

**June 23, 2010
NSBRI-RFA-10-01**

**National Space Biomedical Research Institute
One Baylor Plaza, NA-425
Houston, TX 77030**

**NSBRI Announcement
Soliciting Postdoctoral Fellowship
Applications**

**A Request for Applications for the
National Space Biomedical Research Institute**

**Notices of Intent Due: July 23, 2010
Applications Due: August 18, 2010**

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NSBRI Request for Applications Soliciting Postdoctoral Fellowship Applications

Summary of Opportunity

This National Space Biomedical Research Institute (NSBRI) Request for Applications (NSBRI-RFA) is soliciting applications for the Postdoctoral Fellowship Program. Postdoctoral Fellowships will be competitively available for two years, with a competitive opportunity for a third year, in any laboratory in the United States carrying out space-related biomedical/biotechnological research in accordance with NSBRI's goals (Appendix A). Non-NSBRI researchers qualify as Mentors for this competitive funding. **The program is open to U.S. citizens, permanent residents or persons with pre-existing visas obtained through their sponsoring institutions that permit postdoctoral training for the project's duration. To be eligible for this program, Postdoctoral Fellows may not have more than three years (cumulative) of previous postdoctoral training.** Selected Postdoctoral Fellows will become a member of an integrated countermeasure/technology development team of the NSBRI described in Appendix A.

The Postdoctoral Fellowship award will be funded as a stipend of \$40,000 for the first year with a 6.25% increase in the second year; an additional allowance for health insurance will be included. A competitive opportunity for a third year of funding is available depending on existing NSBRI resources and if evaluation by the NSBRI Executive Science and Medicine Council determines that this is warranted based on the awardee's performance during the first two years of funding. Additional funding will be provided for travel to a mandatory NSBRI meeting of Postdoctoral Fellows at the annual NSBRI/NASA Investigators' Workshop, a research team meeting, and a scientific meeting of the Postdoctoral Fellow's choice. The Postdoctoral Fellow will also be expected to attend a 4-5 day NSBRI Summer Bioastronautics Institute at Baylor College of Medicine in Houston hosted by the NSBRI Postdoctoral Fellowship Program Coordinator and the NSBRI Education Team and will include a visit at the NASA Johnson Space Center to become familiar with the research facilities and programs available at that institution (costs also covered by NSBRI). The time period for the Johnson Space Center visit will be arranged by the Fellowship Program and will occur during June 2011.

A budget is not necessary for completion of an application. Funding is not provided for administrative costs, supplies, reagents, equipment and instrumentation, or animals. The Mentor is responsible for supervision of the NSBRI Postdoctoral Fellow and for providing all necessities important to the completion of the research proposed by the Fellow. After Postdoctoral Fellowships have been awarded, the NSBRI will work with the funded institutions to execute the awards, which will include development of a budget for funding. **Indirect costs will not be awarded to the funded institution.** Additionally, NSBRI's traditional cost sharing of 10% of the funded award is welcomed, but not required, from institutions who receive awards for postdoctoral training.

Postdoctoral Fellowship Program applicants must prepare proposals with the support of a Mentor and institution (university, national lab, etc.), and all proposals will be objectively and rigorously evaluated by an external peer review panel. Mentors should have previous experience in training of postdoctoral fellows and/or graduate students. **It is the responsibility of the Postdoctoral Fellowship Program applicant to arrange for a Mentor.**

Selected postdoctoral research projects will become part of an NSBRI integrated countermeasure/technology development team focused on advancing the research toward an applied intervention to ensure the health of astronauts in response to spaceflight. Each Postdoctoral Fellowship Program applicant must identify the Countermeasure Readiness Level (CRL) and/or Technology Readiness Level (TRL) the research proposal addresses. Applicants should refer to Figures 1 and 2 in Appendix A for detailed descriptions of CRLs and TRLs.

In order to facilitate electronic submission from the institution at which the Postdoctoral Fellow will conduct the research, please note that the NSPIRES proposal submission system requires that the Mentor be identified as the Principal Investigator and the trainee be identified as the Postdoctoral Fellow.

In this NSBRI-RFA,

- Appendix A provides an introduction and overview of the goals, objectives and research implementation strategies of NSBRI.
- Appendix B contains descriptions of the opportunity and eligibility, specific instructions for submitting a Notice of Intent, and instructions for proposal submission.
- Appendix C contains the standard instructions for responding to NSBRI Requests for Applications.
- Appendix D contains information on additional requirements for proposals utilizing vertebrate animals. This is a new NASA-wide requirement beginning in 2010 for all proposals utilizing vertebrate animals.

NSBRI's scientific and educational goals are to fund research and development that will result in the delivery of countermeasures to ensure the health of astronauts in response to spaceflight, and to apply findings from research supported by the Institute to benefit human health on Earth. NSBRI is committed to maintaining a strong, openly competitive, peer-reviewed research program. The Institute also aims to inspire the next generation of space life scientists. Proposals submitted in response to this NSBRI-RFA must address one or more of the research emphases described in this document (see Appendix B, Section II for more details). Those that do not will be returned without review.

Proposals that synergistically bridge multiple disciplines for the purpose of modeling the effects of microgravity on the human body, aid in the development and testing of countermeasures, or develop technologies that enable research in one or more NSBRI research areas are strongly encouraged.

All proposals will be evaluated for overall scientific and technical merit by an external peer review panel. Relevance to NSBRI's programmatic needs and goals will also be evaluated by NSBRI management. NSBRI's obligation to make award(s) is contingent upon the availability of appropriated funds from which payment can be made and the receipt of proposals that NSBRI determines are acceptable for award under this NSBRI-RFA.

Participation in this NSBRI-RFA is open to all categories of organizations, industry, educational institutions, other nonprofit organizations, NASA laboratories, and other agencies of the U.S. government.

Inclusion of Women and Minorities in Research Involving Human Subjects – NASA and NSBRI have adopted the policy of the NIH regarding this matter. Women and members of minority groups and their subpopulations must be included in NSBRI-supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

An electronic Notice of Intent from Postdoctoral Fellowship Program applicants is requested, but not required, by July 23, 2010. Proposals must be submitted electronically by August 18, 2010, 5:00 p.m. Eastern Time. (See Appendix B, Section V of this NSBRI-RFA for specific instructions for these activities.)

The following items apply only to this NSBRI-RFA:

Solicitation NSBRI-RFA Identifier: NSBRI-RFA-10-01

Application Format Required: Electronic application using NASA's NSPIRES System (See Appendix B, Section V for details)

Notices of Intent Due (not required): July 23, 2010

Proposals Due: August 18, 2010, 5:00 p.m. ET

Selection Announcement: Fall 2010

Funding Begins: Approximately 30-90 days following notification of selection

Selecting Official: Director, National Space Biomedical Research Institute

Information about NSBRI's research program and Postdoctoral Fellowship Program is available from:

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Email: postdoc@www.nsbri.org

All prospective applicants to this NSBRI-RFA are advised that the highest priority in all of NASA's programs is given to safety and mission assurance, occupational health, environmental protection, information technology, export control, and security. NASA's safety priorities are to protect (i) the public, (ii) astronauts and pilots, (iii) the NASA workforce (including employees working under NASA instruments), and (iv) high-value equipment and property. All proposals submitted in response to this solicitation are expected to comply with this policy.

NSBRI points of contact will be identified in selection letters to begin the funding process. Potential Postdoctoral Fellowship Program applicants should read with care the program descriptions that are of interest and focus their proposals on the specific research emphases defined in this NSBRI-RFA.

Your interest and cooperation in participating in this effort is appreciated.

NSBRI Request for Applications Soliciting Postdoctoral Fellowship Applications

Introduction and Overview: Goals, Objectives and Research Implementation Strategies of NSBRI

NOTE: It is critical for Postdoctoral Fellowship Program applicants to read carefully all of the instructions in this NSBRI-RFA. Each Appendix includes guidelines, requirements and instructions for preparing and submitting proposals, and defines the administrative policies governing the particular components described in this NSBRI-RFA.

I. Introduction to NSBRI

NSBRI is a NASA-funded, nonprofit research consortium charged with developing biomedical countermeasures and technologies for potential health problems that could occur in astronauts either during long-duration spaceflight, on exploration missions or on their return to Earth. NSBRI's current program, aligned with NASA's exploration objectives, consists of approximately 60 science and technology projects organized into research teams.

NSBRI invites ground-based research applications. Proposals can either address one of the seven existing NSBRI research teams, or the supplemental cross-cutting research area of Nutrition, which has importance to both NSBRI and the NASA Human Research Program (HRP). The seven research teams are as follows:

1. *Cardiovascular Alterations* – Determining the effect of long-duration spaceflight on the heart and blood vessels and designing novel therapies to combat cardiovascular deconditioning.
2. *Human Factors and Performance* – Improving daily living and keeping crewmembers healthy, nourished, productive and safe by developing countermeasures to reduce performance errors and mitigate habitability, environmental and other behavioral factors that pose a significant risk to mission success.
3. *Musculoskeletal Alterations* – Addressing bone loss and inherent fracture risks as well as loss of skeletal muscle mass, strength and endurance during spaceflight.
4. *Neurobehavioral and Psychosocial Factors* – Investigating methods and tools that can be used to enable crews to cope with stress, isolation, and crew compatibility and cohesion.
5. *Radiation Effects* – Determining the risks and deleterious effects of exposure to various types of radiation, with an emphasis on acute effects, and on mitigating these effects through countermeasure development.
6. *Sensorimotor Adaptation* – Addressing the role of sensorimotor disturbances that occur during and after flight on vehicle control and task performance, and development of pre- and in-flight training countermeasures to help astronauts rapidly adjust to microgravity and other gravitational environments.

7. *Smart Medical Systems and Technology* – Designing new methods for remote and autonomous medical monitoring, diagnosis and treatment, and developing small, low-power and noninvasive instrumentation.

Each of the seven research teams consists of a set of complementary projects focused on a common theme. Team management and coordination is the responsibility of the Team Leader. A Team Leader, assisted by an Associate Team Leader, heads each research team. Team Leaders play a pivotal role in guiding the Institute’s science and technology program and in the ultimate success of the Institute. Their expertise and “hands-on” approach to research management adds value across both projects and teams. The seven Team Leaders are guided by the Integrated Research Plan (see Appendix A, Section III), which is the cornerstone for developing each team’s integrated strategic research plan, which collectively constitute the keys to accomplishing the Institute’s mission. (See Appendix B, Section II for more information on NSBRI research areas.)

Within the supplemental area of Nutrition, proposals that investigate the following topics are encouraged:

1. Assessment of nutrient kinetics to enable estimations of the nutrient content of a food over its shelf life without conducting an actual shelf life study. Nutrients to be assessed may include, but are not limited to, vitamin A, vitamin C, folic acid, and thiamin.
2. Studies of nutrient quality and/or availability. Because vitamin degradation is known to depend on environmental factors, pH, oxygen availability, percent moisture, and processing history, any or all of these factors may be considered.

II. NSBRI Mission and Infrastructure

NSBRI is responsible for the development of countermeasures and risk-mitigation strategies to alleviate the deleterious effects of long-duration spaceflight and for the support of applied space biomedical research directed toward this specific goal. Its mission is to lead a national effort in integrated, critical path space biomedical research that supports NASA’s exploration objectives by focusing on the enabling of long-term human presence in, development of, and exploration of space. This is accomplished by:

- designing, testing and validating effective countermeasures to address the biological and environmental impediments to long-term human spaceflight;
- defining the molecular, cellular, organ-level, and integrated responses and relationships that ultimately determine these impediments, where such knowledge is essential for the development of novel countermeasures;
- establishing biomedical support technologies to maximize human performance in space, reducing biomedical hazards to an acceptable level, and delivering quality medical care;
- transferring and disseminating these biomedical advances in knowledge and technology to the general benefit of mankind; and
- ensuring open involvement of a diverse scientific community, industry and the public in the Institute’s activities and fostering a robust partnership with NASA.

Institute Infrastructure

NSBRI is governed by a consortium of twelve institutions: Baylor College of Medicine; Brookhaven National Laboratory; Harvard Medical School; The Johns Hopkins University; Massachusetts Institute of Technology; Morehouse School of Medicine; Mount Sinai School of Medicine; Rice University; Texas A&M University; the University of Arkansas for Medical Sciences; the University of Pennsylvania Health System; and the University of Washington. The Institute's Headquarters are located in Houston at Baylor College of Medicine.

This is an open solicitation. Consortium membership is not a requirement for Postdoctoral Fellowship Program participation and non-NSBRI researchers are encouraged to apply as Mentors.

An independent Board of Scientific Counselors is responsible for assuring excellence in the Institute's research program through independent and objective external peer review. The External Advisory Council is responsible for advising Institute management and the Board of Directors (comprised of, but not limited to, representatives from the senior management of each of the 12 NSBRI consortium-member institutions) concerning program strategy, tactical implementation and effectiveness. NSBRI also has a User Panel of former and current astronauts and flight surgeons responsible for assuring that the research program is focused squarely on astronaut health and safety. An Industry Forum of representatives from space- and biomedically-related industries advises and assists NSBRI concerning Earth- and space-based applications for Institute research.

In addition to its research program, NSBRI has developed a robust education and outreach program that takes advantage of the Institute's core research activities. The Institute coordinates its research activities with NASA through a joint NASA/NSBRI Steering Committee and other NASA/NSBRI strategic and tactical working groups.

III. The Integrated Research Plan (IRP)

The Integrated Research Plan (http://humanresearch.jsc.nasa.gov/files/hrp-47065_reva_IRP.pdf) describes NASA's research activities that are intended to address the needs of human space exploration and serve Human Research Program (HRP) customers. The IRP illustrates NASA's research plan through the timescale of early lunar missions of extended duration. Updated content to the HRP IRP for the area of Sensorimotor Adaptation is available at <http://humanresearch.jsc.nasa.gov/elements/smo/nra.asp> under "Related Documents."

With the ultimate goal of protecting the health and safety of spaceflight crews, this guiding document facilitates the ability of NASA and the external community of scientific investigators to better define and focus research required for development and validation of operational health care "deliverables." Doing so will help to prevent, treat and rehabilitate humans following spaceflight and will create and support appropriate habitation and medical care systems.

Postdoctoral Fellowship Program applicants should review these documents and must identify in their proposals the risk(s), as listed in the HRP IRP, addressed by the proposed research. Applicants must also provide the rationale for why their proposed line of investigation will

provide one or more insights into mitigation of the risk(s). Proposals that do not comply with this requirement will be returned without review.

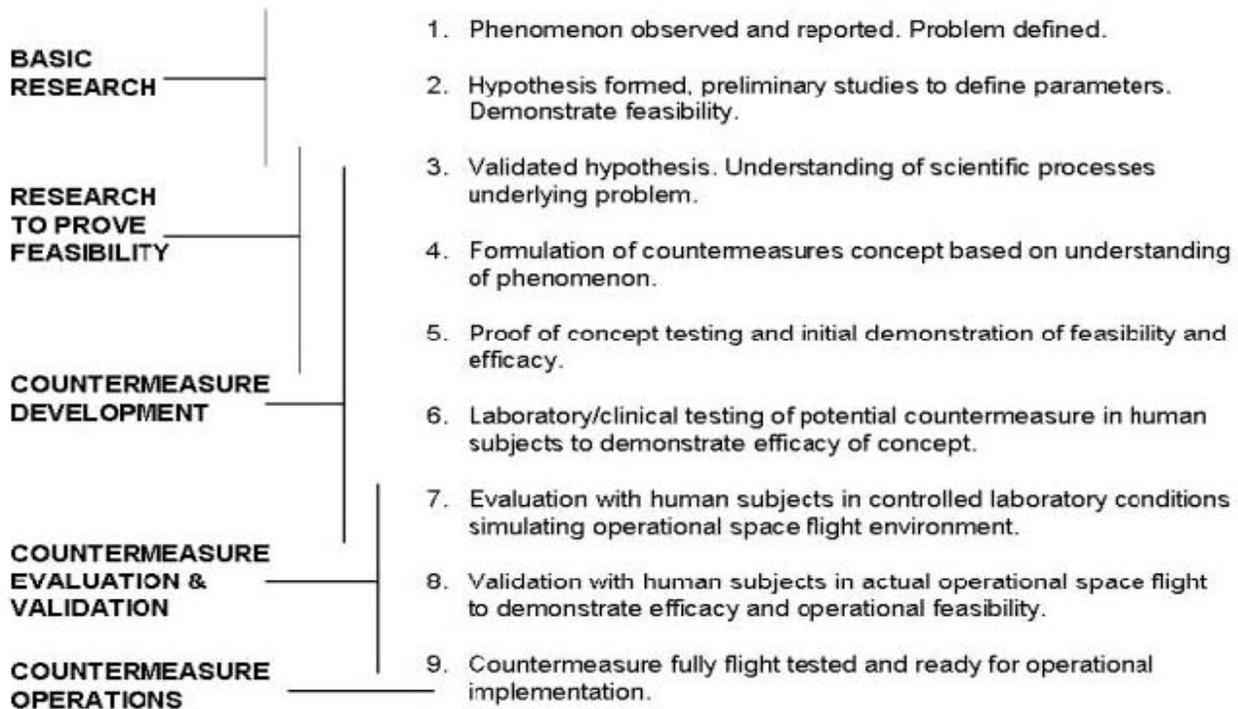
IV. Explanation of Countermeasure Readiness Level and Technology Readiness Level

Countermeasure Readiness Level (CRL)

The use of the CRL scale allows NSBRI to: 1) define, assess and quantify the level of “countermeasure readiness;” 2) determine and describe how each funded research project fits into the countermeasure development “flow;” and 3) monitor progress in countermeasure development. This section describes this scale and how it is used. **The CRL of the proposed research must be identified in the application.**

Figure 1 illustrates the CRL scale. It describes an incremental research program ranging from fundamental studies that suggest potential countermeasures to applied studies that allow the systematic evaluation and validation of countermeasures ready for operational implementation. Countermeasure development usually progresses through systematic research. Research flows through various levels of countermeasure readiness.

Figure 1. Countermeasure Readiness Level Scale



Technology Readiness Level (TRL)

Technology Readiness Level is a systematic measurement system that supports assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technology. In short, a TRL is a technology milestone (See Figure 2). **Technology projects must identify the TRL of the proposed research.**

Figure 2. Technology Readiness Level Scale

<u>Level</u>	<u>Definition</u>
TRL1	Basic principles observed
TRL2	Technology concept and/or application formulated
TRL3	Analytical and experimental critical function/proof-of-concept
TRL4	Component and/or breadboard validation in lab
TRL5	Component and/or breadboard in relevant environment
TRL6	System/subsystem model or prototype demonstration in relevant environment
TRL7	Subsystem prototype in a space environment
TRL8	System completed and flight qualified through demonstration
TRL9	System flight proven through mission operations

V. Bibliography

1. **National Space Biomedical Research Institute Website.** <http://www.nsbri.org/> Contains information on the Institute's science, technology and education programs, including detailed team activities and project summaries for all current and completed projects.
2. **NASA Human Research Program Integrated Research Plan.** The IRP describes the portfolio of HRP research and technology tasks. The IRP is the HRP strategic and tactical plan for research necessary to meet HRP requirements. Available at: http://humanresearch.jsc.nasa.gov/files/hrp-47065_reva_IRP.pdf
3. **NASA Human Research Program Evidence Book.** Available at: http://humanresearch.jsc.nasa.gov/elements/smo/hrp_evidence_book.asp.
4. **Space Life Sciences Directorate Website.** <http://slds.jsc.nasa.gov/>

5. **NASA Human Research Program Task Book (Program Tasks and Bibliography).** The Living Task Book and Task Book Archives are available at:
http://taskbook.nasaprs.com/peer_review/index.cfm
6. **Space Life Sciences Data Archive (LSDA).** An online database containing descriptions and results of completed NASA-sponsored flight experiments. Descriptions are included of experiments, missions, procedures, hardware, biospecimens collected, personnel and documents. Biospecimens that are available for research purposes are described in detail. A limited number of experiments contain final reports and spreadsheet data suitable for downloading. Data from human subjects are unavailable online for reasons of privacy. Internet address: http://lsda.jsc.nasa.gov/lsda_home.cfm
7. **Small Clinical Trials: Issues and Challenges.** Institute of Medicine, National Academy Press, Washington, DC. <http://www.nap.edu/books/0309073332/html/>
8. **Sex and Gender: Exploring the Biological Contributions to Human Health.** *NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508 (1994).*
9. **Safe Passage, Astronaut Care for Exploration.** Institute of Medicine, National Academy Press, Washington, DC (2001).

**NSBRI Request for Applications Soliciting
Postdoctoral Fellowship Applications**

Specific Details Related to the Request for Applications

NOTE: The program is open to U.S. citizens, permanent residents or persons with pre-existing visas obtained through their sponsoring institutions that permit postdoctoral training for the project's duration. Please note that restrictions at NASA installations may impede full participation in some learning experiences by persons who have certain visa classifications. To be eligible for this program, previous postdoctoral training must be limited to three years (cumulative) or less.

I. Research Opportunity – General Information

To carry out NSBRI's primary mission of identifying, designing and developing effective countermeasures to address the biological and environmental impediments to human spaceflight, NSBRI focuses its research program on the primary needs of long-duration missions (e.g., several months on the International Space Station and exploration-class missions). These missions pose the greatest challenge to present and future space travelers, and meeting these challenges with appropriate countermeasures lies at the core of the NSBRI's responsibility.

Potential physiological changes that may occur during prolonged spaceflight include, among others, significant loss of muscle and bone mass, decreased dietary intake of nutrients, metabolic and endocrine alterations, important changes in cardiovascular function, and deleterious effects on sensorimotor performance. By addressing long-term missions, increased crew safety, health and performance will be realized for shorter-duration spaceflights.

NSBRI research is conducted in partnership with NASA using an integrated team approach. The teams focus on high-priority biomedical research problems, and investigators work together, within and between teams, to address complex risks that often require interdisciplinary expertise and resources. The value added in the integrated team approach leads to more effective outcomes-driven research than what is obtainable by a single project alone.

NSBRI has an essential enabling role for NASA: providing capabilities for countermeasures development research. The Institute engages scientists, engineers and clinicians and uses institutional resources to form a biomedical research community. Countermeasures research conducted by NSBRI's research community is integrated with the engineering and operational expertise of NASA to effectively manage health risks for long-duration human spaceflight.

The CRL and/or TRL that will result from the funding and conduct of the proposed research must be identified in the proposal. For further information, refer to Appendix A, Section IV.

II. NSBRI Team-Specific Research Focus and Opportunity

Applications submitted to the NSBRI in response to this RFA should address one of the seven NSBRI research areas (<http://www.nsbri.org/Research>) or either of the two supplementary topics listed below. Proposals that impact more than one area should be directed to only one primary research area. Studies that cross disciplines are particularly encouraged, as are translational efforts aimed at moving from basic to more applied technology or countermeasure readiness levels.

Within the supplemental area of Nutrition, proposals that investigate the following topics are encouraged:

1. Assessment of nutrient kinetics to enable estimations of the nutrient content of a food over its shelf life without conducting an actual shelf life study. Nutrients to be assessed may include, but are not limited to, vitamin A, vitamin C, folic acid, and thiamin.
2. Studies of nutrient quality and/or availability. Because vitamin degradation is known to depend on environmental factors, pH, oxygen availability, percent moisture, and processing history, any or all of these factors may be considered.

It is recommended that Postdoctoral Fellowship Program applicants carefully review the NSBRI website for information on the team(s) relevant to a proposal. These web pages are referenced in the following subsections, which are provided to guide proposers to the key problems and issues that are central to each research area. In all cases, proposals must represent questions and be relevant to priorities enumerated in the IRP at: http://humanresearch.jsc.nasa.gov/files/hrp-47065_reva_IRP.pdf

Proposals in problem modeling, space medicine and technology that are relevant to countermeasure development within the scope of the NSBRI mission are invited but must address one of the research areas discussed below. NSBRI seeks innovative projects of two years in duration and of varying scope that will produce clear deliverables. A competitive opportunity for a third year of funding is available depending on existing NSBRI resources and if evaluation by the NSBRI Executive Science and Medicine Council determines that this is warranted based on the awardee's performance during the first two years of funding. Applicants are encouraged to define clear milestones and to collaborate with experts, as appropriate, to maximize the likelihood of success and the impact of their proposed research.

1. NSBRI Cardiovascular Alterations Team

The Cardiovascular Alterations Team is determining the effects of long-duration spaceflight on the heart and blood vessels and designing novel therapies for combating the effects of prolonged cardiovascular deconditioning. These strategies include developing training regimens as well as pharmacologic and nutritional interventions. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/Cardio.html>.

2. NSBRI Human Factors and Performance Team

The Human Factors and Performance Team is studying ways to improve daily living and keep crewmembers healthy, productive and safe during exploration missions. Overall Team aims are to reduce performance errors and mitigate habitability, environmental and other behavioral factors that pose significant risk to mission success. The Team develops guidelines for human systems design and information tools to support crew performance. Team members are examining ways to improve sleep and scheduling of work shifts as well as how specific types of lighting in the craft and habitat can

improve alertness and performance. Other projects address nutritional countermeasures and how factors in the environment can impact crew health. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/HFP.html>.

3. NSBRI Musculoskeletal Alterations Team

The Musculoskeletal Alterations Team is studying the mechanisms involved in bone and muscle loss and whether reduced gravity increases risk of bone breaks and impairs fracture healing. In addition to identifying ways to enhance the benefits of exercise for maintenance of musculoskeletal function, the Team also seeks to develop methods to prevent or reduce the loss by considering nutritional and pharmaceutical interventions to complement exercise. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/MusculoSkeletal.html>.

4. NSBRI Neurobehavioral and Psychosocial Factors Team

The Neurobehavioral and Psychosocial Factors Team is concerned with methods crews use to deal with stress, isolation, confinement and the challenges of long-duration space missions. In addition to identifying neurobehavioral and psychosocial risks to crew health, safety and productivity, Team objectives include developing methods to monitor cognitive function and behavior and countermeasures to enhance performance, motivation and quality of life. Leadership style, crew composition, organization and communication are also being investigated to optimize crew effectiveness and mission success. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/Psycho.html>.

5. NSBRI Radiation Effects Team

Extended missions will expose astronauts to greater levels and more varied types of radiation. High levels of radiation may kill cells, damage tissue and cause mutations; other effects of acute exposure include prodromal syndrome, skin reactions and hematologic disorders. On exploration missions, radiation exposure from solar particle events could impair an astronaut's performance and result in mission failure. The Radiation Effects Team is focused on understanding and mitigating the risks related to exposure to various types of space radiation, with an emphasis on acute effects. Projects are developing countermeasures to mitigate the effects of radiation exposures and designing devices to monitor radiation during extravehicular activities. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/Radiation.html>.

6. NSBRI Sensorimotor Adaptation Team

The Sensorimotor Adaptation Team is developing pre-flight and in-flight training countermeasures, so that astronauts can adjust more rapidly to gravitational changes that can result in disorientation, motion sickness and a loss of sense of direction. These disturbances can impact operational activities including approach and landing, docking, remote manipulation, extravehicular activity, and post-landing normal and emergency egress. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/Neuro.html>.

7. NSBRI Smart Medical Systems and Technology Team

The Smart Medical Systems and Technology Team is developing smart, integrated medical systems to assist in delivering quality health care. These systems must be small, low-power, noninvasive or minimally invasive, and versatile. Possible technologies needed include ultrasound diagnostics and therapeutics, routine risk and health-monitoring systems, and automated systems and devices to aid in

decision-making, training and diagnosis. New technologies developed by this Team will have immediate benefits to medical care on Earth. Team information, including research goals and priorities, is located at <http://www.nsbri.org/Research/SmartTech.html>.

III. Award Information

Selected proposals are expected to be funded for two years. A competitive opportunity for a third year of funding is available depending on existing NSBRI resources and if evaluation by the NSBRI Executive Science and Medicine Council determines that this is warranted based on the awardee's performance during the first two years of funding. The assumed starting date will be October 1, 2010. This date is somewhat flexible, however, and will be negotiated with each selected Postdoctoral Fellow. The Postdoctoral Fellowship award will be funded as a stipend of \$40,000 for the first year with a 6.25% increase in the second year; an additional allowance for health insurance will be included. Additional funding will be provided for travel to a mandatory NSBRI meeting of Postdoctoral Fellows at the annual NSBRI/NASA Investigators' Workshop, a research team meeting, and a scientific meeting of the Postdoctoral Fellow's choice.

The Postdoctoral Fellow will also be expected to attend a 4-5 day NSBRI Summer Bioastronautics Institute at Baylor College of Medicine in Houston hosted by the NSBRI Postdoctoral Fellowship Program Coordinator and the NSBRI Education Team and will include a visit at the NASA Johnson Space Center to become familiar with the research facilities and programs available at that institution (costs also covered by NSBRI). The time period for the Johnson Space Center visit will be arranged by the Fellowship Program and will occur during June 2011.

The mechanism of support will be an NSBRI cooperative sub agreement with funds provided by NASA to the NSBRI through a cooperative agreement (Cooperative Agreement NCC 9-58) with NASA Johnson Space Center.

IV. Eligibility

A. Eligibility of Applicants

Scientists or physician-scientists who hold any of the following degrees are eligible: Ph.D., MD., M.D./Ph.D., M.B.B.S, D.Sc., Sc.D., or D.O. Applicants must have completed the clinical portion of the training program, if applicable to their field, by the time of award activation.

Research proposals will be accepted from all categories of organizations, public and private, and for profit and nonprofit, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal Government. In most cases, only approved applications from U.S. institutions will be selected for funding. Postdoctoral Fellowship Program applicants 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 Request for Applications. Present or prior support by NASA or the NSBRI of research or training in any institution or for any investigator is neither a prerequisite to submission of an application nor a competing factor in the selection process. Non-NSBRI researchers are encouraged to apply as Mentors.

B. Additional Guidelines Applicable to Foreign Applicants

The program is open to U.S. citizens, permanent residents or persons with pre-existing visas obtained through their sponsoring institutions that permit postdoctoral training for the project's duration. Please note that restrictions at NASA installations may impede full participation in some learning experiences by persons who have certain visa classifications. All proposals must be in English and comply with all other submission requirements stated in the NSBRI-RFA.

V. Application Procedures for the NSBRI Postdoctoral Fellowship Program

A. Source of Application Materials

All information needed to submit an electronic proposal in response to this solicitation is contained in this RFA and in a companion document entitled "Guidebook for Proposers Responding to a NASA Research Announcement (NRA) or Cooperative Agreement Notice (CAN) Edition 2010" (hereafter referred to as the *Guidebook for Proposers*) that is located at: <http://www.hq.nasa.gov/office/procurement/nraguidebook/>.

In cases where the Guidebook for Proposers and this RFA conflict, the RFA language shall take precedence.

Proposal submission questions will be answered and published in a Frequently Asked Questions (FAQ) document. This FAQ will be posted on the NSPIRES solicitation download site alongside this RFA, and will be updated periodically between submission release and the proposal due date.

B. Content and Form of Proposal Submission

1. NSPIRES Proposal Data System

a) NSPIRES Registration

This RFA requires that the proposer register key data concerning their intended submission with the NASA Solicitation and Proposal Integrated Review and Evaluation System (NSPIRES) located at <http://nspires.nasaprs.com>. **Potential applicants are urged to access this site well in advance of the proposal due date(s) to familiarize themselves with its structure and enter the requested identifier information.** It is especially important to note that every individual named on the proposal's *Cover Page* (see below) must be registered in NSPIRES and that such individuals must perform this registration themselves; that is, no one may register a second party, even the Mentor of a proposal in which that person is committed to participate. This data site is secure, and all information entered is

strictly for NSBRI use only. In NSPIRES, the Mentor is identified as the Principal Investigator (PI) and the Trainee is identified as the Postdoctoral Fellow.

Before beginning an online application, the Postdoctoral Fellow must ensure that:

- 1) The Organization to which the Postdoctoral Fellow is applying is registered with NSPIRES.
- 2) The Mentor (PI) is registered with NSPIRES, and is affiliated with the Organization to which the Postdoctoral Fellow is applying.
- 3) The Mentor (PI) knows the name of the Authorized Organizational Representative (AOR) of the Organization, and the AOR is registered with NSPIRES.
- 4) The Postdoctoral Fellow is registered with NSPIRES.

Every organization that intends to submit a proposal in response to this RFA, including educational institutions, industry, nonprofit institutions, NASA Centers, and other U.S. Government agencies, **must be registered in NSPIRES prior to submitting a proposal**. Such registration must be performed by an organization's electronic business point-of-contact (EBPOC) in the Central Contractor Registry (CCR).

NSPIRES help topics may be accessed through the NSPIRES online help site at <http://nspires.nasaprs.com/external/help.do>. For any questions that cannot be resolved with the available online help menus, requests for assistance may be directed by email to nspires-help@nasaprs.com or by telephone to 202-479-9376, Monday through Friday, 8 a.m. to 6 p.m., Eastern Time.

b) Electronic Submission

Notices of Intent and proposals must be submitted electronically, and all proposers are required to use NSPIRES. Any proposals not submitted through the NSPIRES portal and sent directly to NSBRI by email, fax or other means will be returned without review. NSBRI Postdoctoral Fellowship Program proposals must be submitted electronically by one of the officials at the Mentor's (PI) organization who is authorized to make such a submission. It is strongly recommended that the Postdoctoral Fellow work closely with his/her Mentor to ensure the proposal is submitted by the due date and time listed in this solicitation. Proposals will not be accepted after the listed due date and time.

NSPIRES accepts fully electronic proposals through a combination of data-based information (e.g., the electronic *Cover Page* and its associated forms) and an uploaded PDF file that contains the body of the proposal. The NSPIRES system will provide a list of all elements that make up an electronic proposal, and the system will conduct an element check to identify any item(s) that is(are) apparently missing or incomplete. Note that a failed element check will not preclude submission, but rather it will serve as a warning that a proposal may be incomplete. Proposers are particularly encouraged to begin their submission process early. Proposers submitting a Notice of Intent (NOI) will have the option of building a proposal based on the stored NOI information within the NSPIRES database.

Requests for assistance in accessing and/or using NSPIRES may be directed by email to nspires-help@nasaprs.com or by telephone to 202-479-9376, Monday through Friday, 8 a.m. to 6 p.m., Eastern Time. Frequently Asked Questions (FAQs) may be accessed through the Proposal Online Help site at <http://nspires.nasaprs.com/external/help.do>. Tutorials of NSPIRES are available at

<http://nspires.nasaprs.com/tutorials/index.html>.

2. Instructions for Preparation of NOI

To facilitate planning for the review process, applicants are requested to submit an NOI through NSPIRES by following the online instructions. **NOIs must be electronically submitted by July 23, 2010**, through the NSPIRES website (<http://nspires.nasaprs.com>).

The Mentor (PI) must initiate the proposal for the Postdoctoral Fellow in NSPIRES. After logging in to NSPIRES, the Mentor will:

- 1) Select the “Proposals” link
- 2) Select the “Create NOI” link
- 3) Select “NSBRI Announcement Soliciting Postdoctoral Fellowship Applications” from the list of open solicitations
- 4) Create the NOI Title
- 5) Link the NOI to the Mentor’s organization
- 6) Save the NOI
- 7) On the “View NOI” page, select the “Proposal Team” link
- 8) Select the “Add Team Member” button
- 9) Search for the name of the Postdoctoral Fellow, select the Postdoctoral Fellow (*Note: the Postdoctoral Fellow must be registered in NSPIRES prior to this step.*)
- 10) On the “Add Team Member” page, assign Role/Privileges to the Postdoctoral Fellow
- 11) Select “Postdoctoral Fellow Role”
- 12) Grant Edit privileges to the Postdoctoral Fellow
- 13) Select NO to the two questions that follow the section entitled “U.S. Government Agency & International Participation”
- 14) Click “Save”

After being granted editing privileges by the Mentor, the Postdoctoral Fellow must complete the NOI application. The Mentor must submit the NOI to NSBRI through NSPIRES after the Postdoctoral Fellow has completed the application.

Please refer to the NSPIRES tutorial at <http://nspires.nasaprs.com/tutorials/index.html> for online help. All information entered will remain private until the electronic submission is completed. Please note that NOI are requested, but not required, for submission of a Postdoctoral Fellowship Program application. Failure to submit a NOI will not impact the selection process.

3. Instructions for Preparation of Proposals

As with the NOI, the NSPIRES system will guide proposers through submission of all required proposal information. Please note that previously submitted NOI information will be automatically transferred to the proposal. Please refer to the online NSPIRES tutorials at <http://nspires.nasaprs.com/tutorials/index.html> for help.

Proposals must be prepared by the Postdoctoral Fellow in conjunction with their Mentor. Proposals will be submitted by the Mentor (PI) and an official of the Mentor’s organization after

the Mentor (PI) has released the prepared proposal to the Authorized Organizational Representative (AOR). It is strongly recommended that the Postdoctoral Fellow work closely with the Mentor to ensure the proposal is submitted by the due date and time listed in this solicitation. **Proposals will not be accepted after the listed deadline.**

Only the Mentor can initiate the creation of a proposal. To create the proposal from a submitted NOI, the Mentor will:

- 1) Login to NSPIRES and click on “Proposals”
- 2) Click on the “Create Proposal” button in the upper right hand corner of the screen
- 3) Select “NOI” to prepare a proposal from the NOI submission
- 4) Follow the online instructions to save the NOI as a Proposal
- 5) The Postdoctoral Fellow will then be able to complete the proposal application by following the step-by-step instructions provided in NSPIRES.

To initiate a new proposal without having submitted an NOI, the Mentor must create the new proposal and assign the Postdoctoral Fellow as a team member with editing privileges as described in the NOI section. The Postdoctoral Fellow will then be able to access and create the proposal application.

Please note that the Proposal Summary, Business Data, Program Specific Data and Proposal Team are required Cover Page Elements for a proposal. A budget is not required for this solicitation, and the budget forms do not need to be completed. The proposal summary should be between 100-300 words and written for the lay reader.

NSPIRES allows for the upload of several proposal components as individual documents. However, to ensure proper proposal transmission, please provide only **one** PDF attachment upload ordered as follows:

1. *Mentor Statement (See Appendix B, V.B.3.a)*
2. *Biographical Sketches for the Mentor and Postdoctoral Fellow (See Appendix B, V.B.3.b)*
3. *Facilities and Equipment (See Appendix C, c.6)*
4. *Research Plan (See Appendix B, V.B.3.d; no longer than 12 pages)*
5. *Current Support (See Appendix C, c.8)*
6. *Special Matters - Animal Care or Human Subjects Certifications, if applicable (see Appendix B, V.B.3.f)*
7. *Vertebrate Animal Scientific Review (VASR), if applicable (see Appendix B, V.B.3.g)*
8. *References and Citations (See Appendix B, V.B.3.h)*
9. *Appendices and Reprints (See Appendix B, V.B.3.i)*

The NSPIRES proposal submission process ensures that a minimum set of required proposal cover page fields are completed. Provision of the proposal summary and business data elements of the cover page will be necessary in order for the AOR to submit the proposal. If either of these two proposal elements is incomplete, the “View Proposal/Check Elements” function of NSPIRES will display red “error” flags and messages to alert the user to the information that is required but missing, and the “Submit Proposal” button will not be available. Although the PI will be able to release the proposal to the AOR, the proposal cannot be submitted by the AOR until these required fields are complete. Any additional information that is missing will be identified by yellow “warning” flags. Proposers are reminded to

check the solicitation instructions to ensure compliance with all instructions, as adherence to these two element validation checks alone is insufficient to guarantee a compliant proposal. Additionally, in those cases where instruction in the RFA contradicts an NSPIRES warning, the NSPIRES yellow “warning” may be ignored. Proposers should follow the RFA instructions closely to help ensure submission of a compliant proposal.

The NSPIRES system is limited in the character sets that can be used in filling out online forms. Please refer to the online tutorials when using special characters. Alternatively, spell out special characters where possible (such as micro rather than the Greek symbol). Applicants are encouraged to preview their proposal prior to releasing the proposal to their designated Organization by clicking the “Generate” button at the bottom of the View Proposal Screen in NSPIRES. The “Generate” feature allows applicants to preview their entire proposal in a single PDF file prior to submittal, but it is not a required step in the submission process. Please contact the NSPIRES Help Desk for assistance with this feature (e-mail nspires-help@nasaprs.com or by telephone to 202-479-9376).

The following is required, and supersedes the information provided in the *Guidebook for Proposers*.

a) Mentor Statement

The Mentor must provide a “Mentor Statement” indicating that the Postdoctoral Fellow will be fully supported by his/her laboratory if the Fellowship is granted. The statement should specifically address how access will be granted to the Fellow for any specialty supplies, reagents, equipment and instrumentation, animals, and unique expertise deemed important to the completion of the studies proposed by the Fellow. Further, the Mentor Statement must clearly and succinctly include a description of the proposed training plan for the Fellow. The plan must include appropriate career development and professional training components covering such areas as research ethics, human subject research, use of animals in research, grant preparation, effective CV preparation, career interview skills, effective scientific writing and communication skills, and mentoring skills. The Mentor Statement should include a brief summary of the Mentor’s previous successful experiences in guiding the research efforts and career development of students and postdoctoral fellows. Although not required, the Mentor should consider including potential educational and outreach opportunities for the Fellow that target non-science audiences in the community.

The Mentor Statement should be written considering the scientific and educational goals of NSBRI, especially the goal of the Postdoctoral Fellowship Program to train outstanding independent, productive investigators in space-related biomedical/biotechnological research.

The entire Mentor Statement should not exceed four pages of single-spaced text using 12 pt font with 1 inch margins.

b) Biographical Sketches and Information

The applicant should provide a comprehensive CV in a format of his/her choice; this document will not count toward the application page limitation, and should include the month and year of the award of the professional degree (as detailed in Appendix B, Section IV.A). If not included elsewhere, please list the

previous and current teaching responsibilities and educational outreach activities of the candidate. The candidate's CV should include professional activities during all months after the award of the terminal degree. A Biographical Sketch must be provided for the Mentor, and each should not exceed four pages. NIH-style Biographical Sketch format is acceptable. See Appendix C, c.5 for more information.

c) Facilities and Equipment

See Appendix C, c.6 for more information.

d) Research Plan

The length of the Research Plan cannot exceed 12 pages. Please note that the Proposal Summary on the Cover Page is not considered part of the 12-page Research Plan. The Research Plan must be single-spaced, typewritten, English-language text, using an easily read font having no more than ~10 characters per inch (typically a 12-point font). In addition, there shall be no more than 5.5 lines per inch of text. Proposers should not use a smaller font or squeeze lines of text in order to gain more text per page as it makes the evaluation process difficult. Pages should have at least 1-inch (2.5 cm) margins on all sides. Fonts must be embedded.

Referenced figures must be included in the 12 pages of the project description; however, figure captions can use a 10-point font. The figures and legends should be of a size that is easily discernable by the reviewer. The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall scientific merit of the proposed research and about the probability that the Postdoctoral Fellow will be able to accomplish the stated objectives with the resources available and within the timeframe of the NSBRI Fellowship. The hypotheses and specific aims of the proposed research must be clearly stated. **Research Plans that exceed the 12-page limit will be declined without review.** Literature cited and other proposal sections are not considered part of the 12-page limit. Please note that reviewers are not required to consider information presented as appendices or to view and/or consider web links in their evaluation of the proposal. **If this is a resubmission of a previously proposed project, please respond to any comments made in any prior review.**

e) Current Support

See Appendix C, c.8 for more information.

f) Special Matters (Specific information on required animal or human subjects protocol approval, if applicable)

NSBRI utilizes just-in-time practices for approval of the use of human subjects or animals. For proposals employing human subjects and/or animals, assurance of compliance with human subjects and/or animal care and use provisions is required within 90 days of notice of award. Please select "pending" or "approved" for the IRB/IACUC question on the Proposal Cover Page. If the IRB/IACUC certification is already approved at proposal submission, attach a copy of the certification as part of the proposal upload and select "approved." Otherwise, select "pending."

After award, a statement must be provided to NSBRI 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 Institutional Review Board (IRB) approval and/or approval by the Institutional Animal Care and Use Committee (IACUC).

The NSBRI will require current IRB or IACUC certification prior to each year's award.

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

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

Animal use and care requirements are described in the NASA Code of Federal Regulations (CFR) 1232 (*Care and Use of Animals in the Conduct of NASA Activities*):

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=282613b7928a4863f83c757c6e76a41e;rgn=div5;view=text;node=14%3A5.0.1.1.21;idno=14;cc=ecfr>

Additional Requirements for Research Employing Human Subjects and/or Animals

With regard to research involving human subjects, NASA and NSBRI have adopted the National Institutes of Health (NIH) policy. Women and members of minority groups and their subpopulations must be included in NASA-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided showing that inclusion of these groups is inappropriate with respect to the health of the subjects or the purpose of the research.

g) Vertebrate Animal Scientific Review (VASR), if applicable

Responses to this solicitation proposing experiments that require vertebrate animals must address the five points outlined in Appendix D. This response should be presented as part of the main proposal upload and is limited to two pages. These two pages are not considered part of the 12-page Research Plan. A sample VASR is provided in Appendix D.

h) References, Citations and Web Links

References cited are not considered part of the 12-page Research Plan. Reviewers are not, however, required to consider web links in their evaluation of the proposal.

i) Appendices and Reprints

If included, Reprints and Appendices do not count toward the Research Plan page limit and are to be included following all other sections of the proposal. **However, reviewers are not required to consider information presented in reprints or as appendices.**

C. Submission Dates

Solicitation NSBRI-RFA Identifier: NSBRI-RFA-10-01

Notices of Intent Due (not required): July 23, 2010

Proposals Due: August 18, 2010, 5:00 p.m. ET

Selection Announcement: Fall 2010

Funding Begins: Approximately 30-90 days following notification of selection

Selecting Official: Director, National Space Biomedical Research Institute

D. Letters of Reference

Three letters of reference for Postdoctoral Fellowship Program applicants must be received at the address below by August 25, 2010. The applicant's proposed Mentor may provide one of the three letters of reference if this individual is able to credibly address the applicant's strengths as a researcher and the applicant's potential for a successful career in space life sciences research. Postdoctoral Fellowship Program applicants will be notified via email when each letter of reference is received by NSBRI. **Applications without all three required letters received by August 25, 2010, will be considered incomplete and may be returned without review.**

National Space Biomedical Research Institute
RE: Postdoctoral Fellowship Reference Letters
One Baylor Plaza, NA-425
Houston, TX 77030-3411

713-798-7412

VI. Review and Selection Process

Upon receipt, applications will be reviewed for compliance with the requirements of this Request for Applications. This includes the following:

1. Submission of complete applications as specified in this RFA. Proposals must be responsive to the research emphases described in this NSBRI-RFA and include a Research Plan that is **not more than 12 pages in length.**
2. Submission of all other appropriate forms, letters, and institutional and Mentor electronic signatures as required by this NSBRI-RFA and NSPIRES.

Note: Non-compliant applications will be withdrawn from the review process and returned without further review.

Compliant applications submitted in response to this NSBRI-RFA will undergo an intrinsic scientific or technical merit review by an objective, external peer review panel.

Criteria for Evaluation of Applications

Applications will be evaluated on the basis of three criteria: (i) scientific merit and programmatic relevance of the proposal and the probability that the stated research objectives will be accomplished with the resources available (see Appendix B, Section II); (ii) training environment and Mentoring plan;

and (iii) research, teaching and educational outreach background and qualifications of the candidate. Final selections for funding of proposals will be made by the NSBRI Director. Applicants are encouraged to review detailed project summaries for current and completed NSBRI research projects at <http://www.nsbri.org>. The technical summaries appear in the “Science and Technology Research Areas” section.

Development of a Selection Recommendation

A selection recommendation will be developed based on the criteria as described above. **Deficiencies in any of these three criteria factors may prevent selection of an application.** The development of selection recommendations is the responsibility of the peer review panel. Final selections for funding of proposals will be made by the NSBRI Director. Only grants will be awarded as a result of this NSBRI-RFA.

Third-Year Renewal Review

Requests for an optional third year of funding will be evaluated by the NSBRI Executive Science and Medicine Council (ESMC) on the basis of the following four criteria:

1. A written request submitted jointly by the Postdoctoral Fellow and Mentor, not earlier than eight months nor later than five months prior to the completion of year two of the award period, clearly stating the need for, and the value to be added by, a third year of funding to both the research and the Fellow;
2. A statement of work outlining the experimental design, methodologies to be utilized, and anticipated results to be obtained during the third year of the Fellowship;
3. A detailed curriculum vitae for the Fellow outlining the research and outreach accomplishments arising from the NSBRI Fellowship funding; and
4. Copies of abstracts of presentations at scientific meetings, workshops, and symposia, as well as copies of manuscripts published, in press, in review, or in non-submitted manuscript form describing research accomplished by the Fellow during the Fellowship. Other deliverables or products may be considered as evidence of productivity during the Fellowship period, as appropriate, in lieu of, or in addition to, abstracts and papers.

Note that this package of information must be accompanied by a cover page that includes the original signature of the Authorized Organizational Representative from the institution at which the Fellowship is being conducted.

Recommendations to award or reject requests for an optional third year of funding will be developed by the ESMC; final selections for third-year awards will be made by the NSBRI Director.

VII. Travel and Reporting Requirements

Travel Requirements

Each year, Postdoctoral Fellows selected in response to the NSBRI-RFA will be expected to attend the following meetings: a mandatory meeting of Postdoctoral Fellows at the annual NSBRI/NASA Human Research Program Investigators’ Workshop in the Houston area, the appropriate NSBRI research team meeting, and a scientific meeting of the Fellow’s choice. During the first summer of the Fellowship, the Postdoctoral Fellow will also be expected to attend a 4-5 day NSBRI Summer Bioastronautics Institute

at Baylor College of Medicine in Houston hosted by the NSBRI Postdoctoral Fellowship Program Coordinator and the NSBRI Education Team. This meeting will include a visit at the NASA Johnson Space Center. The Johnson Space Center visit will be arranged by the Fellowship Program. Funding, as available, will be provided to cover the costs associated with these meetings.

Peer-Reviewed Publications, Poster Presentations and Abstracts

It is expected that results from funded research will be published in peer-reviewed journals as the work is completed. **Published papers, as well as posters and abstracts, must acknowledge NSBRI support.**

Annual Report

NSBRI uses Annual Reports to assess progress relative to stated research objectives and hypotheses as declared in the original grant proposal by the Postdoctoral Fellow. An Annual Report is due to NSBRI no later than 30 days before the end of the first year of funding to communicate the status of the completed research and to identify peer-reviewed publications to date. A format outlining the report requirements will be provided. **Submission of the first year annual report is required before the funding for the second year will be issued. Likewise, the second year annual report is required before funding for an optional third year will be issued.**

Final Report

A Final Report is required that addresses the entire scope of the project and links the research to IRP risks. The report also includes peer-reviewed publications and intellectual property disclosures resulting from the NSBRI-supported work. This report must be submitted to NSBRI within 60 days after the end of the Fellowship.

Career Tracking

To assess the impact of Postdoctoral Fellowships on the career advancement of young scientists and to provide an active network of investigators in space biomedical research, NSBRI will request brief, periodic updates on the career status and accomplishments of NSBRI Postdoctoral Fellows throughout their careers. Requests for updates will be facilitated mainly by the NSBRI Postdoctoral Fellowship Program Coordinator and will include, but not be limited to, interviews with participants.

Formative Assessment

NSBRI will be actively engaged in the ongoing assessment of the Postdoctoral Fellowship Program to assure that the program has been implemented as planned and to make program enhancements. Formative assessments during the funding period will include, but are not limited to, institutional site visits to assess research facilities and accomplishments, and to interview the Postdoctoral Fellows and Mentors. This formative assessment will be facilitated mainly by the NSBRI Postdoctoral Fellowship Program Coordinator.

**INSTRUCTIONS FOR RESPONDING TO NSBRI
REQUESTS FOR APPLICATIONS**

(a) General.

(1) Proposals received in response to an NSBRI Request for Applications (NSBRI-RFA) will be used only for evaluation purposes. The NSBRI does not allow a proposal, the contents of which are not available without restriction from another source, or any unique ideas submitted in response to an NSBRI-RFA, to be used as the basis of a solicitation or in negotiation with other organizations, nor is a pre-award synopsis published for individual proposals.

(2) A solicited proposal that results in an NSBRI award becomes part of the record of that transaction and may be available to the public on specific request; however, information or material that the NSBRI and the awardee mutually agree to be of a privileged nature will be held in confidence to the extent permitted by law, including the Freedom of Information Act.

(3) NSBRI-RFAs contain programmatic information and certain requirements which apply only to proposals prepared in response to that particular announcement. These instructions contain the general proposal preparation information which applies to responses to all NSBRI-RFAs.

(4) A cooperative sub agreement will be used to accomplish an effort funded in response to an NSBRI-RFA. The NSBRI will coordinate the implementation of the award instrument. Contracts resulting from NSBRI-RFAs are subject to the Federal Acquisition Regulation (FAR) and the NASA FAR Supplement. Any resultant grants or cooperative agreements will be awarded and administered in accordance with the NASA Grant and Cooperative Agreement Handbook (NPG 5800.1).

(5) The NSBRI has a mandatory format for responses to NSBRI-RFAs. All applications must be submitted utilizing the NSPIRES System. For further information, please see Appendix B, Section V.B.

(6) To be considered for award, a submission must, at a minimum, present a specific project within the areas delineated by the NSBRI-RFA; contain sufficient technical information to permit a meaningful evaluation; be signed by an official authorized to legally bind the submitting organization; not merely offer to perform standard services or to just provide computer facilities or services; and not significantly duplicate a more specific current or pending NASA or NSBRI solicitation.

(b) NSBRI-RFA-Specific Items. Several proposal submission items appear in the NSBRI-RFA itself: the unique NSBRI-RFA identifier; dates for proposal deadlines; instructions for submission of proposals; electronic submission format; and sources for

more information. Items included in these instructions may be supplemented by the NSBRI-RFA.

(c) The following information is needed to permit consideration in an objective manner. NSBRI-RFAs will generally specify topics for which additional information or greater detail is desirable.

(1) Proposal Cover Page

- (i) The legal name of the organization and specific division or campus identification if part of a larger organization;
- (ii) A brief, scientifically valid project title intelligible to a scientifically literate reader and suitable for use in the public press;
- (iii) Type of organization: e.g., profit, nonprofit, small business, woman-owned, socially and economically disadvantaged, etc.;
- (iv) Name and telephone number of the Mentor (PI) and business personnel who may be contacted during evaluation or negotiation;
- (v) Identification of the NSBRI-RFA, by number and title, to which the proposer is responding;
- (vi) Desired starting date, and duration of project;
- (vii) Date of submission;
- (viii) Signature of a responsible official or authorized representative of the organization, or any other person authorized to legally bind the organization (unless the signature appears on the proposal itself); and
- (ix) Signature of a Mentor for Postdoctoral Fellowship Program applications.

(2) Restriction on Use and Disclosure of Proposal Information. Information contained in proposals is used for evaluation purposes only. Offerors or quoters should, in order to maximize protection of trade secrets or other information that is confidential or privileged, place the following notice at the beginning of the Research Plan (which is in addition to the specified page limits) and specify the information subject to the notice by inserting an appropriate identification in the notice. In any event, information contained in proposals will be protected to the extent permitted by law, but the NSBRI assumes no liability for use and disclosure of information not made subject to the notice.

Notice

Restriction on Use and Disclosure of Proposal Information

The information (data) contained in [insert page numbers or other identification] of this proposal constitutes a trade secret and/or information that is commercial or financial and confidential or privileged (“Information”). It is furnished to the NSBRI in confidence with the understanding that it will not, without permission of the Offeror, be used or disclosed other than for evaluation purposes; provided, however, that in the event a contract (or other agreement) is awarded on the basis of this proposal the Government shall have the right to use and disclose this Information to the extent provided in the contract (or other agreement). This restriction does not limit the Government’s right to use or disclose this Information if obtained from another source without restriction. The obligations in this Section shall not apply

with respect to any Information which:

- (a) is disclosed in a printed publication available to the public, is described in a patent anywhere in the world, is otherwise in the public domain at the time of disclosure, or becomes publicly known through no wrongful act on the part of NSBRI;
- (b) is known to NSBRI or becomes known to NSBRI through disclosure by sources other than the Offeror having the right to disclose such Information;
- (c) is disclosed pursuant to the requirement of a governmental agency or any law requiring disclosure thereof;
- (d) is generally disclosed to third parties by the Offeror without similar restriction on such third parties; or
- (e) is approved for release by written authorization of the Offeror.

(3) Proposal Summary. Include a concise 100-300 word abstract describing the objective and the method of approach.

(4) Project Description (Research Plan). The main body of the proposal shall be a detailed statement of the work to be undertaken and should include objectives and expected significance; relation to the present state of knowledge; and relation to previous work done on the project and to related work in progress elsewhere. The project description (Research Plan) cannot exceed 12, 8 ½ by 11 inch pages using a standard 12-point font and one-inch margins. The statement should outline the plan of work, including the broad design of experiments to be undertaken and a description of experimental methods and procedures. The project description should address the evaluation factors in these instructions and any specific factors in the NSBRI-RFA. Any substantial collaboration with individuals other than the Mentor, or use of consultants, should be described. Subcontracting significant portions of a research project is discouraged.

(5) Personnel. The Mentor is responsible for supervision of the work. Short biographical sketches for both the Postdoctoral Fellow and the Mentor, a list of principal publications and any exceptional qualifications should be included. Omit social security number and other personal items which do not merit consideration in evaluation of the proposal.

(6) Facilities and Equipment. Describe available facilities and major items of equipment relevant to the proposed project, and any additional major equipment that will be required. Identify any Government-owned facilities, industrial plant equipment, or special tools that are proposed for use. Include evidence of its availability and the cognizant Government points of contact.

(7) Security. Proposals should not contain security-classified material. If the research requires access to, or may generate, security-classified information, the submitter will be required to comply with Government security regulations.

(8) Current Support. For other current projects being conducted by the Postdoctoral Fellow and Mentor, provide title of project, sponsoring agency, percent effort, and project starting and ending dates. Please include a brief description of any potential overlap with the work described in this NSBRI Postdoctoral Fellowship Program application.

(9) Special Matters. Include any required statements of environmental impact of the research, human subject or animal care provisions, conflict of interest, or on such other topics as may be required by the nature of the effort and current statutes, executive orders, or other current Government-wide guidelines.

(10) Length. Unless otherwise specified in the NSBRI-RFA, effort should be made to keep proposals as brief as possible, concentrating on substantive material. Proposals may not exceed 12 pages. Necessary detailed information, such as reprints, should be included as attachments.

(11) Withdrawal. Applications may be withdrawn at any time before award. Applicants are requested to notify the NSBRI if the proposal is funded by another organization or of other changed circumstances which dictate termination of evaluation.

(12) Selection for Award.

(12.1) When an application is not selected for award, the applicant will be notified. The NSBRI will explain generally why the application was not selected. Applicants desiring additional information may contact the selecting official who will arrange a debriefing.

(12.2) When an application is selected for award, negotiation and award will be handled by the NSBRI in the funding installation. The application is used as the basis for negotiation. The contracting officer may request certain business data and may forward a model award instrument and other information pertinent to negotiation.

(13) Cancellation of NSBRI-RFA. The NSBRI reserves the right to make no awards under this NSBRI-RFA and to cancel this NSBRI-RFA. The NSBRI assumes no liability for canceling the NSBRI-RFA or for anyone's failure to receive actual notice of cancellation.

Vertebrate Animal Scientific Review (VASR)

A. Vertebrate Animal Scientific Review (VASR)

If vertebrate animals are to be used, the following five points must be addressed completely by applicants in the VASR worksheet of their proposal:

1. Detailed description of the proposed use of animals, including species, strains, ages, sex and number to be used
2. Justification of the use of animals, choice of species and numbers to be used, and proposer's assessment of potential benefits and knowledge to be gained.
3. Information on the veterinary care of the animals
4. Description of procedures for ensuring discomfort, distress, pain and injury are minimized
5. Method of euthanasia and the reasons for its selection

Each of the five points must be addressed, for all performance sites, in the VASR worksheet. The VASR worksheet will be reviewed by the scientific merit review panel and the proposal coded as either No Vertebrate Animals, No Concerns/Acceptable, or Concerns/Unacceptable. If coded as Unacceptable, NSBRI staff will work with the applicant to resolve concerns prior to award. Coding of the proposal as "Acceptable" or "No Vertebrate Animals" is required prior to award.

In order to be coded as "No Vertebrate Animals," the vertebrate tissue used in the study must be obtained from other sources (e.g., tissue repository, animals euthanized for an unrelated purpose). The source of the tissue should be included in the VASR to validate the coding as "No Vertebrate Animals" used. If vertebrate tissues are obtained through euthanasia for tissue harvest, the proposed research is coded as "Use of Live Vertebrate Animals." The generation of custom antibodies is coded as "Use of Live Vertebrate Animals."

A "performance site(s)" is defined as the institutions where procedures with animals will be performed. If the applicant institution is not the site where animal work will be performed, the performance site must be identified. If there is more than one performance site, the description of animal care and use at each site must be included and must address the five points.

Applicants should be aware that NSBRI may release information contained in specific funded proposals pursuant to Freedom of Information Act requests.

B. Detailed Instructions for Preparation of the VASR

These instructions are to assist applicants in preparing their VASR information.

Preparation of the VASR Worksheet:

Typically, all of the required elements for the VASR can be addressed within 1-2 pages.

Point 1 - Description of animals and how they will be used

A concise, complete description of the proposed procedures must be included in the VASR. While additional details may be included in the Research Strategy, a coherent, albeit brief, description of the proposed use of the animals must be provided within the VASR. The description must include sufficient detail to allow evaluation of the procedures. Examples of the types of procedures that should be described include blood collection, surgical procedures, administration of substances, tumor induction and post-irradiation procedures. In describing the animals, investigators must provide the following information for each species and/or strain to be used:

- Species
- Strain
- Ages
- Sex
- Number of animals to be used

Point 2 - Justifications for use of animals

Investigators must justify the use of animals in the proposed research. The justification must indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used and should indicate the potential benefits and knowledge to be gained. In addressing this point, researchers are encouraged to consider means to replace, reduce and refine the use of animals. Rationale for the choice of species must be provided. The rationale should indicate the advantages of the species chosen and why alternative species are not appropriate. If less highly evolved or simpler animal models are available, justification must be provided for using more advanced species. For example, the use of non-human primates (NHP), dogs or cats should be thoroughly justified. If NHP species are to be used, a comparison to other NHP species may be appropriate. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and the number of animals used.

Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used should include considerations of animal availability, experimental success rate, inclusion of control groups and requirements for statistical significance; cite power calculations where appropriate.

Point 3 - Veterinary care

Descriptions of veterinary care should indicate the availability of veterinarians or veterinary technicians. For example, the VASR might indicate the number of veterinarians and veterinary technicians associated with the applicant institution, and their proximity to the performance site(s). The frequency with which veterinary staff observe or monitor animals should be stated. If survival surgeries are proposed, veterinary involvement or post-surgical monitoring should be described. For example, if animal use involves invasive approaches that might result in discomfort, distress or pain, the investigator should indicate if or when veterinary care is necessary. The indicators for veterinary intervention to alleviate discomfort, distress or pain should be described. The ways in which veterinary

staff may intervene should be described.

Point 4 - Provisions to minimize discomfort, distress, pain and injury

Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury should be identified. Methods to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agent(s) should be specified by name or class. Any additional (e.g., non-pharmaceutical) means to avoid discomfort, distress, pain or injury should be described briefly. The manner, circumstances and duration of all post-surgical provisions and care should be described. If special housing is necessary following surgery or manipulations, the VASR should describe these provisions, the duration and type of monitoring provided. If procedures (e.g., pharmacological or surgical) might lead to severe discomfort, distress, pain or injury, indicators for humane endpoints and euthanasia (e.g., severe infection, respiratory distress, failure to eat, tumor size) should be described. All of these issues are particularly important for survival surgeries. If multiple surgeries are proposed, these must be well justified and provisions to avoid any potential complications must be described. Describe how restraining devices will be used, if applicable.

Point 5 - Euthanasia

The method(s) of euthanasia must be described and must comply with the *AVMA Guidelines on Euthanasia*. If the method(s) do not comply with AVMA recommendations, the rationale and scientific justification for use of the method(s) must be provided. The indicators for euthanasia (i.e., termination of experiment or humane endpoints) should be stated. It is not sufficient to state simply that humane methods consistent with the recommendations of the *AVMA Guidelines on Euthanasia* or the Institutional Animal Care and Use Committee (IACUC) will be used.

References

Guidance in this document is based on NASA and PHS Policy, and federal requirements. The NASA and PHS Policy incorporate the standards in the *Guide for the Care and Use of Laboratory Animals* and require that euthanasia be conducted according to the *AVMA Guidelines on Euthanasia*. Additional background information and references are available on the Office of Laboratory Animal Welfare website (<http://olaw.nih.gov>).

NASA Policy and Requirements <http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPD&c=8910&s=1B>
<http://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=8910&s=1B>

PHS Policy

<http://grants.nih.gov/grants/olaw/references/phspol.htm>

Guide for the Care and Use of Laboratory Animals

http://www.nap.edu/openbook.php?record_id=5140

AVMA Guidelines on Euthanasia

http://www.avma.org/issues/animal_welfare/euthanasia.pdf

C. Worksheet to Assist in Addressing the Required Five Points of the VASR

Performance site(s):

The five points must be addressed for all performance sites.

If the applicant's institution is not where animal work will be performed, are all collaborative performance site(s) identified?

If more than one performance site is planned, are descriptions of animal care and use for each site provided?

Point 1 - Describe the animals and their proposed use; address the following for all species to be used:

Species

Strains

Ages

Sex

Number of animals to be used

A concise, but complete, description of proposed procedures (i.e., sufficient information for evaluation)

Point 2 - Provide justifications for:

The use of animals

Choice of species

Number of animals to be used (cite power calculations, if appropriate)

Point 3 - Provide a general description of veterinary care, including veterinary support that is specifically relevant to the proposed procedures. Indicate the following:

A brief account of veterinary staff and their availability

The regular schedule of monitoring of animals by veterinary staff

Any additional monitoring and veterinary support that may be required to ensure humane care, if relevant to the procedures proposed (e.g., post-surgical)

Indicators for veterinary intervention to alleviate discomfort, distress or pain, if relevant

Point 4 - Describe procedures to minimize discomfort, distress, pain and injury. Indicate the following:

Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain or injury

Procedures to alleviate discomfort, distress, pain or injury

Identify (by name or class) any tranquilizers, analgesics, anesthetics and other treatments (e.g., antibiotics) and describe their use

Provisions for special care or housing that may be necessary after experimental procedures

Plans for post-surgical care, if survival surgeries are proposed

Indicators for humane experimental endpoints, if relevant

Describe the use of restraint devices, if relevant

Point 5 - Describe methods of euthanasia:

- __ Describe the method(s) of euthanasia and rationale for selection of method(s)
- __ Indicate if the method is consistent with AVMA Guidelines on Euthanasia
 - __ Provide a scientific justification for the choice of method if not AVMA recommended

D. Example of a complete VASR

(This VASR worksheet has been modified from the original. It addresses all five points concisely.)

Vertebrate Animals

Aims 1-3 will be addressed *in vitro*; Aim 4 will be addressed using a mouse model of ocular infection.

1. Female Balb/c mice will be used to determine if virions treated with enzyme can cause viral keratitis, and to test the *in vivo* efficacy of the test articles. The studies will require 700 mice, 4 to 6 weeks old. Based on prior experience, 70 groups, each including 10 mice will be required over five years to achieve adequate statistical power. Ocular infection is accomplished by scratching the cornea of anesthetized mice with a sterile needle and exposing the scarred portion of the cornea to inoculum. Test articles are applied directly to the scarified cornea as liquid or cream. Following inoculation and recovery, mice are monitored for 30 days. With the mice under anesthesia, the eyes will be examined at intervals, microscopically, and are flushed with medium with 2% serum to determine viral titers. Thirty days post-infection, with the mice under deep anesthesia, the trigeminal ganglia are removed aseptically for viral assay, followed immediately by euthanasia.

2. The proposal is to study mechanisms for the prevention of ocular disease caused by viral infections, a leading cause of blindness in the US. Mice are needed for these experiments because no alternative *in vitro* model incorporates all elements of the mammalian ocular immune system; too little is known about this system for the development of computer simulations. Mice are a well accepted model for studying viral keratitis, assessing the virulence of viral strains and testing the efficacy of antivirals. Mice provide several advantages: a) The murine ocular immune system is similar enough to that of humans to allow extrapolation of the results; b) Their small size allows the use of smaller amounts of drugs for testing; c) The entire mouse genome is known and easily manipulated genetically, allowing extension of the work in future genetic studies. Female mice will be used due to compatibility issues. Balb/c mice will be used because they have intermediate resistance to infection. ABC-4 knockout and ABC-4 test-strains will be used. For the enzyme study, we will use 4 treatment groups: enzyme-1, enzyme-2, enzyme-3, and mock treated virus. We will also use different amounts of inoculum for each condition allowing a more accurate calculation as to the effect of the digestions on infectivity. For the test-article peptide study, we will use two formulations (one aqueous and one hydrophobic), test 4 different concentrations and also vary the treatment protocol. Two groups will receive a single dose of drug in each of the two formulations prior to the addition of virus to assess prophylactic activity. These groups will not receive any additional enzyme treatments. Two groups will be infected with virus and beginning 4 h post-infection, we will treat with each formulation and concentration 4 times daily for 7 days.

3. All mice are housed in the Animal Resources Center of the University. Animal housing rooms are under temperature and humidity control. The mice will not be subjected to water or food restrictions, and bedding material is placed in each cage. The facility is staffed by four full time veterinarians and six veterinary technicians; the veterinary staff is on site and a clinical veterinarian is available at all times. Animal care staff conducts routine husbandry procedures (e.g., cage cleaning, feeding and watering) and checks animals daily to assess their condition. Laboratory staff monitors mice when

treatments are given, disease is scored or samples are collected for titring. The veterinary staff monitors mice in their home cages, weekly. If animals exhibit any indication of infection or distress, the veterinary staff confers with laboratory personnel to recommend appropriate antibiotics, analgesics or other pharmaceuticals. The veterinary staff may intervene or recommend euthanasia based on animal welfare concerns.

4. Mice will be anesthetized with isoflurane (3-5%) during the infection process, when treatments are administered and titer samples are collected. This eliminates the need for restraint devices and topical anesthetics that would interfere with the infection and disease process. For post-procedural pain relief, we will administer buprenorphine twice daily for the duration of the experiments (i.e., approximately two weeks post-inoculation). Death is not an endpoint for the studies; the Balb/c strain was chosen because of its resiliency and resistance to this particular virus. Our goal is to avoid severe infections leading to death. Though unlikely, if an animal reacts severely, it will be euthanized, based on humane indicators (e.g., failure to groom or feed). These experiments involve no post-surgical survival animals.

5. All mice will be euthanized by cervical dislocation under isoflurane anesthesia. Isoflurane ensures that the mice are unconscious, while dislocation ensures quick death. This minimizes animal distress, is effective and efficient; it is consistent with the recommendations of the *AVMA Guidelines on Euthanasia*.