Human Research Program
Science Management Plan

December 11, 2008

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

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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 guidelines utilized in the management of the science within 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 exploration missions. HRP research and technology development is focused on the risks to astronaut health and performance with the goal of providing human health and performance countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration. The intent of the HRP Science Management Plan is to provide guidelines, rather than detailed processes, for managing the science component of the Human Research Program.

The exploration missions include 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 phased to supply appropriate deliverables in time to meet the challenges of each mission type 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.

1.2 SCOPE

The policies 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).

1.3 AUTHORITY

The *Human Research Program Plan* (HRP-47051) defines the need to document the Human Research Program science management policies in the Science Management Plan. This Science Management Plan is compliant with NASA Procedural Requirement (NPR) 1080.1A, *Requirements for the Conduct on NASA Research and Technology (R&T)* (http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR& c=1080&s=1A), NPR 5800.1, *NASA Grant and Cooperative Agreement Handbook* (http://ec.msfc.nasa.gov/hq/ grcover.htm), as updated and amended by the active *Grant Information Circulars* (http://ec.msfc.nasa.gov/hq/ gic/gic.html)~~,~~, and with NPR 7120.8, *NASA Research and Technology Program and Project Management Requirements* (http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PR_7120_0008_)

1.4 HEALTH AND MEDICAL TECHNICAL AUTHORITY

The NASA governance model defines two basic authority processes, the programmatic authority process and the technical authority process. Management of the Human Research Program falls within the programmatic authority process, as explained in the previous section. However, the HRP is strongly connected to one of the three technical authority processes, that of the Health and Medical Technical Authority (HMTA).

The NASA Administrator has assigned HMTA responsibility to the NASA Chief Health and Medical Officer (CHMO). Thus, the CHMO is responsible for the development, implementation and maintenance of standards for levels of medical care and the health status of crewmembers during spaceflight (see NPR 8900.5A *NASA Health and Medical Policy for Human Space Exploration* (http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPD&c=8900&s=5A) and OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification). NASA Standard (STD) 3001, *NASA Space Flight Human System Standard - Volume 1: Crew Health* (http://standards.nasa.gov/released/NASA/NASA_STD_3001_Vol_1.pdf

defines 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 spaceflight. *Volume II: Habitability and Environmental Health* (TBD) defines the limits on environmental factors, habitat and workspace design, and task design that will enable the crew to perform their duties.

With the goal of increasing efficiency, the CHMO has assigned responsibility for implementing an effective HMTA process in support of the International Space Station (ISS), Space Shuttle, Constellation, and Human Research Programs to the JSC Chief Medical Officer. It is the responsibility of the JSC Chief Medical Officer (CMO) to ensure technical expertise is being provided to each program/project and provide a path to escalate technical concerns outside of the program chain of command, if warranted. The JSC CMO is also responsible for ensuring support is provided to programs and projects in order to develop requirements that are in alignment with agency standards. These spaceflight health standards for human performance guide the Human Research Program with regard to the initiation and development of research which will result in high criticality applied research/technology development deliverables and inform the development of new standards or the modification of established standards.

2.0 PROGRAM RESEARCH CONTENT OVERVIEW

2.1 BACKGROUND

The Exploration Systems Mission Directorate has defined the top-level requirements for the Human Research Program in the *Exploration Architecture Requirements Document* (ESMD-EARD-08-07) as:

- NASA's Human Research Program shall develop knowledge, capabilities, countermeasures, and technologies to mitigate the highest risks to crew health and performance and enable human space exploration [Ex-0061]
- NASA's Human Research Program shall provide data and analysis to support the definition and improvement of human spaceflight medical, environmental and human factors standards [Ex-0062]

- NASA's Human Research Program shall develop technologies to reduce medical and environmental risks and to reduce human systems resource requirements (mass, volume, power, data, etc.) [Ex-0063]

The human health and performance risks associated with the EARD requirements are identified and assigned to the HRP by the Human System Risk Board (HSRB). The JSC CMO established the HSRB to ensure a consistent, integrated process is established and maintained for managing human system risks. The EARD requirements are merged with applicable HSRB human system risks to form requirements of the HRP documented in the *Human Research Program Requirements Document* (HRP-47052). Each of the defined risks is then assigned to one of the HRP's Elements (see 2.2) for appropriate action. Several actions are possible, including: development of recommendations to avoid the risk by operational rules; new research to either fill a knowledge or information gap; or development of an appropriate countermeasure to mitigate the risk. These activities are carried out as individual tasks assigned to Projects within the Element in question.

2.2 ELEMENTS, PROJECTS AND TASKS

As mentioned above, the Human Research Program's research activity is divided into distinct Elements, each of which is focused on critical areas of research and technology development or on core service activities that maximize the utilization of a common research platform. As illustrated in Figure 1, some Elements consist of a single Project and some contain multiple Projects. In the case where multiple Projects exist within an Element, cross-discipline dependencies and interactions are important, and thus the Projects must be integrated at the Element level. Integration across Elements is also essential and is the responsibility of the Program Scientist and supported by Element Scientist coordination. All research tasks in the HRP are assigned to a Project within one of the Elements; if multiple projects don't exist within an Element, then research tasks are managed directly by the Element. While funding for the NSBRI cooperative agreement is centralized through NSBRI management, NSBRI researchers communicate and coordinate with their NASA counterparts within the Elements to ensure that research is complementary and synergistic (see 2.3).

Figure 1 also shows that HRP research consists of two categories: applied research and technology development activities, and core service activities (see Appendix A for a definition of these categories). Such a categorization facilitates the definition of science management processes and allows for maximum efficiency in managing associated research activities.

The HRP Elements are:

- Behavioral Health and Performance
- Exploration Medical Capability
- Human Health Countermeasures
- ISS Medical Project
- Space Radiation
- Space Human Factors and Habitability

These Elements are described further in the *HRP Program Plan* (HRP-47051).

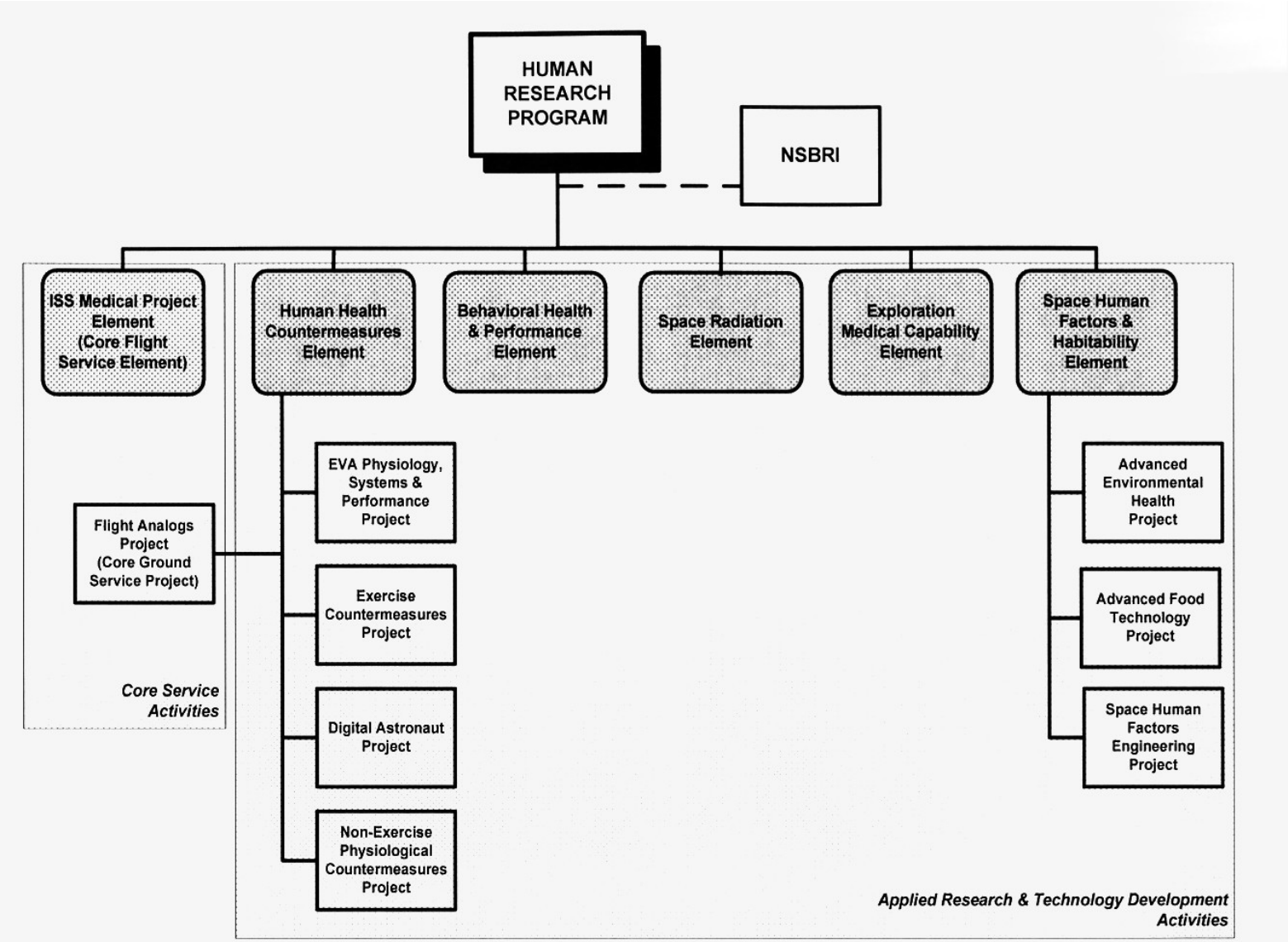

Figure 1. The general structure of Elements and Projects within the HRP. Since the Projects could change from time to time, this figure should be considered illustrative only.

2.3 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 to close knowledge, countermeasure and technology gaps in all the major discipline areas required to support space exploration. The NSBRI contributes to defining risk areas, identifying and demonstrating candidate countermeasures, developing medical technologies and maintaining 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 and will be aligned with HRP's stated goals and objectives. NASA and NSBRI are committed to maximizing the return on research investments through open communication and dialog concerning human health and performance risks.

2.4 OTHER RESEARCH ACTIVITIES CONTRIBUTING TO THE HRP

Although most of the activities of the HRP are funded by HRP, there are a few alternative mechanisms for funding research and development that contribute to the HRP. Two of these alternative funding sources are the Small Business Innovation Research (SBIR) Program and the NASA Experimental Program to Stimulate Competitive Research (EPSCoR).

The SBIR Program was established by Congress in 1982 to provide increased opportunities for small businesses to participate in research and development. The SBIR and related Small Business Technology Transfer (STTR) programs are ways to contribute to HRP's technology development activities. Additional up-to-date information about these programs is provided at http://sbir.gsfc.nasa.gov/SBIR/SBIR.html.

The NASA EPSCoR provides states possessing modest research infrastructure with funding to develop a more competitive research base within their state and member academic institutions. Nineteen states are eligible to participate in this program. For further information, see http://www.nasa.gov/audience/forstudents/postsecondary/programs/Experimental_Program_to_Stimulate_Competitive_Research.html.

3.0 SCIENCE MANAGEMENT ROLES AND RESPONSIBILITIES

As described in the *Human Research Program Plan* (HRP-47051), responsibility for HRP science management, planning, coordination and integration across the program is delegated to the Program Scientist. The Science Management Office (SMO) supports the Program Scientist in carrying out these responsibilities.

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. Project Scientists are responsible for the scientific content and direction within their

Project and Element Scientists are responsible for the scientific management, planning, coordination and integration across all Projects within their Element. Element/Project Managers are responsible for overall performance of the Element/Project, including enabling the research within their areas to occur in a timely, efficient 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 addressing Agency needs, goals and objectives.

The critical function of science management is to maintain the scientific integrity of the Program. Therefore, all research and technology development tasks are reviewed for merit prior to implementation and ongoing tasks are reviewed annually. However, if, for reasons not under the control of the investigator, an ongoing task extends beyond five years, then that task should be reviewed for merit every five years at least. The Program Scientist is responsible for the implementation of this comprehensive policy.

The HRP seeks an integrated and validated countermeasure suite to meet standards and provide deliverables that manage human health and performance risks. The products include: identification, definition and characterization of risks; maintenance of the evidence base for the risks; recommendations to the CHMO for definition and refinement of standards; products to monitor risk; products to reduce risk; and products to treat adverse health events.

NASA's core capabilities associated with understanding the effects of spaceflight on the human body are aligned by discipline. In order to evaluate and translate this discipline-based knowledge into operationally relevant research, Discipline Integrated Product Teams (see 4.3) have been formed to: (a) provide inputs to and update the current evidence base for risks within their discipline (see 5.3), and (b) develop and propose new research gaps and an alternative research strategy when new evidence warrants it (see 4.3 and 7.2). The teams contain science expertise (NASA, NSBRI and external researchers) and operations personnel, and meet as required 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 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 the scientific coordination panels (defined in Section 4), research plans (defined in Section 5), and review panels (defined in Section 7). 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

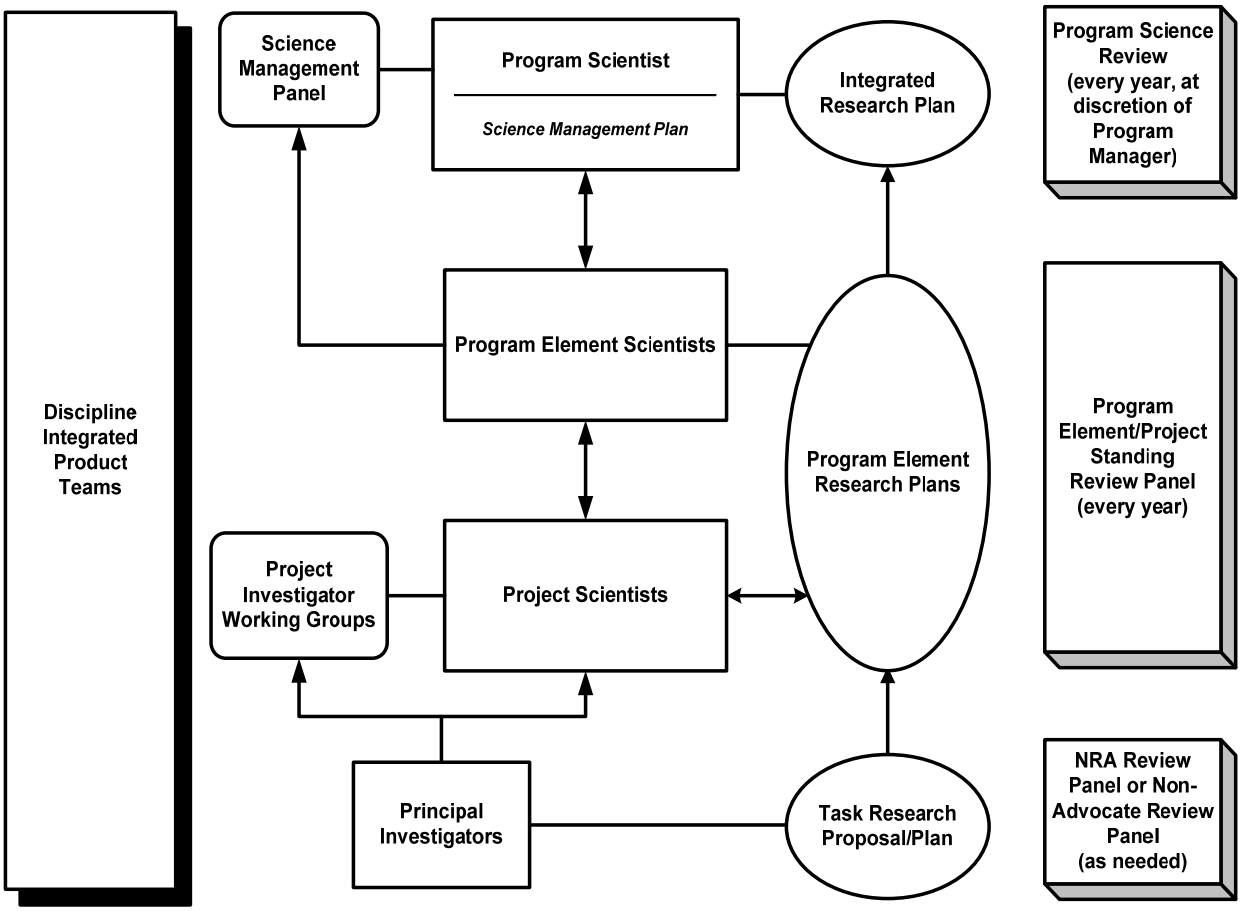

Figure 2. The general relationships among the various parts of the HRP research management, planning and review infrastructure.

Program Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences or the equivalent experience, and shall possess extensive experience in designing and conducting experiments and in managing space-flight related investigations and projects.

The responsibilities of the Program Scientist include, but are not limited to, the following duties.

Maintain the scientific integrity of the HRP:

- Based on recommendations from the HRP Project and Element Scientists and Managers, provide the Program Manager with a Program selection position on all scientific proposals that have completed the appropriate reviews
- Manage the Program's merit review system
- Chair the Science Management Panel composed of the Element Scientists and other designated members

- Work with the Element and Project Scientists to integrate science activities across the program
- Manage the Standing Review Panels (see 7.2), including the Panel's charter and membership profile and, in consultation with the Panel chair, the membership roster and service term for members
- Determine which Element should disposition any unsolicited proposals related to this Program that are submitted to NASA (if no Element is appropriate, the Program Scientist dispositions the proposal)
- Chair annual reviews of science progress (see 7.3)
- Ensure the existence of an unbiased, open process for evaluating the legitimacy of scientific dissents and supporting evidence (see 10.0)
- 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

Balance the HRP research portfolio:

- Provide the specifications for the contents of the Integrated Research Plan (IRP) and review the content submissions to assure that the IRP contains sufficient information for scientific review purposes
- Integrate among all HRP Elements to ensure that science activities are focused on the highest risks to crew health and performance in support of exploration missions and that resources are used most efficiently as science goals are obtained by eliminating redundancy
- 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

Represent HRP positions to Constellation, ESMD, OCHMO, outside organizations, etc.:

- 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
- Present HRP’s scientific program to ESMD, other governmental entities and others, as appropriate

Coordinate research activities within the HRP:

- Coordinate, with recommendations from the appropriate Element and Project Scientists, the preparation and release of any scientific solicitations necessary to carry out the HRP research program
- Manage and coordinate the schedule for Standing Review Panel activities and meetings
- Coordinate the schedule for the HRP science management reviews
- Coordinate the development, review, maintenance and publication of the HRP integrated Risk Evidence Book

- 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
- Solicit and coordinate inputs from other NASA Field Centers, as appropriate, in the execution of all of the Program Scientist's duties

Develop partnerships with the science community and international partners:

- Identify and cultivate strategic partnerships to leverage HRP capabilities in support of exploration missions
- Work with other domestic and international agencies to assure effective integration between their research activities and those of the HRP
- 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

Foster HRP science, advocating for science to organizations outside of HRP and enabling science within HRP:

- Support and coordinate, as needed, the presentation of HRP-sponsored research findings at appropriate national and international scientific and technological meetings
- Oversee the preparation of the section in the HRP Annual Report having to do with science activities of the HRP
- Compile and publish an annual publication report containing the list of HRP-sponsored research papers that have appeared in peer-reviewed journals
- Coordinate the maintenance of the HRP Task Book, an open, web-based description of all of the funded activities of the HRP
- Oversee the process used to periodically update the Human Research Roadmap and the Integrated Research Plan
- 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 DEPUTY PROGRAM SCIENTIST

The Deputy Program Scientist is responsible for assisting the Program Scientist in carrying out all of the duties of the Program Scientist and any special duties assigned to the Deputy. In particular, he/she functions as the Program Scientist in his/her absence. The

Deputy Program Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences or the equivalent experience, and shall possess extensive experience in designing and conducting experiments and in managing space-flight related investigations and projects.

3.3 MANAGER, SCIENCE MANAGEMENT OFFICE

The Manager of the Science Management Office is responsible for supporting the Program Scientist in the execution of the responsibilities above. In so doing, the Manager assigns personnel from the Science Management Office to act as the Program Scientist's representative or delegate and coordinates their activities to make certain that the work is carried out efficiently. The Manager of the Science Management Office will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences or the equivalent experience.

3.4 ELEMENT SCIENTIST

The Element Scientist is responsible for the scientific components within the Element. The Element Scientist will be a senior scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences 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 will:

- Ensure that the research carried out by the Element is organized to mitigate the high-priority, operationally-relevant risks and to develop countermeasures and/or technologies that support exploration missions
- Develop and maintain the Element Research Plan, which clearly demonstrates the integration and coordination of the various projects within the Element, or with other NASA organizations, as necessary
- Scientific integration and coordination of science performed within Element projects
- Support the meetings of an Element Standing Review Panel, if such a panel exits
- Maintain a strong liaison with the NSBRI to enable appropriate coordinated and complementary research activities by periodically conferring with appropriate NSBRI Team leadership
- Support the activities of the Discipline Integrated Product Teams
- Work closely with the Element Manager to ensure that all Element scientific or technological activities are synchronized with the Element schedule, cost, and milestones and that the Element reviews are properly supported
- Provide scientific solicitation input to the Program Scientist as needed
- Chair the Element Science Panel, where one exists, composed of the Project Scientists within the Element;

- Recommend to the Program Scientist whether any unsolicited proposals submitted to NASA and concerned with the Element's research areas are strongly relevant and, thus, should be formally reviewed for merit
- Provide approval for Project Directed Study proposals to be formally reviewed for merit and forward such approved proposals to the Program Scientist
- Conduct scientific merit reviews for the directed research that falls within the responsibility of the Element to review
- 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 with a recommendation 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
- Serve as the Element representative to the Science Management Panel.

Although the Element 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. The HRP Manager may, on the recommendation of the Program Scientist, grant an exception to this rule if the scientific project is funded and managed by a different Element, or if it is otherwise in the best interests of the Government.

3.5 PROJECT SCIENTIST

The Project Scientist is the key person managing the Project's scientific tasks and working closely with the Project Manager to ensure that all project scientific or technological research tasks are synchronized with the project schedule, cost and milestones. The Project Scientist will be a scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences 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 the Element Scientist (if applicable) and with discipline experts from the Discipline Integrated Product Teams (see 4.3) and elsewhere to execute this function.

The Project Scientist will:

- Ensure that the research carried out by the Project is directed at mitigating the high-priority, operationally-relevant risks and at developing countermeasures that support exploration missions
- Develop and maintain the Project's portion of the Element Research Plan, defining the Project's scientific goals and objectives within the Project's defined structure and schedule, and submit that information to the Element Scientist for incorporation within the Element Research Plan

- Develop an in-depth understanding of all investigations within the Project, as well as NSBRI investigations and non-HRP funded (e.g., SBIR, EPSCoR, other Federal funding sources) investigations that address the research gaps assigned to the project
- Maintain a strong liaison with the NSBRI to enable appropriate coordinated and complementary research activities by periodically conferring with appropriate NSBRI Team leadership
- Evaluate the progress that each task within the Project is making to achieve its goals and provide that evaluation to the Element and annually to the Standing Review Panel assigned to the Project (see 7.2)
- Evaluate the results and conclusions from each task within the Project to assess the impact to closing gaps or new countermeasures and provide the Project Manager, Element Scientist and Program Scientist with recommendations for additional research closing the gap(s) or transitioning technology/information/countermeasures to the appropriate operational organization
- Chair the Project IWG (see 4.2), 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 one or more Project Directed Study proposals (see 6.1.3)
- Recommend to the Element Scientist Project Directed Study proposals when they are complete and ready to be submitted for formal review
- Maintain current knowledge of all grants and contracts associated with Project milestones and deliverables
- Develop a selection recommendation for Project-related proposals after merit review, avoiding all real or perceived conflicts of interest (see 3.7), unless specific selection decisions are mandated otherwise in NASA Research Announcements

The Project Scientist may not serve as an scientific investigator within the Project to which they are assigned. The HRP Manager may, on the recommendation of the Program Scientist, grant an exception to this rule if the scientific project is in the best interests of the Government and does not compete with other funded investigators within the Project.

3.6 DISCIPLINE INTEGRATED PRODUCT TEAM LEAD

The Discipline Integrated Product Team Lead coordinates the Discipline Integrated Product Team (DIPT, see 4.3) in the periodic updating of the evidence base of research, clinical and operational information about the risks pertaining to the discipline and in the evaluation of that information. The Discipline Integrated Product Team Lead leads the development of annual recommendations concerning the discipline status and existing knowledge and research gaps by updating the evidence-based Risk Reports and by developing alternatives to the current Element/Project Research Plan when new evidence suggests that is appropriate. The Discipline Integrated Product Team Lead shall be a scientist with an advanced degree in the life or medical sciences, the social or behavioral sciences, the physical sciences, the appropriate engineering sciences or the equivalent experience in the relevant discipline, and an active, current understanding of the scientific issues related to that discipline in space and on the ground.

The Discipline Integrated Product Team Lead will:

- Coordinate and lead meetings of the DIPT throughout the year
- Develop and maintain, with the assistance of the DIPT, the current discipline evidence for health and performance risks associated with the various identified spaceflight mission types through updates of the appropriate risk report(s) contained in the *HRP Evidence Book*, HRP-47060, (see 5.4)
- Review, with the assistance of the DIPT, the available strategies to understand or minimize these risks, and the current Element Research Plan and propose specific changes to that Plan when new evidence warrants (see 4.3 and 7.2) the opening or closing of risks and gaps
- Act as the main contact and advocate for development or revision, from a research perspective, of the health and performance standard(s) related to that discipline
- Ensure that the DIPT 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
- Support the Program and Element Scientists 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 Integrated Product Team Lead may be an active investigator, and can openly compete for research opportunities within any project of the HRP. The Discipline Integrated Product Team Lead may not act as a Project Scientist for a project assigned risks and gaps in their specific discipline area. The HRP Manager may, on the recommendation of the Program Scientist, grant an exception to this rule if it is in the best interests of the Government. Discipline Integrated Product Team Leads 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-specific, evidence-based Risk Reports and suggested modifications to the Element Research Plan.

3.7 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. This includes the ability to directly determine the contents of solicitations by NASA or other Federal agencies. 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 not function as a scientific investigator within the Project
- Standing Review Panels (see 7.2) 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
- If a waiver to the above guidelines is granted by the Program Manager, the respective 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 scientist should not be involved in the evaluation or selection of any proposals in which he/she has a role

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 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 located in https://sa.jsc.nasa.gov/BPSCM/dashBoard/?boardName=SMP&action=showCharter.

4.2 PROJECT INVESTIGATOR WORKING GROUPS

If the Project Scientist decides that it is in the best interests of the Project, then the project may maintain an Investigator Working Group (IWG) composed of all of the Principal Investigators (PIs) leading the 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 carried out (NASA Field Centers, universities, non-profit research entities or for-profit organizations). The IWG, managed by the Project Scientist, is 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 Discipline Integrated Product Teams (DIPTs) in those disciplines with high relevance to the HRP's mission. These include, but are not limited to:

- Behavioral Health & Performance
- Bone
- Cardiovascular
- Immunology, Infection and Hematology
- Medical Capabilities
- Muscle
- Nutrition
- Pharmacology
- Radiation
- Sensorimotor
- Advanced Environmental Health
- Advanced Food Technology
- Space Human Factors Engineering

New Discipline Integrated Product Teams may be formed by the Program Scientist in response to an identified need of the HRP or in response to a request from an Element Scientist. The Discipline Integrated Product Team Lead (see 3.6) and a few key members of each DIPT, representing clinical and operational expertise in the discipline area, are appointed by the Program Scientist with the concurrence of the HRP Manager. The NSBRI will identify appropriate NSBRI members of each team to assure that the NSBRI is well represented in the DIPT's discussions. The Discipline Integrated Product Team Lead then identifies, with the assistance of the key members, the additional members of the team, drawn from both the intramural and extramural research community and from intramural clinical and operational groups.

The DIPTs are responsible for updating the appropriate evidence-based risk report(s) in the *HRP Evidence Book*, HRP-47060, (see 5.3) containing the current evidence base of discipline-related research data, clinical data and knowledge relevant to specific space exploration mission categories and assessing the significance of this evidence in relation to the current risks and identified gaps in knowledge.

In addition, the DIPTs will develop a proposed set of activities to address those gaps that are not being addressed adequately by the current research program. Once a year, each DIPT will examine the current Integrated Research Plan (IRP) and identify those gaps revealed by the updated evidence that are not being addressed fully. For these gaps, the DIPT will bring forward recommendations for changing the Element Research Plan and IRP, as appropriate.

It is expected that DIPT meetings or teleconferences will occur regularly throughout the year.

4.4 NASA-NSBRI STEERING COMMITTEE

In order to ensure that the activities of the NSBRI are fully integrated with the rest of the Human Research Program, a Steering Committee is established to coordinate both the acquisition and the execution of research activities between NASA and its NSBRI component. The permanent members of the Steering Committee will consist of the following:

- NASA Members from the HRP
  - Program Manager
  - Deputy Program Manager
  - Program Scientist
  - Manager, Science Management Office
- NSBRI Members
  - Chair, NSBRI Board of Directors
  - Director
  - Associate Director

Monthly meetings will be held at sites that alternate between JSC and NSBRI. Other personnel may participate in the meetings, at the discretion of the permanent members.

5.0 RESEARCH PLANS

One of the major responsibilities of science management within the HRP is to participate in the development of the different research plans by ensuring that the research content in these plans meets the HRP requirements, as documented in the *HRP Program Requirements Document* (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 requirements.

The research 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 B provides further guidelines for producing these plans.

With the support of the DIPTs, the gaps associated with the allocated program needs are developed and documented in the Element Plans and Project Plans as Element or Project requirements. Element, Project and DIPT scientists develop a research approach and notional plan to address the gaps and requirements. The notional research plan is documented as the Element Research Plan and provided as an appendix to the Element Plan.

Many of the annual activities involved in research plan development follow a schedule that is based, in large measure, on events contained in the annual cycle of activities followed by the HRP. A nominal template for that cycle is presented in Appendix C.

5.1 INTEGRATED RESEARCH PLAN

The Integrated Research Plan (HRP-47065) is a collection of most components of the five Element plans that looks across the Program to identify synergies and dependencies among the Elements. In effect, it is the 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 human-system standards for health and human performance and are addressing the complete set of risks assigned to the HRP. These standards provide a declaration of accepted medical risk from the deleterious health and performance effects of spaceflight, 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 (see Section 1.4). In addition, the standards identify spacecraft environmental and design limits that are required to sustain crew health and performance, and describe operational limits to requirements the system can impose on the crew members. Research within the HRP refines and narrows the uncertainties associated with standards and provides the evidence required to modify the standards, if necessary. Research also provides the pathway to appropriate countermeasures to mitigate risks.

Appendix B, Section B.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 led to the development of the current Program Portfolio. The HRP Control Board approves the Integrated Research Plan.

5.2 ELEMENT RESEARCH PLANS

The Element Scientist is responsible for the development and maintenance of the Element Research Plan. To accomplish this, the Element Scientist works closely with each of the Element's Project Scientists and Project Managers to develop synergy and minimize inappropriate overlap across the projects. The Program Scientist approves the Element Research Plan.

Appendix B, Section B.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 Element Research Plan should clearly demonstrate how the risks and other requirements assigned to the Element are being addressed through the research contained within the Element Portfolio.

Research within the Element is carried out by one or more clearly defined projects. The Project Scientist, in partnership with the Element Scientist, is responsible for managing the scientific tasks carried out within each project. Although stand-alone project research plans are not required by the HRP, the multiple tasks within each project must be presented clearly and fully in the Element Research Plan. This includes, but is not limited to, the risks, knowledge and countermeasure gaps that are assigned to the project, and the individual tasks designed to fill those gaps. The rationale and relative criticality of the gaps and tasks and the complete merit

review history of each of the ongoing tasks must be included, as well as the research strategy that underlies the relationship of the tasks to the gaps they are meant to fill.

It should be noted that there are two basic types of activities: applied research and technology development activities, and core service activities. Each should be addressed in the Element Research Plan. Most core service activities provide a program-level integration function to a spaceflight vehicle or flight analog and do not require separate research plans. However, if a service project contains additional cross-cutting tasks and measurements that go beyond the specific activities required by other tasks, then those additional crosscutting tasks not presented elsewhere should be included as a separate research task within the core service project. Note that the Element Research Plan should include all relevant tasks, including those carried out at JSC, at other NASA Field Centers, through NSBRI, and at universities directly funded by the HRP or other NASA funding sources.

5.3 RISK EVIDENCE BOOK

The *HRP Evidence Book* (HRP-47060) is a collection of evidence-based Risk Reports for each individual risk contained within the *HRP Program Requirements Document* (HRP-47052). The Book provides a current record of the state of knowledge from research and operations for each of the risks, written for the scientifically-educated, non-specialist reader.

5.4 HUMAN RESEARCH ROADMAP

The *Bioastronautics Roadmap* is an important reference document that captures the human system risks associated with exploration missions. 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). In the future, the document that will replace the *Bioastronautics Roadmap* will be called the *Human Research Roadmap*. This new document will be updated as needed to reflect the current state of knowledge.

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 major 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 HRP procurement process.

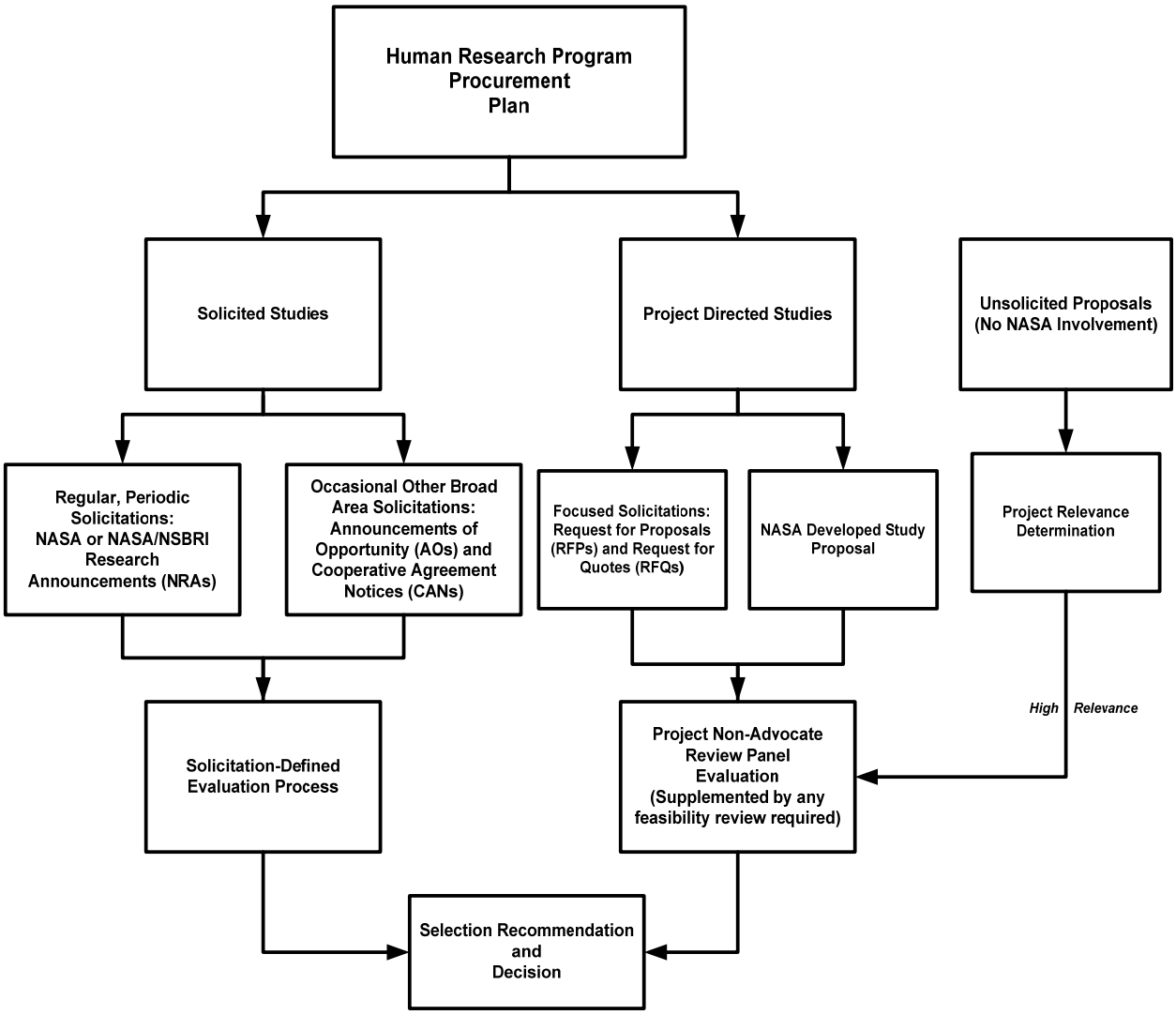

Figure 3. Human Research Program procurement process.

6.1.1 Solicited Proposals

NASA generally uses Broad Agency 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 spaceflight 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
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 Space 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.

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

- Not be an advance proposal for a known agency requirement that can be acquired by competitive methods

Note that the third item on the list above precludes NASA personnel and associated contractors from submitting "unsolicited" proposals. NASA personnel and associated contractors have other means of presenting their ideas within the HRP (see *Human Research Program Unique Processes, Criteria and Guidelines* (HRP-47069)). 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, at least one of the following criteria must be satisfied:

- Insufficient time for solicitation. In certain cases, NASA must define scientific activities in a short time (e.g., because of the emergence of new opportunities to carry out activities in space 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 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 (e.g., the research task may involve extensive operational practices and associated operational personnel who must be heavily involved in the development of the study design).

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 D and will be evaluated as described in 6.3.3 and Appendix E.

In certain cases, non-competitive proposals for directed studies that satisfy the constraints may be guided by the Project Scientist or his/her designee. However, in these cases, great care must be taken to avoid real or perceived conflict of interest and the appearance of conflict of interest in the development of such proposals (see 3.7).

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 and the "Guidebook for Proposers Responding to a NASA Research Announcement (NRA)" at 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).

6.2.3 Project Directed Study Proposal Format

The general format for Project Directed Study proposals is presented in Appendix D.

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.

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 an appropriate non-advocate review (NAR) panel. The Program Scientist reviews this material, and if it warrants approval, 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 (see Section 6.5). Following the relevance and merit reviews, the Element or Project Scientist communicates with the applicant and provides the results of these reviews.

6.3.3 Project Directed Study Proposal Evaluation

A Project Directed Study proposal must be highly relevant to the Project which requested the proposal. Such proposals will be reviewed by an *ad hoc* NAR panel managed by the Program Scientist or by a lower level review managed by the Element or Project (see *Human Research Program Unique Processes, Criteria and Guidelines* (HRP-47069) for the process that determines the level of review). Following the review, the results are provided to the Program Scientist, Element Scientist and Project Scientist and Principal Investigator. Based on the evaluations and recommendations, the proposal may be approved (Section 6.5) without alteration, with alterations addressing the proposal's identified weaknesses, or the proposal may be disapproved. Selected proposals involving human or animal subjects must subsequently receive certification by an appropriate Institutional Review Board or Animal Care and Use Committee. Subsequently, selected proposals requesting spaceflight resources must be evaluated for feasibility by the ISSMP and those requesting flight analog resources must be evaluated by the Flight Analogs Project.

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 appropriate review panel, the Project Scientist, in consultation with the Project Manager, prepares a selection recommendation, to be approved by the Element Scientist, which will include a budgetary component. Proposals requiring spaceflight must also be evaluated for flight feasibility by the ISS Medical Project (ISSMP) Element before the final selection recommendation is prepared (see *Human Research Program Unique Processes, Criteria and Guidelines* (HRP-47069) for the appropriate process). Proposals requiring a flight analog must be evaluated for feasibility by the Flight Analogs Project before the final selection recommendation is prepared. Proposals requiring use of the NASA Space Radiation Laboratory must be evaluated for feasibility by the Space Radiation Element before the final selection recommendation is prepared. In each case, 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, at least, or whenever new evidence warrants it, the Element Scientist coordinates a schedule with the Program Scientist and the Project Scientists to review each of the Discipline Integrated Product Teams (DIPTs) assessment of any new evidence available to update the evidence-based risk report(s) in the *HRP Evidence Book*, HRP-47060, with the Project, Element and Program Scientists and other personnel interested in these assessments. These assessments will focus on what that evidence means to exploration related adverse-outcome risks to human health and performance, to current gaps or uncertainties in the knowledge associated with those risks, or to 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.

7.2 ELEMENT/PROJECT SCIENCE REVIEW

The Program Scientist, with inputs from the Project and Element Scientists, will establish a Standing Review Panel for each non-service Project within every Element in the HRP. In certain cases, an Element Standing Review Panel composed of representatives of the Project Standing Review Panels within the Element may also exist to advise the Element Scientist concerning integration of the multiple projects activities. If such an Element panel exists, the review described below will begin with Element activities and then move to project activities.

The Project 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 by the Program Scientist. Each Panel will consist of (primarily external) discipline specialists, engineers and project management specialists who will serve for a fixed period of from two to four years with staggered terms. The Panel's primary responsibility is to review and comment on all scientific or technological aspects of a Project through an annual face-to-face review of the relevant sections

of the Element Research Plan (see Appendix B.2) which describe the multiple tasks within each project clearly and fully. This includes, but is not limited to the:

- Risks, knowledge and countermeasure gaps and the individual tasks designed to fill those gaps
- Rationale for and relative criticality of the gaps and tasks
- Complete merit review history of each of the ongoing tasks
- Research strategy that defines the relationship of the tasks to the gaps they are meant to fill
- Project Scientist evaluation of the scientific progress of all ongoing tasks

In addition to the Element Research Plan, the Project will supply the Panel with: (a) the limitations of the Plan, as identified by the various Discipline Integrated Product Teams (DIPTs, see 4.3); (b) one or more alternative research activities not included in the Plan and generated by the DIPTs; and (c) the Project's response to these ideas for alternative research activities.

Although the Panel should meet face-to-face at least once a year to review progress and activities of the Project, Panels may meet more frequently by teleconferences to discuss particular issues, particularly at the beginning of the Project. The annual review meetings will focus on Project strategy and tactics, as well as on a thorough discussion of the Project's future procurement plan, including the need for future specific Project Directed Studies. All of the Panel's reviews will provide not only the strengths and weaknesses of plans 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.

7.3 PROGRAM SCIENCE REVIEW

Each year, at the discretion of the Program Manager, the Program Scientist, working closely with the Element and Project Scientists, will coordinate 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 *HRP Program Requirements Document* (HRP-47052), and the gaps that remain to be addressed. This internal Program Science Review by the Program Scientist and Program Manager 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.

7.4 ANNUAL HRP INVESTIGATORS WORKSHOP

Each year, the HRP will hold an Investigators Workshop, bringing most of its investigators and managers together to communicate the results of their activities to HRP's stakeholders (space

medicine, astronauts, and NASA management) and its Agency customers (ESMD, Space Operations Mission Directorate, and Office of the Chief Health and Medical Officer).

7.5 PROGRAM IMPLEMENTATION REVIEW

Every two years, the Agency conducts an independent assessment of the HRP's continuing relevance to the Agency's Strategic Plan and its performance to the approved technical baseline, budget, schedule, and all risks and their mitigation plans. The Program Implementation Review (PIR) provides Agency management with an independent assessment of HRP's compliance with Agency management policies and procedures and readiness to continue with implementation. The PIR is designed to review the HRP's management approach, not specific scientific content.

7.6 RISK AND EVIDENCE REVIEW

At least every five years, the NASA Chief Health and Medical Officer will commission an external review of the current risks assigned to the HRP, and of the evidence that forms the basis for the risks. This review will result in a publicly available document describing the level of evidence supporting each risk and will include a discussion of human health and performance risks that exist but are not included within HRP's research activities. The document provides recommendations for the HRP to consider that may or may not be adopted by Program.

7.7 PRE-DELIVERY ACCEPTANCE REVIEW

As stated in the Program Plan (HRP-47051), the HRP will ensure validation of all HRP research and technology development deliverables, such as standards updates, new technologies, countermeasures, design models and risk projection models. The Program Scientist is responsible for conducting a pre-delivery acceptance review in order to validate a product prior to delivery to an external customer. The Program Scientist is responsible for establishing validation guidelines and approving validation plans for each type of deliverable, with support from the applicable Element Scientist. If the deliverable is identified in a stakeholder agreement, the acceptance review must verify all deliverable requirements specified in the agreement are met.

8.0 DATA MANAGEMENT

Data 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. In accordance with the National Aeronautics and Space Act of 1958, as amended, all research data gathered under the HRP will be made publicly available in a non-attributable form. HRP policy dictates this will take place within one year of the completion of data collection.

Each Element prepares and maintains an Element Data Management Plan describing how the scientific data generated within the Element are managed. This plan is a component of the Element Research Plan. The plan includes a definition of data rights and services and access to samples, as appropriate and describes 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 Element Data Management Plan will adhere to the requirements of NPD 2200.1A (*Management of NASA Scientific and Technical Information*), NPR 2200.2B (*Requirements for*

Documentation, Approval, and Dissemination of NASA Scientific and Technical Information), and NPR 1441.1D (*NASA Records Retention Schedules*), as applicable to science data.

9.0 TECHNOLOGY DEVELOPMENT PROCESS

As described in the *Human Research Program Plan* (HRP-47051), 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 technology deliverables meet the customer's requirements.

The HRP technology development process begins with the identification of technology needs and gaps. Once identified, the responsible Element or Project will perform a complete technology market analysis to identify potential sources for the technologies and the 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 associated customer 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 (TD) and infusion is a component of each specific technology plan. 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 (e.g., 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 baseline 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 F describes the general content of the Stakeholder Agreement and may be tailored to the unique needs of the project. The Element Manager will 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. The Element Manager's final selection recommendation is then submitted through the Program Scientist to the HRP Program Manager, the selecting official.

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 of this document as a part of the HRP project they are supporting. For example, the Standing Review Panel reviews all appropriate scientific or technological aspects of a Project and the Program Science Review reviews 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 regarding a risk within scope of the HRP. 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 from the scientific 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 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 DIPT reviews and/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 dissenting opinion 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. All historical information related to the dissenting opinion should be included in the written dissenting opinion 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 Program Scientist will be the final level of consideration for written dissenting opinions submitted to the Human Research Program.

The dissenting opinion in written form will be assessed using a systematic evaluation of the evidence supporting the dissent. The dissenting opinion will be evaluated for clarity, relevant supporting evidence, and credible, realistic treatment of scientific uncertainties by the Program Scientist and members of the Science Management Panel. The written dissent has the responsibility to inform the reviewers of any potential impacts to human health or performance if the dissenting scientific opinion is not investigated.

All assessments and final comments to the formal written dissent are to be completed in a timely manner, considered to be within six weeks from the acceptance of the dissent to the final 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), the rationale for the decision, the evidence and references supporting the rendered opinion, and a list of 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, he/she 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. RESEARCH CATEGORY DEFINITIONS

Applied Research and Technology Development Activities

Applied research and development activities are those research investigations that are designed to provide the knowledge and data necessary to inform system standards for health and performance, as well as enable definition and validation of risk mitigation strategies. HRP technology development activities consists of those investigations focused on the development of new or improved technologies and capabilities, including 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.

Core Service Activities

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

APPENDIX B. 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 elements or program.

B.1 INTEGRATED RESEARCH PLAN

The Program Scientist will oversee the creation and maintenance of an Integrated Research Plan that contains (at least) the following information:

- **Executive Summary**

  Provides an executive summary of the Integrated Research Plan

- **Introduction and Background**

  Provides the background and context of the HRP's research program in the context of NASA's exploration missions and describes the requirements that are HRP's responsibility

- **Element Research Plans**

  Provides a summary of the research activity within each Element. Each of the complete Element Research Plans should be referenced explicitly.

- **Risk-Related Charts**

  A series of charts presenting the information included in each of the Element Research Plans, but arranged by the specific risks being addressed rather than by Element.

B.2 ELEMENT RESEARCH PLAN

Each Element Scientist will create and maintain the Element Research Plan. This Plan should contain (at least) the information specified below. Note that the HRP may require that this information be prepared in both graphical and narrative format; instructions will be provided annually concerning the appropriate format.

- **Element Risks**

  Lists the risks assigned to the Element, describes the relevance of the assigned risks to the exploration missions, and provides the level of criticality for each risk for both the lunar and Mars mission scenarios. In addition, this section presents an overview of the various research tasks and activities related to each of the assigned risks. This section should refer to the *HRP Evidence Book*, HRP-47060 as needed to provide the evidence underlying the risks.

- **Gaps**

  Presents the knowledge or mitigation gaps for each of the Element risks and provides the rationale and level of criticality for the gaps that are identified.

- **Research Strategy**

  Provides the research plan to close the gaps and address the risk appropriately. The research plan must provide an explanation of how the gaps were identified and should clearly describe the individual research tasks required to fill each gap, the Project or other management component assigned to carry out those tasks, the product or deliverable expected to result from each task, the research platforms necessary to carry out each task, the schedule for completing the research (in relation to the key milestones for the Constellation Program), and key decision points related to possible adjustments in the research strategy. The research strategy information should include the rationale and priority of each of the individual tasks within a given Project, a complete scientific/technology merit review history of each of the ongoing tasks within each Project, the Project Scientist's evaluation of the scientific progress of each ongoing task, and a statement concerning the procurement method to be used for future tasks.

- **Data Management Plan**

  Describes the Element's Data Management Plan (see Section 8.0).

APPENDIX C. TEMPLATE FOR HRP ANNUAL CYCLE

The management activities of the HRP repeat annually because the Federal budget system follows an annual cycle, with the President's budget submission to Congress during the first quarter of each calendar year. That budget is for the next Fiscal Year (October 1 - September 30). Thus, each year, NASA must prepare a revised budget submission to the Office of Management and Budget and submit it during the third quarter of the calendar year. This means that each component within NASA, including the HRP, must prepare a revised budget during the second quarter of the calendar year. This annual cycle of budget preparation and submission defines a fixed point in the management activities of the HRP. A nominal annual cycle of related science management and procurement events is presented in Figure D-1. Note that, for simplicity, the figure does not include a second NASA Research Announcement (NRA) focusing on space radiation activities that takes place with a six-month offset from the one pictured.

This figure utilizes the following abbreviations:

DIPT - Discipline Integrated Product Team,

EM - Element Manager,

ES - Element Scientist,

IRP - Integrated Research Plan,

NRA - NASA Research Announcement,

NSBRI - National Space Biomedical Research Institute,

OCHMO - Office of the Chief health and Medical Officer,

PIO - Program Integration Office,

PjM - Project Manager,

PjS - Project Scientist,

PM - Program Manager,

PPBE - Planning, Programming, Budgeting, and Execution

PRD - Program Requirements Document,

PS - Program Scientist,

SMO - Science Management Office,

Step 1 proposals - A brief proposal submitted in response to an NRA, leading to an invitation or non-invitation to submit a full proposal, and

Step 2 proposals - A complete proposal submitted in response to an NRA following an invitation based on a Step 1 proposal.

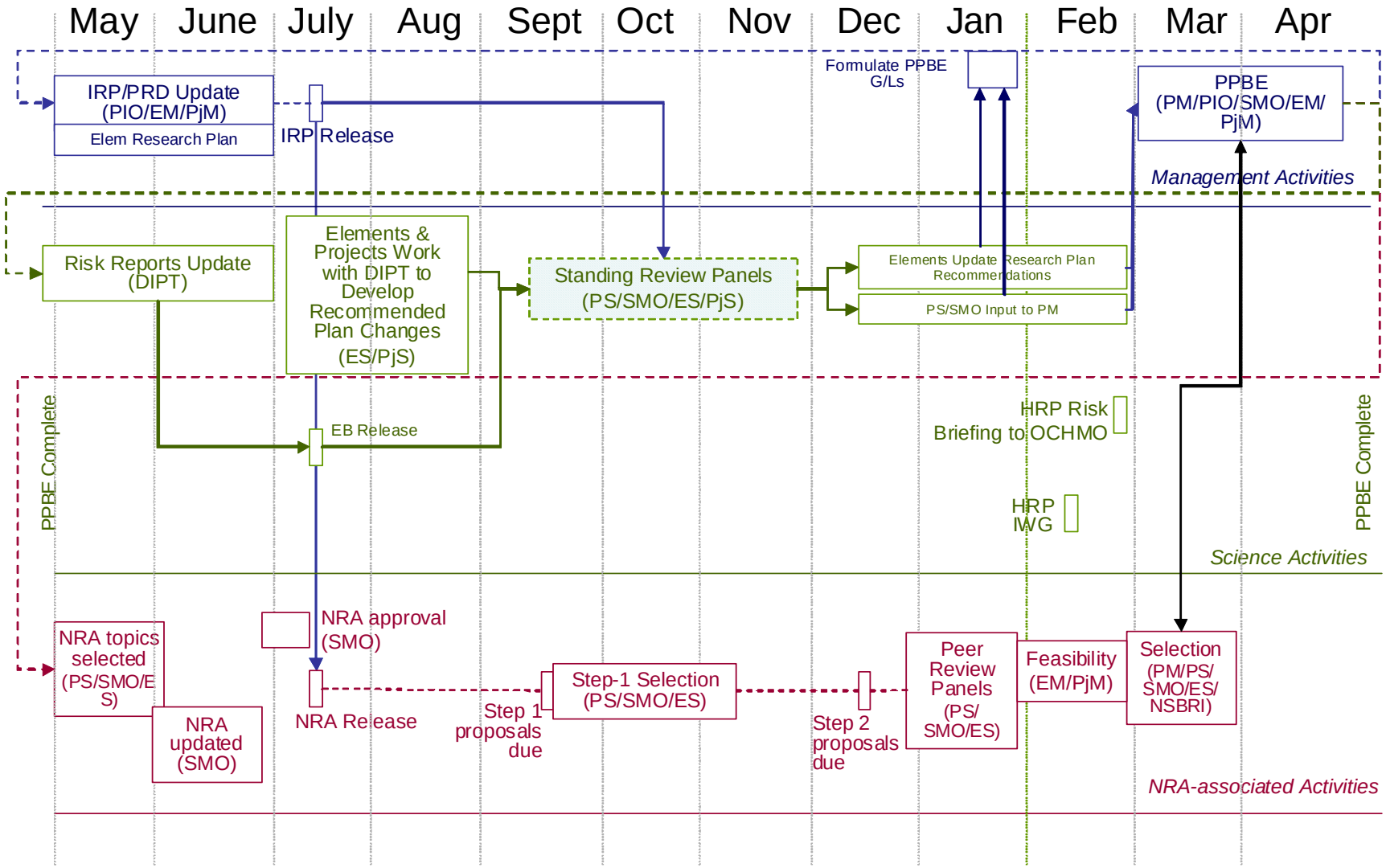

Figure C-1. Template for nominal annual cycle of events within the HRP. This is a representative template only and is subject to variation as events unfold throughout the year.

APPENDIX D. 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 in consultation with the Program Scientist, 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, and normally should not exceed 75 pages.

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 25 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 spaceflight 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 (IRB) certification) or animal subject use (Institutional Animal Care and Use Committee (ACUC) certification). Note that at Johnson Space Center, the IRB is called the Committee for the Protection of Human Subjects (CPHS).

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: http://nodis.hq.nasa.gov/displayDir.cfm?Internal_ID =N_PD_7100_008E_ &page_name=main.

Animal care and use requirements are described in the NASA Code of Federal Regulations (CFR) 1232 available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title14/14cfr1232_main_02.tpl.

If the IRB or ACUC certification is approved at the time of submission, the proposal should include a copy of the certification. If IRB or ACUC certification is pending when the proposal is submitted, the proposal should include a letter signed by the IRB and/or ACUC chair identifying the proposal by title and indicating the status of the IRB/ACUC review process at the time of submission.

Supporting Budgetary Information

Full cost 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 E. 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 Projected Directed Study Proposals will be reviewed by an *ad hoc* non-advocate review (NAR) panel especially constituted to provide a thorough review of the proposal. The NAR panel may choose to review the proposal at a face-to-face meeting or through a mail review with telephone discussions among panel members.

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 NAR 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 Project's Standing Review Panel, prior to the development of the proposal.

Scientific/Technical Merit Criteria

- Clarity of the specific aims;
- Importance of the study to the originating Project;
- 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: 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: The overall design of the Study will adequately achieve the Study's specific aims, but the study has one or more weaknesses that can be corrected by appropriate partial study redesign. The Program Scientist will determine whether revision of one or more sections of the proposal should be followed by resubmission of those sections to this Panel for further evaluation.

Good: The overall design of the Study will not adequately achieve the Study's specific aims, but the serious weaknesses can be corrected by an appropriate partial study redesign. Revision of one or more sections of the proposal must be followed by resubmission of those sections to this Panel for further evaluation.

Weak: 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 F. 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 7123.1A, *NASA Systems Engineering Processes and Requirements (* http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=7123&s=1A). 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; able to be implemented; 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 G. TEMPLATE FOR WRITTEN DISSENTING SCIENTIFIC OPINION

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

1.0 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, and
- Recommendation (1 sentence).

2.0 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.

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.

3.0 Potential Impact

Discuss the potential impacts to Project, Element or Program, validated safety issues, and likely outcomes if the recommendation is not accepted.

4.0 Recommendation

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

5.0 References

Document all references. References may include minutes of boards and panels, e-mails, personal communications, and other correspondence discussed in Section 3.

APPENDIX H. LIST OF ACRONYMS

ACD	Advanced Capabilities Division
ACUC	Animal Care and Use Committee
AO	Announcement of Opportunity
ATP	Authority to Proceed
BAA	Broad Agency Announcement
BDC	Baseline Data Collection
BHP	Behavioral Health & Performance
CAN	Cooperative Agreement Notice
CFR	Code of Federal Regulations
CHMO	Chief Health and Medical Officer
CMO	Chief Medical Officer
COTR	Contracting Officer's Technical Representative
CPHS	Committee for the Protection of Human Subjects
CSA	Customer Supplier Agreement
DIPT	Discipline Integrated Product Team
EARD	Exploration Architecture Requirements Document
EM	Element Manager
EPSCoR	Experimental Program to Stimulate Competitive Research
ES	Element Scientist
ESMD	Exploration Systems Mission Directorate
EVA	Extra-Vehicular Activity
ExMC	Exploration Medical Capability
HHC	Human Health Countermeasures
HMTA	Health and Medical Technical Authority
HRP	Human Research Program
HRPCB	Human Research Program Control Board
IRB	Institutional Review Board
IRP	Integrated Research Plan
ISS	International Space Station
IWG	Investigator Working Group
JSC	Johnson Space Center
KSC	Kennedy Space Center
MD	Mission Day
MRID	Medical Requirements Integration Document
MUREP	Minority University Research and Education Program
NAR	Non-Advocate Review
NASA	National Aeronautics and Space Administration
N.B.	*Nota Bene* (Note Well)
NPD	NASA Policy Directive
NPR	NASA Procedural Requirement
NRA	NASA Research Announcement
NSBRI	National Space Biomedical Research Institute
OCHMO	Office of the Chief Health and Medical Officer
PIO	Program Integration Office
PIR	Program Implementation Review
PjM	Project Manager
PjS	Project Scientist
PPBE	Planning, Programming, Budgeting, and Execution
PRD	Program Requirements Document
PS	Program Scientist
RFP	Request for Proposals
RFQ	Request for Quotes
RO	Requirement Owner
SBIR	Small Business Innovative Research
SLSD	Space Life Sciences Directorate
SMO	Science Management Office
SMP	Science Management Panel
STD	Standard
STTR	Small Business Technology Transfer
TBD	To Be Developed
TD	Technology Development
TRL	Technology Readiness Level