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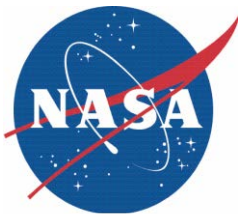

National Aeronautics and Space Administration
Johnson Space Center
Human Exploration and Operations Mission Directorate
Human Research Program
Houston, TX 77058

Human Exploration Research Opportunities (HERO)

National Aeronautics and Space Administration

NASA Research Announcement

Catalog of Federal Domestic Assistance (CFDA) Number: 43.003

NNJ15ZSA001N
NRA Issued: July 31, 2015

OVERVIEW

Proposals Due
Starting no earlier than September 4, 2015
Through no later than September 3, 2016

REFER TO APPENDICES FOR EXACT DUE DATES

Human Exploration Research Opportunities

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A. Executive Summary

This National Aeronautics and Space Administration (NASA) Research Announcement (NRA), entitled Human Exploration Research Opportunities (HERO)–2015, solicits applied research in support of NASA's Human Research Program (HRP). The HRP contains six Elements: Space Radiation, Human Health Countermeasures, Exploration Medical Capability, Behavioral Health and Performance, Space Human Factors and Habitability, and International Space Station Medical Project. Fourteen disciplines or areas support the Program: the Behavioral Health and Performance, Bone, Cardiovascular, Extravehicular Activity, Immunology, Medical Capabilities, Muscle, Nutrition, Pharmacology, Radiation, Sensorimotor, Advanced Food Technology, Advanced Environmental Health, and Space Human Factors Engineering Disciplines. The National Space Biomedical Research Institute (NSBRI) is a nonprofit organization competitively selected by NASA that uses an integrated team approach to advance biomedical research and countermeasure development. The NSBRI works in close partnership with the HRP through a Cooperative Agreement. This NRA covers all aspects of research to provide human health and performance countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration.

Awards generally range from under $100K per year for focused, limited efforts (e.g., data analysis) to $450K per year for extensive activities (e.g., development of scientific hardware) and will be made as grants. The funds available for awards in each research opportunity offered in this NRA range from less than one to several million dollars. This range allows selection from a few to as many as a dozen proposals depending on the program objectives and the submission of meritorious proposals. The period of performance for an award can range from one to five years. All categories of United States (U.S.) institutions are eligible to submit proposals in response to this NRA. Any changes or modifications to any of these guidelines will be specified in the descriptions of the relevant research opportunities in the solicited research response area appendices of this solicitation.

Details of the solicited research opportunities are given in the solicited research response area appendices of this NRA, and it is anticipated that several response area appendices will be issued throughout the year as needed. Most research opportunities will use a two-step proposal submission process, though some research opportunities may use a one-step submission process. Proposals that do not conform to the standards outlined in this solicitation will be declared noncompliant and will be handled in accordance with NASA Federal Acquisition Regulation Supplement 1815.305-70 (http://www.hq.nasa.gov/office/procurement/regs/1835.htm). Proposal due dates are given in this NRA, which will be posted at http://nspires.nasaprs.com/. Interested proposers should monitor the website or subscribe to the Human Exploration and Operations Mission Directorate electronic notifications system through their NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES) account for new research opportunities or amendments to this NRA through July 2016, at which time release of a subsequent HERO NRA is planned. Proposers should monitor Frequently Asked Questions (FAQs), posted alongside this solicitation, that will be updated periodically with questions and answers posed by potential investigators.

B. Human Research Program

1. Background

The HRP investigates and mitigates the highest risks to astronaut health and performance in exploration missions. The goal of the HRP is to provide human health and performance countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration. The scope of this goal includes both the successful completion of exploration missions and the preservation of astronaut health over the life of the astronaut.

The National Space Biomedical Research Institute (NSBRI) in Houston, Texas, is a nonprofit organization competitively selected by NASA that uses an integrated team approach to advance biomedical research and countermeasure development. The NSBRI works in close partnership with the HRP through a Cooperative Agreement. Program information for each of the NSBRI research teams is available at http://www.nsbri.org.

Two foundational documents of the HRP are the Human Research Program Requirements Document (PRD, Rev. G) and the Human Research Program Integrated Research Plan (IRP, Rev. G). The PRD lists the crew health and performance risks that the HRP must understand and mitigate. The IRP describes the plan to understand and reduce the risks. Proposers should note that the IRP is more recently updated and should be considered correct when differences are seen between the documents.

The PRD (https://www.nasa.gov/hrp/research/announcements) describes the high-level requirements that the HRP must meet. The requirements in the PRD are divided into the following three categories: (1) human system standards (PRD section 4), (2) human health and performance risks (PRD section 5) and (3) provisions of enabling capabilities (PRD section 6). Table 3 of the PRD contains Human Research Program Risks. All of the risks in the table are dynamic. New risks will likely be identified with further spaceflight experience. Other risks may be retired if they are successfully mitigated, or if increased understanding lessens their severity. The research topic areas described in the appendices of this NRA derive from the need to address crew health and performance risks articulated in Table 3 of the PRD.

The IRP describes HRP's research activities that are intended to address the needs of human space exploration and serve HRP customers. The IRP illustrates the HRP's research plan through 2025. The Human Research Roadmap (http://humanresearchroadmap.nasa.gov) is a Web-based version of the IRP that allows users to search HRP risks, gaps, and tasks.

In the past, NASA has conducted their spaceflight research on six-month missions on the International Space Station (ISS). However, starting in 2017, there will be a series of one-year missions on the ISS in addition to the six-month missions. The one-year missions will be supplemented with shorter 45-day missions. When appropriate, the proposed research should consider these different mission durations on the ISS.

2. Goals and Objectives

The goal of the HRP is to provide human health and performance countermeasures, knowledge, technologies, and tools to enable safe, reliable, and productive human space exploration. The scope of this goal includes both the successful completion of exploration missions and the preservation of astronaut health over the life of the astronaut. The following specific objectives support this goal:

1. Quantification of the crew health and performance risks associated with human spaceflight for the various exploration missions.
2. Development of countermeasures to provide mission planners and system developers with strategies for mitigating crew health and performance risks.
3. Development of technologies to provide mission planners and system developers with strategies for monitoring and mitigating crew health and performance risks.

This NRA solicits research that addresses at least one of these specific objectives.

C. Solicitation

It is critical for investigators to read carefully ALL of the instructions in this NRA. Proposals submitted in response to this NRA should be submitted to the most relevant research opportunity described in the solicited research response area appendices (see also the *Table of Contents* that prefaces this NRA). Many of the research topic area emphases are different from those that have appeared in previous NRAs. All proposals will ultimately undergo a scientific merit peer review using similar processes and procedures, but procedures and forms for proposal submission differ for each solicited research response area appendix. The eventual funding of selected proposals will vary for the different types of awards. Proposers must determine whether their proposed research is best suited to being conducted with NASA or as part of an integrated research team of the NSBRI. **Do not submit the same research proposal to more than one opportunity within this solicitation (e.g., submit either a NASA individual investigator proposal or an NSBRI team proposal)**.

1. Proposal Solicitation Process

Most research topic area opportunity appendices require that proposals be submitted using a two-step process, but some appendices use a one-step process. In the two-step process, Step-1 proposals submitted in response to this NRA will be evaluated by NASA or the NSBRI to determine how well they match one of the stated areas of emphasis identified in the solicited research response area appendices. Only the proposals that NASA or the NSBRI considers responsive to their respective areas of emphasis will be invited to submit Step-2 proposals. NASA reserves the right to act in the best interests of the Federal Government in the matter of acceptance and evaluation of all proposals. NASA HRP, NASA Space Biology (http://www.nasa.gov/pdf/541222main_10-05-17%20FSB%20Sci%20Plan-Signed_508.pdf), and the NSBRI may share Step-1 and Step-2 proposals submitted in response to this solicitation.

Investigators of Step-1 proposals submitted in response to one opportunity described in this solicitation may be invited to submit a Step-2 proposal to a different opportunity described in this solicitation. In the one-step process, proposers will submit only one proposal, which will be evaluated for merit and relevancy to HRP.

2. Solicited Research Opportunities

This NRA solicits proposals in response to the topic areas described in the following research opportunity appendices:

- **Appendix A:** NASA Research and Technology Development to Support Crew Health and Performance in Space Exploration Missions - proposals are solicited that address specific research emphases of the Behavioral Health and Performance, Human Health Countermeasures, and Space Human Factors and Habitability Elements. Unless otherwise noted, these projects are expected to be multiple- year efforts.
- **Appendix B:** NSBRI Research and Technology Development to Support Crew Health and Performance in Space Exploration Missions - proposals are solicited in the NSBRI team areas of Human Factors and Performance, Musculoskeletal Alterations, Neurobehavioral and Psychosocial Factors, Radiation Effects, and Smart Medical Systems and Technology. These projects are expected to last no more than one year.
- **Appendix C:** NASA Human Research Program Omnibus Opportunity - proposals are solicited that address any of the risks listed in the Integrated Research Plan. These projects are expected to last no more than one year.
- **Appendix D:** NASA Human Research Program Artificial Gravity Opportunity - proposals are solicited that address research emphases related to Artificial Gravity. Unless otherwise noted, these projects are expected to be multiple-year efforts.
- **Appendix E:** NASA Ground-Based Studies in Space Radiobiology - proposals are solicited in the area of Space Radiation Biology to use beams of high-charge, high-energy particles simulating space radiation at the NASA Space Radiation Laboratory (NSRL), at Brookhaven National Laboratory (BNL) in Upton, New York. These projects are expected to be multiple-year efforts.

Additional solicited proposal opportunity appendices may be issued throughout the year as needed. Investigators may submit more than one proposal in response to this NRA; **however, identical proposals may NOT be submitted to more than one solicited research response area appendix.**

3. Education and Public Outreach

Research projects funded by NASA present an opportunity for NASA to enhance and broaden public knowledge, understanding of, and appreciation for biological and biomedical research, and the value of this research in space environments. Individuals participating in NASA research projects have a responsibility to foster the development of a scientifically informed public. Therefore, all participants in this NRA are strongly encouraged to promote general scientific literacy and public understanding of biological and biomedical sciences, space environments, and NASA projects through formal and informal education opportunities.

4. Vertebrate Animal Scientific Review

NASA requires that any and all research proposals that request funding for vertebrate animal research shall be reviewed as described in the Vertebrate Animal Scientific Review (VASR) section posted alongside each applicable solicited research response area. Each response that requires vertebrate animals must address the five points outlined in the VASR. The VASR requirements are in addition to Institutional Animal Care and Use Committee (IACUC) requirements, if appropriate.

5. Sample Size Specification Guidelines for NASA Research Studies

Statistical planning plays an important role in virtually all scientific research. It plays a particularly valuable role in the design of experiments, including specification of sample size(s), and also in the analysis of outcomes that address primary aims and hypotheses. As a result, principal investigators (PI) are highly encouraged to recruit statisticians as co-investigators (Co-I), so that they can apply their skills to help produce high-quality research proposals.

The Sample Size Specification Guidelines document posted alongside this NRA gives particular emphasis to the problem of how to arrive at and justify experiment sample size(s). The recommendations are necessarily general, and may not be universally applicable. Nevertheless, these guidelines are intended to clarify an understanding among PI's, grant reviewers, and NASA pertaining to sample-size issues for NASA research studies.

It is the responsibility of the PI to propose a study that has a reasonable likelihood of detecting an effect with some clinical, operational, or scientific meaning. If applicable, the study description should include a range of possible sample sizes and their associated power. If your study is selected as a candidate for funding, you may be asked to explain or modify assumptions and calculations pertaining to sample size prior to funding determination.

6. NASA Safety Policy

Safety is NASA's highest priority. Safety is the freedom from those conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property, or damage to the environment. NASA's safety priority is to protect: 1) the public, 2) astronauts and pilots, 3) the NASA workforce (including employees working under NASA instruments), and 4) high-value equipment and property. All research conducted under NASA auspices shall conform to this philosophy.

It is the intent of NASA to implement the results of its funded research as rapidly as possible if it can have an impact on crew health and safety. To that end, NASA requests that PIs with such findings bring them to the attention of the appropriate party within the NASA Human Health and Performance Directorate as soon as possible after discovery. An example of such a finding is one in which an immediate danger to crew health is discovered, or which identifies a potentially harmful situation which could be alleviated by rapid modification of crew operations.
The appropriate person to contact will depend on the perceived severity of the finding:

Immediate danger to crew health and safety:

Jeff Davis, MD
Director, Human Health and Performance Directorate
281-483-0393
jeffrey.r.davis@nasa.gov

Terry Taddeo, MD
Supervisory Medical Officer
281-483-7041
terrance.a.taddeo@nasa.gov

Serious but not imminent concern about crew health and safety:

Mark Shelhamer, ScD
Chief Scientist, Human Research Program
281-244-7330
mark.j.shelhamer@nasa.gov

In some cases, the PI may be requested to come to Johnson Space Center (JSC) and make a presentation on the findings to the Human System Risk Board (HSRB), which assesses the status of the major risks to crew health and performance on a continuing basis. Nothing in this procedure is intended to interfere with rights to intellectual property such as publication and presentation at scientific conferences; HSRB is a closed forum not open to the public. Questions about this safety policy can be directed to Dr. Mark Shelhamer.

7. Human Genetic Research

NASA JSC requires that genetic research on human volunteers must be in compliance with JID 1800.4 that can be found at http://irb.nasa.gov/docs/nasaCPHS-JID1800_4.pdf. The purpose of these regulations is to protect the privacy and personal medical information of the individuals on whom the genetic information is obtained for research purposes.

8. Consideration of Sex as a Biological Variable

NASA expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Proposers should note that achieving an equal ratio of male to female participants for spaceflight studies may be difficult due to crew priorities and that it may be challenging to determine differences between sexes for in-flight studies due to small sample sizes. Ground-based studies should attempt to reach a more even distribution of sexes in the subjects. For both in-flight and ground-based studies, strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.

9. Availability of Funds for Award

Funds are not currently available for awards under this NRA. The Government's obligation to make award(s) is contingent upon the availability of the appropriated funds from which payment can be made, and the receipt of proposals that are determined acceptable for NASA award under this NRA.

10. Additional Funding Restrictions

The construction of facilities is not an allowed activity, unless specifically stated so in the program description. For further information on the allowability of costs, refer to the cost principles cited in the *NASA Federal Acquisition Regulations Supplement (NFS)* and the *Guidebook for Proposers (*http://www.hq.nasa.gov/office/procurement/nraguidebook/). Travel, including foreign travel, is allowed as may be necessary for the meaningful completion of the proposed investigation, as well as for publicizing its results at an appropriate professional meeting.

This solicitation will result in grant awards only. Profit to commercial organizations under grants is not allowed.

Regardless of whether functioning as a team lead or as a team member, personnel from NASA centers must propose budgets based on Full Cost Accounting (FCA). Non-NASA U.S. Government organizations should propose based on FCA unless no such standards are in effect; in that case such proposers should follow the Managerial Cost Accounting Standards for the Federal Government as recommended by the Federal Accounting Standards Advisory Board. For further information, see http://www.hq.nasa.gov/fullcost/.

11. Award Information

The selected proposal is expected to be funded as a research grant in one-year increments for activities lasting one to five years as stipulated for each solicited research response area. The mechanism for funding each successful proposal will be a single grant, with funding allocations to participating investigators based on the submitted budget, available funds and project review. The funding duration will depend on proposal requirements, review panel recommendations, and continuing progress of the activity. Proposals will be evaluated as described under each solicited research response area. Proposals to continue or supplement existing grants, if selected, will result in a new grant.

Anticipated award amounts are listed in each solicited research response area appendix. NASA does not provide separate funding for direct and indirect costs; thus, the amount of the award requested is the total of all costs submitted in the proposed budget.

D. Eligibility Information

1. Eligibility of Applicants

All categories of United States (U.S.) institutions are eligible to submit proposals in response to this NRA. Principal Investigators may collaborate with universities, Federal Government laboratories, the private sector, and state and local government laboratories. In all such arrangements, the applying entity is expected to be responsible for administering the project according to the management approach presented in the proposal.

The applying entity must have in place a documented base of ongoing high quality research in science and technology, or in those areas of science and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this NRA. Present or prior NASA support of research or training in any institution or for any investigator is not a prerequisite to submission of a proposal.

2. Guidelines for International Participation

a. Guidelines for International Team Members on U.S. Proposals

HRP welcomes international team members on U.S. proposals. International collaborations that demonstrate clear scientific benefits or cost savings are particularly encouraged.

Services and direct purchases provided by international team members are allowable as subcontracts on U.S. proposals. Additional information on international participation can be referenced at http://www.hq.nasa.gov/office/procurement/regs/1835.htm.

b. Guidelines for International Proposals

NASA welcomes proposals from outside the U.S. However, foreign entities are generally not eligible for funding from NASA. Therefore, unless otherwise noted in the NRA, proposals from foreign entities should not include a cost plan unless the proposal involves collaboration with a U.S. institution, in which case a cost plan for only the participation of the U.S. entity must be included. Proposals from foreign entities and proposals from U.S. entities that include foreign participation must be endorsed by the respective government agency or sponsoring institution in the country from which the foreign entity is proposing. Such endorsement should indicate that the proposal merits careful consideration by NASA, and if the proposal is selected, sufficient funds will be made available to undertake the activity as proposed.

All foreign proposals must be typewritten in English and comply with all other submission requirements stated in the NRA. All foreign proposals will undergo the same evaluation and selection process as those originating in the U.S. All proposals must be received before the established closing date. Those received after the closing date will be treated in accordance with NASA FAR Supplement 1852.235-72, paragraph (g). Sponsoring foreign government agencies or funding institutions may, in exceptional situations, forward a proposal without endorsement if

endorsement is not possible before the announced closing date. In such cases, the NASA sponsoring office should be advised when a decision on endorsement can be expected.

Successful and unsuccessful foreign entities will be contacted directly by the NASA sponsoring office. Copies of these letters will be sent to the foreign sponsor. Should a foreign proposal or a U.S. proposal with foreign participation be selected, NASA's Office of External Relations will arrange with the foreign sponsor for the proposed participation on a no-exchange-of-funds basis, in which NASA and the non-U.S. sponsoring agency or funding institution will each bear the cost of discharging their respective responsibilities.

Depending on the nature and extent of the proposed cooperation, these arrangements may entail:

(i) An exchange of letters between NASA and the foreign sponsor; or

(ii) A formal Agency-to-Agency Memorandum of Understanding (MOU).

NASA's policy is to conduct research with non-U.S. organizations on a cooperative, no exchange-of-funds basis. Although Co-Investigators or collaborators employed by non-U.S. organizations may be identified as part of a proposal submitted by a U.S. organization, NASA funding through this NRA may not be used to support research efforts by non-U.S. organizations at any level; however, the direct purchase of supplies and/or services that do not constitute research from non-U.S. sources by U.S. award recipients is permitted. See NASA FAR Supplement Part 1835.016-70 for additional information on international participation, which can be referenced at http://www.hq.nasa.gov/office/procurement/regs/1835.htm.

Also see NASA Policy Directive 1360.2B Initiation and Development of International Cooperation in Space and Aeronautics Programs, which is located at http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PD_1360_002B_&page_name=main

c. Assurance of Compliance – China Funding Restriction

All proposals submitted to this NRA must comply with the following: Assurance of Compliance with the Department of Defense and Full-Year Appropriation Act, Public Law 112-10 Section 1340(a); The Consolidated and Further Continuing Appropriation Act of 2012, Public Law 112-55, Section 539; and future-year appropriations herein after referred to as "the Acts", whereas:

a) NASA is restricted from using funds appropriated in the Acts to enter into or fund any grant or cooperative agreement of any kind to participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level and at all sub-recipient levels, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement.
b) Definition: "China or Chinese-owned Company" means the People's Republic of China, any company owned by the People's Republic of China, or any company incorporated under the laws of the People's Republic of China.
c) The restrictions in the Acts do not apply to commercial items of supply needed to perform a grant or cooperative agreement.

d) By submission of its proposal, the proposer represents that the proposer is not China or a Chinese-owned company, and that the proposer will not participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level or at any sub-recipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement.

d. Export Control Guidelines Applicable to Proposals Including Foreign Participation

Proposals including foreign participation must include a section discussing compliance with U.S. export laws and regulations, e.g., 22 CFR Parts 120-130 and 15 CFR Parts 730-774, as applicable to the circumstances surrounding the particular foreign participation. The discussion must describe in detail the proposed foreign participation and is to include, but not be limited to, whether or not the foreign participation may require the prospective investigator to obtain the prior approval of the Department of State or the Department of Commerce via a technical assistance agreement or an export license, or whether a license exemption/exception may apply. If prior approvals via licenses are necessary, discuss whether the license has been applied for or, if not, the projected timing of the application and any implications for the schedule. Information regarding U.S. export regulations is available at http://www.bis.doc.gov/licensing/exportingbasics.htm

3. Cost Sharing or Matching

If an institution of higher education, hospital, or other non-profit organization wants to receive a grant from NASA, cost sharing is not required. However, NASA can accept cost sharing if it is voluntarily offered. If a commercial organization wants to receive a grant, cost sharing is required unless the commercial organization can demonstrate that they are unlikely to receive substantial compensating benefits for performance of the work. If no substantial compensating benefits are likely to be received, then cost sharing is not required, but can be accepted. Acceptable forms of cost sharing are discussed in NFS 1816.303-70: http://prod.nais.nasa.gov/cgi-bin/common/wg/mfs.cgi/data/glimpse/archives/63?link=http://prod.nais.nasa.gov:80/far/far0553-nfs0463/1816.htm&file=/data/web/html/far/far0553-nfs0463/1816.htm&line=528#mfs

4. Data Management Plan

Each proposal must include a Data Management Plan (DMP) that describes how data generated by the proposed research will be shared and preserved and how data collected will be made available to the public on completion of flight and ground-control experiments. If there is a valid reason why data-sharing and/or preservation is not possible or scientifically appropriate, there must be some justification. The DMP must describe how data sharing and preservation will enable validation of results, or how results could be validated if data are not shared or preserved. DMPs must provide a plan for making all research data underlying results and findings in publications digitally accessible at the time of publication. NASA will review DMPs during the second tier review of the research proposal.

5. Data Sharing

Investigators should have an expectation of data sharing with other efforts where projects are synergistic or use the same spaceflight analog facility. Proposers should include a cost estimate to account for any anticipated data sharing. The adequacy of the data sharing plan will be considered by NASA when making recommendations about funding applications as appropriate. In making such considerations, prior to funding, NASA may negotiate modifications of data sharing plans with the PI. Any data sharing plans represent a commitment by the institution (and its subcontractors as applicable) to support and abide by the plan.

6. Study Archive

The Federal Government exercises its license rights to all data collected through research programs sponsored by NASA. See 14 C.F.R. 1260.30. Therefore, all research data resulting from NASA funded studies must be submitted to NASA. These data are then archived in the NASA Life Sciences Data Archive (LSDA) (http://lsda.jsc.nasa.gov/) for the benefit of the greater research and operational spaceflight community. Archival data products may include but are not limited to low-level (raw) data, high-level (processed) data, and data products such as calibration data, documentation, related software, and other tools or parameters that are necessary to interpret the data. Plans for archiving should be detailed in the DMP section of the NRA grant proposal. Once a grant is awarded, the PI and the supporting NASA Element Scientist shall work with LSDA to outline specific archiving requirements in an LSDA Data Submission Agreement (DSA). These requirements shall include which data are to be included, the format of the data, and the timeframe in which the data is expected to be submitted for archiving. Per 2 CFR 1800.909, the Government has the right to use and disclose all data generated from this grant:

"The Recipient grants to the Federal Government, a royalty-free, nonexclusive and irrevocable license to use, reproduce, distribute (including distribution by transmission) to the public, perform publicly, prepare derivative works, and display publicly, data in whole or in part and in any manner for Federal purposes and to have or permit others to do so for Federal purposes only."

NASA recognizes the importance of the right of first publication in demonstrating and maintaining the scientific credentials of its funded investigators. In general, NASA intends to continue its discretionary policy of allowing the funded PIs a period of one (1) year after final data collection from subjects or acquisition of final specimen in spaceflight or ground-based investigations, before making the data available to other investigators through release from the LSDA. The details and any exceptions or special circumstances of this policy will be documented in each investigation's Data Submission Agreement. However, the HRP Chief Scientist has the prerogative, at any time, to include all extant results, whether published or unpublished, in HRP's internal analyses as needed for decisions pertaining to astronaut safety, health and performance and programmatic scope and direction. These analyses will not be published within the one-year period described above unless required by law or NASA policy.

For NASA-funded projects that necessitate overlap and/or coordination of methods and measures in a shared sample, investigators must specify that a shared sample will be used and define the

data sharing measures in their Institutional Review Board (IRB) protocols and in the associated informed consents. Investigators must use any data sharing processes and forms mandated by the IRB. Investigators are expected to share flight and ground-based data with other PIs consistent with the approved protocols, upon request from a PI, and with the approval of the request by HRP. Timing of such between-investigator data sharing will happen as soon as possible after the data collection and investigators will be responsible for planning the timing and logistics of such sharing jointly, and will inform HRP of these plans prior to transferring data. IRB protocols must include language in informed consent forms notifying subjects of the potential for data sharing, language indicating the possibility of data sharing to the IRB, and any measures being requested via data sharing from other investigators. Once the investigation is complete, the full data set should be submitted to LSDA and may be released to other investigators for alternate uses.

7. Individual Researcher Reporting

a. Annual Reporting

The PI shall provide an annual written report to NASA. This report is due 60 days prior to the anniversary of the start of funding. Receipt of the annual report is a prerequisite for continued funding installments. This information will be used to assess the degree of progress of the project. A component of this annual report will be used for the NASA Space Life & Physical Sciences Research & Applications Division Task Book (https://taskbook.nasaprs.com/Publication/welcome.cfm). The Task Book includes descriptions of all peer-reviewed activities funded by the Human Exploration and Operations Mission Directorate (HEOMD). The Task Book is an invaluable source of information for NASA biological and biomedical researchers as well as the external scientific and technical communities. This information will consist primarily of:

- an abstract;
- a bibliographic list of publications;
- invention disclosures;
- a statement of progress, including a comparison with the originally proposed work schedule; and
- results of periodic data reviews

Additional reporting requirements may be added to ensure timely integration of the research or technology development into NASA.

b. Intellectual Property Reporting

The PI's institution must report each invention disclosure or patent application resulting from the grant to NASA within 60 days of investigator disclosure at https://ntr.ndc.nasa.gov.

> Submit either a hard copy of Form 1679 (see https://invention.nasa.gov/assets/downloads/nf1679.doc) to NASA Innovative Partnerships Office, Mail Code AF2, 2101 NASA Parkway, Houston, TX 77058 OR submit online at https://ntr.ndc.nasa.gov. In the field designating contract number, please cite NCC 9-58.

c. Final Report

A final report must be provided to NASA at the end of the award funding period, including a detailed listing of all peer-reviewed publications. The final report is a requirement for eligibility for future NASA/NSBRI solicitations. The information in this report will consist primarily of:

- statement of the specific objectives;
- significance of the work;
- background;
- overall progress during the performance period;
- narrative discussion of technical approaches including problems encountered;
- accomplishments related to approach; and
- an appendix with bibliography, copies of all publications and reports, and intellectual property disclosures. Any publications or other public materials containing data are particularly important to include in this section.

8. Software Sharing Policy

A software dissemination plan, with appropriate timelines, is expected in the application only if software development is a part of the application. There is no prescribed single use license for software produced through grants responding to this announcement. In accordance with federal law, NASA will protect the privacy and ownership rights of software developers. However, HRP does have goals for software dissemination, and reviewers will be instructed to evaluate the dissemination plan relative to these goals:

1. The software should be freely available to biomedical researchers and educators in the non-profit sector, such as institutions of education, research institutions, and government laboratories.
2. The terms of software availability should permit the dissemination and commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages.
3. To preserve utility to the community, the software should be transferable such that another individual or team can continue development in the event that the original investigators are unwilling or unable to do so.
4. The terms of software availability should include the ability of researchers to modify the source code and to share modifications with other colleagues. An applicant should take responsibility for creating the original and subsequent “official” versions of a piece of software.
5. To further enhance the potential impact of their software, applicants are expected to propose a plan to manage and disseminate the improvements or customizations of their tools and resources by others. This proposal may include a plan to incorporate the enhancements into the “official” core software, may involve the creation of an infrastructure for plug-ins, or may describe some other solution.

The plan for software sharing will be evaluated during peer review together with any other resource sharing plans.

The adequacy of the software sharing plans will be considered by NASA when making recommendations about funding applications as appropriate. In making such considerations, prior to funding, NASA may negotiate modifications of software sharing plans with the PI. Any software dissemination plans represent a commitment by the institution (and its subcontractors as applicable) to support and abide by the plan.

Software documentation must be turned over to NASA upon request and include any information necessary to transition the software to NASA information systems, servers, networks, etc. for use in the operations environment. The documentation must include source code and any information necessary to operate (e.g., operators manual).

9. Publications

All publications (including websites, presentations, or other electronic products) of any material based on or developed under NASA sponsored projects should conclude or begin with the following acknowledgement:

“This material is based upon work supported by the National Aeronautics and Space Administration under Grant/Contract/Agreement No. <xxxxxx>.” Except for articles or papers published in peer-reviewed scientific, technical, or professional journals, the exposition of results from NASA supported research should also include the following disclaimer:

"Any opinions, findings, and conclusions or recommendations expressed in this article <or report, material, etc.> are those of the author(s) and do not necessarily reflect the views of the National Aeronautics and Space Administration."

As a courtesy, any releases of NASA photographic or illustrative data products should list NASA first on the credit line followed by the name of the PI institution, for example,

"Photograph <or illustration, figure, etc.> courtesy of NASA <or NASA Center managing the mission or program> and the <Principal Investigator institution>."

Please note that any research publications or presentations utilizing research data from Life Sciences Data Archive (LSDA) or crew medical data from Lifetime Surveillance of Astronaut Health (LSAH) must be submitted for review to ensure that no personally identifiable information data is included. In addition, recognition of either or both of these data sources must be included in the publication’s or presentation’s acknowledgments section if not otherwise included in the document.

HRP requires public disclosure of the results of its sponsored research within one year of the grant completion and, therefore, expects significant findings from supported research to be promptly submitted for peer reviewed publication with authorship(s) that accurately reflects the contributions of those involved. For all funded projects, HRP requests but does not require that scientific manuscripts prepared under HRP or NSBRI support be sent to the office of the HRP Chief Scientist before submission for publication. This is to determine if there may be inadvertent release of identifiable crew information, to identify synergies between projects, and

to track program status. It will not be used to otherwise control the content of such manuscripts. In addition, any published manuscript funded by HRP should be submitted to the HRP Chief Scientist or his designee within one month of publication.

10. Other Considerations

Required Travel
The proposal must include travel costs for the following: Annual NASA Human Research Program Investigators' Workshop. All NASA and NSBRI PIs are required to attend this workshop usually scheduled for February of each year in the vicinity of Houston, Texas.

Optional Travel
Visits to JSC
Presentation at a professional society meeting (highly desirable)

E. Proposal Information

1. Types of Research Environments

Ground-Based, Analog Definition, Flight Definition

Proposals selected for support through this NRA will be designated as either: 1) ground-based, 2) analog definition, or 3) flight definition. Commitment by NASA to proceed from analog definition or flight definition to the execution phase will be made only after additional engineering and feasibility assessments have been performed.

Proposals that use appropriate non-human experimental models will be considered, for solicitations, if the proposer can demonstrate that the approach will accelerate the achievement of one or more of the three HRP program goals enumerated in section B.2 or if it will enable the achievement of one of the goals entirely without the use of human subjects.

Proposers who wish to use a facility that is not under their direct control must submit with their proposal application a letter from the respective facility manager or organization manager that states the following:
1. The PI has permission to use the particular facility.
2. The PI will pay the respective organization for the use of the facility. The cost of the facility should be included in the letter as well as in the proposal budget.

a. Ground-Based

Investigations that do not propose to use analog facilities or to conduct flight studies are referred to as ground-based proposals in this solicitation. Investigators offered support for a ground-based study addressing topics in Section II or Section III of this solicitation will normally be expected to provide results useful to NASA after no more than three years for NASA and NSBRI awards.

If additional research is necessary to obtain results, the investigator will be required to submit a new proposal for competitive renewal after no more than three years of support from a NASA or NSBRI award. Such follow-on proposals may be ground-based (with or without use of analog facilities) or flight-based.

b. Analog Definition

Proposals that propose to use spaceflight analog facilities, but not flight resources, are referred to as analog definition proposals in this solicitation. Analog definition investigations must represent mature studies strongly anchored in previous ground-based research or previous analog research and must be thoroughly justified.

Additional information for analog definition proposals will be collected through an Analog Study Resource Worksheet as part of the proposal upload. This worksheet is required for a complete Step-2 proposal. It is very important that this information be clear and accurate as it will be used to determine the feasibility of implementing the experiment. Examples of such information for are: number of subjects required from an appropriate power analyses, age of subjects, gender composition of sample, physical characteristics of subjects.

Selected proposals will enter a definition period usually lasting between three to 12 months, depending on the complexity of the experiment. During this definition period the detailed experiment requirements of the proposal and implementation approaches and options are prepared in cooperation with an assigned representative from the HRP. In addition, where appropriate, NASA and the NSBRI reserve the right to form teams of investigators whose experiments have compatible requirements for human subjects, specimens, operations, data, and treatment and sharing of biological samples. A selected investigator who becomes a member of a research team will be required to work with other team members to develop an integrated set of objectives that can be met within fiscal and analog resource constraints. Development of this integrated approach may result in modification, transfer, or deletion of some objectives put forth in an individual proposal. Specifics associated with the definition period will be addressed with the investigator at the time of selection.

Selection for definition neither assures an analog study, nor continued funding beyond the definition period. Investigations selected for analog experiment definition must successfully complete subsequent development steps to be considered for an analog assignment. NASA and NSBRI do not guarantee that any investigation selected for definition will advance to analog experiment status. Commitment by NASA and the NSBRI to proceed from analog definition to the execution phase of an analog experiment will be made only after several additional engineering and scientific reviews and project milestones have established the feasibility and continued relevance of the proposed experiment.

Analog experiments will also be reviewed periodically for continued relevance, availability of analog opportunities and implementation feasibility. These reviews may result in a decision by the appropriate Selection Official to discontinue an analog experiment before its implementation or completion.

c. Flight Definition

Any proposal, selected either by NASA or the NSBRI, which proposes to use NASA flight resources, is referred to as flight definition proposals in this solicitation. Flight definition investigations must represent mature studies strongly anchored in previous ground-based research or previous flight research and must be thoroughly justified. Two types of flight experiments are germane for this solicitation:

1. Research performed on long duration human subjects prior to and on return from space; and
2. On-orbit experiments that can be implemented on the ISS.

Additional information for flight definition proposals will be collected through a Flight Experiment Resource Worksheet as part of the proposal upload. This worksheet is required for a complete Step-2 proposal. The information requested includes number of subjects, pre/in/post-flight testing and crew time requirements, flight hardware requirements, cold stowage requirements, etc. It is very important that this information be clear and accurate, as it will be used to determine the feasibility of implementing the experiment.

Selected flight definition proposals will enter a definition period usually requiring six to twelve months. During this definition period the detailed experiment requirements of the proposal and implementation approaches and options are prepared in cooperation with an assigned representative from the HRP. In addition, where appropriate, NASA reserves the right to form teams of investigators whose experiments have compatible requirements for human subjects, specimens, operations, data, and treatment and sharing of biological samples. A selected investigator who becomes a member of a research team will be required to work with other team members to develop an integrated set of objectives that can be met within fiscal and flight resource constraints. Development of this integrated approach may result in modification, transfer, or deletion of some objectives put forth in an individual proposal. Specifics associated with the definition period will be addressed with the investigator at the time of selection.

Selection for definition neither assures a flight opportunity, nor continued funding beyond the definition period. Investigations selected for flight experiment definition must successfully complete subsequent development steps to be considered for a flight assignment. NASA and the NSBRI do not guarantee that any investigation selected for definition will advance to flight experiment status. Commitment by NASA to proceed from flight definition to the execution phase of a flight experiment will be made only after several additional engineering and scientific reviews, and project milestones have established the feasibility of the proposed experiment.

Once an experiment is selected for flight implementation, it will be also reviewed periodically for availability of flight opportunities and implementation feasibility. These reviews may result in a decision by the Selection Official to discontinue a flight experiment before its implementation or completion.

Flight definition proposals must be compatible with the operational constraints and capabilities of the spaceflight environment, as well as the Soyuz landings. There are certain human life sciences experimental requirements that, while not impossible to perform, are difficult to

implement. Investigators should consider these limitations when developing their experiment protocols, knowing that technical feasibility is an important part of the overall assessment. The Flight Experiment Resources Worksheet posted alongside this NRA (http://nspires.nasaprs.com/external/) specifically addresses several of these requirements, and investigators should fill this out carefully and thoroughly in order for technical reviewers to better understand the experiment's requirements.

Those requirements that may be difficult to accommodate include:

1. Any new flight hardware required. The extent of how difficult this development will be is dependent on how much design and development is required for custom made equipment and how extensive off the shelf equipment will have to be modified.
2. Return of hardware for refurbishment or data retrieval. Down mass resources will be protected for critical science samples; data should be planned to be downlinked and hardware will likely be discarded.
3. Requirements for cold stowage that exceed the capabilities of the equipment identified on the cold stowage website. Experiment unique refrigerators or freezers will not be developed.
4. Studies requiring more than twelve subjects.
5. Studies requiring overly invasive or complicated procedures that may hinder crew consent.
6. Total pre-flight Baseline Data Collection (BDC) requirements of more than 10 hours per subject.
7. Single BDC sessions requiring more than two hours per subject.
8. More than two hours of BDC per subject required within three months of launch.
9. BDC testing requirements within two months of launch.
10. In-flight procedures that require a high degree of proficiency and training prior to crewmember launch (e.g., requires more than three, two-hour sessions for one unique procedure or skill; requires refresher session within 60 days of launch).
11. Two or more hours of testing required per subject within the first three days of landing.
12. More than three hours of total testing per subject in the first week post-flight.
13. Strenuous or provocative sessions on Return Day (R)+0 or R+1. Any activity that could be considered strenuous or provocative for a healthy normal subject may not be feasible for crewmembers in this time frame.
14. Complicated in-flight sessions before the second week in-flight (e.g., requires set-up of multiple pieces of equipment, followed by testing session of more than an hour; sessions that require privatized voice or video).
15. More than five complicated in-flight sessions involving multiple pieces of equipment. (e.g., requires set-up of multiple pieces of equipment, followed by testing of more than two to three hours, requires extensive privatized resources).
16. A single session with one crewmember requiring four hours in one day.
17. Crew activity that must be performed daily or more than once a week.
18. Very precise or inflexible timing requirements for sessions (e.g., +/- window for testing of less than one week, multiple timed blood draws, sessions that are linked to other crew

activities like eating, Extravehicular Activity (EVA), etc.). Note that occasional fasting data collections upon crew wake up are not difficult to implement.

19. Extended, continuous activities over multiple days that could interfere with other operations.

The HRP Flight Experiment Information Package posted alongside this NRA (http://nspires.nasaprs.com/external/) provides detailed information on these constraints as well as a description of the unique aspects of the evaluation and selection process for flight experiments. Proposals that require spaceflight equipment, facilities, or other resources not identified in this NRA or in the accompanying HRP Flight Experiment Information Package will have a lower priority for selection.

d. Special Matters

For proposals employing animals, assurance of compliance with animal care and use provisions is required. In addition, the application must include a statement from the applicant institution certifying that the proposed work will meet all Federal and local human subject requirements and animal care and use requirements.

Animal use and care requirements are described in Title 14 of the Code of Federal Regulations (CFR) 1232 (http://www.ecfr.gov/cgi-bin/text-idx?SID=0f9ead361196e5c93e16529a88b785f2&mc=true&node=pt14.5.1232&rgn=div5).

NASA utilizes a just-in-time practice for approval of the use of human subjects or animals. If the Institutional Review Board (IRB)/ Institutional Animal Care and Use Committee (IACUC) certification is already approved at proposal submission, attach a copy of the certification as part of the proposal.

After award, a statement must be provided from the Applicant institution which identifies the selected proposal by name and which certifies that the proposed work will meet all Federal and local requirements for human subjects and/or animal care and use. This includes relevant documentation of IRB approval and/or IACUC. NASA will require current IRB and IACUC certification prior to each year's award.

2. Types of Research Products

The three types of objectives listed in section B.2 of this document give rise to three types of research products. If applicable for the specific research topic, proposers will identify, through answers to questions prompted by NSPIRES, which of the three types of research products best characterizes the proposed research:

1. For the quantification of a crew health and performance risk objective, the research product should define the likelihood or the consequence of a risk more completely. Such proposals must specify how much the uncertainty in the likelihood or the consequence of the risk is anticipated to be reduced by the proposed research.

2. For the countermeasure development objective, the research product should be a

countermeasure to mitigate a risk, or reduce the impact of a risk factor, or reduce the resources required to mitigate a risk. Such proposals must specify the Countermeasure Readiness Level (CRL) at the beginning of the proposed work and the anticipated CRL at the conclusion of the proposed work.

3. For technology development objective, the research product should be a technology to mitigate a risk, reduce the impact of a risk factor, or better define a risk or risk factor. Such proposals must specify the Technology Readiness Levels (TRL) at the beginning of the proposed work and the anticipated TRL at the completion of the proposed work.

a. Countermeasure Readiness Level

A countermeasure is any means or procedural strategy that prevents or reduces the negative effects on crew health or performance or facilitates recovery upon return to Earth. The astronaut corps is diverse, comprised of men and women 30-60 years of age and of various ethnic backgrounds. Countermeasures should be robust enough to be efficacious across this population, but also be flexible enough to be tailored for individual specificity.

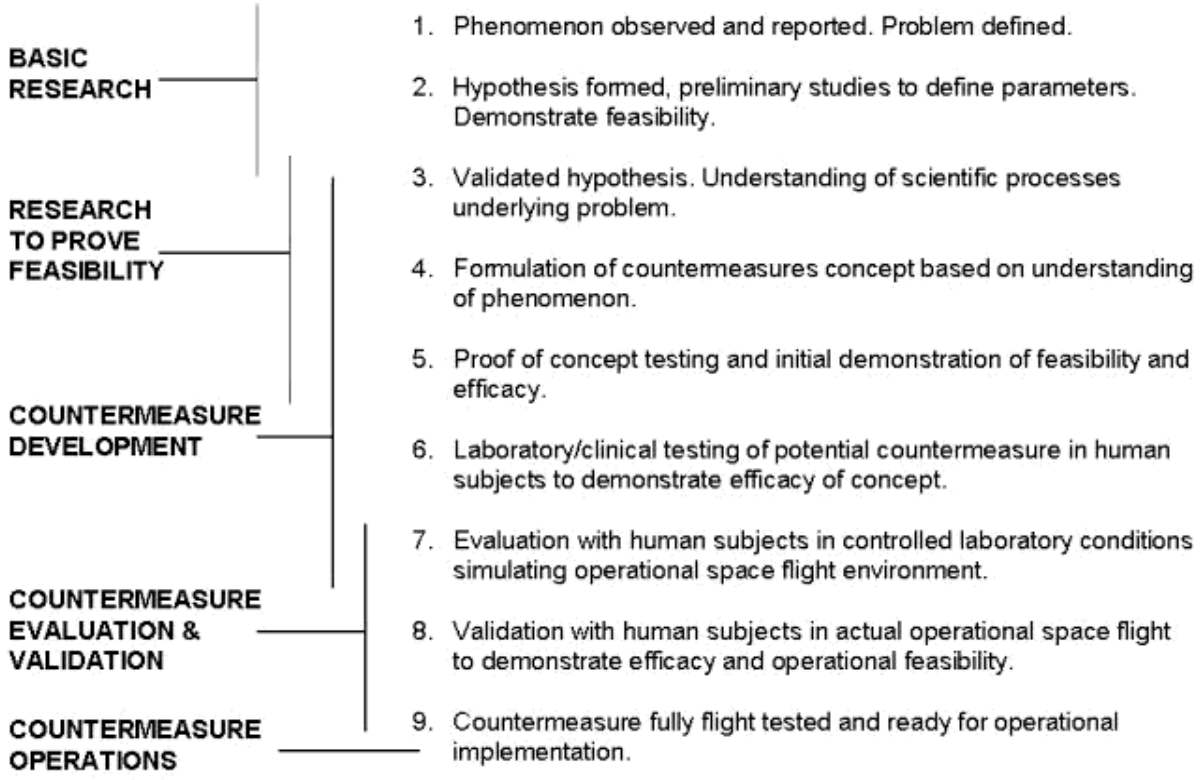


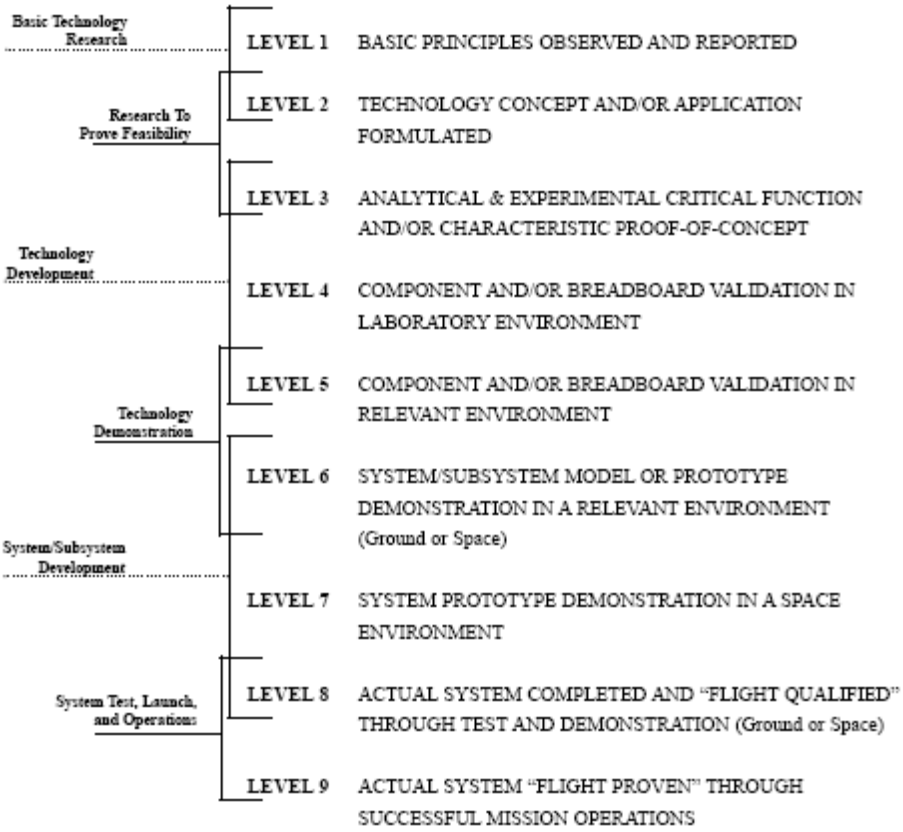
Figure 1. Countermeasure Readiness Levels

NASA has developed a scale to allow it to define, assess, and quantify the level of "countermeasure readiness." The use of this scale allows Program Managers to determine and describe how each funded research project fits into the countermeasure development "pipeline"

and to monitor progress in countermeasure development. Each investigator must examine and understand the CRL scale and specify in the proposal the CRL that will result from the funding and conduct of their proposed research. Figure 1 illustrates the CRL scale, which describes the level of scientific maturity of research ranging from the fundamental studies that suggest potential countermeasures to studies that allow the systematic evaluation and validation of countermeasures prior to operational implementation.

b. Technology Readiness Level

Within NASA strategy, nine TRLs have been defined, ranging from the basic physical principles to a "flight-proven" system. The figure below provides these definitions. Typically, the goal is to take technology to TRL 6 after which it can be picked up and used in an exploration mission. Each investigator must examine and understand the TRL scale and specify in the proposal the TRL that will result from the funding and conduct of their proposed research. Figure 2 illustrates the TRL scale.



F. Proposal Review Information

1. Evaluation Criteria

Evaluation by the panel review will be used to assess each proposal's intrinsic scientific and technical merit, its relevance to NASA's stated objectives, statistical plan, and its cost realism. See Appendix C.2 of the *NASA Guidebook for Proposers* for further discussion of these criteria and their relative weights. The evaluation criteria include factors evaluated by peer reviewers, as well as programmatic factors evaluated by NASA program personnel. Note the following specific points:

- The solicited research response areas may give specific factors, based on the solicited research objectives, which will be considered when evaluating a proposal's science and/or technical merits and/or its relevance to program objectives.
- Relevance will be judged in part by the proposal's focus on specific strategic and science objectives for that HERO solicited research response area, as given in the NRA. This focus on relevance to the call, rather than NASA's broader goals, supersedes any instructions in the *Guidebook for Proposers.*
- Cost data for U.S. proposals will be evaluated both by peer review (for cost realism and cost reasonableness) and by NASA program personnel (for total cost and comparison to available funds). Proposers must follow the budget requirements in Section 2.3.10 of the *NASA Guidebook for Proposer*. In evaluating the cost reasonableness of the proposals, reviewers will assess whether the proposed level of effort (i.e., labor Full Time Equivalents (FTE)) and the proposed other direct costs (i.e., supplies, equipment, travel) are commensurate with those required to accomplish the goals of the investigation.
- Neither the existence of proposed voluntary cost sharing nor the lack thereof, or the magnitude of such cost sharing will be used as evaluation criteria or as a precondition for award. If voluntary cost sharing is proposed, the proposer should describe, in detail, any proposed cost sharing arrangements.

2. Review and Selection Processes

Review of proposals submitted to this NRA will be consistent with the general policies and provisions given in Sections C.1 through C.4 of Appendix C of the *NASA Guidebook for Proposers*, and selection procedures will be consistent with the provisions of Section C.5 of that document. For some solicited research response areas, the desire to achieve a balance of efforts across the solicited program objectives may play a role in the selections, taking into account not only the new proposals of merit that are suitable for selection, but also those that seek an extension of activities initiated through previous but now concluded selections, i.e., "successor" proposals.

Unless otherwise specified, the HRP Manager (or his/her delegate) is the Selection Official for NASA Appendices. Unless otherwise specified, the NSBRI Director (or his/her delegate) is the Selection Official for NSBRI Appendices.

3. Selection Announcement and Award Dates

NASA's goal is to announce selections within 150 days of the final proposal due date. In order to announce selection decisions as soon as is practical, even in the presence of budget uncertainties, the Selection Official may decide to defer selection decisions on some proposals while making selection decisions on others. If a Selection Official uses this option, then proposals will be selected, not selected, or not selected at this time. Proposals that are not selected at this time will be considered for a supplemental selection when circumstances allow. All proposers whose proposals are not selected at this time will eventually be notified whether their proposal is selected through a supplemental selection or is no longer being considered for a supplemental selection. Proposers will be notified via NSPIRES and offered a debriefing consistent with the policy in Section C.6 of the *NASA Guidebook for Proposers*.

4. Ombudsman

A NASA ombudsman has been appointed to hear and facilitate the resolution of concerns from proposers during the pre-award and post-award phases of this solicitation. When requested, the ombudsman will maintain strict confidentiality as to the source of the concern. The existence of the ombudsman is not to diminish the authority of the selecting official. Further, the ombudsman does not participate in the evaluation of the proposals, source selection process, or the adjudication of formal disputes. Therefore, before consulting with an ombudsman, interested parties must first address their concerns, issues, disagreements, and/or recommendations to the contracting officer for resolution.

If resolution cannot be made by the contracting officer, interested parties may contact the installation ombudsman, Perri Fox, 2101 NASA Parkway, Houston, TX, 77058, 281-483-3157, E-mail perri.e.fox@nasa.gov. Concerns, issues, disagreements, and recommendations which cannot be resolved a the installation level may be referred to the NASA ombudsman, Ron Poussard, Director of the Contract Management Division, at 202-358-0445, fax 202-358-3083, E-mail agency-procurementombudsman@nasa.gov. Please do not contact the ombudsman to request copies of the solicitation, verify due date, or clarify technical requirements. Such inquiries shall be directed to the contacting officer as specified in Section H of this document.

G. Research Resources

1. Current Research Portfolios for NASA and NSBRI

Investigators are encouraged to review summaries of currently funded NASA and NSBRI research by accessing the NASA Task Book at http://taskbook.nasaprs.com/peer_review/index.cfm and the NSBRI website at http://www.nsbri.org/SCIENCE-and-TECHNOLOGY/. In order to achieve programmatic balance, specific topics that are currently well represented in the scope of NASA or the NSBRI research may be de-emphasized.

2. Biomedical and Biological Data Archives

Access to NASA's human and animal life sciences data can assist the research community in providing a better understanding of the appropriate strategies required to mitigate spaceflight-related health risks. These archives include data collected on the astronaut corps as part of medical evaluations and research studies. Researchers who are awarded a grant may submit more detailed data requests for retrospective astronaut data. These requests are evaluated on a case-by-case basis and data are preferentially provided in grouped or de-identified format; however, not all types of data are able to be deidentified. Identifiable (attributable) human medical and research data are only available with the informed consent of the astronaut.

GeneLab Database
Because omics experiments will generate large data sets, NASA will create special omics data archiving tools where the results of investigations generating such data will be placed to insure that in the future, all such biological data can be compared across as well as within species. This data repository will enable sharing and understanding of such data across experiments to enhance the biological science derived from flight opportunities. NASA will work with selected investigators to provide access to the database and tools that it is developing.
Depending on the nature of the data generated, researchers will be contacted by NASA personnel to discuss archiving of project data or providing specimens from the experiments for the broader GeneLab science campaign. For more information, please contact GeneLab at http://genelab.nasa.gov/

Research Data: Life Sciences Data Archive
The Life Sciences Data Archive (LSDA) (http://lsda.jsc.nasa.gov/lsda_home.aspx) is a publicly accessible archive of data from NASA-funded spaceflight, flight analog and ground-based life sciences research experiments. This searchable database includes human (astronaut and ground test subject), animal and plant studies conducted from 1958 to the present. It contains over 2,200 experiment descriptions, and non-attributable data for many investigations that can be downloaded directly from the website.

Additional information on and inquiries about the LSDA data can be made online at: http://lsda.jsc.nasa.gov/common/dataRequestFAQ.aspx or by email at jsc-lsda@mail.nasa.gov

Medical Data: The Lifetime Surveillance of Astronaut Health Project
The Lifetime Surveillance of Astronaut Health (LSAH) (http://lsda.jsc.nasa.gov/lsah_home1.aspx) is a proactive occupational surveillance program for the astronaut corps to screen and monitor astronauts for occupational related injury or disease. The LSAH program examines the incidence of acute and chronic morbidity and mortality of astronauts, and defines the risks of morbidity and mortality associated with the occupational exposures encountered by astronauts. Data associated with the LSAH project includes clinical, mission, and occupational health information recorded throughout each astronaut's career as a NASA astronaut or payload specialist and LSAH physical examinations after retirement from the astronaut corps.

Limitations of the Data: The primary goal for collecting these data is for clinical purposes, rather than for a research study. The data content is driven by crew surgeon need for care of a patient.

Therefore the data may contain numerous gaps compared to a research data set. For example, the data may list outcome (e.g., "normal") rather than a specific value; the data may not always be collected for each crew member, or at an expected time point, or the data may be taken under different circumstances (e.g., an astronaut returning on a Soyuz may have different types of tests or test dates than an astronaut returning on a Shuttle). Several types of clinical data (e.g., ultrasonography, vision testing, MRI, etc.) require special qualifications to interpret, and thus research teams should include personnel with the requisite expertise before data may be released.

Information about the medical requirements (MR) for both short-duration and long-duration human spaceflight is available online at http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.aspx

Additional information on and inquiries about the LSAH data can be made online at: http://lsda.jsc.nasa.gov/common/dataRequestFAQ.aspx or by email at jsc-lsah@mail.nasa.gov

3. Bio-specimen Sharing Program

Animal bio-specimen sharing provides the scientific community with access to NASA's inventory of biological materials from organisms that have flown in space or from related ground control studies. Make inquiries about questions or visit the Frequently Asked Questions about Bio-specimens at http://lsda.jsc.nasa.gov/common/dataRequestFAQ.aspx
Search: For specific information regarding which samples are still available, characteristics of each mission from which the samples were obtained, experimental conditions used to obtain and preserve the samples, and protocols (e.g., diet, light/dark cycle, housing, fixation, storage, etc.) visit the LSDA website at http://lsda.jsc.nasa.gov

4. Spaceflight Microbial Isolates

NASA scientists have continuously performed routine environmental monitoring of the air, surfaces and water systems of the ISS. Surface sample collection began in 2000 (Expedition 1), air sample collection began in 2001 (Expedition 2) and water monitoring of the U.S. water potable system has occurred since the instillation of the potable water dispenser in 2009. Samples are collected and enumerated during spaceflight operations. Identification of these isolates occurs on samples returned to the ground-based laboratory. For the purposes of this NRA, the NASA Microbiology Laboratory has several isolates collected and identified during the microbial monitoring efforts available for research evaluation. The organisms have been identified as either being collected from Air and Surface or the Potable Water Dispenser. Several types of microorganisms have been identified multiple times during sampling and are available for evaluation as a time course indicated as early, mid, and late in the life of ISS. Table 1 lists the organisms available including the location of collection and the time course availability. It is important to note that microbial identifications were performed during ground processing of samples returned from spaceflight and nominal identification procedures included molecular (16S) methods. Further characterization was not performed.

Table 1: Microorganisms collected during spaceflight operations available for selected research

Organism	Location Isolated	Time course
Staphylococcus aureus	ISS Air and Surface	Early ISS, Mid ISS, and Late ISS
Bacillus cereus/thuringiensis	ISS Air and Surface	Early ISS, Mid ISS, and Late ISS
Staphylococcus epidermidis	ISS Air and Surface	Single time point
Bacillus subtilis	ISS Air and Surface	Single time point
Ralstonia pickettii	Potable Water Dispenser	Early ISS, Mid ISS, and Late ISS
Burkholderia multivorans	Potable Water Dispenser	Early ISS, Mid ISS, and Late ISS
Cupriavidus metallidurans	Potable Water Dispenser	Early ISS, Mid ISS, and Late ISS

5. Flight Capabilities

The HRP Flight Experiment Information Package (http://nspires.nasaprs.com/external/) provides detailed information on flight capabilities and constraints as well as a description of the unique aspects of the evaluation and selection process for flight experiments.
A comprehensive list of research facilities on board the ISS may be found at (http://www.nasa.gov/mission_pages/station/research/facilities_category.html).

Proposals that require spaceflight equipment, facilities, or other resources not identified in this NRA or in the accompanying HRP Flight Experiment Information Package will have a lower priority for selection.

6. Radiation Capabilities

The NSRL is an irradiation facility capable of supplying particles from protons to gold with primary energies in the range of 50-2500 MeV for protons and 50-1100 MeV/n for HZE particles. NASA plans to operate the NSRL for approximately 900 hours per year; selection of beam species and energies for experimental periods will be made by NASA officials in consultation with scientists proposing experiments for these beams. Activities at the NSRL are a joint effort of BNL's Collider-Accelerator Department, providing accelerated particle beams, and the Biosciences Department, providing experimental area support, animal care, and cell and biology laboratories. The NSRL includes irradiation stations, beam controls, and laboratory

facilities required for most radiobiological investigations. Additional information concerning NSRL may be found at http://www.bnl.gov/medical/nasa/nsrl_description.asp

7. Behavioral Health and Performance Laboratory

Overview
The Behavioral Health and Performance (BHP) Research Laboratory was formed in 2014 to conduct research and to provide science support functions toward addressing the Risks of HRP's BHP Research Element at JSC. While the BHP Element utilizes the laboratory for its internal needs, external investigator teams can also request data collection and other support services for their studies.

In responding to solicitations, investigators can consider including in their research plan and budget the use of the BHP Laboratory personnel, its capabilities and equipment, and the ancillary capabilities that may be required to collect and process data/samples. Laboratory personnel offer extensive experience in completing protocols to exacting standards in spaceflight and spaceflight analogs. Personnel also offer the experience and expertise required for real-time problem solving in these field and operational mission settings to maximize the quantity and quality of data.

The BHP Laboratory is located onsite at NASA JSC in Building 37, along with the other Biomedical Research and Environment Sciences Division laboratories and personnel. Examples of recent support services include the following: 1) Human Exploration Research Analog (HERA) training and baseline data collection, as well as in-mission and post-mission data collection; 2) managing the Sleep Medication Study completed at JSC's Astronaut Crew Quarters; 3) coordinating Subject Matter Expert (SME) interviews with astronauts, Mission Control Center (MCC) personnel, Flight Surgeons and Behavioral Health SMEs; 4) coordinating evaluation of a software tool being developed for mission operations planning; 5) managing a Stress Management and Resilience Training study with flight controllers; and 5) facilitating access to ultrasound imaging expertise for HERA campaigns.

Skills
There are wide range of skills available within the BHP Laboratory, including research coordinators, and SMEs in I/O and Clinical Psychology, Neuroscience, Psychiatry, statistical analysis, etc. The BHP Laboratory can also facilitate connection with other capabilities within NASA JSC if helpful for an investigator's data collection plan. Examples of previous projects included involvement of the Clinical Laboratory and ultrasound imaging specialists.

The science coordination and management function has been very successful to date and has allowed investigators to take advantage of BHP Laboratory's location at NASA JSC. Working on behalf of the PI, laboratory personnel are able to work directly with mission operations personnel, Test Subject Screening facility, MCC personnel and other organizations to assist with all phases of protocol implementation.

Equipment and Facility Space
Additionally, the BHP Laboratory has a small collection of hardware that can be made available to the investigators for onsite data collection. This allows the opportunity to avoid costs and

possible damage associated with shipping, as well as cost-savings if the PI does not already own hardware required for their data collection. The BHP laboratory also has space which can be reserved for meetings, interviews and subject testing. A list of hardware is provided below.

For further information about BHP Laboratory services and capabilities, and how they might be able to support your investigation, please contact Steve Vander Ark, stephen.t.vanderark@nasa.gov.

Hardware List:

Portable/Movable Equipment

- 7 Windows Laptops with Windows 7 Ultimate 64-bit and Office 2013
  - 1 Eee PC 1215N (In Use For Current Study)
    - Atom™ D525 1.8GHz Processor, 250 GB HD, 2 GB RAM, 12.1" Display
  - 1 Dell Inspiron N4010 (In Use For Current Study)
    - Core i5 460M 2.53GHz Processor, 500 GB HD, 4GB RAM, 14" Display
  - 5 Dell Inspiron 1525 (2 In Use For Current Study)
    - Pentium Dual T3200 2GHz Processor, 320 GB HD, 4 GB RAM, 15.4" Display
  - Additional Computers available on request
- 3 LCD Monitors
  - 1 Acer X163Wb Monitor (16")
  - 1 Hyvision MV190T Monitor (19")
  - 1 Optiquest Q241WB Monitor (24")
  - Additional Monitors available on request
- 7 iPads with iOS 8.3
  - 1 iPad 2nd Generation – Wi-Fi/3G Cellular, 64 GB
  - 1 iPad Mini (2nd Generation) – Wi-Fi, 16GB
  - 1 iPad Air (5th Generation iPad) – Wi-Fi, 128 GB
  - 4 iPad Air (5th Generation iPad) – Wi-Fi, 64 GB
- 6 Google Nexus 10 Tablets with Android 5.1
  - 1.7 GHz Dual-core Cortex-A15, 16 GB Storage, 2 GB RAM, 10.1" Display
- 118 Actigraphy Monitors
  - 12 Actigraph wActiSleep-BT
  - 42 Actiwatch-L (with 3 readers)
  - 14 LifeTrack C410 (with firmware & software modified for NASA use)
  - 50 LifeTrack R450 (with firmware & software modified for NASA use)
- 6 Mega eMotion Faros 180° ECG Monitors with 3-electrode cable set
- 6 Sociometric Solutions Badges (In Use For Current Study Jan-Aug)
- 2 CM-0056 CO_2 Meters
- 1 Valkee Bright Light Headset
- 11 BioBright Light Visors
- 2 Yamaha MSR100 Speakers with Stands
- 1 Limitimer Pro-200 with PSL-20V Podium Signal Light
- 1 Magnavox DVD/VCR Player
- 1 Olympus Stylus 740 Digital Camera

Shared Equipment Usable from Room 202c in Building 37 (BHP Lab Interview/Testing/Meeting Room)

- Konica Minolta bizhub 363 Copier/Printer/Scanner/Fax
- HP Color LaserJet CP5225dn Printer
- Sharp LC60LE650U Monitor/TV (60")
- Samsung BD-F5700 Blu-ray Disc Player
- Barco ClickShare CSM-1 Presentation System
- HP EliteDesk 800 G1
    - Windows 7 Ultimate 64-bit and Office 2013
    - HP EliteDisplay E221 Monitor (21.5")
    - Core i5-4570 3.2 GHz Processor, 500 GB HD, 8GB RAM
- Cisco Model 7937 IP Telephone Conference Station

8. Analog Capabilities

Proposers who require the use of any of the analogs listed below (a-d) should fill out the Analog Study Resource Worksheet (http://nspires.nasaprs.com/external/) **and include the worksheet as part of their proposal upload**.

a. Human Exploration Research Analog

The HRP Human Exploration Research Analog (HERA) Experiment Information Package posted alongside this NRA (http://nspires.nasaprs.com/external/) provides information on the capabilities of this exploration research analog. This habitat is located on site at JSC and is housed in building 220.The HERA is a two-story, four-port habitat unit. It is cylindrical with a vertical axis, and connects to a simulated airlock and hygiene module. Currently, the HERA represents an analog for simulation of isolation, confinement and remote conditions of mission exploration scenarios. Studies suitable for this analog may include, but are not limited to, behavioral health and performance assessments, communication and autonomy studies, human factors evaluations and exploration medical capabilities assessments and operations. Proposals that require resources beyond those described in the HRP HERA Experiment Information Package (i.e., experiment unique resources) should include adequate budget for those resources. All Step-2 proposers wishing to use the HERA should fill out the Analog Study Resource Worksheet posted alongside this NRA (http://nspires.nasaprs.com/external/).

b. Suborbital Capabilities

PLEASE NOTE: NASA is presently not considering human-tended payloads to be flown on suborbital reusable launch vehicles (sRLVs) and there will not be any NASA-sponsored participants on sRLV flights. The payloads to be flown on sRLV flights must either be automated or remotely operated. Remote operation capability should be confirmed with the flight operator.

Suborbital spaceflight opportunities are expected to be available during the lifetime of selected proposals from this solicitation which may provide longer—but still brief—exposure to weightlessness and other spaceflight conditions than parabolic aircraft flights. Suborbital flight

opportunities are described at https://flightopportunities.nasa.gov/.

Reusable suborbital research enables a new generation of science by providing frequent access to a new region of space heretofore unexplored with user-friendly g-loads in a pressurized, temperature-controlled environment and payload accommodation from 1 to 100kg, soda-can sized to human sized. Short-duration flights will permit researchers to access payloads both pre- and post-flight.

A typical suborbital flight will accelerate briefly using rocket propulsion to achieve high vertical velocity. When above the sensible atmosphere, will follow a typical ballistic arc providing reduced gravity for approximately four minutes, then will decelerate on re-entry into the atmosphere. Landing on Earth may use some or all of winged flight, parachutes or rocket propulsion. Proposals employing suborbital flights must make a strong case that the use of that modality is necessary to meet NASA's objectives of reducing the human risks of space exploration.

c. Exercise Countermeasures Laboratory

Exercise Countermeasures Laboratory (ECL) at NASA Glenn Research Center (Cleveland, OH) is a ground-based test bed which provides high-fidelity weightlessness, lunar (1/6g) and Martian (1/3g) human-in-the-loop exercise simulations for developing exercise countermeasure devices, equipment, and exercise protocols for spaceflight, and quantifying the physiological demands of performing exercise in shirt-sleeve environment. The enhanced Zero-g Locomotion Simulator (eZLS) exercise platform orients human test subjects horizontally, such that they exercise in simulated Zero-g (oriented 90 degrees relative to the gravity vector) against a three degree-of-freedom air-bearing exercise simulator which allows frictionless translation and rotation. The test subjects are suspended in this supine orientation from a motorized system of bungees for weightlessness locomotion or exercise simulation, or at the appropriate pitch angle for whole-body partial gravity simulations. Kick loads assessments, sensorimotor challenges, lower and upper body kinematics can all be assessed in this way in simulated zero-g, without the time limitations of parabolas on parabolic flight. A subject load device (SLD) interface provides gravity-replacement loads via Series Bungee System bungees, or a near-constant force pneumatic SLD whereby load is proportional to system pressure. Both are used to provide gravity-replacement loads at the desired levels, similar to the International Space Station (ISS) T2 Treadmill. The current data acquisition user interface is programmed in LabVIEW and is setup to continuously monitor foot forces under treadmill belt, in-line SLD force, accelerations, displacements, heart rate, and treadmill speed. The laboratory uses a BTS Bioengineering motion capture system (SMART-DX500) to analyze human movement, either while in the eZLS or on the ground. Wireless electromyography (EMG) data, wearable accelerometry, and force plates are available for a full suite of biomechanical analysis capability. Test protocols are conducted under approval of the JSC Institutional Review Board, and the PI's host institution IRB. Medical monitoring is provided at Level 3 (http://irb.nasa.gov). Recent human in the loop test protocols include a ISS T2 Treadmill harness development and T2 treadmill vibration isolation system evaluation with NASA JSC and Boeing, a kinematic and electromyographic study comparing gait parameters and muscle-activation patterns during treadmill running in the eZLS, 1-g upright, and in parabolic flight, lunar gravity locomotion studies and Daily Load Stimulus

characterizations during various lunar tasks, evaluations of; compact advanced exercise equipment, compact subject load devices, sensorimotor balance challenge countermeasures, and development of wireless biometric sensors that have also been also evaluated in parabolic flight.

The ECL boasts a cadre of talented and dedicated engineers and scientists who bring knowledge of spaceflight payloads, flight analog and ground research and technology development, and are truly collaborative.

More detailed information available by contacting the NASA Glenn Research Center Project Manager in the ISS and Human Health Office, Gail Perusek at gail.p.perusek@nasa.gov.

d. Parabolic Aircraft

For proposals that require use of parabolic flight, NASA will identify and fund an appropriate parabolic flight platform. Investigators should plan on coordinating flights with a commercial provider with assistance from a NASA liaison office. Proposers should budget for travel and experiment support at the testing site.

H. Bibliography

The **Human Research Program, Program Requirements Document** is available online at: https://www.nasa.gov/hrp/research/announcements

The **Human Research Program, Human Research Roadmap** is available online at: http://humanresearchroadmap.nasa.gov

The **Human Research Program Evidence Book** is available online at: http://humanresearchroadmap.nasa.gov/evidence/

The **Human Research Program Task Book** is available online at: http://taskbook.nasaprs.com/peer_review/index.cfm

National Space Biomedical Research Institute (NSBRI)**.** The Institute's research overview, as well as the program information for each of the NSBRI teams, is available at: http://www.nsbri.org.

NASA Life Sciences Data Archive (LSDA) is an online database containing descriptions and results of completed NASA-sponsored flight experiments. Descriptions are included of experiments, missions, procedures, hardware, bio-specimens collected, personnel, and documents. The LSDA is available online at: http://lsda.jsc.nasa.gov/lsda_home.aspx.

Medical Requirement Integration Document (MRID) defines integration activities to support the medical requirements (MR) for both short-duration and long-duration human spaceflight for the Space Shuttle/International Space Station (ISS) programs. The MRID is available online at: http://lsda.jsc.nasa.gov/docs/MRID/MRIDhome.aspx.

Guidebook for Proposers Responding to a NASA Research Announcement (NRA) is available online at: http://www.hq.nasa.gov/office/procurement/nraguidebook/

NASA Federal Acquisition Regulations Supplement Instructions for Responding to NASA Research Announcements (Provision NFS 1852.235-72 November 2004) is available online at the following address: http://www.hq.nasa.gov/office/procurement/regs/nfstocA.htm

Standard Format for NASA Research Announcements (NRAs) and other Announcements for Grants and Cooperative Agreements are available online at: http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PR_5810_0001_&page_name=main

NASA Grant and Cooperative Agreement Manual is available online at: https://prod.nais.nasa.gov/pub/pub_library/Grant_and_CooperativeAgreementManual.doc

HRP Flight Experiment Information Package is available online at: http://nspires.nasaprs.com/external/

Safe Passage, Astronaut Care for Exploration. Institute of Medicine, National Academy Press, 2101 Constitution Avenue NW, Washington DC 20418 (2001).

National Academy of Sciences. National Research Council Committee on Space Biology and Medicine. Mary J. Osborn, Committee Chairperson. **A Strategy for Research in Space Biology and Medicine in the New Century.** 1998. Washington D.C.: National Academy Press. This document is available online at: http://www.nap.edu/catalog.php?record_id=6282

I. NASA Contact

NASA Selecting Official: HRP Program Manager or his designee

Additional technical information for the NASA programs is available from:

Mark J. Shelhamer, Sc.D.
Chief Scientist, Human Research Program
NASA Johnson Space Center (Mail Code SA2)
Houston, TX 77058
Telephone: 281-244-7330
Fax: 281-483-6089
E-mail: mark.j.shelhamer@nasa.gov

JSC Procurement Point of Contact:

La Toy Jones
Contracting Officer
NASA Johnson Space Center (Mail Code BH4)
Houston, Texas 77058
Telephone: 281-244-8023
Fax: 281-483-4066
Email: latoy.j.jones@nasa.gov

J. List of Acronyms

AEH	Advanced Environmental Health
AFT	Advanced Food Technology
AVMA	American Veterinary Medical Association
B	Bone
BDC	Baseline Data Collection
BHP	Behavioral Health and Performance
BMed	Behavioral Medicine
BSC	Board of Scientific Counselors
CASIS	Center for the Advancement of Science in Space
CCR	Central Contractor Registry
CFR	Code of Federal Regulations
CRL	Countermeasure Readiness Level
Co-I	Co-Investigator
CV	Cardiovascular
CV	Curriculum Vitae
DSA	Data Submission Agreement
EAC	External Advisory Council
EO	Education and Outreach
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulations
FCA	Full Cost Accounting
FTE	Full-Time Equivalent
EBPOC	Electronic Business Point-of-Contact
ESMC	Executive Science and Medicine Council
EVA	Extra-Vehicular Activity
GCRC	General Clinic Research Center
HARI	Human and Automation/Robotic Integration
HEOMD	Human Exploration and Operations Mission Directorate
HERO	Human Exploration Research Opportunities
HRP	Human Research Program
HRPEO	Human Research Program Education and Outreach
IACUC	Institutional Animal Care and Use Committee
IM	Immunology
IRB	Institutional Review Board
IRP	Integrated Research Plan
ISS	International Space Station
ISSMP	International Space Station Medical Project
LSAH	Lifetime Surveillance of Astronaut Health
LSDA	Life Sciences Data Archive
M	Muscle
MOU	Memorandum of Understanding
MR	Medical Requirements
MRID	Medical Requirement Integration Document
N	Nutrition

NASA	National Aeronautics and Space Administration
NPD	NASA Policy Directive
NRA	NASA Research Announcement
NSBRI	National Space Biomedical Research Institute
NSPIRES	NASA Solicitation and Proposal Integrated Review and Evaluation System
NSSC	NASA Shared Services Center
OMB	Office of Management and Budget
PDF	Portable Document Format
PH	Pharmacology
PHS	Public Health Service
PHYS	Physical Environment
PI	Principal Investigator
PRD	Program Requirements Document
SHFE	Space Human Factors Engineering
SM	Sensorimotor
STS	Space Transport System
TRL	Technology Readiness Level
USOS	U.S. Operating Segment
UTMB	University of Texas Medical Branch
UWS	Usability, Workload, and Scheduling
VASR	Vertebrate Animal Scientific Review
VIIP	Visual Impairment and Intracranial Pressure