the scientific activities of a single scientific project and working closely with the Project Manager to ensure that all project scientific or technological research activities are synchronized with the project schedule, cost and milestones. The Project Scientist shall be a scientist with an advanced biomedical or biological degree or the equivalent experience in the Project area, and shall possess some experience in designing and conducting experiments and in managing space-flight related investigations. The Project Scientist provides the general scientific interpretation of the project’s activities as they relate to HRP and Agency goals and objectives. The Project Scientist consults with discipline experts from the Discipline Integrated Product Teams (see 4.3) and elsewhere to execute this function.

The Project Scientist shall:

- Ensure that the research carried out by the Project is directed at mitigating the high-priority, operationally-relevant risks and developing countermeasures that support NASA’s Vision for Space Exploration;
- Develop and maintain the Project Research Plan, the research component of the Project Plan (see 5.3), defining the Project’s scientific goals and objectives within the Project’s defined structure and schedule, and submit that plan to the Element Scientist for approval and to the Project Manager for inclusion in the Project Plan;
- Develop an in-depth understanding of all investigations within the Project, regardless of where the investigations are carried out;
- Chair the Project IWG (see 5.2), if one exists, containing the Principal Investigators from all Project investigations;
- Support the Project Manager in developing a recommended Project procurement plan for all types of scientific or technological activities necessary to carry out the Project;
- Determine the need for and, with Project and Element management concurrence, coordinate the development of, and participate in, if appropriate, the development of one or more Project Directed Study proposals (see 6.1.3);
- Recommend to the Element Scientist that a Project Directed Study proposal is ready to be submitted for formal review;
- Act as the COTR for all non-NSBRI investigator grants & contracts belonging to the Project and managed from the Project Scientist’s Field Center; and
- Develop a selection recommendation for Project-related proposals after peer review, avoiding all real or perceived conflicts of interest (see 3.5).

The Project Scientist may function as a scientific investigator within the Project, but if such is the case, then special care must be taken to avoid conflict of interest (see 3.5).
3.4 DISCIPLINE TEAM LEAD

The Discipline Team Lead leads the Discipline Integrated Product Team (see 4.3) to communicate and evaluate research, clinical and operational information about the discipline, and based on their analysis, to make annual recommendations concerning the discipline status and research gaps that exist through the preparation of a Discipline Proposed Research Profile. The Discipline Team Lead shall be a scientist with an advanced biomedical or biological degree or the equivalent experience in the relevant discipline, and shall possess experience in designing and conducting experiments related to space flight.

The Discipline Team Lead shall:

- Coordinate and lead meetings of the Discipline Integrated Product Team throughout the year;
- Develop, with the assistance of the Discipline Integrated Product Team, materials summarizing the Team’s view of the current evidence for health and performance risks associated with the various identified space flight mission types, available mitigation strategies to minimize these risks, and prioritized, identified gaps in knowledge or countermeasures related to these risks;
- Review, update and present annually, the Discipline Proposed Research Profile (see 5.4 and Appendix A.4) derived from the viewpoint of the Team;
- Act as the main contact and advocate for development or revision, from a research perspective, of the health and performance standard(s) for that discipline.
- Ensure that the Discipline Integrated Product Team has adequate representation by scientific and operations personnel. Team membership should be drawn from both the intramural and extramural research community, including NSBRI scientists and from intramural clinical and operational groups; and
- Support the Program Scientist in building partnerships with other agencies, biomedical industry, international partners, NSBRI and others with common objectives to maximize synergy between NASA and its partners.

The Discipline Team Lead shall have a strong research background in the appropriate discipline area and an active, current understanding of the scientific issues related to that discipline in space and on the ground. The Discipline Team Lead may be an active investigator or a Project Scientist, but, if so, should avoid bias in weighing all the research needs of the discipline and should be able to consider the clinical and operational needs of the HRP while shaping the Discipline Proposed Research Profile.

3.5 CONFLICT OF INTEREST IN SCIENCE MANAGEMENT

Science management personnel must avoid real conflicts of interest in carrying out their responsibilities. In general, this means that management personnel must avoid actions biased by personal gain, personal relationships, and conflicting management responsibilities. It is the responsibility of each science manager within the HRP to identify any real or perceived conflict of interest and report it to the Program Scientist, who will determine the appropriate action to be taken. In addition, others within the HRP may report potential conflicts of interest to the Program Scientist for investigation and resolution.
To avoid conflicts of interest, the:

- Program Scientist may not function as a scientific investigator or in any other science management position within the HRP;
- Element Scientist, under normal circumstances, may not function as a scientific investigator within any of the Element’s projects nor simultaneously serve as a Project Scientist within the HRP. However, when such a dual role is necessary, care must be taken to avoid science management activities that produce real or perceived conflicts of interest;
- Project Scientist may function as a scientific investigator within the Project, but if this is the case, then the Project Scientist’s own scientific investigation-related budget and other resources must be allocated and managed in a way that clearly avoids conflict of interest. In addition, the Project Scientist should not be involved in the evaluation or selection of any proposals in which he/she has a role; and
- Standing Review Panels (see 7.2.1) or their equivalent will be appointed and managed by the Program Scientist. These Panels will be asked to report any real or perceived conflicts of interest to the Program Scientist for resolution.

Conflict of interest related to project or proposal evaluation is addressed further in Section 6.4.

4.0 SCIENTIFIC COORDINATION PANELS

4.1 SCIENCE MANAGEMENT PANEL
The purpose of the Science Management Panel is to facilitate HRP science management and ensure that an integrated science program is maintained. The Science Management Panel should advise the Program Scientist on the strategy to integrate program Element science priorities, objectives, activities, and outcomes across the Human Research Program, focusing on science products and deliverables that are operationally relevant. Details of the panel's operating procedures may be found in the Charter (see https://sa.jsc.nasa.gov/BPSCM/dashBoard/?boardName=SMP&action=showCharter).

4.2 PROJECT INVESTIGATOR WORKING GROUPS
Applied research and development projects may maintain an Investigator Working Group (IWG) composed of all of the Principal Investigators (PIs) leading tasks or investigations within the project. The Project’s investigations may consist of both ground and flight studies, including those utilizing special flight analog facilities furnished by NASA, irrespective of where the actual study is actually carried out (NASA Field Centers, universities, non-profit research entities or for-profit organizations). The IWGs, managed by the Project Scientist, are the primary working-level forum for project research discussions and planning. At face-to-face IWG meetings, attended by the Project Manager, the PIs can exchange scientific and technological information concerning their investigations and have an opportunity to discuss the Project’s future research strategy with the other PIs and with the Project Scientist. In addition, it is expected that representatives of the two core service projects (ISS Medical Project and Flight Analogs Project), if utilized by the Project, may attend the IWG meetings and report on any issues related to Project investigation implementation through the service components. The IWG meeting may be supplemented by telecommunication discussions as needed to keep the investigators informed of Project activities.
4.3 DISCIPLINE INTEGRATED PRODUCT TEAMS

Historically, the scientific knowledge, technical expertise and operational experience in the space life sciences has been embedded in scientific discipline research areas. In order to maintain and utilize this expertise, the HRP has established integrated product teams in those disciplines with high relevance to the HRP’s mission. These include:

- Behavioral Health & Performance,
- Bone,
- Cardiovascular,
- Immunology,
- Medical Capabilities,
- Muscle,
- Nutrition,
- Pharmacology,
- Radiation,
- Sensorimotor, and
- Space Human Factors and Habitability.

The Discipline Team Leads and a few key members of each Discipline Integrated Product Team, representing clinical and operational expertise in the discipline area, are appointed by the Program Scientist with the concurrence of the HRP Manager. The NSBRI shall appoint appropriate NSBRI members of each team to assure that the NSBRI is well represented in the Integrated Product Team's discussions. The Team Lead then identifies additional members, drawn from both the intramural and extramural research community and from intramural clinical and operational groups.

The Discipline Integrated Product Teams are responsible for annually assessing the current evidence base of discipline-related research data, clinical data and knowledge that has relevance to specific space exploration mission categories. These annual assessments will pay particular attention to adverse-outcome risks to human health and performance and to current gaps or uncertainties in knowledge associated with those risks or with the mitigation strategy. The Teams will present their findings as an annual list, in order of importance, of these gaps and a proposed set of activities to address the gaps. Information about these activities must include the exploration mission(s) affected by the gaps, a proposed schedule for the activities, and the research platform necessary for carrying out the activities. These Discipline Proposed Research Profiles (see 5.4 and Appendix A.4) will be used by the Project Scientists to update Project Research Plan annually, thus updating the Element and Integrated Research Plans. The updated Plans will contain both current and future activities.

It is expected that Discipline Integrated Product Team meetings, or telecommunication discussions, will occur regularly throughout the year.

5.0 RESEARCH PLANS

One of the major responsibilities of science management within the HRP is to participate in the Element and Project Plan development by designing and maintaining the research portion of these plans and ensuring that the research content in these plans meets the HRP requirements, as documented in the Human Research Program Requirements Document (PRD) (HRP-47052). The PRD describes an integration of customer and stakeholder needs, goals, and objectives that are relevant to the HRP and provides a traceable allocation of those needs to HRP Elements.
Use of this PRD to guide research planning maintains the alignment of the HRP research program with those needs.

The plans rely on knowledge and evidence gained through many years of multidisciplinary space-related research. This section summarizes the approach used to develop the HRP research plans and Appendix A provides further guidelines for producing these plans.

5.1 INTEGRATED RESEARCH PLAN
The Integrated Research Plan is the HRP combined strategic, tactical and implementation plan for research necessary to meet HRP requirements. It documents the time-phased approach required to address the research and technology development necessary to serve the Constellation Program needs and the exploration mission timelines. It also defines research dependencies, such as the flight research that must be accomplished on the International Space Station.

The Integrated Research Plan should ensure that the Program’s activities are supporting the development of the existing and evolving Space Flight Health Standards for Human Performance. These standards provide a declaration of acceptable medical risk from the deleterious health and performance effects of space flight, and will help focus and prioritize biomedical research and technology development efforts, providing target parameters for products and deliverables that will support the health maintenance of crews during space missions. The Integrated Research Plan should also document the relationship between the Program’s activities, the Bioastronautics Roadmap, and the Discipline Proposed Research Profiles.

Appendix A, Section A.1 provides the basic format for the Integrated Research Plan and describes the general content of the required sections. The contents of this plan should clearly relate how the Program’s requirements have lead to the development of the current Program Portfolio. The HRP Control Board approves the Integrated Research Plan.

5.2 ELEMENT RESEARCH PLANS
In the case of a program Element containing multiple projects, the Element Scientist is responsible for the development and maintenance of the research component of the Element Management Plan, hereinafter called the Element Research Plan.

Appendix A, Section A.2 provides the basic format for the Element Research Plan, as a component of the Element Plan, and describes the general content of the required sections. The contents of the Element Research Plan should clearly relate how the Element’s requirements have lead to the development of the current Element Portfolio. The Program Scientist approves the Element Research Plan, the research component of the Element Plan.

In the case of a program Element containing technology projects, the Element Scientist is responsible for developing the technology gaps and priorities in accordance with Section 9.

5.3 PROJECT RESEARCH PLANS
Project Scientists are responsible for the development and maintenance of the Project Research Plans. A single project may contain applied research and development activities, technology development activities, core service activities, as well as NSBRI-funded activities directly
related to the Project. The Project Research Plan shall contain sections devoted to each type of activity in accordance with the templates provided in Appendix A.3.

5.3.1 Applied Research & Development/Technology Development Projects
Project Scientists in the applied research and technology development areas shall develop Project Research Plans. These research plans are the research component of the Project Plan. Appendix A, Section A.3 provides the basic format for the Project Research Plan as a component of the Project Plan and describes the general content of the required sections. Technology development projects with no applied research content require Project Plans developed in accordance with Section 9.

5.3.2 Core Service Projects
A core service project does not require a Project Research Plan when it has no scientific investigations or secondary studies other than those that are part of a separate applied research & development or technology development project. However, the Project must have a Project Plan. The methods used for accepting investigations, prioritization and allocation of the resources of a service project shall be clearly defined in the Project Plan. A summary of the various investigations and their associated Program Element must be contained in the annual Project report. If the service project contains additional cross-cutting activities and measurements that go beyond the individual investigations’ needs, then the Project Manager, supported by the Project Scientist shall ensure those additional crosscutting activities not presented elsewhere, are included in the Project Plan, using those sections of the research plan described in 5.3.1 and Appendix A.3 that apply.

5.4 DISCIPLINE PROPOSED RESEARCH PROFILES
Each Discipline Integrated Product Team will develop a Discipline Proposed Research Profile, including a list, in order of relative importance, of discipline-related research and knowledge gaps for particular exploration mission types and a set of proposed activities to address those gaps. These Profiles should be traceable to the Program Requirements Document, HRP-47052, and should follow the guidelines presented in Appendix A, Section A.4. Detailed information about those activities will include relative importance, initiation and completion dates, requirements for particular mission scenarios, and requirements for specific research platforms. These Discipline Proposed Research Profiles will be updated annually by a defined process.

5.5 BIOASTRONAUTICS ROADMAP
The Bioastronautics Roadmap is an important reference document that captures the human system risks associated with exploration missions. It will be updated regularly to reflect the current state of knowledge, allowing it to remain a valuable reference. The current content and format of the Roadmap are available on the web (http://bioastroroadmap.nasa.gov) as an interactive version. In 2005, the Institute of Medicine carried out an external review of the Roadmap; its report is available on-line (http://iom.edu/CMS/3740/20027/30501.aspx).
6.0 RESEARCH AND TECHNOLOGY PROPOSALS

6.1 SOURCES OF PROPOSALS

In the HRP, research and technology proposals are of three types: solicited proposals, unsolicited proposals and Project Directed Study proposals. A project’s research and technology portfolio may contain activities generated from all three proposal types. All funded scientific and technology development activities within a project must be based on one of these proposal types. It is the HRP’s policy to utilize full and open competition for research and technology investigations through periodic research solicitations issued by both NASA and the NSBRI and to maintain a balance between selected intramural and extramural investigations. Figure 3 depicts the research and technology procurement process described in this section.

Figure 3. Human Research Program procurement process.

6.1.1 Solicited Proposals

NASA generally uses Broad Area Announcements (BAAs) to solicit proposals for research and technology investigations. Such BAAs may take the form of Announcements of Opportunity (AOs), NASA Research Announcements (NRAs) or, less frequently, Cooperative Agreement Notices (CANs). In addition, for specific, well-defined research end points or tests, NASA may elect to use Request for Proposals (RFPs) or a Request for Quotes (RFQs).

The AO is used to solicit and competitively select research investigations characterized as having a well-defined purpose and end product; for example, science investigations with hardware responsibility for a unique space flight mission, a program of flight missions (such as Explorer and Discovery), or unique but large-cost non-flight programs (such as NASA support of the Keck Telescope). The AO can also be used for the selection of a science team for a flight mission, with responsibility for data analysis and mission operations.
Investigations selected through an AO can range in cost from a few hundred thousand dollars to several hundred million dollars. The key features of the AO process are:

a. The opportunity is relatively unique,
b. The supporting budget is usually a unique line item authorized by Congress, and
c. It is both a program-planning system and an acquisition system contained in one procedure.

The NRA is used to solicit research that is characterized as being a part of the HRP's ongoing approved research program under the budgetary discretion of the HRP Program Manager. Normally, the HRP will issue at least two NRAs annually in partnership with the NSBRI, one for research in support of the radiation element and one for the remainder of the Program. In general, an NRA solicits relatively low-cost supporting research investigations that are characterized as being of high relevance to NASA's program interests but in which a specific end product or service is not well-defined but left to the creativity of the proposer. NRAs are typically used to solicit and competitively select proposals for ongoing programs (although some may be singular in nature such as a data analysis program).

The CAN is used to solicit and competitively select proposals to support NASA program interests that require a high degree of cooperation between NASA and the selected institution. The scope of activities solicited by a CAN may be as modest as those through an NRA or as complex as those through an AO. The cooperative agreements awarded as a result of a CAN are similar to grants except that both NASA and the selected institution are required to provide resources, and both are involved in decisions related to the activities carried out by the selected institution.

Preparation of BAAs for the HRP will be coordinated by the Program Scientist based on the needs identified in the approved Program Science procurement plan.

6.1.2 Unsolicited Proposals

Within NASA, an unsolicited proposal is defined as a written proposal that is submitted to NASA on the initiative of the submitter for the purpose of obtaining a NASA grant, contract or other agreement and which is not submitted in response to a formal or informal request (other than an Agency request constituting a publicized general statement of needs). In general, NASA encourages the submission of unique and innovative unsolicited proposals which will further the Agency’s mission.

To be considered as a valid unsolicited proposal, a submission must:

- Be innovative and unique;
- Be independently originated and developed by the proposer;
- Be prepared without Government supervision, endorsement, direction, or direct Government involvement;
- Include sufficient technical and cost detail to permit a determination that Government support could be worthwhile and the proposed work could benefit the agency's research and development or other mission responsibilities; and
• Not be an advance proposal for a known agency requirement that can be acquired by competitive methods.

Further details concerning unsolicited proposals are available in the Unsolicited Proposal Handbook (http://ec.msfc.nasa.gov/hq/library/unSol-Prop.html).

6.1.3 Project Directed Study Proposals

In certain situations, constraints on necessary research are incompatible with the use of the BAAs described in 6.1.1. In these situations, where normal BAA solicitations are impractical, the HRP may utilize Project Directed Studies to accomplish the desired research.

In order to utilize a Project Directed Study, one or more of the following criteria must be fulfilled:

• Insufficient time for solicitation. In certain cases, NASA must define scientific activities in a short time because of the emergence of new opportunities to carry out activities in space on the Shuttle or the International Space Station. When this is the case, use of a Project Directed Study may be the only practical way to respond.

• Highly constrained research. In this case, the project requires sharply focused and constrained data gathering and analysis that is more appropriately obtained through a well-defined solicitation using a request for proposals (RFP) or by a non-competitively developed proposal.

• Research involving space flight operations. In this case, the research activity directly involves operational practices and the associated operational personnel. Thus, these groups must be heavily involved in the development of the study design.

Project directed studies, when justified under the above criteria, may either be competitive or non-competitive. If a competitive solicitation (RFP) is used to obtain proposals, the preparation of such proposals should follow the guidelines described in the RFP. In other cases, Project Directed Study Proposals must be prepared according to guidelines stated in Appendix B and will be evaluated as described in 6.3.3.

In certain cases, non-competitive proposals for directed studies that adhere to the constraints may be prepared by the Project Scientist or his/her designee. However, in these cases, great care must be taken to avoid conflict of interest and the appearance of conflict of interest in the development of such proposals (see 3.5). Note that a very specific, newly identified short-term study related to already selected scientific investigations may be considered as modifications to on-going activities, not as a new study; such identification is left to the discretion of the Project Scientist with the advice and consent of the Standing Review Panel Chair.

Directed study proposals may involve both intramural (NASA) and extramural investigators and may be for activities that will be accomplished in space, at NASA Field Centers or at universities or research institutions. Care should be taken to assure that the investigators are established scientists currently active in the research area and have the expertise and laboratory capability necessary to carry out the project. Generally, directed study proposals should involve both intramural and extramural investigators working as a team.
6.2 GENERAL PROPOSAL FORMAT

6.2.1 Solicited Proposal Format
The format for proposals submitted in response to BAAs (AOs, NRAs, CANs) and other solicitations (RFPs, RFQs) is defined in the solicitation itself and submitters are expected to adhere strictly to that format. Otherwise, proposals may be deemed unresponsive and returned to the applicant. General guidelines and instructions do exist for preparing and submitting proposals in response to NASA solicitations (for NRAs, see the “Instructions for Responding to NASA Research Announcements” at [http://www.hq.nasa.gov/office/procurement/regs/5228-41.htm#52_235-72](http://www.hq.nasa.gov/office/procurement/regs/5228-41.htm#52_235-72) and the “Guidebook for Proposers Responding to a NASA Research Announcement (NRA)” at [http://www.hq.nasa.gov/office/procurement/nraguidebook/](http://www.hq.nasa.gov/office/procurement/nraguidebook/). However, these instructions may be superseded by instructions contained in the solicitation and applicants should always follow the instructions in the BAA.

6.2.2 Unsolicited Proposal Format
There is no prescribed format for an unsolicited proposal, as long as it includes the following items:

- Transmittal Letter or Introductory Material
- Abstract
- Project Description
- Management Approach
- Personnel
- Facilities and Equipment
- Proposed Costs
- Other Matters

More information about each of these items is available in the Unsolicited Proposal Handbook mentioned in 6.1.2 ([http://ec.msfc.nasa.gov/hq/library/unSol-Prop.html](http://ec.msfc.nasa.gov/hq/library/unSol-Prop.html)).

6.2.3 Project Directed Study Proposal Format
The general format for Project Directed Study proposals is presented in Appendix B.

6.3 PROPOSAL EVALUATION

6.3.1 Solicited Proposal Evaluation
All BAAs and other solicitations must specify the research and technology emphases being solicited, the criteria and specific evaluation factors used to evaluate the submitted proposals, and the method that will be followed for proposal evaluation. Although most solicitations include proposal merit, relevance to the announcement, feasibility of implementation and cost as evaluation factors, other factors can also be included and the weight applied to each factor can differ from announcement to announcement. Thus, interested parties should read the solicitation carefully for this information. Evaluating proposals for merit or scientific quality may involve ad hoc scientific review panels established for the purpose of supporting a solicitation. In order to foster continuity and consistency among such panels, the HRP will establish a group of about 15 nationally and internationally recognized experts in the relevant Program research areas to
lead these *ad hoc* panels. This group, managed by the Program Scientist, will be known as the Clinical and Operational Research Working Group.

### 6.3.2 Unsolicited Proposal Evaluation

Unsolicited proposals that are deemed appropriate for the HRP are examined by the Program Scientist to determine which Element should consider it. If no Element is appropriate to carry out an initial review, then the Program Scientist dispositions the proposal and communicates with the applicant. Otherwise, the Element Scientist, working with the Project Scientists, reviews the proposal and determines if the proposal is highly relevant to one of the Project areas within the Element and of potential value to that area. If so, the Element Scientist forwards the proposal to the Program Scientist with an analysis supporting a recommendation that it be reviewed for merit by the appropriate Standing Review Panel. The Program Scientist reviews this material, approves the recommendation, coordinates the review with the NAR Panel and transmits the review results to the appropriate Element and Project Scientists. Selection and funding by a Project depends on the merit of the proposal, the level of relevance to the Project, feasibility and the cost. Following the relevance and merit reviews, the Element or Project Scientist communicates with the applicant.

### 6.3.3 Project Directed Study Proposal Evaluation

A Project Directed Study proposal is highly relevant to the Project which generated the proposal. Such proposals will be reviewed by the Standing Review Panel (see 7.2.1), or by an *ad hoc* NAR Panel if no Standing Review Panel exists. Once a directed study proposal is written, the Element Scientist forwards the proposal to the Program Scientist who coordinates the NAR process. Proposals requesting space-flight resources are evaluated in parallel for flight feasibility by the ISSMP. Following these reviews, the results are provided to the Element and Project Scientists. Based on the evaluations and recommendations, the proposal may be selected without alteration, with alterations addressing the proposal’s identified weaknesses, or the proposal may be declined.

### 6.4 CONFLICT OF INTEREST IN PROJECT OR PROPOSAL EVALUATION

Regardless of the type of evaluation selected, all personnel involved in the evaluation of projects or proposals must avoid any possible real or apparent conflict of interest. Basically, a conflict of interest in project or proposal evaluation exists when a reviewer has an interest in a project or research application or proposal that is likely to bias his or her evaluation of it.

If a project or proposal evaluator is also an investigator within a project research group, then it is a clear conflict of interest for that person to make any recommendations or decisions regarding selection or funding of that research group. Such recommendations or decisions must be made independently and not involve the investigator in any way.

Other bases for conflict of interest include bias generated by personal relationships, longstanding professional disagreements, and multiple and conflicting management responsibilities, among others. Proposal peer review panels will be instructed in the criteria used to determine whether a real or apparent conflict of interest exists; a reviewer who has a real conflict of interest with an application or proposal may not participate in its review.
6.5 PROPOSAL SELECTION AND FUNDING

Solicitations for research or technology proposals specify the selection and funding process to be used to finally disposition the submissions. This includes identifying the selecting official, in addition to the evaluation factors, criteria and evaluation method to be applied. Applicants should see the specific solicitation for further information on selection and funding.

Once an unsolicited or Project Directed Study proposal is reviewed by the Standing Review Panel or its equivalent (see Section 7.2.1), the Project Scientist, in consultation with the Project Manager, prepares a selection recommendation, to be approved by the Element Scientist, which will include, if appropriate, a budgetary component. Proposals requiring space flight must also be evaluated for flight feasibility by the ISSMP before the final selection recommendation is prepared (see Appendix D for an example Pre-Definition Phase Worksheet that is used in this evaluation). The final selection recommendation is then submitted through the Program Scientist to the HRP Program Manager, the selecting official.

7.0 REVIEWS

7.1 DISCIPLINE SCIENCE REVIEW

Once a year, on a schedule coordinated by the Program Scientist, each of the Discipline Integrated Product Teams shall review their assessment of the current evidence base of discipline-related space research, as well as clinical and operational data and knowledge with the Project, Element and Program Scientists and other personnel interested in these assessments. These annual assessments will focus on exploration related adverse-outcome risks to human health and performance and to current gaps or uncertainties in the knowledge associated with those risks, or in the current countermeasure development plan. Assessment should focus on gaps associated with each class of exploration missions, such as lunar sortie missions, long lunar stays, or missions to Mars. Each Discipline Integrated Product Team will document their assessment in a Discipline Proposed Research Profile that is linked to the Program Requirements Document (HRP-47052), listing the identified gaps and uncertainties together with a proposed set of activities to address the gaps, including the space mission(s) affected by the gaps, a proposed schedule for the activities, and the research platform necessary for carrying out the activities.

7.2 PROJECT SCIENCE REVIEW

7.2.1 Standing Review Panels

The Program Scientist, with inputs from the Project and Element Scientists, will establish a Standing Review Panel or its equivalent for each non-service Project in the HRP. (Until these Standing Review Panels are established, ad hoc NAR Panels may be used to accomplish any necessary proposal reviews.) These Standing Review Panels will exist for the life of the Project. To avoid any real or apparent conflict of interest, these panels will be coordinated and managed at the Program Scientist level on behalf of the Applied Research and Development/Technology Development Projects. Each Panel will consist of (primarily external) discipline specialists, engineers and project management specialists who serve for a fixed period of from two to four years with staggered terms. The Panel’s responsibility is to review and comment on all appropriate scientific or technological aspects of a Project. This includes review of any Project Directed Study proposals or unsolicited proposals relevant to the Project. Although the Panel
should meet at least once a year, Panels may meet more frequently, particularly at the beginning of the Project activity. Single proposal review may take place at any time by mail or sub-Panel meetings, followed by a telecommunication discussion with the entire Panel, if necessary. Particular face-to-face review meetings should focus on Project strategy and tactics, as well as on a thorough discussion of the need for future specific Project Directed Studies. All of the Panel’s reviews will provide not only the strengths and weaknesses of plans and proposals but also a set of recommendations on how to address and correct the weaknesses, so that the resulting Project is as strong as possible, given the constraints under which the Project must operate.

7.2.2 Project Science Management Review
Once a year, or as necessary, the Element Scientist for a multiple-project Element will review all of the scientific activities of each Project within the Element. These substantial reviews will focus on the Project’s scientific activities, the activities and advice of the Standing Review Panel and how the Project intends to respond to that advice, and the response of the Project to the latest Discipline Proposed Research Profile.

7.3 ELEMENT SCIENCE REVIEW
Following the Project Science Management Review above, the Program Scientist will review all of the scientific activities of each Element. For Elements with only one Project, the review will cover the same material as specified in 7.2.2. For multi-project Elements, the review will focus on the way that the projects within the Element are integrated into a cohesive, synergistic set of mutually beneficial activities.

7.4 PROGRAM SCIENCE REVIEW
Each year the Program Scientist, working closely with the Element and Project Scientists, will provide an overview of the entire scientific program to the HRP Program Manager, pointing out the significant accomplishments, risks and challenges to the current program, the traceability of activities to the Program Requirements Document (HRP - 47052), and the gaps that remain to be addressed. This review will be coordinated with NASA’s annual budgetary planning schedule and will be based on established criteria for the evaluation of HRP research in terms of risk mitigation and operational relevance. Preliminary criteria include: (1) the documentation of new scientific evidence that further mitigates stated risks or identifies new ones; (2) the advancement of Technology Readiness or Countermeasure Readiness Levels; and (3) the delivery of tangible products that are accepted by HRP's customers.

The Program Science Review will include an assessment of the need for continuation, modification, expansion or termination of scientific studies and investigations based on evolving results, evidence and program needs.

7.5 ANNUAL RESEARCH AND TECHNOLOGY FORUM
Each year, the HRP will conduct a research and technology forum, bringing most of its investigators and managers together to communicate the results of their activities to HRP's stakeholders (space medicine, astronauts, NASA management and the public) and its Agency customers (ESMD, Space Operations Mission Directorate, and Office of the Chief Health and Medical Officer).
8.0  DATA, INFORMATION, AND KNOWLEDGE MANAGEMENT

Data, information, and knowledge management, including issues related to archiving and accessing data and physical samples from ground and flight studies, is an important component of the Human Research Program. This section will describe the general structure, function and operation of the distributed data, physical sample and information management system that is necessary to serve the needs of the research community while preserving the rights of the subjects. The Space Life Sciences Directorate (SLSD) Division Configuration Control Boards maintain the configuration control and quality management oversight for the HRP's Element and Project information, as described in the SLSD Configuration Control Management Plan (JSC 28330).

This section will be updated in subsequent revisions of this Science Management Plan.

9.0  TECHNOLOGY DEVELOPMENT PROCESS

As described in the Human Research Program Plan, critical human systems technologies will normally be developed within the HRP up to Technology Readiness Level (TRL)-6 and will stem from HRP Element and NSBRI basic and applied research. Since these technologies are developed to satisfy requirements for medical care, environmental control, human factors, etc., it is important that the technology gaps are clearly identified, the most cost effective approach selected and the "customers" for these technologies (stakeholders) agree that the technologies are appropriate. Therefore, it is essential that formal Stakeholder Agreements (see 9.2) be developed at the initiation of the development process to ensure that the ultimate technology deliverables meet the customer’s requirements.

The HRP technology development process begins with the identification of technology needs and gaps. The identified needs and gaps related to HRP risks will be approved and maintained by the Science Management Office. Once approved, the technology development project (or project element) will perform a complete technology market analysis to identify potential sources for the technologies and current TRL and prepare a recommended technology development plan. Selected developments will undergo appropriate merit reviews prior to Authority to Proceed (ATP).

The HRP technology development process ends with the handover to the customer of technology deliverables for continued development to higher TRLs and ultimate insertion into the Exploration Program.

9.1  TECHNOLOGY DEVELOPMENT PROJECT REQUIREMENTS

Ensuring that the technology is carried on to complete implementation in the intended operational environment is key in formulating the project. HRP Technology development and infusion is a component of the Project Plans. These plans should outline the strategy for the entire lifecycle of the technology development activity, not just the period for which the HRP is financially responsible. The plans should include (at least) the following components:

- A clear description and basis for the technology need and chosen approach,
- The planned method for assessment of the current state of technology,
- The rationale and method for make vs. buy decisions,
- How the TD activity aligns with the HRP Program Plan and Program Requirements
• A defined list of customers and plan to present to/discuss with them the proposed technology development,
• Technology needs and requirements that the technology addresses,
• The implementation alternatives to meeting the requirement that were evaluated,
• The planned method of project implementation,
• Any external requirements that should be taken into account in the technology development or those that present particular challenges to bringing the technology to its ultimate application (such as environmental requirements for the operations environment in which the technology will work),
• The anticipated TRL level to which the technology will be developed,
• Identification of key performance parameters throughout the technology lifecycle (special key performance parameters that the technology must meet when at a higher TRL level, but that affect the earlier technology development, should be identified),
• The anticipated method of infusion of the technology into operations (anticipated method, and timeframe for transfer of management and financial responsibility for operational development),
• A plan for synergies or partnerships with any other HRP projects with similar technology requirements,
• Reviews to be held with the customer and other key requirement owners throughout the life-cycle of the TD,
• Method of independent assessment and customer review at the time of the technology hand-off to the customer for operational development

NSBRI’s Technology Development Process (TBD), in keeping with the mutual human health exploration risk reduction goals and synergism between NASA and NSBRI, describes NSBRI’s requirements for technology development and deliverables as well as for Stakeholder Agreements.

9.2 STAKEHOLDER AGREEMENTS

Stakeholder Agreements between the developer, HRP projects and the customers (ex: OCHMO, ESMD) should be obtained before ATP to the implementation phase of technology development activities. These agreements are essential in defining expected use, operational concepts, and stakeholder expectations and requirements for the projected technology development through all lifecycle phases. Agreements will also describe the responsibilities that the project has for transitioning the technology to the customer’s program and assisting the infusion of the technology into their program.

For those customers who have their own baselined requirements for a stakeholder agreement, the customer’s template may be used. For example, the Constellation Program requires a Customer Supplier Agreement, CSA, CxP 70079, which describes the Constellation Program requirements for a mutually developed, and signed document between the technology supplier and the Constellation Program Requirement Owner (RO).
The stakeholder agreement process is as follows:

- Establish a list of stakeholders
- Elicit stakeholder expectations
- Establish the technology operations concept and support strategies
- Define stakeholder expectations and definitive requirements
- Analyze expectation statements for measures of effectiveness
- Validate that the defined requirements reflect traceability
- Obtain stakeholder commitments to the validated set of expectations and requirements
- Baseline stakeholder expectations and derived requirements

Appendix A.5 describes the general content of the Stakeholder Agreement and may be tailored to the unique needs of the project. The Element Manager shall determine, based on the complexity of the projects in the Element portfolio, if individual element project stakeholder agreements are needed or if one overall Element stakeholder agreement will be sufficient.

The Element Manager, will also identify the stakeholders and determine the level of stakeholder management approval required, which is dependent on the complexity of the Element technology development activity. Stakeholder Agreements will be required prior to implementation funding and concurred by the SMP and HRPCB.

Note: There may be some cases where stakeholder agreements will not be feasible and therefore waived by the HRPCB. For example, a risk is not yet documented by the Constellation Program and the Element Manager can provide evidence to the HRPCB that 1) a requirement is forthcoming and 2) that the proposed TD project is the only way to address the requirement.

9.3 TECHNICAL REVIEWS

HRP Technology Development activities will go through merit reviews prior to ATP as well as the standard HRP scientific and status reviews listed in section 7, “Reviews”, of this document as a part of the HRP project they are supporting. For example, the Standing Review Panel requires the review of “all appropriate scientific or technological aspects of a Project” and the Program Science Review, requires the review of “the advancement of Technology Readiness or Countermeasure Readiness Levels”.

Other reviews, in mutual agreement with the stakeholder and documented in the Stakeholder Agreement, should be held in an appropriate frequency to keep the stakeholder apprised of the continuing progress of the technology development and for the exchange of important information such as evolving changes in requirements.

10.0 DISSENTING SCIENTIFIC OPINION

This section defines a method for presenting a dissenting scientific opinion. The Science portfolio of the HRP is developed from risk profiles based on scientific evidence and non-experimental (i.e. anecdotal or clinical) flight data. Decisions on the existence and/or seriousness of risks, of the adequacy of evidence supporting the risks and on the robustness of the resulting conclusions for the evidence based and non-experimental flight data can be disputed. The
submission of a written dissenting scientific opinion is the intended route for addressing and resolving these disputes.

A scientific dissent will involve a detailed, well-documented analysis of good scientific practices and relevant risk assessment. A scientific dissent does not address whether one agrees with management of risk or resources, but rather whether or not the science supporting the risk assessment is sound, reliable, defensible, and accurate. The Program Scientist will be responsible for ensuring an unbiased, open process for evaluating the legitimacy of scientific dissents and supporting evidence.

Normal HRP processes and required reviews should enable discussion of the dissenting opinion/alternative point of view at the lower level forums such as Discipline Integrated Product Team reviews &/or Standing Review Panels. Any dissenting scientific opinion should be addressed at the lowest level forum first and progress to the next higher level only if the initiator feels their concern was not properly considered or addressed. If not satisfied with the decision in the lower level forum, the initiator of the dissent should discuss the matter with the responsible Project Scientist and/or Element Scientist. In the event the initiator of the dissenting scientific opinion believes their perspective needs further consideration, the scientific dissent is written and submitted to the Program Scientist for discussion and review. The Program Scientist will not consider a dissenting opinion unless it has been through the appropriate lower-level discussions.

The template for developing the written dissenting scientific opinion is available in Appendix F of the Science Management Plan. All historical information related to the dissent should be included in the written dissent package (meeting minutes, DIPT reports where the issue was previously raised, etc.). The written dissent submitted to the Program Scientist will be the final level of consideration for the dissent within the Human Research Program. The written dissent will be handled through existing Science Management Office configuration management processes to ensure complete tracking of the review, disposition and dissemination of the final decision. The Program Scientist has the option of convening the Science Management Panel to address the issue. In addition, any unresolved dissenting opinion should be clearly recorded in any product from the lower level forum and documented by the related Project.

The dissenting opinion in written form will be assessed using a systematic evaluation of the evidence supporting the dissent, including unbiased, non-conflicted review for relevant objectives. The dissenting opinion will be evaluated for a clearly stated dissenting scientific opinion, relevant supporting evidence, and credible, realistic treatment of scientific uncertainties. The written dissent has the responsibility to inform the reviewers of any potential impacts to human health or performance if the scientific opinion is not investigated or validated.

All assessments and final comments to the formal written dissent are to be completed in a timely manner, considered to be within 42 calendar days from the acceptance of the dissent to written disposition at each level of panel review or advisory review.
The final disposition of the matter will include the rendered opinion (agreed with dissent, disagree with dissent, need more information), rationale for the decision, evidence and references supporting the rendered opinion, and those who reviewed the dissent and their affiliation. If any of the reviewers have a real or perceived conflict of interest or bias, then this is noted and explained.

If the initiator of the scientific dissent does not agree with the Program Scientist’s final disposition, they may elevate the dissent utilizing the current NASA Governance Model, the Health and Medical Technical Authority (HMTA) process. The Science Management Office or the Center specific Ombudsman Office can provide guidance for how to access the Health and Medical Technical Authority.
APPENDIX A. GUIDELINES FOR DEVELOPING THE RESEARCH PLANS

These guidelines contain a suggested format for the presentation of the various research plans within the HRP. The guidelines are general and may be adapted to fit the particular needs of the actual projects, elements or program.

A.1 Integrated Research Plan

The Program Scientist shall create and maintain an Integrated Research Plan that contains (at least) the following sections:

I. **Introduction and Background**
   Definition of the scientific component of the HRP, including a clear statement of scope and a short relevant synopsis of the HRP background, including its relationship to the Vision for Space Exploration.

II. **Program Requirements Summary**
   Program-level health & performance requirements, additional Program-level requirements applied to the Element Plans (Element Research Plans), and requirements related to the Program-level need for key scientific personnel to access and disseminate vital ground and space data to other research, clinical and operational personnel.

III. **Program Scientific Goals and Objectives**
   Brief but clear statement of the specific goals and objectives of the Program, derived from its requirements. This section should also include an elaboration of how the Program intends to strengthen the value of the individual Projects by developing synergistic, cross-Element activities and by fostering integration of data and information across Element boundaries.

IV. **Program Portfolio**
   Summary description of each of the Elements included in the Program, with details of how the cross-Element integration has influenced the resultant Element Portfolios. It is not necessary to include the Element or Project Res Plans as part of the Integrated Research Plan; they may be included by reference. However, the Appendix should include the Program Portfolio, derived from an integration of each of the Element Portfolios.

V. **Short-Term Strategy: Program Procurement Plan**
   Description of the Program procurement/solicitation plan to acquire, over the next three years, the scientific or technological activities necessary to carry out the Program.

VI. **Long-Term Strategy: Future Program Needs**
   Integrated description of the future research and technology needs of the Program beyond three years, derived from the long-term strategies of all the Elements within the Program.
VII. **Program Sample and Data Management Plan**

Description of the activities related to developing and maintaining a Program-level physical sample and biomedical data management system that will integrate the function and operation of the many distributed sample and data components. This includes development of a uniform process for accessing and disseminating data and for obtaining existing samples for scientific use, while maintaining the rights of the subjects.

**Appendices: A. Detailed Description of the Program Portfolio**

This Appendix provides charts and tables describing each of the currently funded scientific investigations that make up the Program Portfolio. This information should include, at least: title, investigator(s), current and projected funding (including the funding project), brief rationale (links to risks and gaps and relevance to mission needs and milestones), countermeasure or technology readiness level, research subjects, research platform, and projected completion schedule.

**B. Summary Charts: Current and Future Program Strategy**

This Appendix provides a set of Gantt charts describing current Program Portfolio and the short- and long-term Program strategy in terms of the gaps addressed, the required research platforms, the needs of the various exploration missions, and the Constellation Program schedule and milestones.

**A.2 Element Research Plan**

Each Element Scientist shall create and maintain the research component of the Element Plan. This component will be called the Element Research Plan; it should contain (at least) the sections specified below. For Elements containing a single project, the Project Research Plan and the Element Research Plan are identical and this section should be ignored.

I. **Element Requirements Summary**

Health & performance requirements related to Element, any specific Element requirements that focus the Element’s scope, and a discussion of any Element requirements derived from specific Project Research Plans associated with that Element.

II. **Element Scientific Goals and Objectives.**

Brief but clear statement of the specific goals and objectives of the Element, derived from its requirements. This section should also include an elaboration of how the Element intends to strengthen the value of the individual Projects by developing synergistic, cross-Project activities and by integrating data and information across Project boundaries.

III. **Element Portfolio**

Summary description of each of the Projects included in the Element, with details of how the cross-project integration has influenced the resultant Project Portfolios. It is not necessary to include Project Research Plans as part of the
Element Research Plan; they may be included by reference. However, the Appendix should include the Element Portfolio, derived from an integration of all of the portfolios for all of the Projects within the Element.

IV. Short-Term Strategy: Element Research Procurement Plan
Description of the Element research procurement/solicitation plan to acquire, over the next five years, the scientific or technological research activities necessary to carry out the various Projects within the Element.

V. Long-Term Strategy: Future Element Needs
Integrated description of the future research and technology needs of the Element beyond three years, derived from the long-term strategies of all the Projects within the Element.

VI. Element Data Management Plan
Specific plans for archiving, accessing and distributing the scientific data resulting from carrying out the investigations of this Element.

Appendices: A. Detailed Description of the Element Portfolio
This Appendix provides charts and tables describing each of the currently funded scientific investigations that make up the Element Portfolio. This information should include, at least: title, investigator(s), current and projected funding (including the funding project), brief rationale (links to risks and gaps and relevance to mission needs and milestones), countermeasure or technology readiness level, research subjects, research platforms and projected completion schedule.

B. Summary Charts: Current and Future Element Strategy
This Appendix provides a set of Gantt charts describing current Element Portfolio and the short- and long-term Element strategy in terms of the gaps addressed, the required research platforms, the needs of the various exploration missions, and the Constellation Program schedule and milestones.

A.3 Project Research Plan
Each Project Scientist shall create and maintain the research component of the Project Plan. This component will be called the Project Research Plan; it should contain (at least) the sections specified below. The Plan’s contents may be enlarged to include other items of particular importance to specific projects. Note that a single project may contain both research and technology development components and service components, and the NSBRI-funded activities directly related to the Project. If that is the case, the Project Research Plan should contain sections devoted to each type, as necessary (see 5.3). In addition, if a Project has a unique structure, these guidelines should be followed in spirit, but interpreted as necessary to enable a clear presentation of the Project’s Research Plan.
The Project Research Plan should contain the following sections:

I. **Project Requirements Summary**
   Health & performance requirements related to Project, requirements related to the Space Flight Health Standards for Human Performance, specific project requirements that focus the Project’s scope, and requirements derived from Discipline Proposed Research Profiles.

II. **Project Scientific/Technology Goals & Objectives**
   Brief but clear statement of the specific goals and objectives of the Project. Goals and objectives should lead to scientific metrics documenting the Project’s scientific/technological achievements.

III. **Project Portfolio**
   Summary description of each of the investigations and technologies currently included in the Project. Each of the investigations should be related to the research platform being used and to the specific needs of the different exploration missions, as well as the Constellation Program schedule and milestones. Detailed information concerning the Project Portfolio should be included in an Appendix. (N.B., the Portfolio should contain all activities within the Project’s domain, regardless of funding source or site of the research. In addition, those activities implemented through the core service components, but originating in the Project, should be reported here.)

IV. **Rationale for Investigations**
   Rationale for each of the investigations included in the Project Portfolio, including the process utilized to select them, the criteria that led to the specific selection choices, and the method to identify and promote synergistic and integrated multidisciplinary activities. In addition, any dependencies on activities taking place in other Projects should be described.

V. **Short-Term Strategy: Project Procurement Plan**
   Description of the Project procurement/solicitation plan to acquire, over the next five years, the scientific or technological activities necessary to carry out the Project’s near-term strategy, including the need for the development of one or more solicitations and/or Project Directed Study proposals.

VI. **Long-Term Strategy: Future Project Needs**
   Brief description of the future research and technology needs of the Project beyond five years, linking these needs to the current portfolio and near-term strategy and relating these needs to Constellation Program milestones and schedule and to future research platform availability.

VII. **Project Data Management Plan**
   Specific plans for archiving, accessing and distributing the scientific data resulting from carrying out the investigations of this Project.
Appendices: A. Detailed Description of the Project Portfolio

This Appendix provides charts and tables describing each of the currently funded scientific investigations that make up the Project Portfolio. This information should include, at least: title, investigator(s), current and projected funding, brief rationale (links to risks and gaps and relevance to mission needs and milestones), countermeasure or technology readiness level, research subjects, research platforms and projected completion schedule.

B. Summary Charts: Current and Future Project Strategy

This Appendix provides a set of Gantt charts describing current project portfolio and the short- and long-term project strategy in terms of the gaps addressed, the required research platforms, the needs of the various exploration missions, and the constellation program schedule and milestones.

A.4 Discipline Proposed Research Profile

Each Discipline Integrated Product Team shall annually develop and present to the HRP a Discipline Proposed Research Profile traceable to the Program Requirements Document (HRP - 47052) focused towards an operationally relevant program that contains the following information:

- Gaps in the Discipline knowledge base, including knowledge related to standards, and gaps in the current Program’s research program in developing appropriate countermeasures, identified in order of relative importance or priority; and

- Activities to address those gaps (current and proposed short and long-term future strategies) with the following associated information:
  - Name and identifying number for activity, if currently existing;
  - Approximate activity initiation and duration time;
  - Relative priority or order of importance relative to other activities addressing the same gap;
  - Need for activity in order to carry out a given exploration mission; and
  - Required platform upon which activity is performed (Earth, shuttle, ISS, lunar sortie, lunar outpost, Mars)

Appendices: Discipline risk summaries

This set of appendices should provide the evidence and rationale for the existence of the gaps defined above in the Discipline Proposed Research Profile. Each adverse outcome related to a particular risk should be provided as a separate risk summary. These risk summaries should concisely describe: brief evidence for the risk, contributing risk factors, relevance of the risk to specific missions, current discipline standards and associated lower level human system requirements, mitigation strategies and the relationship of any of the preceding items to current gaps.
Appendix A.5 Stakeholder Agreements

HRP Stakeholder Agreements are formal documents that should ensure that the technology deliverables desired by both the technology developer and the customers (stakeholders) will be a product or products that were first agreed to by all parties and will ultimately be useful to the customers. In accordance with NPR 7123.1, NASA Systems Engineering Processes and Requirements, Stakeholder Agreements should contain the following components:

I. A list that identifies customers and other stakeholders that have an interest in the technology development and its products;

II. A list of technology performance requirements;

III. Customer and other stakeholder expectations (needs, wants, desires, capabilities, external interfaces, and constraints, expected TRL level maturation and eventual handover) from the identified stakeholders;

IV. A set of operational concepts and support strategies based on stakeholder expected use of the product(s) over the system's life;

V. Defined stakeholder expectations in the form of acceptable statements and derived requirements that are complete sentences and have the following characteristics: individually clear, correct, and feasible; implementable; only one interpretation of meaning; and can be validated at the level of the system structure at which it is stated;

VI. A set of measures (measures of effectiveness) by which overall product effectiveness will be judged and customer satisfaction will be determined;

VII. A set of validated stakeholder expectation statements that are upward and downward traceable to reflect the elicited set of stakeholder expectations and that any anomalies identified are resolved;

VIII. Commitments from the customer and other stakeholders that the resultant set of stakeholder expectation statements and derived requirements are acceptable (this should also include status meeting commitments to ensure good communication and upfront anomaly recognition and corrective action with the customer/stakeholder throughout the technological development life cycle); and

IX. Signatures affirming the agreed to set of stakeholder expectation statements and derived requirements.
APPENDIX B. GUIDELINES FOR DEVELOPING A NON-COMPETITIVE PROJECT DIRECTED STUDY PROPOSAL

These guidelines are intended to serve as a helpful model of the contents and structure of a general, non-competitive directed study proposal. In particular cases, these guidelines should be adapted, if necessary, to fit the special needs of an individual study proposal. The proposal should be prepared in 12 font Times, 1" margins, header and footer.

Proposal Title Page

The proposal title page should provide the:
- Directed Study Title
- Originating Project
- Principal and Co-Investigators with Affiliation and Contact Information

Abstract

The abstract should be a short, succinct description of the directed study being proposed. It should be no longer than one page.

Table of Contents

The Table of Contents should provide page numbers.

Directed Study Description

This part of the proposal should provide all of the information necessary to understand and evaluate the scientific or technological aspects of the proposed study. Usually, this part of the proposal should not exceed 20 pages.

I. Specific Aims

A concise list of the specific aims of the proposed study, either as hypotheses to be tested or as expected outcomes or both.

II. Relevance of the Study to the Originating Project

An explanation of why this study is important to the Originating Project and of the rationale for carrying this study out without using a competitive research announcement.

III. Background and Significance

A summary of important previous work relevant to the proposed study and a discussion of the significance of the proposed study to the research area or to clinical and operational needs.

IV. Research Design and Methods

A detailed description of the research to be undertaken, including a discussion of the research protocol, subject issues, data collection and analysis, and statistical design.

V. References

A list of the key references cited in the text.
Management Plan

This section should specify how this study will be managed. In particular, if there are several members of the investigator team, the management plan should provide a clear description of the authority and responsibility of these different individuals.

Biographical Sketches

A biographical sketch, not to exceed two pages, should be provided for each named investigator participating in the study.

Required Service Components

If space flight or special ground analogs provided through one of the HRP Core Service Projects are needed to carry out all or part of the study, these requirements should be clearly specified in this section.

Use of Human or Animal Subjects

This section should provide appropriate evidence that the proposed study meets the appropriate requirements for human subject use (Institutional Review Board certification) or animal subject use (Institutional Animal Care and Use Committee certification).

Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Policy Directive (NPD) 7100.8E Protection of Human Research Subjects available at:


Proposers are responsible for submitting their proposals to the JSC Committee for the Protection of Human Subjects (CPCS) and having their proposal approved by the CPCS prior to submission for peer review (see the Guidelines for Investigators Proposing Human Research for Space Flight and Related Investigations, JSC 20483 Rev. C).

Supporting Budgetary Information

Budgetary detail provided in this section must be sufficient to allow evaluation of costs for realism, reasonableness, and allocation.

Other Supporting Information

This section should be used for any Appendices that provide additional information supporting the proposed study.
APPENDIX C. GUIDELINES FOR EVALUATING A NON-COMPETITIVE PROJECT DIRECTED STUDY PROPOSAL

These guidelines describe the general review criteria that would be used to evaluate a non-competitive Project Directed Study Proposal, and the general form of the resulting evaluation. However, these criteria and the form of the evaluation may be modified in specific instances due to the special nature of some individual proposals. Generally, non-competitive Project Directed Study Proposals will be reviewed by a Standing Review Panel. The Panel may choose to review individual proposals at a face-to-face meeting or through a mail review among select Panel members. However, all proposals will be reviewed by no fewer than three Panel members. If the Panel feels that it does not have the all of the specific expertise required to carry out a review, additional ad hoc experts may be added to the review team.

In general, all research proposals to NASA, including Project Directed Study proposals, are evaluated for scientific or technical merit, relevance to the NASA program or project, feasibility of implementation, and cost. The Standing Review Panel evaluation will focus on scientific or technical merit, but will include the Panel’s comments on cost. Relevance to the Project is determined by the Project Scientist and Project Manager, in consultation with the Standing Review Panel, prior to the development of the proposal. Feasibility of implementation is determined by other Project personnel prior to submission of the proposal for review.

Scientific/Technical Merit Criteria

- Clarity of the specific aims,
- Importance of the study to the originating Project,
- Innovation and adequacy of the research design,
- Appropriateness and adequacy of the research protocol, methods and procedures to acquire the data,
- Adequacy of the statistical model and of the data analysis procedures,
- Documented evidence concerning the investigators’ skills and abilities to carry out the study, and
- Familiarity of the investigators with the relevant published literature.

Evaluation Form

The Project Directed Study should be placed in one of the following categories.

Excellent (Scoring Range: 85 - 100 Points): The overall design of the Study has no major weakness that requires a revised study strategy. Weaknesses that do exist may be corrected by appropriate management action without reexamination of the approach by this Panel.

Very Good (Scoring Range: 75 - 84 Points): The overall design of the Study has one or more serious weaknesses that can be corrected by appropriate partial study redesign. Revision of one or more sections of the proposal should be followed by resubmission of those sections to this Panel for further evaluation.
Weak (Scoring Range: 0 - 74 Points): The overall design of the Study has significant weaknesses that cannot be removed without a major revision of the study design. Special advice will be provided concerning the appropriate next steps in study development.

Narrative Evaluation
The narrative evaluation should reflect the strengths and weaknesses of the Study in relation to the criteria listed above.

Cost Evaluation
The Panel will evaluate the budget plan for the Study in relation to reasonableness and reality. The comments in this section will be used in developing a final Study funding plan.

Panel Recommendations
This section will contain suggestions concerning ways to remove any weaknesses present in the Study design. These helpful suggestions are meant to serve as guidelines to the investigators, not as commands to be followed. However, if the Panel feels very strongly about certain approaches to remedying the weaknesses, that information should be transmitted clearly to the investigators.
APPENDIX D.  EXAMPLE PRE-DEFINITION PHASE WORKSHEET

This is an example of the pre-definition worksheet that provides, for potential space-flight studies, the information required to determine the feasibility of carrying out an investigation in space. This material is provided to the ISSMP for evaluation prior to final selection of a flight investigation.

1. Principal Investigator or point of contact name:
2. Investigation/Activity title:
3. Type of Study (check one):
   - [ ] Short duration; Pre/Postflight only
   - [ ] Short duration; Pre/In/Postflight
   - [ ] Long Duration; Pre/Postflight only
   - [ ] Long Duration; Pre/In/Postflight
   - [ ] Short and Long Duration; Pre/Postflight only
   - [ ] Short and Long Duration; Pre/In/Postflight

4. How many subjects are required?
   a. Short Duration:
   b. Long Duration:
   c. Ground control:

5. Provide a pre- and postflight testing schedule for baseline data collection (BDC). Include the name of the test/activity, dates required (L-X days preflight, R+X days postflight), and estimated crew time requirements in the table below. Crew time estimates should reflect the time required for testing of one subject. Identify which sessions are already components of MRIDs, and if an existing MRID is to be augmented. NOTE: Training sessions should not be included unless they are considered part of the data set.

<table>
<thead>
<tr>
<th>Preflight Test/Activity</th>
<th>Schedule</th>
<th>Crew Time (min)</th>
<th>Postflight Test/Activity</th>
<th>Schedule</th>
<th>Crew Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g., DEXA</td>
<td>L-180 and L-45</td>
<td>60</td>
<td>DEXA</td>
<td>R+6 and R+180</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>120</td>
<td></td>
<td></td>
<td>120</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL PREFLIGHT BDC</td>
<td></td>
<td></td>
<td>TOTAL POSTFLIGHT BDC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(per subject)</td>
<td></td>
<td></td>
<td>(per subject)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

D-1
7. Launches and landings of long-duration crewmembers may occur in either Russia (via Soyuz) or the US (via Shuttle). If this experiment requires long-duration crewmembers:
   a. If preflight BDC is required within 30 days of launch and/or postflight BDC is required within the first 3 weeks of landing, can these tests be performed in Russia (check one)?
      □ Yes    □ No
   b. BDC requiring test equipment in Russia will have to remain there for the duration of the experiment (only consumables and supplies will be shipped routinely). Do you have sufficient quantities of required equipment to support BDC activities at JSC, KSC, and Russia?

8. If R+0 data collection is planned, please state whether or not this is a firm requirement; i.e., what are the science impacts of delaying the session to R+1 and, if this occurs, are the objectives of the experiment compromised (i.e., will those subjects not count towards the study "n")?

9. Provide an in-flight testing schedule. Include the name of the test/activity, dates required (MD X days in-flight), and estimated crew time requirements in the table below. Crew time estimates should reflect the time required for testing of one subject; however, if an operator is required for an in-flight activity, their time should be included as well. Activities that are performed once regardless of the number of participants (e.g., set-up and stow) should be listed separately. Note that long-duration experiments with periodic activities should assume a six-month mission while short-duration experiments should assume a 12-day mission. Identify which sessions are already components of MRIDs, and if an existing MRID is to be augmented.

<table>
<thead>
<tr>
<th>Test/Activity</th>
<th>Schedule</th>
<th>Crew time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g., Experiment Protocol (per subject)</td>
<td>MD 30 and monthly thereafter</td>
<td>60 360</td>
</tr>
</tbody>
</table>

TOTAL IN-FLIGHT CREW TIME (per subject)

   a. Is real-time data transmittal either required or highly desirable? (NOTE: “Required” means that the experiment cannot be performed if downlink is not available; “highly desired” means that the experiment data will be transmitted if the downlink is available.)

   b. How critical is the timing of the in-flight sessions? Please explain any flexibilities in the schedule provided in the table above. Examples of in-flight timing requirements
that will be difficult to implement are: early in-flight (especially during the first 10 days on-orbit for any duration mission and through the 3rd or 4th week for ISS), late in-flight (for ISS), any activity that must be performed daily or weekly, and any activity requiring precisely timed operations.

10. Please list all of the flight hardware required for in-flight data collection along with the quantity required (indicate if item is for one subject, one increment, etc.) and the estimated total mass and volume for the given quantity. In the comments, provide additional explanatory information such as development status, past flight history, assumptions made when calculating quantities required, etc.

<table>
<thead>
<tr>
<th>Hardware Item</th>
<th>Qty.</th>
<th>Mass (kg)</th>
<th>Volume (m³)</th>
<th>New, Previously Flown, or On-Orbit (specify)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>E.g., Urine Collection Kit</td>
<td>5 kits/3 subj.</td>
<td>10</td>
<td>0.045</td>
<td>Previously Flown</td>
<td>Flown on ISS Increments 3-6, 8, &amp; 11-12; five kits provide supplies for three 24 hr urine collections with three subjects</td>
</tr>
</tbody>
</table>

11. If flight software is required, please answer the following:
   a. Is the software experiment-unique or commercial off-the-shelf?
   b. If it is experiment-unique, what is the status of development and who is the developer?

12. Storage of equipment and samples (for all flight experiments):

<table>
<thead>
<tr>
<th>Is temperature control of equipment/supplies needed:</th>
<th>Yes</th>
<th>No</th>
<th>Not Known</th>
<th>Temperature (°C)</th>
<th>Estimated Volume (cm³ or x number of y ml vials)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-- for launch?</td>
<td></td>
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<td>-- in flight?</td>
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<td>-- for return?</td>
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</table>
13. Can all of your flight hardware and supplies be stowed for launch at L-2 months?  
   ☐ Yes  ☐ No  
   If "No", list each item that must be late-loaded along with the L-requirement (indicate if units 
   are in hours or days):  

14. Do any flight hardware or supply items expire in two years or less?  
   ☐ Yes  ☐ No  
   If "Yes", list each item along with estimated shelf life (indicate if units are in days or 
   months):  

15. Is removal of any experiment samples, data, or equipment required less than 24 hours after 
   landing?  
   ☐ Yes  ☐ No  
   If "Yes", explain why.
APPENDIX E. RESEARCH CATEGORY DEFINITIONS

Applied Research and Development

Applied research and development activities are those research investigations and projects that are designed to provide the knowledge and data necessary to inform human health and performance standard development, as well as enable definition and validation of risk mitigation strategies. Applied research and development activities are found within the Human Health and Countermeasures, Behavioral Health and Performance, Exploration Medical Capability and Space Radiation program Elements. In addition, most of the NSBRI activities can be considered applied research and development.

Technology Development

HRP technology research consists of those investigations and projects focused on the development of new or improved technologies and capabilities. The HRP technology developments are focused on advanced technologies involved in the maintenance and management of crew health and performance. For example, equipment to manage the medical risks must be smaller and more reliable than the current state of the art. HRP technology research also seeks to develop capabilities to reduce the risk of mission impacting human performance issues. Technology research is contained within the Exploration Medical Capability and Space Human Factors & Habitability program Elements. The NSBRI also invests in these important areas.

Core Service Activities

The core services activities consist of those whose purpose is to provide a service to the investigations being carried out within the applied research & development component and the technology component. This approach allows for more efficient management of core capabilities necessary to enable the needed flight and ground research. HRP core service activities are the ISS Medical Project program Element and the Flight Analogs Project within the Human Health and Countermeasures program Element.

APPENDIX F.  TEMPLATE FOR WRITTEN DISSENTING SCIENTIFIC OPINION

The following is guidance for developing a written scientific dissenting opinion.

1. Executive Summary
Provide a half page executive summary of the report:

- Problem/Issue requiring a decision (1 sentence)
- Identify the decision makers/stakeholders (Discipline Integrated Product Team, Project Scientist, Element Scientist and other related authorities)
- Brief executive summary of the dissenting scientific opinion
- Recommendation (1 sentence)

2. Problem/Issue Description
Describe fully the data supporting the dissenting scientific argument. Provide background, history, and a high quality, accurate, clear, and relevant discussion in support of the dissenting scientific opinion. A flawed study addressing critical issues is not an acceptable alternative to a high quality study. The Issue Description should demonstrate the data being submitted in support of the dissenting scientific opinion is relevant, reliable, reproducible, and robust.

Background should consist primarily of evidence supporting the dissenting opinion, with limited assumptions, but also include the potential impacts to crew health and performance. Use the background section to outline scientific principles used in subsequent analyses or discussion. The supporting evidence included in the discussion must be organized in a concise manner to enable a clear, consistent evaluation of the data.

3. Potential Impact
Discuss the potential impacts to project, element or Program, validated safety issues, and likely outcomes if the recommendation is not accepted.

4. Recommendation
Describe the recommendation (with rationale) that is being made to the Review Authorities.

5. History of the Dissent
Provide the history of where the dissenting opinion was discussed previously. Include which boards, working groups, review panels heard the alternative point of view and what the comments or disposition of the opinion was at those previous levels.

6. References
Document all references. References may include minutes of boards and panels, e-mails, personal communications, and other correspondence discussed in Section 5.
# APPENDIX G. LIST OF ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AO</td>
<td>Announcement of Opportunity</td>
</tr>
<tr>
<td>BAA</td>
<td>Broad Agency Announcement</td>
</tr>
<tr>
<td>BDC</td>
<td>Baseline Data Collection</td>
</tr>
<tr>
<td>BHP</td>
<td>Behavioral Health &amp; Performance</td>
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<tr>
<td>CAN</td>
<td>Cooperative Agreement Notice</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>COTR</td>
<td>Contracting Officer's Technical Representative</td>
</tr>
<tr>
<td>CPHS</td>
<td>Committee for the Protection of Human Subjects</td>
</tr>
<tr>
<td>ESMD</td>
<td>Exploration Systems Mission Directorate</td>
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<tr>
<td>EVA</td>
<td>Extra-Vehicular Activity</td>
</tr>
<tr>
<td>ExMC</td>
<td>Exploration Medical Capability</td>
</tr>
<tr>
<td>HHC</td>
<td>Human Health Countermeasures</td>
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<tr>
<td>HRP</td>
<td>Human Research Program</td>
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<tr>
<td>HRPCB</td>
<td>Human Research Program Control Board</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>ISS</td>
<td>International Space Station</td>
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<tr>
<td>IWG</td>
<td>Investigator Working Group</td>
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<tr>
<td>JSC</td>
<td>Johnson Space Center</td>
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<tr>
<td>KSC</td>
<td>Kennedy Space Center</td>
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<tr>
<td>MD</td>
<td>Mission Day</td>
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<tr>
<td>MRID</td>
<td>Medical Requirements Integration Document</td>
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<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration</td>
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<tr>
<td>N.B.</td>
<td><em>Nota Bene</em> (Note Well)</td>
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<td>NASA Policy Directive</td>
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<td>NASA Procedural Requirement</td>
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<td>NASA Research Announcement</td>
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<td>National Space Biomedical Research Institute</td>
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<td>Program Requirements Document</td>
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<td>Request for Proposals</td>
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<tr>
<td>RFQ</td>
<td>Request for Quotes</td>
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<td>Space Life Sciences Directorate</td>
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