

OMB Clearance No. 2700-0087

**National Aeronautics and Space Administration Headquarters  
Office of Biological and Physical Research  
Washington, DC 20546**

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**Research Opportunities Soliciting  
Ground-Based Studies for  
Human Health in Space**

**Biomedical Model Systems Program  
Biomedical Research and Countermeasures Program  
National Space Biomedical Research Institute**

**New  
NASA Research Announcement  
NNH04ZUU003N**

Catalog of Federal Domestic Assistance (CFDA) Number: 00.000

**NRA Issued: June 4, 2004  
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Proposals Due: September 8, 2004**

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space

## I. Funding Opportunity Description

### A. Summary and Background Information

The National Aeronautics and Space Administration (NASA) Vision is:

*To improve life here,  
To extend life to there,  
To find life beyond.*

On January 14, 2004, the President of the United States announced a new vision for NASA to:

- Implement a sustained and affordable human and robotic program to explore the solar system and beyond;
- Extend human presence across the solar system, starting with a human return to the Moon by the year 2020, in preparation for human exploration of Mars and other destinations;
- Develop the innovative technologies, knowledge, and infrastructures both to explore and to support decisions about the destinations for human exploration; and
- Promote international and commercial participation in exploration to further U.S. scientific, security, and economic interests.

The vision affirms the nation's commitment to space exploration and provides a clear direction for the civil space program. The activities carried out to implement this vision will be paced by experience, technology readiness, and affordability. Implementation involves key missions, including Moon and Mars exploration.

The Office of Biological and Physical Research (OBPR) contributes to this Vision through its support of research that addresses the following questions:

- How can we assure the survival of humans traveling far from Earth?
- How does life respond to gravity and space environments?
- What new opportunities can research bring to expand understanding of the laws of nature and enrich lives on Earth?
- What technology must we create to enable the next explorers to go beyond where we have been?
- How can we educate and inspire the next generations to take the journey?

## B. Solicitation Focus

*Proposals outside the stated area of emphasis will be considered non-responsive and will be returned without review. NASA reserves the right to act in the best interests of the Federal Government in the matter of acceptance and evaluation of all proposals.*

### 1. Goals and Objectives

This NASA Research Announcement (NRA) solicits ground-based research for the Biomedical Model Systems (BMS) Program, a component of the Fundamental Space Biology Division and for the Biomedical Research and Countermeasures (BRC) Program, a component of the Bioastronautics Research Division, including the National Space Biomedical Research Institute (NSBRI). This consolidated NRA supports the following goals and objectives of the NASA Office of Biological and Physical Research (OBPR):

- Understand the physiological mechanisms responsible for space-flight-related biomedical and behavioral changes in humans in support of countermeasure development;
- Develop countermeasures that allow humans to live and work in microgravity for long durations, minimize the risks in readapting to gravity, and optimize crew safety, well-being, and performance; and
- Identify, characterize, and mitigate health, environmental, and other operational human medical risks associated with space exploration.

**Proposers may apply as an individual NASA investigator, or as an investigator to join one of the established research teams of the NSBRI. Investigators may submit more than one proposal in response to this NRA; however, identical proposals may NOT be submitted to multiple programs.**

- **Individual BMS Investigator Research (see NNH04ZUU003N-BMS).** The BMS program sponsors research seeking to understand the effects of spaceflight on the molecular, cellular and organismal levels in support of human space exploration. This research, utilizing appropriate cellular, tissue, plant, animal, and human models, will enable NASA to develop the biological knowledge to enable a long-duration human presence in space and to support other NASA biology-related activities.
- **Individual BRC Investigator Research (see NNH04ZUU003N-BRC).** The BRC Program is responsible for sponsoring research that will lead to development of practical health-related methods for the prevention, diagnosis, treatment, and/or rehabilitation of humans who live and work in microgravity. It also responds directly to the requirements, approved by the Office of Health and Medical Systems, which deals with the health and safety of human space travel (see Guidance for NASA Medical Board Procedures: [http://peer1.nasaprs.com/peer\\_review/prog/mpbhand.pdf](http://peer1.nasaprs.com/peer_review/prog/mpbhand.pdf)).
- **NSBRI Team Research (see NNH04ZUU003N-NSBRI).** The NSBRI is a NASA-initiated and funded, non-profit research consortium charged with developing biomedical

countermeasures for potential health problems that could occur in astronauts either during long-duration spaceflight or on their return to Earth. The current NSBRI program consists of approximately 70 research and technology projects organized into research teams.

**It is critical for investigators to read carefully ALL of the instructions in this NRA. All proposals will undergo peer review using similar processes and procedures, but procedures and forms for proposal submission differ for the different programs and elements, and the eventual funding of selected proposals will differ for the different types of awards.**

Programmatic balance is maintained by the selecting official(s) for the program.

**This NRA does not request proposals for flight. Proposals that require flight resources, including pre- and post-flight astronaut subjects, will be returned to the proposer without being reviewed.** It is important that the proposer read all instructions in this NRA carefully, as many of the programmatic emphases are different from those appearing in previous NRAs. In addition, each section includes guidelines, requirements, and instructions for preparing and submitting proposals, and defines the administrative policies governing the particular components described in this NRA.

To be responsive to this research solicitation, proposed studies should be hypothesis-driven and lead to new knowledge within accepted scientific standards. Purely phenomenological approaches with no significant mechanistic basis or likely gain in scientific knowledge are not acceptable. Proposals should take into account the impact of gender, age, nutrition, stress, genetic predisposition, or sensitivity to other factors of importance.

Investigators are encouraged to review summaries of the research currently funded in this program by accessing the NASA Office of Biological and Physical Research (OBPR) Tasks and Bibliography (OBPR Task Book) at [http://research.hq.nasa.gov/code\\_u/code\\_u.cfm](http://research.hq.nasa.gov/code_u/code_u.cfm). It should be noted that in order to achieve programmatic balance, specific topics that are currently well represented in the portfolio would be de-emphasized.

The research programs described in this NRA support the utilization of specialized NASA ground-based facilities and the development of special technologies required in the pursuit of their research goals. Investigators should refer to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these NASA specialized ground-based facilities into their proposal online at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

## 2. Bioastronautics Critical Path Roadmap (BCPR)

In order to identify and make publicly known the biomedical and health risks of spaceflight, and the research questions that must be answered to reduce those risks, NASA has developed the Bioastronautics Critical Path Roadmap (BCPR). The BCPR is an interdisciplinary tool to assess, understand, mitigate, and manage the risks to humans that are associated with long-term exposure to the space environment. It assumes an overarching strategy that integrates requirements, risks, risk factors, enabling questions, tasks, deliverables, and risk mitigation with

the intent of directing biomedical research in support of human spaceflight, especially human missions of exploration. The BCPR is based in part on recommendations from internal NASA experts, NSBRI scientists, advisory committees representing the United States science community, task forces, and published reports such as the National Research Council (NRC) Space Studies Board's "A Strategy for Research in Space Biology and Medicine in the New Century;" the Aerospace Medical Advisory Committee; the NASA Task Force on Countermeasures; the International Space Life Sciences Working Groups publications on Radiation, Bone, Muscle, Cardiovascular, Human Factors, and Neuroscience Workshops; and the NASA Medical Policy Board Document.

The ultimate goal of the BCPR is to protect the health and safety of spaceflight crews by allowing NASA and the community of scientists to better define and focus the research that is required for development and validation of operational health care "deliverables" for the prevention, treatment, and rehabilitation of spaceflight changes and of appropriate habitation and medical care systems.

The BCPR is not a "critical path" analysis in the strict engineering sense. The BCPR will evolve to accommodate new information and technology development and will enable a formal critical path analysis in the future.

The current BCPR identifies 50 risks and over 400 enabling questions. The BCPR should be reviewed by potential investigators at [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm).

**The proposer must examine and understand the BCPR, and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will address. An example is shown in Table I, and the sample form (Form B) can be found attached to this NRA or at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). A similar assessment will be performed by NASA and the NSBRI to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify what BCPR risks and questions are being addressed by the research will be returned to the proposer without review.**

**Table 1: Bioastronautics Critical Path Roadmap (BCPR) Form**

*EXAMPLE ONLY – Complete Form B for specific proposal*

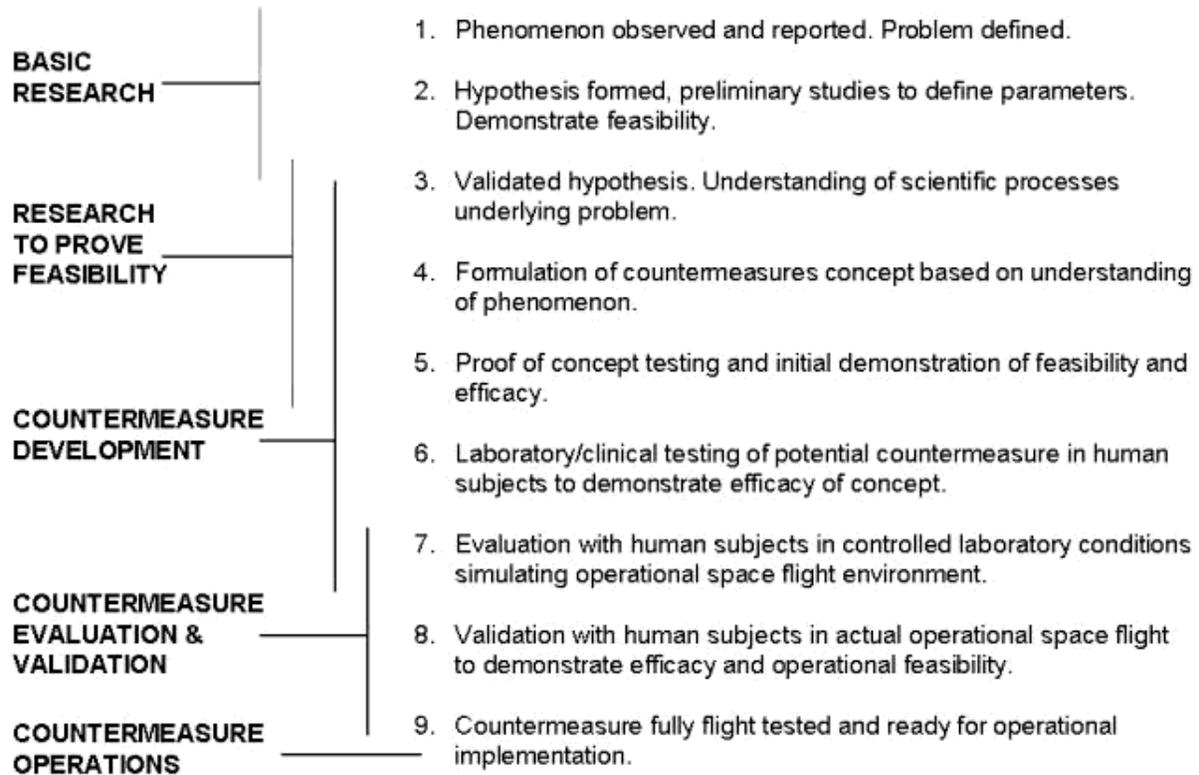
<u>Hypotheses</u>	<u>Risk Number</u> <b>(from BCPR)</b>	Bioastronautics Critical Question Number <b>(from BCPR)</b>	<u>Enabling Question</u> <b>(from BCPR)</b>	<u>Specific Aim</u>
The combined effects of hypergravity (simulating launch and landing) and bedrest (simulating spaceflight) along with associated physical and psychological stress will decrease virus specific cellular immunity and reactivate latent herpes viruses.	Risk #12 Allergies and Autoimmune	12a	What are the molecular and genetic mechanisms of loss of immunoregulation and immune tolerance that occur with exposure to the spaceflight conditions of radiation, microgravity, isolation, stress, microbial contamination, sleep deprivation, extreme environments and nutritional deficiency?	#1: Assess stress levels utilizing measures of biochemical and psychological stress.  #2: Determine virus specific T-lymphocyte immunocompetence.
	Risk #22 Immunodeficiency, Infections	12c	What are the allergies and autoimmune diseases that are likely to occur in astronauts exposed to spaceflight conditions of different missions and durations?	3: Quantify latent herpes virus reactivation
Additional hypotheses as required.				

### 3. Countermeasures Readiness Levels (CRLs)

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 “flow” 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

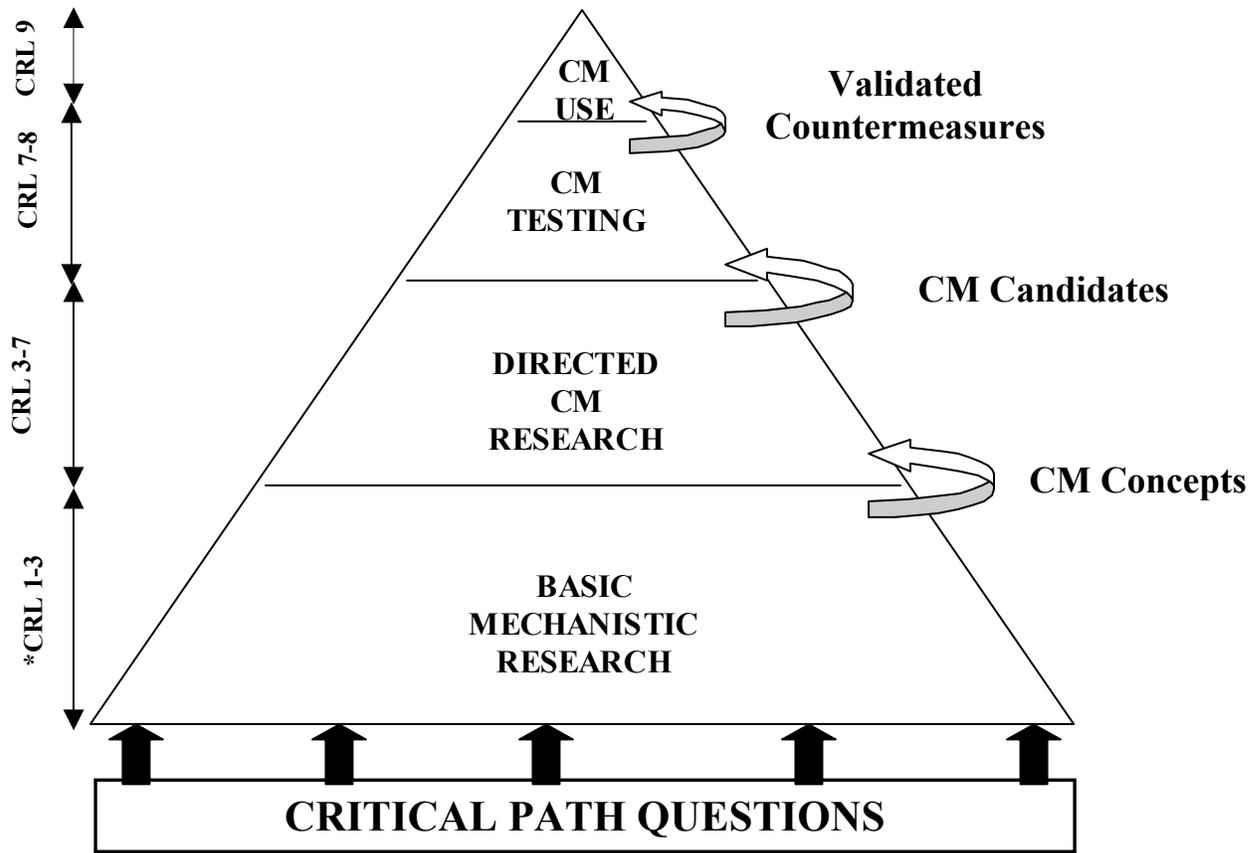
describes the level of scientific maturity of BRC or BMS research ranging from the fundamental studies that suggest potential countermeasures to studies that allow the systematic evaluation and validation of countermeasures prior to operational implementation.

**Figure 1. Countermeasure Readiness Levels**



Countermeasure development usually progresses through systematic research. Research flows through various levels of countermeasure readiness. Figure 2 represents this general progression. The boundaries between the types of activities are approximate. A potential countermeasure ready for validation in flight is one that has a thorough, successful history of ground-based, clinical, and/or flight analog testing. This NRA does not solicit CRL 7 and 8 research sponsored by the Countermeasure Evaluation and Validation Project. Other NASA Research Announcements may be issued throughout the year to call for studies to evaluate potential countermeasures. To have NASA notify you by email in the future about its requests for research proposals, register at <http://proposals.hq.nasa.gov/proposal.cfm>.

**Figure 2. Countermeasure Development Process**



\* Countermeasures Readiness Level (CRL)

#### 4. Biomedical Data

Biomedical data are being collected in both the Longitudinal Study of Astronaut Health (LSAH) and the Life Sciences Data Archive (LSDA). These databases can be made available for research activities subject to scientific merit review, ethical issues related to the protection of subjects, and privacy issues. Identifiable human medical and research data are only available with the consent of the astronaut and/or research subject. Additional information can be obtained from Victor S. Schneider, M.D. (email: vschneider@nasa.gov or phone: 202-358-2204)

The LSAH is an electronic database of medical information collected over the active career and post career life of the astronauts. Data are also available on a comparison group matched to the astronauts at a 3:1 ratio by age, sex, and initial body mass index. The data recorded include annual and flight related medical evaluation and medical debriefs following spaceflights for astronauts and routine annual medical evaluations for the comparison group.

The LSDA is an online archive of data from spaceflight experiments funded by NASA. This

searchable database of life sciences experiments includes human, animal and plant studies from 1961 to the present. Proposers are encouraged to consider utilization of archived non-human biospecimens from previous spaceflight and ground control experiments.

## 5. Utilization of Archived Non-Human Tissues

The Biological and Physical Research Enterprise (BPPE) is interested in maximizing knowledge that can be gained from spaceflight research on biomedical model organisms and applying that knowledge in support of the vision for human exploration of space. To that end, the Life Sciences Data Archive (<http://lsda.jsc.nasa.gov/>) (LSDA) describes a number of tissues (flight and ground) obtained from past investigations that are available for analysis.

A new opportunity for biospecimen tissue sharing has arisen from a commercial flight investigation on space shuttle mission STS-108 (Commercial Biomedical Testing Module (CBTM), December, 2001). Specifically, 24 mice (C57BL/6J, 64 days old) were housed for 11 days, 20 hours on the space shuttle Endeavour in Animal Enclosure Modules (AEMs). An additional 48 animals, 24 in AEMs and 24 in standard cages, served as ground controls. Pre-flight tissues were obtained from an additional set of mice for baseline comparisons. Half of the mice were treated with a novel bone therapeutic (Osteoprotegerin (OPG), Amgen Corp., Thousand Oaks, CA) and half were given a placebo. A number of secondary tissues were obtained from the mice shortly after the conclusion of the STS-108 mission and have been preserved by formalin fixation (paraffin embedded) or by freezing on liquid nitrogen (stored at -70°C). A full list of available murine tissues from STS-108 and associated experiment details are provided at the LSDA website.

The Office of Biological and Physical Research (OBPR) is soliciting proposals from researchers interested in obtaining and analyzing murine tissues from the STS-108 CBTM investigation. Proposals can either be dedicated (stand-alone) or be included in a larger proposal through this NRA as a means to provide initial or complementary data. Stand-alone proposals are expected to be consistent with guidelines described at the LSDA website (under “Tissue Requests”) for “short proposals”, and should be submitted as stated therein. A modest budget request to cover the costs of reagents, analysis consumables, outside lab analyses, etc., may be included with the proposal. Due to the commercial nature of the primary research objectives for the CBTM investigation, selected investigators may be required to sign a Material Transfer Agreement (MTA) with the commercial research sponsor, Amgen Corp. The need and details for an MTA will be determined at time of award.

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**Research Opportunities Soliciting  
Ground-Based Studies for  
Human Health in Space:  
Biomedical Model Systems Program**

**NASA Research Announcement  
NNH04ZUU003N-BMS**

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: Biomedical Model Systems Program

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: Biomedical Model Systems Program

## I. Funding Opportunity Description

### A. Introduction

The Biomedical Model Systems (BMS) program sponsors research seeking to understand the effects of spaceflight on the molecular, cellular, and organismal levels in support of human space exploration. This research, utilizing appropriate cellular, tissue, plant, animal, and human models, will enable NASA to develop the biological knowledge to enable a long-duration human presence in space and to support other NASA biology-related activities.

It is critical for investigators to read carefully **ALL** of the instructions in this NRA. All proposals will undergo peer review using similar processes and procedures, but procedures and forms for proposal submission differ for the different programs and elements, and the eventual funding of selected proposals will differ for the different types of awards. Programmatic balance is maintained by the selecting official(s) for the program.

To be responsive to this research solicitation, proposed studies should be hypothesis-driven and lead to new knowledge within accepted scientific standards. Purely phenomenological approaches with no significant mechanistic basis or likely gain in scientific knowledge are not acceptable. Proposals should take into account the impact of gender, age, nutrition, stress, genetic predisposition, or sensitivity to other factors of importance.

The proposer must examine and understand the Bioastronautics Critical Path Roadmap (BCPR), and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will answer [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm). NASA and the NSBRI will perform an assessment to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify what BCPR risks and questions are being addressed by the research will be returned to the proposer without review.

Investigators are encouraged to review summaries of the research currently funded in this program by accessing the NASA Office of Biological and Physical Research (OBPR) Tasks and Bibliography (OBPR Task Book) at [http://research.hq.nasa.gov/code\\_u/code\\_u.cfm](http://research.hq.nasa.gov/code_u/code_u.cfm). In order to achieve programmatic balance, specific topics that are currently well represented in the scope of our research will be de-emphasized.

The research programs described in this NRA support the utilization of specialized NASA ground-based facilities and the development of special technologies required in the pursuit of their research goals. Investigators should refer to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these NASA specialized ground-based facilities into their proposal online at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

## B. Research Elements and Emphases

This NRA seeks research proposals that support human space exploration by providing a biomedical foundation on the mechanisms by which biological processes respond and adapt to space environments. Research can be accomplished by using a spectrum of gravitational conditions or model systems (e.g., hypergravity, simulated microgravity) as research tools or by determining the effects of the interaction of gravity with other space environmental factors on biological systems. Studies may include cells, tissues, or entire organisms. Researchers should use species most appropriate for their research and are encouraged to take advantage of functionally characterized transgenic and mutant species as well as comparative biology approaches that enhance the research scope. Assurance of compliance with applicable federal regulations regarding human subjects or animal care and use is required as part of the proposal submission process.

Human health risk areas receiving a Countermeasures Readiness Level (CRL) rating of yellow or red for ISS, Moon, or Mars design reference missions as described in the Bioastronautics Critical Path Roadmap (BCPR) have been identified as most relevant to program goals ([http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm)).

**Studies employing simulated microgravity (e.g. rotating wall vessel, hind-limb suspension), hypergravity conditions (e.g. centrifugation), and gravity level transitions (e.g. simulated  $\mu\text{g}$  to  $1\text{g}$ , or  $1\text{g}$  to  $2\text{g}$ ) are of particular interest.** In addition, proposers are encouraged to consider utilization of archived non-human biospecimens from previous spaceflight and ground control experiments. A complete inventory of available specimens may be accessed at: <http://lsda.jsc.nasa.gov/>.

This NRA does not solicit proposals for flight research. Proposals that require flight resources will be returned to the proposer without being reviewed. Additionally, this BMS NRA does not solicit proposals for radiation research. Radiation research will be solicited in a future NRA.

In addressing strategic research for the support of human space exploration, proposals in the following topic areas will be considered:

### 1. Physiology

Research in this area should address how space environments affect physiological systems. Research should focus on identifying or developing the most appropriate models to study the physiological systems that may be affected by spaceflight. Examples include ground-based research at all levels of complexity (genes, cells, tissues, whole organisms) on metabolism, nutrition, musculoskeletal systems, cardiovascular systems, and nervous systems. Of particular interest is the identification of cellular model research systems that could be used during spaceflight to directly identify human health risks and therapies. In addition to focusing efforts on specific areas of physiology to meet research goals, the interplay of systems within an organism is of particular interest (e.g. body's response to wound healing).

## 2. Immunology and Microbiology

The detection and characterization of the effects of space environments on immunological function is of interest to NASA. Examples of ground-based research would include experiments to better understand how aspects of the immune system are affected by spaceflight or altered gravity conditions (e.g. antigen presentation, helper cell activation, immune cell motility, antibody production and response). Physiological stress is known to be detrimental to proper immune system response. Therefore, studies examining the effects of stress, in particular the combination of stress and altered gravity conditions, are encouraged. NASA is interested in investigating issues of altered microorganism growth, pathogenicity, virulence, and host-pathogen interactions through the establishment of appropriate ground-based space simulation models.

## 3. Pharmacology

Previous research has indicated that microgravity can affect pharmacological parameters. The aim of this element is to support ground-based research in pharmacology using appropriate altered gravity models to study the pharmacokinetic, pharmacodynamic, and toxicological properties of therapeutics. Of particular interest are: the characterization (type and magnitude) of alterations in therapeutic absorption, distribution, metabolism, and excretion; the potential for a deleterious therapeutic outcome in space environments; the examination of cell and molecular pathways responsible for spaceflight effects; and the validation of ground-based model systems for conducting pharmacological studies. Clinical care in an extreme environment relies on the ability of therapeutics to maintain identity, purity and strength after extended storage. Therefore, proposals are sought for ground-based research to examine the efficacy of therapeutics that have been stored and subjected to an extreme environment (e.g. radiation exposure, varying temperatures, changes in humidity). Proposals for the continued development of novel pharmacological countermeasures to respond to physiological changes in space environments are also strongly encouraged.

## C. Education and Public Outreach

OBPR programs represent an opportunity for NASA to enhance and broaden public knowledge, understanding, and appreciation of biological and biomedical research, and the value of this research in space environments. Individuals participating in NASA's OBPR programs 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 OBPR programs through formal and informal education opportunities.

OBPR envisions that the selected proposals will be structured and operated in a manner that supports the nation's educational initiatives and goals (including support of historically black colleges and universities and other minority universities), and in particular the need to promote scientific and technical education at all levels. OBPR envisions that the selected proposals will

support the goals for public awareness and outreach to the general public. The selected principal investigators are invited to participate in OBPR-funded educational programs.

The successful research project represents an opportunity for NASA to enhance and broaden the public's understanding of and appreciation for the value of OBPR research in the context of NASA's mission. Therefore, all investigators are strongly encouraged to promote general scientific literacy and public understanding of OBPR research through formal and/or informal education opportunities. If appropriate, proposals should include a clear and concise description of the education and outreach activities proposed. Examples include involving students in the research activities, technology transfer plans, public information programs that will inform the general public of the benefits being gained from the research, and/or plans for incorporation of scientific results obtained into curricula consistent with educational standards.

Where appropriate, the supported institution will be required to produce, in collaboration with NASA, a plan for communicating to the public the value and importance of their work. Once NRA selections are made, the selected PIs will have an opportunity to request additional funding through an OBPR-sponsored pilot program to implement an education outreach program at the grades 6-12 level, at an amount not to exceed \$10,000 per year for the term of the grant. A request for proposal will accompany the selection notification letter. Proposals will be due within 60 days of selection notification and shall be limited to 4 pages. A review of these proposals by educational specialists will determine which proposals will be funded.

#### D. 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.

#### E. Availability of Funds for Award

Funds are not currently available for awards under this announcement. 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 NASA determines are acceptable for award under this announcement.

## II. Award Information

The selected proposal will be funded as a research grant in one-year increments for activities lasting up to **three years**. The mechanism for funding the successful proposal will be a single grant, with funding allocations to participating investigators based on the submitted budget and project review. The funding duration will depend on proposal requirements, review panel recommendations, and continuing progress of the activity. All proposals will be evaluated for

overall merit by independent peer review panels and a second review for NASA relevance and proposed cost by the cognizant NASA program office. NASA reserves the right to “partner” research projects that it determines will augment one another.

It is anticipated that a typical award will average \$150,000 (total annual costs). Separate funding for direct and indirect costs is not provided; thus, the amount of the award requested is the total of all cost submitted in the proposed budget. NASA reserves the right to return proposals, without review, that exceed the described award amounts. It is estimated that the initial selection will be announced by **February 2005** and the grant awarded in a reasonable timeframe thereafter.

### **III. Eligibility Information**

#### **A. Eligibility of Applicants**

All categories of 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 Announcement. Present or prior NASA support of research or training in any institution or for any investigator is not a prerequisite for submission of a proposal or a competing factor in the selection process.

#### **B. Cost Sharing or Matching**

If an institution of higher education, hospital, or other non-profit organization wants to receive a grant or cooperative agreement from NASA, cost sharing is not required. However, NASA can accept cost sharing if it is voluntarily offered (See the Handbook, Section B, Provision 1260.123, “Cost Sharing or Matching,” which describes the acceptable forms of cost sharing). If a commercial organization wants to receive a grant or cooperative agreement 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 (See the Handbook, Section D, Provision 1274.204, “Costs and Payments”.) For NSBRI specific rules, see page NSBRI-9, Section III. B.

## C. Guidelines for International Participation

**Export Control Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation.** Foreign proposals and 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.pmdtc.org/> and <http://www.bis.doc.gov/>. Investigators are advised that under U.S. law and regulations, spacecraft and their specifically designed, modified, or configured systems, components, and parts are generally considered “Defense Articles” on the United States Munitions List and are subject to the provisions of the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120-130.

## IV. Proposal and Submission Information

### A. Source of Application Materials

All information needed to apply to this solicitation is contained in this announcement and in the companion document entitled “Guidebook for Proposers Responding to NASA Research Announcements” (hereafter referred to as the Guidebook for Proposers) that is located at <http://www.hq.nasa.gov/office/procurement/nraguidebook/>. This solicitation and any modifications or updates to this solicitation are available at: [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

Except where specifically stated otherwise in this NRA, applicants must prepare proposals in accordance with the Guidebook for Proposers. Proposals that do not conform to the standards outlined in this NRA and included in the Guidebook for Proposers may be declared noncompliant and returned without review. Note that the NASA policy for proposals involving non-U.S. participants is given in Section (I) of Appendix B of this Guidebook. Comments and suggestions of any nature about the Guidebook for Proposers are encouraged and welcomed and may be directed at any time to Mr. Tom Sauret, Office of Procurement, Code HK, NASA Headquarters, 300 E Street SW, Washington, DC 20546-0001; E-mail: [Tsauret@mail.hq.nasa.gov](mailto:Tsauret@mail.hq.nasa.gov).

### B. Content and Form of Proposal Submission

The following information is specific to this NRA and **supersedes** the information contained in the Guidebook for Proposers.

## 1. SYS-EYFUS Registration

SYS-EYFUS is an electronic system used by NASA Headquarters to manage research solicitation activity, plan for the receipt of research proposals, track the receipt and peer evaluation of these proposals, and manage funded research (grants, cooperative agreements, etc.).

The SYS-EYFUS Help Desk is available at (202) 479-9376. Help desk hours are from 8 a.m. to 6 p.m. Eastern time.

All investigators planning to submit a proposal to this solicitation are required to register online with SYS-EYFUS. Comprehensive help, instructions, and contact information are provided online. SYS-EYFUS can be accessed at the following Web address:

<http://proposals.hq.nasa.gov/proposal.cfm>

If you have previously registered with SYS-EYFUS, you are asked to verify and update your user information. If you have forgotten your user ID or password, select the “Forgot Your Password” option and type in your first and last name to search our database. The system will send an automatic e-mail message with your username and password to the e-mail address listed in our database.

## 2. Instructions for Preparing and Electronically Submitting a Notice of Intent

All investigators planning to submit a proposal in response to this solicitation are requested to submit a **non-binding** Notice of Intent (NOI) to propose by the due date identified in the Submission Dates and Times Section of this NRA via the Web at the following address:

<http://proposals.hq.nasa.gov/proposal.cfm>

- 1) Login to SYS-EYFUS at the URL listed above and select “New Notice of Intent.”
- 2) The Division Specific Opportunities screen will appear. In the selection window, highlight “**UU-OBPR**” and click on “Continue.”
- 3) The List of Existing Opportunities screen will appear. In the selection window, highlight “**NNH04ZUU003N – Research Opportunities Soliciting Ground-Based Studies for Human Health in Space**” and then click on “Continue.”
- 4) This will bring you to the Notice of Intent Submission Form. **All fields are required.**
  - a. The proposal summary should be a succinct and accurate description of the proposed work when read separately from the project description. The summary should contain a brief description stating the specific aims of the proposed work. Describe concisely (300-500 words) the research design and methods for

achieving these aims.

- b. Please select from **only** the following three options: For the proposal type field on this form, new/no prior support means that the investigator has not received NASA funding from 2001 through 2003, new/prior support means that the investigator has received NASA funding between 2001 through 2003, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 2001 through 2003, but not funded. A proposal previously submitted but not funded should be identified as being “revised” even if the original Principal Investigator has changed.
- c. Indicate the status of IRB/IACUC for your proposal. If IRB or IACUC review is unavoidably delayed beyond the submission of the application, enter “Pending” on the Proposal Cover Page, and be advised that the certification must be received within 90 days after the due date for which the application is submitted.
- d. Provide your DUNS and CAGE numbers. If you do not know your DUNS and CAGE numbers, contact your Office of Sponsored Research or equivalent office. All applicants must provide the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number for their organization in the Cover Page of their proposal. This requirement applies to renewals of awards as well as to prospective new awards. The DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). Organizations will use the same DUNS number with every proposal submitted for a Federal grant and cooperative agreement. Note that the DUNS number is site-specific. Applicants may call D&B at 1-866-705-5711 to register and obtain a DUNS number, or access the D&B website at: <http://www.dnb.com/us/>.

NASA also requires the applicant’s organization to be registered in the Central Contractor Registration (CCR) database and obtain a Commercial And Government Entity (CAGE) code prior to submitting a proposal. The purpose of this requirement is to help centralize information about grant recipients and provide a central location for grant recipients to change organizational information. Information for registering in the CCR and online documents can be found at <http://www.ccr.gov/>. Before registering applicants and recipients should review the Central Contractor Registration Handbook, which is also located at <http://www.ccr.gov/>. The process for obtaining a CAGE code is incorporated into the CCR registration.

- 5) Click on “Submit NOI Page.”
- 6) The Team Member Page screen will appear, where you can add or remove team members. Select continue if there are no other team members. To add a team member, highlight the role option on the selection list, type in first and last name and click on search. When the resulting set appears, choose the appropriate radio button

and click on ADD to add the person to the NOI. After you are done, click on “Continue.” **IMPORTANT:** If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.

- 7) After continuing from the Team Members Page, your NOI will be displayed. Click on “Resubmit NOI Page” to complete your NOI submission.
- 8) You may edit and resubmit your NOI at any time before the submission deadline. Once you submit an NOI, it cannot be deleted, only edited. For title, team member, or any other changes, please edit your existing NOI and resubmit changes to avoid duplicate records.

### 3. Instructions for Preparing and Electronically Submitting a Proposal Cover Page

All investigators planning to submit a proposal in response to this solicitation must electronically submit proposal cover page information online and provide a hardcopy of the cover page attached to each proposal copy by the due date indicated in the Submission Dates and Times Section of this NRA. The proposal cover page can be submitted and printed via the Web at the following address:

<http://proposals.hq.nasa.gov/proposal.cfm>

- 1) Login to SYS-EYFUS at the URL listed above.
- 2) To submit a New Proposal Cover Page, click the “New Proposal Cover Page” option on the SYS-EYFUS Options screen, and the New Proposals Cover Page screen will appear.
- 3) If you previously submitted an NOI in response to this solicitation, choose to carry over the existing NOI. This option will populate the cover page fields with the NOI information. Edit the information as necessary, click “Continue,” and proceed to #8 below.
- 4) If you did not previously submit an NOI, click on New Proposal Cover Page option, and the Division Specific Opportunities screen will appear.
- 5) In the selection window, highlight “**UU-OBPR**” and click on “Continue.”
- 6) The List of Existing Opportunities screen will appear. In the selection window, highlight “**NNH04ZUU003N – Research Opportunities Soliciting Ground-Based Studies for Human Health in Space**” and then click on “Continue.”
- 7) This will bring you to the Proposal Cover Page Submission Form. Fill in all the fields. All fields are required.

- a. The proposal summary should be a succinct and accurate description of the proposed work when read separately from the project description. The summary should contain a brief description stating the specific aims of the proposed work. Describe concisely (300-500 words) the research design and methods for achieving these aims.
- b. Please select from **only** the following three options: For the proposal type field on this form, new/no prior support means that the investigator has not received NASA funding from 2001 through 2003, new/prior support means that the investigator has received NASA funding between 2001 through 2003, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 2001 through 2003, but not funded.. A proposal previously submitted but not funded should be identified as being “revised” even if the original Principal Investigator has changed.
- c. Indicate the status of IRB/IACUC for your proposal. If IRB or IACUC review is unavoidably delayed beyond the submission of the application, enter “Pending” on the Proposal Cover Page, and be advised that the certification must be received within 90 days after the due date for which the application is submitted.
- d. Provide your DUNS and CAGE numbers. If you do not know your DUNS and CAGE numbers, contact your Office of Sponsored Research or equivalent office. All applicants must provide the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number for their organization in the Cover Page of their proposal. This requirement applies to renewals of awards as well as to prospective new awards. The DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). Organizations will use the same DUNS number with every proposal submitted for a Federal grant and cooperative agreement. Note that the DUNS number is site-specific. Applicants may call D&B at 1-866-705-5711 to register and obtain a DUNS number, or access the D&B website at: <http://www.dnb.com/us/>.

NASA also requires the applicant’s organization to be registered in the Central Contractor Registration (CCR) database and obtain a Commercial And Government Entity (CAGE) code prior to submitting a proposal. The purpose of this requirement is to help centralize information about grant recipients and provide a central location for grant recipients to change organizational information. Information for registering in the CCR and online documents can be found at <http://www.ccr.gov/>. Before registering applicants and recipients should review the Central Contractor Registration Handbook, which is also located at <http://www.ccr.gov/>. The process for obtaining a CAGE code is incorporated into the CCR registration.

Click on “Continue.”

- 8) The Team Member Page screen will appear, where you can add or remove team members. Every proposal must specify the critically important personnel who are expected to play a significant role in the execution of the proposed effort and their institution of employment. Categories of personnel to be included as Team Members are described in Guidebook for Proposers.

**You must include your authorizing official as a team member.** When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

**IMPORTANT:** If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.

- 9) After continuing from the Team Member Page, the Proposal Options Page appears.
- 10) Please fill out the budget form by clicking on the “Budget” button, filling in project costs, and clicking “Continue.” This will bring you to the Proposal Budget Review Page. Click “Continue” if the information is correct.
- 11) After verifying your budget information, you will be returned to the Proposal Options Page. Click the “Show/Print” button.
- 12) For detailed budget information, you must use the budget forms provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html) Sample copies of these forms are also available as attachments to this NRA and must be filled out for each year of grant support requested. These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.
- 13) At the page entitled Proposal Information Item List, click “Continue” to preview your Proposal Cover Page. Print the cover page from your Internet browser once you have reviewed the information. The cover page must be signed by both the Principal Investigator and the authorizing official and attached to the front of your proposal before submission of hard copies to NASA.

By signing and submitting the proposal identified on the cover sheet, the authorizing official of the proposing institution (or the individual investigator if there is no proposing institution) 1) certifies that the statements made in the proposal are true and complete to the best of his/her knowledge; 2) agrees to accept the obligations to comply with NASA Award terms and conditions if an award of a grant or cooperative agreement is made as a result of this proposal (does not apply to contract awards); and 3) provides certification to the following that are: (i) Certification Regarding Debarment, Suspension, and Other Responsibility Matters, (ii) Certification Regarding Lobbying, and (iii) Certification of Compliance with the NASA Regulations Pursuant to Nondiscrimination in Federally Assisted Programs.

**Once you print your cover page, the electronic portion of your NASA proposal submission is complete.**

- 14) You may edit and resubmit your proposal cover page at any time before the submission deadline as indicated in the Submission Dates and Times Section of this NRA. Please note that once you submit a proposal cover page, it can only be edited, not deleted. For title, team member, budget or any other changes, please edit your existing proposal cover page and resubmit changes to avoid duplicate records. After you print your edited cover page, your changes are automatically submitted to NASA.

#### 4. Instructions for Preparation of Proposals

**All** proposals submitted must include the completed cover page form as described above. The name of the Principal Investigator should appear in the upper right hand corner of each page of the proposal, except on the cover page form, where fields are provided for this information. Note that the proposal **must** specify the period of performance for the work described; periods of performance may be up to any duration up to the maximum duration identified in the Announcement section of this NRA but should be suitable for the project proposed.

**The proposal must include the following material, in this order:**

- (1) Proposal Cover Page: Solicited Proposal Application, including certification of compliance with U.S. code (if applicable). One signed original required. Please see “Instructions for Preparing and Electronically Submitting a Proposal Cover Page” in Section IV.B.3 above for instructions on how to complete the proposal cover page information.
- (2) Checklist for proposers. This checklist is provided in the forms appendix of this document and can be downloaded from :  
[http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html)
- (3) Transmittal Letter or Prefatory Material, if any (see Guidebook for Proposers).
- (4) Proposal Title Page, with Notice of Restriction on Use and Disclosure of Proposal Information, if any (see Guidebook for Proposers).
- (5) Project Description: The length of the Project Description section of the proposal **cannot exceed 20 pages** using regular (12 point) type. Text must be printed on one side only and should have the following margins: left = 1.5”; Right, top, bottom = 1.0”. Referenced figures must be included in the 20 pages of the Project Description. The Bibliography, Management Approach, and all following sections are not considered part of the 20-page project description. Proposals that exceed the 20-page limit for the project description will not be reviewed. The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall merit of the proposed research and about the probability that the investigators will be able to accomplish their stated objectives with

current resources and the resources requested. In addition, the proposal should clearly indicate the relationship between the proposed work and the research emphases defined in this Announcement. Reviewers are not required to consider information presented as appendices or to view and/or consider Web links in their evaluation of the proposal.

- (6) Management Approach: Each proposal must specify a single Principal Investigator who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. In proposals that designate several senior professionals as key participants in the research project, the management approach section should define the roles and responsibilities of each participant and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal must clearly and unambiguously state whether these key personnel have reviewed the proposal and endorsed their participation.

Investigators are strongly encouraged to identify only the most critically important personnel to aid in the execution of their proposals. Should such positions be necessary, Co-Investigators (co-Is) may be identified who are critical for the successful completion of research through the contribution of unique expertise and/or capabilities, and who serve under the direction of the PI, regardless of whether or not they receive compensation under the award. Most NRAs require a co-I to have a well-defined role in the research that is defined in the Management section of the proposal. Evidence of a co-I's commitment to participate is often requested through a brief letter to be included with the proposal.

There are three subcategories of co-Is that a proposal may identify, as appropriate:

- A co-I may be designated as the *Science PI* for those cases where the proposing institution does not permit that individual to formally serve as the PI as defined above. In such a case, the Science PI will be understood by NASA to be in charge of the scientific direction of the proposed work, although the formally designated PI is still held responsible for the overall direction of the effort and use of funds.
- A co-I may be designated as an *Institutional PI* when their institution is making a major contribution to a proposal submitted by a PI from another institution.
- A co-I from a non-U.S. institution may be designated as a *co-Principal Investigator* (co-PI) should such a designation serve required administrative purposes in that co-I's institution and/or for the procurement of funding by that co-I from their sponsoring funding authority.

Additional category positions are often included in proposals as defined as follows:

- A *Postdoctoral Associate* holds a Ph.D. or equivalent degree and is identified as a major participant in the execution of the proposed research. Such personnel may be identified by name or only by function in those

cases where their recruitment depends on the successful selection of the proposal.

- *Other Professional* is a description appropriate for personnel who support a proposal in a critical albeit intermittent manner, such as a consulting staff scientist or a key Project Engineer and/or Manager, who is not identified as a co-I or Postdoctoral Associate.
- A *Graduate Student* included in a proposal is working for a post-graduate degree and will support the proposed research under direction of the PI. Such a student may be identified by name or only by function in case their recruitment depends on the successful selection of the proposal.
- A *Collaborator* is an unfunded position included in a proposal, whose participation is less critical than a co-I, but who is committed to provide a specific contribution to the proposal

- (7) The investigator must examine and understand the Bioastronautics Critical Path Roadmap (BCPR), and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will answer [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm). NASA and the NSBRI will perform an assessment to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify what BCPR risks and questions are being addressed by the research will be returned to the investigator without review.
- (8) Personnel/Biographical Sketches: The biographical sketch for each investigator should not exceed two pages. If the list of qualifications and publications exceeds two pages, select the most pertinent information. List, in chronological order, the titles, all authors, and complete references to all publications pertinent to this application (see Guidebook for Proposers.) A sample biographical sketch form can be downloaded at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). A sample copy of the form is available as an attachment to this NRA. These forms cannot be electronically submitted. Omit social security numbers and other personal items that do not merit consideration in evaluation of the proposal. Provide similar biographical information on other senior professional personnel who will be directly associated with the project. Provide the names and titles of any other scientists and technical personnel associated substantially with the project in an advisory capacity. Universities should list the approximate number of students or other assistants, with information as to their level of academic attainment. Any special industry-university cooperative arrangements should be described. Fill out the forms and attach them to your proposal
- (9) Facilities and Equipment: Describe the available facilities and major items of equipment specially adapted or suited to the proposed research activities, and any additional major equipment that will be required. Identify any government-owned facilities, industrial plant equipment, or special tooling that are proposed for use in the research activities.. The research plan must provide evidence that such facilities or equipment will be made available if the proposal is accepted. Before requesting a major item of capital equipment, the proposer should determine the availability of equipment already within the organization as an alternative to purchase. Where such arrangements cannot be made, the

proposal should state this explicitly. The need for items that can be typically used for research and non-research purposes should be explained.

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

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

Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Management Instruction (NMI) 7100.8B (*Protection of Human Research Subjects*). 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*). Both documents are available from the Office of Biological and Physical Research, Code UB, NASA Headquarters, Washington, DC 20546.

Additional Requirements for Research Employing Human Subjects

A letter signed by the Chair of the Institutional Review Board (IRB) identifying the proposal submitted to NASA by title and certifying approval of proposed human subjects protocols and procedures should be included with each copy of the proposal. IRB certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IRB certification is pending on the proposal due date, select “pending” from the IRB/IACUC section menu on the Proposal Cover Page, and include with each copy of the proposal a letter signed by the IRB Chair identifying the proposal by title and indicating the status of the IRB review process at the time of submission. IRB certification must be received no later than 90 days after the proposal due date. An application lacking the required IRB certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

NASA will require current IRB certification prior to each year’s award.

Additional Requirements for Research Employing Animals

**Specific information describing and justifying the use of animal subjects must be included in the proposal.**

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) identifying the proposal submitted to NASA by title and certifying approval of the proposed animal research protocols and procedures should be included with each copy of the proposal. The institution’s Public Health Service Animal Welfare Assurance

Number must be included on the IACUC certification and entered in the IRB/IACUC section of the Proposal Cover Page. IACUC certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IACUC certification is pending on the proposal due date, select “pending” from the IRB/IACUC selection menu on the Proposal Cover Page, and include with each copy of the proposal a letter signed by the IACUC Chair identifying the proposal by title and indicating the status of the IACUC review process at the time of submission. IACUC certification must be received no later than 90 days after the proposal due date. An application lacking the required IACUC certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review. NASA will require current IACUC certification prior to each year’s award.

#### (11) Detailed Budget and Supporting Budgetary Information

For detailed budget information, you must use the forms provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). Sample copies of these forms are also available as attachments to this NRA. These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.

NASA is expected to be operating on the basis of full cost accounting as soon as possible, including all Civil Service salaries with overhead. In the interim period, proposals should use the accounting method authorized at their institutions at the time proposals are due and for the entire proposed period of performance. Funds to support the Resident Research Assistant (RRA) Postdoctoral Program costs (e.g., stipend, travel, computer time, supplies, etc.) are to be budgeted within the NASA intramural Principal Investigator budget.

If travel is planned, the proposal budget should include appropriate travel funds for visits to NASA field centers (as appropriate) and presentation of findings at professional society meetings.

In this solicitation, the terms “cost” and “budget” are used synonymously. Sufficient proposal cost detail and supporting information are required; funding amounts proposed with no explanation (e.g., Equipment: \$1,000, or Labor: \$6,000) may cause delays in evaluation and award. Generally, costs will be evaluated for realism, reasonableness, allowability, and allocation. The budgetary forms define the desired detail, but each category should be explained. Offerors should exercise prudent judgment in determining what to include in the proposal, as the amount of detail necessarily varies with the complexity of the proposal.

The following examples indicate the suggested method of preparing a cost breakdown:

##### Direct Labor

Labor costs should be segregated by titles or disciplines with estimated hours and rates

for each. Estimates should include a basis of estimate, such as currently paid rates or outstanding offers to prospective employees. This format allows the Government to assess cost reasonableness by various means including comparison to similar skills at other organizations.

### Other Direct Costs

Please detail, explain, and substantiate other significant cost categories as described below:

- Subcontracts: Describe the work to be contracted, estimated amount, recipient (if known), and the reason for subcontracting.
- Consultants: Identify consultants to be used, why they are necessary, the time they will spend on the project, and the rates of pay.
- Equipment: List separately. Explain the need for items costing more than \$5,000. Describe basis for estimated cost. General-purpose equipment is not allowable as a direct cost unless specifically approved by the NASA Grant Officer. Any equipment purchase requested as a direct charge must include the equipment description, how it will be used in the conduct of the basic research proposed, and why it cannot be purchased with indirect funds.
- Supplies: Provide general categories of needed supplies, the method of acquisition, and estimated cost.
- Travel: Describe the purpose of the proposed travel in relation to the grant, and provide the basis of estimate, including information on destination and number of travelers (if known). **Note: Investigators are required to include travel to an annual PI meeting in their budget.**
- Other: Enter the total of direct costs not covered by a) through e). Attach an itemized list explaining the need for each item and the basis for the estimate.

### Indirect Costs

Indirect costs should be explained to an extent that will allow the Government to understand the basis for the estimate. Examples of prior year historical rates, current variances from those rates, or an explanation of other basis of estimates should be included. Where costs are based on allocation percentages or dollar rates, an explanation of rate and application base relationships should be given. For example, the base to which the General and Administrative (G&A) rate is applied could be explained as: application base equals total costs before G&A less subcontracts.

All awards made as a result of this NRA maybe funded as grants or contracts. However, while proposals submitted by “for profit” organizations are allowed, they cannot include a “fee.”

(12) Other Support: You must provide information on other support for specific sources of other support for the principal investigator and each Co-Investigator (not consultants). A sample form is provided at:

[http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). A sample

copy of the form is also available as attachment to this NRA

(13) Appendices, if any (**reviewers are not required to consider information presented in appendices**).

## 5. Submission Dates and Times

One (1) signed original cover page and proposal and twenty (20) copies of the proposal cover page and proposal **must be received by 4:30 p.m. Eastern Time, September 8, 2004**. Proposals shall not be submitted electronically, except for parts specified in this NRA. Proposals mailed through the U.S. Postal Service by express, first class, registered, or certified mail are to be sent to the following address:

NASA Peer Review Services  
SUBJECT: **Biomedical Model Systems**  
500 E Street SW  
Suite 200  
Washington, DC 20024

Proposals that are hand delivered or sent by commercial delivery or courier services are to be delivered to the above address between 8:00 a.m. and 4:30 p.m. Proposals must be received by 4:30 p.m. Eastern time on the proposal due date. The telephone number (202) 479-9030 may be used when required for reference by delivery services. NASA Peer Review Services (NPRS) cannot receive deliveries on Saturdays, Sundays, or federal holidays. NPRS will send notification to the investigator confirming proposal receipt within 5 business days of the proposal receipt date; however, there will not be a response from the Office of Biological and Physical Research.

The following items apply only to this Announcement:

<b>Solicitation Announcement Identifier:</b>	<b>NRA NNH04ZUU003N</b>
<b>Number of Copies Required:</b>	<b>Original + 20 copies</b>
<b>Proposals Due:</b>	<b>September 8, 2004</b>
<b>Estimated Selection Announcement:</b>	<b>February 2005</b>
<b>Selecting Officials:</b>	<b>Terri L. Lomax, Ph.D.</b> <b>Fundamental Space Biology Division</b>

## 6. 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 Guidebook for Proposers.
- 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.

- U.S. research award recipients may directly purchase of supplies and/or services that do not constitute research from non-U.S. sources, but award funds may not be used to fund research carried out by non-U.S. organizations. However, subject to possible export control restrictions, foreign nationals may conduct research while employed by a U.S. organization.
- Profit for commercial organizations is allowed under contract awards only.
- 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.
- 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/>.

## V. Proposal Review Information

The following information is specific to this NRA and **supersedes** the information contained in the Guidebook for Proposers.

### A. Intrinsic Scientific or Technical Merit Review and Evaluation Criteria

The overall evaluation process for proposals submitted in response to this Announcement will include review of relevance, cost criteria, and merit criteria. All of the following merit criteria, of equal consideration, will be used in determining the merit score of the proposal:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field? Is there a significant societal or economic impact?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Does the project employ appropriate novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and any co-investigators? Is the evidence of the investigator's productivity satisfactory?
- **Environment:** Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of

unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

## B. Review and Selection Process

### 1. Compliance Matrix

All proposals must comply with the general requirements of the Announcement as described in both this solicitation and the Guidebook for Proposers. Upon receipt, proposals will be reviewed for compliance with these requirements including:

1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
2. Submission of appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) certification for all proposals using human or animal test subjects.
3. Submission of a budget that is within the guidelines specified in this Announcement and is for a funding period not exceeding that described in the Announcement.
4. Proposals that are revised versions of proposals previously submitted to NASA must be clearly designated as such on the proposal cover page and must contain an explanation of how the revised proposal has addressed criticisms from previous NASA review. This explanation should be presented at the beginning of the project description in a separate section of no more than two pages, and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
5. Submission of gender and minority inclusion data as appropriate.
6. Submission of all other appropriate information as required by this Announcement.

***Note: At NASA's discretion, non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.***

Compliant proposals submitted in response to this Announcement will undergo an intrinsic scientific or technical merit review. Only those proposals most highly rated in the merit review process will undergo additional reviews for program relevance and cost.

## 2. Review and Selection

The overall evaluation process for proposals submitted in response to this Announcement will include the following reviews:

**First Tier Merit Review:** A review for intrinsic technical or scientific merit and overall impact will be conducted for all proposals.

**Second Tier Review for Relevance and Cost:** Relevance to NASA, program balance and proposed project cost.

The **first review tier** will be a merit review by a panel of scientific or technical experts. The number and diversity of experts required will be determined by the response to this NRA and by the variety of disciplines represented in the proposals relevant to the research emphases described in Appendix A. The merit review panel will assign *a score from 0-100* based upon the intrinsic scientific or technical merit of the proposal. This score will reflect the consensus of the panel.

The score assigned by this panel *will not be affected by the cost of the proposed work nor will it reflect the programmatic relevance of the proposed work to NASA*. The panel will be asked to include in their critique of each proposal any comments they may have concerning the proposal's budget and relevance to NASA.

The **second review tier will** evaluate the programmatic relevance, balance and cost of all proposed work. This review will be conducted by NASA Program Scientists and Managers. Evaluation of the cost of a proposed effort includes consideration of the realism and reasonableness of the proposed cost and the relationship of the proposed cost to available funds. Programmatic relevance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks required by critical research issues faced by NASA and OBPR.

In order to optimize resources, NASA is pursuing the intentional formation of investigator partnerships between individual investigators whose experiments will leverage resources by addressing different facets of the same critical question. NASA anticipates that such intentional teaming arrangements will result in better utilization of available resources to resolve specific critical questions. NASA strongly encourages individual investigators submitting applications in response to this NRA to consider identifying collaborations between individual investigators as part of the development of their individual proposals and to identify this pre-coordination in their management plan.

The information resulting from these two levels of review, as described above, will be used to prepare a **selection recommendation** developed by NASA program scientists and managers for each of the program elements described in this Announcement. This recommendation will be based on:

1. The scientific or technical merit review score from the peer review panel.

2. The programmatic relevance.
3. The cost of each proposal.

This **selection recommendation** is the responsibility of the NASA program scientist(s). Selection for funding will be made by the selecting official identified in the Submission Dates and Times Section of this NRA. There will be one selection.

## **VI. Award Administration Information**

### **A. Award Notices**

At the end of the selection process, each proposing organization is notified of its selection or nonselection status. NASA provides debriefings to those investigators who request one. The selection letters will include a statement indicating the selected organization's business office will be contacted by a NASA Contracting or Grant Officer, who is the only official authorized to obligate the Government, and a reminder that any costs incurred by the investigator in anticipation of an award are at their own risk. Selection notification will be made by a letter signed by the selecting official.

The NASA Procurement Office will determine the type of award instrument, request further business data, negotiate the resultant action, and are the only personnel with the authority to obligate government funds.

NASA reserves the right to offer selection of only a portion of a proposal. In these instances, the investigator will be given the opportunity to accept or decline the offer.

### **B. Administrative and National Policy Requirements**

This solicitation does not invoke any special administrative or National policy requirements, nor do the award(s) that will be made involve any special terms and conditions that differ from NASA's general terms and conditions as given in the Guidebook for Proposers.

### **C. Program Reporting/Individual Researcher Reporting**

It is expected that results from funded research will be submitted to peer-reviewed journals as the work progresses. Only published papers that acknowledge NASA's support and identify the grant or contract will be counted as resulting from the research project and used to evaluate its productivity.

**Annual Reporting.** The Office of Biological and Physical Research publishes a comprehensive online document titled OBPR Program Tasks and Bibliography (Task Book) which includes descriptions of all current peer-reviewed activities funded by the division. Since its inception, the Task Book has served as an invaluable source of information for OBPR as well as the scientific and technical communities.

Investigators are required to provide NASA with this summary information at a minimum of once per year. This information will be made available to the scientific community and will be used to assess the strength of the Division's programs. It will also serve as the basis for determining the degree of progress of the project. The information provided for the Task Book will meet both the requirements for program annual reporting requirements and the individual researcher task book reporting. Updates can be made throughout the duration of the project at anytime during the year, with a due date of at least once per year 60 days prior to the anniversary date of the grant start date.

The information requested will include:

- an abstract,
- a brief statement of progress during,
- a brief statement of benefits of the research with respect to life on Earth,
- an updated bibliographic list,
- a copy or reprint of each publication listed in the bibliography,
- a listing of presentations or activities conducted at 6-12 educational institutions,
- a listing of interactions, presentations, or other activities with the general public, and
- a statement of potential scientific, technological, economic or societal impact.

Note that although this publication will be made available to the general scientific community, it is not a substitute for traditional scientific reporting in journals and elsewhere.

All articles submitted for publication must include the following statement: "This research was funded in whole or in part by a grant from the Office of Biological and Physical Research of the National Aeronautics and Space Administration." Publications not including this acknowledgement will not be considered to be the product of NASA-funded research when NASA assesses the progress of the grant.

**Final Report.** A final report must be provided to the appropriate Division Director at NASA HQ at the end of the funding period, including a detailed listing of all peer-reviewed publications. Information required for inclusion in final reports is:

- summary of the research activities;
- 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 and copies of all publications and reports. Any publications or other public materials containing data are particularly important to include in this section.

## **VII. NASA Contacts**

Additional technical information for the NASA programs is available from

Elaine P. Akst, Ph.D.  
Fundamental Space Biology Division  
Mail Code UF  
NASA Headquarters  
Washington, DC 20546-0001  
Telephone: (202) 385-1860  
Fax: (202) 358-1468  
E-mail: [elaine.akst@nasa.gov](mailto:elaine.akst@nasa.gov)

The contracting point of contact will be specified in each selection notification letter.

Potential investigators should read with care the program descriptions that are of interest and focus their proposals on the specific research emphases defined in this Announcement.

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

## **VIII. Additional Forms and Proposal Submission Frequently Asked Questions (FAQs)**

### *(Independent Investigator Research Projects Only)*

#### **A. Frequently Asked Questions (FAQs)**

The information provided here is in response to questions from investigators such as yourself. Additional information regarding submission procedures and requirements can be found in the research announcement to which you are responding, and at the NASA online proposal site:

<http://proposals.hq.nasa.gov/proposal.cfm>

#### **1. What forms should I use when submitting a proposal?**

Currently, the NASA proposal site does not support the uploading of information or forms other than the information gathered while completing the online cover page. Please complete the online cover page early in the process (you can always return and edit the cover page at any time up to the due date). After completing the cover page, any additional information you are required to provide or wish to provide can be submitted in hardcopy in any format you choose.

Please find included in this document several sample forms that you may use when providing additional information. A standard checklist of materials to include is also provided.

Information outside of the online proposal cover page can be provided in any format you choose, as long as it adheres to the NRA requirements. Please reference the NRA for information on all material required when submitting your proposal. Please be aware that we ask for copies of the completed proposal package, not just the project description, and must **receive** the copies by the proposal due date. The additional information requested in the NRA does not count towards the 20 page limit of your project description.

#### **2. Where does my authorizing official sign?**

You must include your authorizing official as a team member. When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

To be added as a team member to your proposal, the individual must be registered with the SYS-EYFUS system. If you try and add a team member and they are not found in the database, you must contact and have that individual register as a new SYS-EYFUS user. You will then be able to add them as a team member.

#### **3. Who should I contact if I receive errors or have additional problems while using the NASA proposal site?**

For technical support, please e-mail [proposals@hq.nasa.gov](mailto:proposals@hq.nasa.gov) or call 202-479-9376 (Monday to Friday 8 a.m.-6 p.m. EST/EDT).

## B. Checklist for Proposers and Additional Forms

**Form A**

### **CHECKLIST FOR PROPOSERS** *(Independent Investigator Research Projects Only)*

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Proposal Cover Page (completed online)

Checklist for Proposers (Form A)

Proposal Title Page

Response to previous reviews (if applicable, these 2 pages are not included in the 20 page proposal page limit)

Project Description

Bioastronautics Critical Path Roadmap (BCPR) Form (Form B)

Biographical Sketches (Form C)

Facilities and Equipment Description

IRB or ACUC letter/form (if applicable)

Targeted/Planned Enrollment (FOR HUMAN SUBJECTS ONLY, Form D)

Summary Budget Form/Budget Justification (Form E)

Detailed 12-Month Budget (for each year of support, Form F)

Other Support (Form G)

Letters of Collaboration/Support (if applicable)

Appendices, if any

**Form B**

## BIOASTRONAUTICS CRITICAL PATH ROADMAP (BCPR) FORM

*(Independent Investigator Research Projects and NSBRI Team Research Projects)*

<u>Hypotheses</u>	<u>Risk Number</u> (from BCPR)	Bioastronautic s Critical Question <u>Number</u> (from BCPR)	<u>Enabling Question</u> (from BCPR)	<u>Specific Aim</u>

## Form C

*(Independent Investigator Research Projects Only)*

### **BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel.  
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION(S) AND LOCATION	DEGREE(S) (if applicable)	YEAR(S)	FIELD(S) OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years, and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

**TARGETED/PLANNED ENROLLMENT FORM**  
*for human subjects only*

Principal Investigator/Program Director (Last, First, Middle):

**This report format should NOT be used for data collection from study participants.**

**Study Title:** \_\_\_\_\_

**Total Planned Enrollment:** \_\_\_\_\_

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
<b>Ethnic Category: Total of All Subjects *</b>			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
<b>Racial Categories: Total of All Subjects *</b>			

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

*(Independent Investigator Research Projects Only)*

**BUDGET FOR ENTIRE PROJECT PERIOD  
DIRECT COSTS ONLY**

<i>BUDGET CATEGORY TOTALS</i>		<i>1<sup>st</sup> BUDGET PERIOD</i>	<i>ADDITIONAL YEARS OF SUPPORT REQUESTED</i>		
			<i>2<sup>nd</sup></i>	<i>3<sup>rd</sup></i>	<i>4<sup>th</sup></i>
<b>PERSONNEL (Salary and Fringe Benefits) (Applicant organization only)</b>					
<b>SUBCONTRACTS</b>					
<b>CONSULTANT COSTS</b>					
<b>EQUIPMENT</b>					
<b>SUPPLIES</b>					
<b>TRAVEL</b>	<b>DOMESTIC</b>				
	<b>NON-DOMESTIC</b>				
<b>OTHER EXPENSES</b>					
<b>TOTAL DIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL INDIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL DIRECT + INDIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL DIRECT + INDIRECT COSTS FOR ENTIRE PROJECT</b>					

**JUSTIFICATION FOR UNUSUAL EXPENSES :**

**Form F**

*(Independent Investigator Research Projects Only)*

<b>DETAILED BUDGET FOR 12-MONTH BUDGET PERIOD</b>		FROM		THROUGH	
<b>DIRECT COSTS ONLY</b>		FUNDING AMOUNT REQUESTED			
Duplicate this form for each year of grant support requested					
<b>PERSONNEL</b> (Applicant Organization Only)					
<b>NAME</b>	<b>ROLE IN PROJECT</b>	<b>EFFORT ON PROJECT</b>	<b>SALARY</b>	<b>FRINGE BENEFITS</b>	<b>TOTALS</b>
	Principal Investigator				
SUBTOTALS					
SUBCONTRACTS					
CONSULTANT COSTS					
EQUIPMENT (Itemize; use additional sheet if needed)					
SUPPLIES (Itemize by category; use additional sheet if needed)					
TRAVEL	DOMESTIC				
	NON-DOMESTIC				
OTHER EXPENSES (Itemize by category; use additional sheet if needed)					
<b>TOTAL DIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD</b>					
<b>INDIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD</b>					
<b>TOTAL COST FOR FIRST 12-MONTH BUDGET PERIOD</b>					

**OTHER SUPPORT**

*(Independent Investigator Research Projects Only)*

Please provide information regarding specific sources of other support for the principal investigator and each co-investigator (not consultants). This information should be provided separately for each individual in the format shown below. List all active support for an individual before listing pending support. Include the investigator's name at the top of each page and number pages consecutively.

<b>NAME OF INDIVIDUAL</b>		
<b>ACTIVE/PENDING</b>		
Project Number (Principal Investigator)	Dates of Approved/ Proposed Project	Percent Effort
Source	Annual Direct Costs	
Title of Project (or Subproject)		
One-sentence description of project goals. (The major goals of this project are...)		
Brief description of potential scientific or commitment overlap with respect to this individual between this application and projects described above (summarized for each individual).		

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**Research Opportunities Soliciting  
Ground-Based Studies for  
Human Health in Space:  
Biomedical Research and Countermeasures Program**

**NASA Research Announcement  
NNH04ZUU003N-BRC**

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: Biomedical Research & Countermeasures Program

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: Biomedical Research & Countermeasures Program

## I. Funding Opportunity Description

### A. Introduction

The Biomedical Research and Countermeasures (BRC) Program is responsible for sponsoring research that will lead to development of practical health-related methods for the prevention, diagnosis, treatment, and/or rehabilitation of humans who live and work in microgravity. The program also responds directly to the requirements, approved by the Office of Health and Medical Systems, which deal with the health and safety of human space travel (see Guidance for NASA Medical Board Procedures - [http://peer1.nasaprs.com/peer\\_review/prog/mpbhand.pdf](http://peer1.nasaprs.com/peer_review/prog/mpbhand.pdf)).

It is critical for investigators to read carefully **ALL** of the instructions in this NRA. All proposals will undergo peer review using similar processes and procedures, but procedures and forms for proposal submission differ for the different programs and elements, and the eventual funding of selected proposals will differ for the different types of awards. Programmatic balance is maintained by the selecting official(s) for the program.

To be responsive to this research solicitation, proposed studies should be hypothesis-driven and lead to new knowledge within accepted scientific standards. Purely phenomenological approaches with no significant mechanistic basis or likely gain in scientific knowledge are not acceptable. Proposals should take into account the impact of gender, age, nutrition, stress, genetic predisposition, or sensitivity to other factors of importance.

The proposer must examine and understand the Bioastronautics Critical Path Roadmap (BCPR), located at [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm), and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will answer. NASA and the NSBRI will perform an assessment to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify which BCPR risks and questions are being addressed by the research will be returned to the proposer without review.

Investigators are encouraged to review summaries of the research currently funded in this program by accessing the NASA Office of Biological and Physical Research (OBPR) Tasks and Bibliography (OBPR Task Book) at [http://research.hq.nasa.gov/code\\_u/code\\_u.cfm](http://research.hq.nasa.gov/code_u/code_u.cfm). In order to achieve programmatic balance, specific topics that are currently well represented in the scope of our research will be de-emphasized.

The research programs described in this NRA support the utilization of specialized NASA ground-based facilities and the development of special technologies required in the pursuit of its research goals. Investigators can access NASA specialized ground-based facilities for their

research. Please refer to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these facilities into a proposal is online at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

## B. Research Elements and Emphases

The emphasis of the ground-based component of the Biomedical Research and Countermeasures (BRC) program is to develop insights into physiologic changes that are likely to occur as a consequence of extended periods of flight. The BRC Program supports basic, applied and clinical research. Researchers may use hypogravity simulation models or hypergravity for their research studies. Experiments may use human subjects, animal models, or other appropriate models in the development of countermeasures. The program is composed of five research elements, each focused on the development and ultimate use of countermeasures to the deleterious effects of spaceflight: 1) Physiology, 2) Behavior and Performance, 3) Environmental Health, 4) Clinical Research in Support of Space Missions, and 5) Radiation Health. The BRC NRA is not soliciting **Radiation Health research in this NRA**.

Mechanistic, ground-based research is solicited that supports the development of biomedical countermeasures to the effects of spaceflight. A countermeasure to help astronauts is any means or procedural strategy that prevents or reduces the negative effects of space or aids in the recovery upon return to Earth. It should be noted that 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, and be tailored for individual specificity. This program encourages integrated approaches that study interactions that occur between different physiological systems in the design and application of potential countermeasures. Identifying the effects of experimental interventions on non-target systems as well as the targeted system is deemed to be of particular importance. Research is also sought to support the solution to operational and clinical problems. This section describes the elements and research emphases within the BRC Program. High priority in FY 2005 will be given to proposals for research in the areas of Sensorimotor Physiology, Behavior and Performance, Environmental Health, and Clinical Studies.

### 1. Physiology

Proposals are requested for ground-based studies that will lead to a better understanding of the effects of spaceflight and exposure to microgravity on physiological function. Proposals for research experiments in the following areas will be given higher priorities: 1) neuroscience, including sensorimotor function; 2) immunology, infection, and hematology; 3) nutrition, metabolism and endocrine control; and 4) integrative physiology. Studies that use integrated approaches are particularly encouraged. Proposals must address the highest import (red and yellow) questions and priorities enumerated in the BCPR. Proposals for experiments in the following areas will be given lower priorities: 5) fluid volume and cardiopulmonary, including cardiovascular alterations; 6) musculoskeletal, including bone loss and muscle alterations and atrophy.

Contact: Bruce M. Hather, Ph.D./Bioastronautics Research Division  
Telephone: 202-358-1796  
Email: bhather@hq.nasa.gov

## 2. Behavior and Performance

The Behavior and Performance element of the program addresses issues of 1) perception and cognition; 2) human physical performance; 3) personal, interpersonal, and group dynamics (coping, response to stress, etc.); and 4) habitability. Studies should be directed towards understanding the effects of spaceflight on behavior and performance.

This element includes ground-based experiments designed to understand the mechanisms by which microgravity, confinement, mission design and events, spacecraft environment, noise and light, and sensory/cognitive or sensorimotor changes affect the behavior and performance of flight crews and ground-support crews. It also addresses psychosocial, gender, and cross-cultural aspects of human missions in space. Studies of relationships between individuals and individuals in groups are also addressed. Proposers may utilize existing databases and ground simulations in extreme and isolated analogs and test beds used to extrapolate to responses that might be expected in long-duration spaceflight. Behavior and performance research priorities for ground-based studies include the following:

### **a. Psychological Research**

Research is solicited that will lead to the development and validation of predictive tools for the assessment of psychological well-being, cognitive processing, mood, and emotion, especially as those are affected by multi-cultural and gender variables in long-duration space missions. Also of interest are hypothesis-driven ground-based studies that would suggest and evaluate potential proactive techniques or strategies for reducing stress and improving well-being, mood, emotion, and cognitive processing in long-duration crews. Such techniques or strategies might include crew manipulation of environmental factors.

### **b. Psychiatric Issues**

Research is required to understand how to detect and treat behavioral disorders that might occur in locations remote from usual health care facilities, e.g., during long-duration spaceflight.

Contact: David L. Tomko, Ph.D./Bioastronautics Research Division  
Telephone: 202-358-2211  
Email: dtomko@nasa.gov

## 3. Environmental Health Research

Research within the Environmental Health element includes three interrelated disciplines, each dealing with a specific aspect of the spacecraft environment; Barophysiology, Microbiology, and

Toxicology. The Environmental Health element has established the following goals: (1) to understand the effects of the spacecraft environments on humans and other organisms; (2) to develop standards and countermeasures, where necessary, to optimize crew health, safety, and productivity.

For FY 2005, proposals are particularly sought for ground studies to determine the effects of potential toxins found on the International Space Station on human health. Since the work and living environment of the spaceflight crew is one and the same, the individual may be exposed to these potential toxins for extended times as compared to limited work hours here on Earth. Additionally, proposed studies that evaluate the added risk of several potential toxins with other space factors are encouraged. NASA is also interested in proposals that try to determine if the space environment can cause microbes to be more virulent. Barophysiology proposals are not being solicited in this NRA.

Contact: Bette Siegel, Ph.D./Bioastronautics Research Division  
Telephone: 202-358-2245  
e-mail: [bette.seigel@nasa.gov](mailto:bette.seigel@nasa.gov)

#### 4. Clinical Research in Support of Space Missions

The Clinical Research in Support of Space Missions element of the program focuses on research that will lead to development of medical knowledge and technologies required to maintain human health and performance in space and on return to Earth. Medical knowledge must be expanded so that the practice of Space Medicine in the microgravity environment can be evidence-based. Medical and surgical procedures, treatment, and imaging systems are required to diagnose and treat illnesses and injuries that may occur in space. The Clinical Research in Support of Space Missions element of the program solicits research required to improve or answer specific questions about in-flight diagnosis, therapy, and postflight rehabilitation.

##### **a. Diagnosis**

Ground-based research analogs for spaceflight research are required to complete the understanding of the patho-physiology, diagnosis, and therapeutic modalities required for implementation of an evidence-based practice of Space Medicine. Proposals for the development of non-invasive diagnostic tests and autonomous and semi-autonomous patient monitoring systems are requested. Research is also sought for the development of medical information systems that support the onboard medical provider.

##### **b. Therapy**

High priority will be given to research proposals to study the mechanisms of changes that could occur during spaceflight in the therapeutic effectiveness and adverse drug interactions of medications for common illnesses. Proposals are sought for research to enhance surgical capabilities in space. High priority will be given to proposals that investigate the application of fiber optic-based and minimally invasive surgical techniques.

Proposals are sought in medical education focused on the development and maintenance of medical capabilities for both physicians and non-physician crew medical officers. Priority will be given to those research proposals that develop and test new training paradigms. Priority will be given to proposals that address the development of spaceflight treatment capabilities for acute medical and surgical emergencies such as wounds, lacerations, and burns; toxic exposures; decompression illness; and dental, ophthalmologic, urologic, gastrointestinal, and gynecologic emergencies.

#### **c. Risk Evaluation**

High priority will be given to research proposals that will evaluate whether the presence of a patent foramen ovale increases the medical risk (incidence and morbidity) related to decompression sickness.

#### **d. Rehabilitation**

Proposals are sought for research to develop more effective rehabilitation techniques for deconditioned space travelers on their return to Earth.

#### **e. Blood Replacement Solutions**

Proposals are sought for ground-based research that emphasizes efficacy and route of administration of intravenous fluids, and blood replacement substances that are stored for extended periods of time and would be required for clinical care of patients in extreme environments (e.g. storage at ambient temperature, small volume, etc.).

Contact: Victor S. Schneider, M.D./Bioastronautics Research Division  
Telephone: 202-358-2204  
Email: vschneider@nasa.gov

### **C. Education and Public Outreach**

OBPR programs represent 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's OBPR programs 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 OBPR programs through formal and informal education opportunities.

OBPR envisions that the selected proposals will be structured and operated in a manner that supports the nation's educational initiatives and goals (including support of historically black colleges and universities and other minority universities), and in particular the need to promote scientific and technical education at all levels. OBPR envisions that the selected proposals will

support the goals for public awareness and outreach to the general public. The selected principal investigators are invited to participate in OBPR-funded educational programs.

The successful research project represents an opportunity for NASA to enhance and broaden the public's understanding of and appreciation for the value of OBPR research in the context of NASA's mission. Therefore, all investigators are strongly encouraged to promote general scientific literacy and public understanding of OBPR research through formal and/or informal education opportunities. If appropriate, proposals should include a clear and concise description of the education and outreach activities proposed. Examples include involving students in the research activities, technology transfer plans, public information programs that will inform the general public of the benefits being gained from the research, and/or plans for incorporation of scientific results obtained into curricula consistent with educational standards.

Where appropriate, the supported institution will be required to produce, in collaboration with NASA, a plan for communicating to the public the value and importance of their work. Once NRA selections are made, the selected PIs will have an opportunity to request additional funding through an OBPR-sponsored pilot program to implement an education outreach program at the grades 6-12 level, at an amount not to exceed \$10,000 per year for the term of the grant. A request for proposal will accompany the selection notification letter. Proposals will be due within 60 days of selection notification and shall be limited to 4 pages. A review of these proposals by educational specialists will determine which proposals will be funded.

#### D. 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.

#### E. Availability of Funds for Award

Funds are not currently available for awards under this announcement. 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 NASA determines are acceptable for award under this announcement.

## II. Award Information

The selected proposal will be funded as a research grant in one-year increments for activities lasting up to **four years**. The mechanism for funding the successful proposal will be a single grant, with funding allocations to participating investigators based on the submitted budget and project review. The funding duration will depend on proposal requirements, review panel recommendations, and continuing progress of the activity. All proposals will be evaluated for

overall merit by independent peer review panels, and a second review for NASA relevance and proposed cost by the cognizant NASA program office. NASA reserves the right to “partner” research projects that it determines will augment one another.

The total annual cost for ground research should not exceed \$450,000. Separate funding for direct and indirect costs is not provided: thus the amount of the award requested is the total of all cost submitted in the proposed budget. NASA reserves the right to return proposals, without review, that exceed the described award amounts. 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. It is estimated that the initial selection will be announced by **February 2005** and the grant awarded in a reasonable timeframe thereafter.

### **III. Eligibility Information**

#### **A. Eligibility of Applicants**

All categories of 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 Announcement. 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 or a competing factor in the selection process.

#### **B. Cost Sharing or Matching**

If an institution of higher education, hospital, or other non-profit organization wants to receive a grant or cooperative agreement from NASA, cost sharing is not required. However, NASA can accept cost sharing if it is voluntarily offered (See the Handbook, Section B, Provision 1260.123, “Cost Sharing or Matching,” which describes the acceptable forms of cost sharing). If a commercial organization wants to receive a grant or cooperative agreement 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 (See the Handbook, Section D, Provision 1274.204, “Costs and Payments”.) For NSBRI specific rules, see page NSBRI-9, Section III. B.

## C. Guidelines for International Participation

**Export Control Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation.** Foreign proposals and 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.pmdtc.org> and <http://www.bis.doc.gov>. Investigators are advised that under U.S. law and regulations, spacecraft and their specifically designed, modified, or configured systems, components, and parts are generally considered “Defense Articles” on the United States Munitions List and are subject to the provisions of the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120-130.

## IV. Proposal and Submission Information

### A. Source of Application Materials

All information needed to apply to this solicitation is contained in this announcement and in the companion document entitled “Guidebook for Proposers Responding to NASA Research Announcements” (hereafter referred to as the Guidebook for Proposers) that is located at <http://www.hq.nasa.gov/office/procurement/nraguidebook/>. This solicitation and any modifications or updates to this solicitation are available at: [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

Except where specifically stated otherwise in this NRA, applicants must prepare proposals in accordance with the Guidebook for Proposers. Proposals that do not conform to the standards outlined in this NRA and included in the Guidebook for Proposers may be declared noncompliant and returned without review. Note that the NASA policy for proposals involving non-U.S. participants is given in Section (I) of Appendix B of this Guidebook. Comments and suggestions of any nature about the Guidebook for Proposers are encouraged and welcomed and may be directed at any time to Mr. Tom Sauret, Office of Procurement, Code HK, NASA Headquarters, 300 E Street SW, Washington, DC 20546-0001; E-mail: [Tsauret@mail.hq.nasa.gov](mailto:Tsauret@mail.hq.nasa.gov)

## B. Content and Form of Proposal Submission

The following information is specific to this NRA and **supersedes** the information contained in the Guidebook for Proposers.

### 1. SYS-EYFUS Registration

SYS-EYFUS is an electronic system used by NASA Headquarters to manage research solicitation activity, plan for the receipt of research proposals, track the receipt and peer evaluation of these proposals, and manage funded research (grants, cooperative agreements, etc.).

The SYS-EYFUS Help Desk is available at (202) 479-9376. Help desk hours are from 8 a.m. to 6 p.m. Eastern time.

All investigators planning to submit a proposal to this solicitation are required to register online with SYS-EYFUS. Comprehensive help, instructions, and contact information are provided online. SYS-EYFUS can be accessed at the following Web address:

<http://proposals.hq.nasa.gov/proposal.cfm>

If you have previously registered with SYS-EYFUS, you are asked to verify and update your user information. If you have forgotten your user ID or password, select the “Forgot Your Password” option and type in your first and last name to search our database. The system will send an automatic e-mail message with your username and password to the e-mail address listed in our database.

### 2. Instructions for Preparing and Electronically Submitting a Notice of Intent

All investigators planning to submit a proposal in response to this solicitation are requested to submit a **non-binding** Notice of Intent (NOI) to propose by the due date identified in the Submission Dates and Times Section of this NRA via the Web at the following address:

<http://proposals.hq.nasa.gov/proposal.cfm>

- 1) Login to SYS-EYFUS at the URL listed above and select “New Notice of Intent.”
- 2) The Division Specific Opportunities screen will appear. In the selection window, highlight “**UU-OBPR**” and click on “Continue.”
- 3) The List of Existing Opportunities screen will appear. In the selection window, highlight “**NNH04ZUU003N – Research Opportunities Soliciting Ground-Based Studies for Human Health in Space**” and then click on “Continue.”
- 4) This will bring you to the Notice of Intent Submission Form. **All fields are required.**

- a. The proposal summary should be a succinct and accurate description of the proposed work when read separately from the project description. The summary should contain a brief description stating the specific aims of the proposed work. Describe concisely (300-500 words) the research design and methods for achieving these aims.
- b. Please select from **only** the following three options: For the proposal type field on this form, new/no prior support means that the investigator has not received NASA funding from 2001 through 2003, new/prior support means that the investigator has received NASA funding between 2001 through 2003, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 2001 through 2003, but not funded. A proposal previously submitted but not funded should be identified as being “revised” even if the original Principal Investigator has changed.
- c. Indicate the status of IRB/IACUC for your proposal. If IRB or IACUC review is unavoidably delayed beyond the submission of the application, enter “Pending” on the Proposal Cover Page, and be advised that the certification must be received within 90 days after the due date for which the application is submitted.
- d. Provide your DUNS and CAGE numbers. If you do not know your DUNS and CAGE numbers, contact your Office of Sponsored Research or equivalent office. All applicants must provide the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number for their organization in the Cover Page of their proposal. This requirement applies to renewals of awards as well as to prospective new awards. The DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). Organizations will use the same DUNS number with every proposal submitted for a Federal grant and cooperative agreement. Note that the DUNS number is site-specific. Applicants may call D&B at 1-866-705-5711 to register and obtain a DUNS number, or access the D&B website at: <http://www.dnb.com/us/>.

NASA also requires the applicant’s organization to be registered in the Central Contractor Registration (CCR) database and obtain a Commercial And Government Entity (CAGE) code prior to submitting a proposal. The purpose of this requirement is to help centralize information about grant recipients and provide a central location for grant recipients to change organizational information. Information for registering in the CCR and online documents can be found at <http://www.ccr.gov/>. Before registering applicants and recipients should review the Central Contractor Registration Handbook, which is also located at <http://www.ccr.gov/>. The process for obtaining a CAGE code is incorporated into the CCR registration.

- 5) Click on “Submit NOI Page.”
- 6) The Team Member Page screen will appear, where you can add or remove team members. Select continue if there are no other team members. To add a team member, highlight the role option on the selection list, type in first and last name and click on search. When the resulting set appears, choose the appropriate radio button and click on ADD to add the person to the NOI. After you are done, click on “Continue.” **IMPORTANT:** If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.
- 7) After continuing from the Team Members Page, your NOI will be displayed. Click on “Resubmit NOI Page” to complete your NOI submission.
- 8) You may edit and resubmit your NOI at any time before the submission deadline. Once you submit an NOI, it cannot be deleted, only edited. For title, team member, or any other changes, please edit your existing NOI and resubmit changes to avoid duplicate records.

### 3. Instructions for Preparing and Electronically Submitting a Proposal Cover Page

All investigators planning to submit a proposal in response to this solicitation must electronically submit proposal cover page information online and provide a hardcopy of the cover page attached to each proposal copy by the due date indicated in the Submission Dates and Times Section of this NRA. The proposal cover page can be submitted and printed via the Web at the following address:

<http://proposals.hq.nasa.gov/proposal.cfm>

- 1) Login to SYS-EYFUS at the URL listed above.
- 2) To submit a New Proposal Cover Page, click the “New Proposal Cover Page” option on the SYS-EYFUS Options screen, and the New Proposals Cover Page screen will appear.
- 3) If you previously submitted an NOI in response to this solicitation, choose to carry over the existing NOI. This option will populate the cover page fields with the NOI information. Edit the information as necessary, click “Continue,” and proceed to #8 below.
- 4) If you did not previously submit an NOI, click on New Proposal Cover Page option, and the Division Specific Opportunities screen will appear.
- 5) In the selection window, highlight “**UU-OBPR**” and click on “Continue.”

- 6) The List of Existing Opportunities screen will appear. In the selection window, highlight “**NNH04ZUU003N – Research Opportunities Soliciting Ground-Based Studies for Human Health in Space**” and then click on “Continue.”
- 7) This will bring you to the Proposal Cover Page Submission Form. Fill in all the fields. All fields are required.
  - a. The proposal summary should be a succinct and accurate description of the proposed work when read separately from the project description. The summary should contain a brief description stating the specific aims of the proposed work. Describe concisely (300-500 words) the research design and methods for achieving these aims.
  - b. Please select from **only** the following three options: For the proposal type field on this form, new/no prior support means that the investigator has not received NASA funding from 2001 through 2003, new/prior support means that the investigator has received NASA funding between 2001 through 2003, and revised means that the proposal is a revised version of a proposal submitted to NASA and reviewed from 2001 through 2003, but not funded. A proposal previously submitted but not funded should be identified as being “revised” even if the original Principal Investigator has changed.
  - c. Indicate the status of IRB/IACUC for your proposal. If IRB or IACUC review is unavoidably delayed beyond the submission of the application, enter “Pending” on the Proposal Cover Page, and be advised that the certification must be received within 90 days after the due date for which the application is submitted.
  - d. Provide your DUNS and CAGE numbers. If you do not know your DUNS and CAGE numbers, contact your Office of Sponsored Research or equivalent office. All applicants must provide the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number for their organization in the Cover Page of their proposal. This requirement applies to renewals of awards as well as to prospective new awards. The DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). Organizations will use the same DUNS number with every proposal submitted for a Federal grant and cooperative agreement. Note that the DUNS number is site-specific. Applicants may call D&B at 1-866-705-5711 to register and obtain a DUNS number, or access the D&B website at: <http://www.dnb.com/us/>.

NASA also requires the applicant’s organization to be registered in the Central Contractor Registration (CCR) database and obtain a Commercial And Government Entity (CAGE) code prior to submitting a proposal. The purpose of this requirement is to help centralize information about grant recipients and

provide a central location for grant recipients to change organizational information. Information for registering in the CCR and online documents can be found at <http://www.ccr.gov/>. Before registering applicants and recipients should review the Central Contractor Registration Handbook, which is also located at <http://www.ccr.gov/>. The process for obtaining a CAGE code is incorporated into the CCR registration.

Click on “Continue.”

- 8) The Team Member Page screen will appear, where you can add or remove team members. Every proposal must specify the critically important personnel who are expected to play a significant role in the execution of the proposed effort and their institution of employment. Categories of personnel to be included as Team Members are described in Guidebook for Proposers.

**You must include your authorizing official as a team member.** When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official.. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

**IMPORTANT:** If the team member is not listed in our database, please have them add themselves as a new user to the system. You may then add them to your team member list.

- 9) After continuing from the Team Member Page, the Proposal Options Page appears.
- 10) Please fill out the budget form by clicking on the “Budget” button, filling in project costs, and clicking “Continue.” This will bring you to the Proposal Budget Review Page. Click “Continue” if the information is correct.
- 11) After verifying your budget information, you will be returned to the Proposal Options Page. Click the “Show/Print” button.
- 12) For detailed budget information, you must use the budget forms provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). Sample copies of these forms are also available as attachments to this NRA and must be filled out for each year of grant support requested. These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.
- 13) At the page entitled Proposal Information Item List, click “Continue” to preview your Proposal Cover Page. Print the cover page from your Internet browser once you have reviewed the information. The cover page must be signed by both the Principal Investigator and the authorizing official and attached to the front of your proposal before submission of hard copies to NASA.

By signing and submitting the proposal identified on the cover sheet, the authorizing

official of the proposing institution (or the individual investigator if there is no proposing institution) 1) certifies that the statements made in the proposal are true and complete to the best of his/her knowledge; 2) agrees to accept the obligations to comply with NASA Award terms and conditions if an award of a grant or cooperative agreement is made as a result of this proposal (does not apply to contract awards); and 3) provides certification to the following that are: (i) Certification Regarding Debarment, Suspension, and Other Responsibility Matters, (ii) Certification Regarding Lobbying, and (iii) Certification of Compliance with the NASA Regulations Pursuant to Nondiscrimination in Federally Assisted Programs.

**Once you print your cover page, the electronic portion of your NASA proposal submission is complete.**

- 14) You may edit and resubmit your proposal cover page at any time before the submission deadline as indicated in the Submission Dates and Times Section of this NRA. Please note that once you submit a proposal cover page, it can only be edited, not deleted. For title, team member, budget or any other changes, please edit your existing proposal cover page and resubmit changes to avoid duplicate records. After you print your edited cover page, your changes are automatically submitted to NASA.

#### 4. Instructions for Preparation of Proposals

**All** proposals submitted must include the completed cover page form as described above. The name of the Principal Investigator should appear in the upper right hand corner of each page of the proposal, except on the cover page form, where fields are provided for this information. Note that the proposal must specify the period of performance for the work described; periods of performance may be for any duration up to the maximum duration identified in the Announcement section of this NRA but should be suitable for the project proposed.

**The proposal must include the following material, in this order:**

- (1) Proposal Cover Page: Solicited Proposal Application, including certification of compliance with U.S. code (if applicable). One signed original required. Please see “Instructions for Preparing and Electronically Submitting a Proposal Cover Page” in Section IV.B.3 above for instructions on how to complete the proposal cover page information.
- (2) Checklist for proposers. This checklist is provided in the forms appendix of this document and can be downloaded from :  
  
[http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html)
- (3) Transmittal Letter or Prefatory Material, if any (see Guidebook for Proposers).
- (4) Proposal Title Page, with Notice of Restriction on Use and Disclosure of Proposal Information, if any (see Guidebook for Proposers).

- (5) Project Description: The length of the Project Description section of the proposal cannot exceed 20 pages using regular (12 point) type. Text must be printed on one side only and should have the following margins: left = 1.5"; Right, top, bottom = 1.0". Referenced figures must be included in the 20 pages of the Project Description. The Bibliography, Management Approach, and all following sections are not considered part of the 20-page project description. Proposals that exceed the 20-page limit for the project description will not be reviewed. The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall merit of the proposed research and about the probability that the investigators will be able to accomplish their stated objectives with current resources and the resources requested. In addition, the proposal should clearly indicate the relationship between the proposed work and the research emphases defined in this Announcement. Reviewers are not required to consider information presented as appendices or to view and/or consider Web links in their evaluation of the proposal.
- (6) Management Approach: Each proposal must specify a single Principal Investigator who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. In proposals that designate several senior professionals as key participants in the research project, the management approach section should define the roles and responsibilities of each participant and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal must clearly and unambiguously state whether these key personnel have reviewed the proposal and endorsed their participation.

Investigators are strongly encouraged to identify only the most critically important personnel to aid in the execution of their proposals. Should such positions be necessary, Co-Investigators (co-Is) may be identified who are critical for the successful completion of research through the contribution of unique expertise and/or capabilities, and who serve under the direction of the PI, regardless of whether or not they receive compensation under the award. Most NRAs require a co-I to have a well-defined role in the research that is defined in the Management section of the proposal. Evidence of a co-I's commitment to participate is often requested through a brief letter to be included with the proposal.

There are three subcategories of co-Is that a proposal may identify, as appropriate:

- A co-I may be designated as the *Science PI* for those cases where the proposing institution does not permit that individual to formally serve as the PI as defined above. In such a case, the Science PI will be understood by NASA to be in charge of the scientific direction of the proposed work, although the formally designated PI is still held responsible for the overall direction of the effort and use of funds.
- A co-I may be designated as an *Institutional PI* when their institution is making a major contribution to a proposal submitted by a PI from another institution.

- A co-I from a non-U.S. institution may be designated as a co-Principal Investigator (co-PI) should such a designation serve required administrative purposes in that co-I's institution and/or for the procurement of funding by that co-I from their sponsoring funding authority.

Additional category positions are often included in proposals as defined as follows:

- A Postdoctoral Associate holds a Ph.D. or equivalent degree and is identified as a major participant in the execution of the proposed research. Such personnel may be identified by name or only by function in those cases where their recruitment depends on the successful selection of the proposal.
- Other Professional is a description appropriate for personnel who support a proposal in a critical albeit intermittent manner, such as a consulting staff scientist or a key Project Engineer and/or Manager, who is not identified as a co-I or Postdoctoral Associate.
- A Graduate Student included in a proposal is working for a post-graduate degree and will support the proposed research under direction of the PI. Such a student may be identified by name or only by function in case their recruitment depends on the successful selection of the proposal.
- A Collaborator is an unfunded position included in a proposal, whose participation is less critical than a co-I, but who is committed to provide a specific contribution to the proposal

- (7) The investigator must examine and understand the Bioastronautics Critical Path Roadmap (BCPR), and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will answer [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm). NASA and the NSBRI will perform an assessment to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify what BCPR risks and questions are being addressed by the research will be returned to the investigator without review.
- (8) Personnel/Biographical Sketches: The biographical sketch for each investigator should not exceed two pages. If the list of qualifications and publications exceeds two pages, select the most pertinent information. List, in chronological order, the titles, all authors, and complete references to all publications pertinent to this application (see Guidebook for Proposers). A sample biographical sketch form can be downloaded at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). A sample copy of the form is available as an attachment to this NRA. These forms cannot be electronically submitted. Omit social security numbers and other personal items that do not merit consideration in evaluation of the proposal. Provide similar biographical information on other senior professional personnel who will be directly associated with the project. Provide the names and titles of any other scientists and technical personnel associated substantially with the project in an advisory capacity. Universities should list the approximate number of students or other assistants, with information as to their level of academic attainment. Any special industry-university cooperative arrangements should

be described. Fill out the forms and attach them to your proposal

- (9) Facilities and Equipment: Describe the available facilities and major items of equipment specially adapted or suited to the proposed research activities, and any additional major equipment that will be required. Identify any government-owned facilities, industrial plant equipment, or special tooling that are proposed for use in the research activities.. The research plan must provide evidence that such facilities or equipment will be made available if the proposal is accepted. Before requesting a major item of capital equipment, the proposer should determine the availability of equipment already within the organization as an alternative to purchase. Where such arrangements cannot be made, the proposal should state this explicitly. The need for items that can be typically used for research and non-research purposes should be explained.
- (10) Special Matters (specific information on animal or human subjects protocol approval required, if applicable)

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

Policies for the protection of human subjects in NASA sponsored research projects are described in NASA Management Instruction (NMI) 7100.8B (*Protection of Human Research Subjects*). 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*). Both documents are available from the Office of Biological and Physical Research, Code UB, NASA Headquarters, Washington, DC 20546.

#### Additional Requirements for Research Employing Human Subjects

A letter signed by the Chair of the Institutional Review Board (IRB) identifying the proposal submitted to NASA by title and certifying approval of proposed human subjects protocols and procedures should be included with each copy of the proposal. IRB certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IRB certification is pending on the proposal due date, select “pending” from the IRB/IACUC section menu on the Proposal Cover Page, and include with each copy of the proposal a letter signed by the IRB Chair identifying the proposal by title and indicating the status of the IRB review process at the time of submission. IRB certification must be received no later than 90 days after the proposal due date. An application lacking the required IRB certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

With regard to research involving human subjects, NASA and the 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. Please fill in the form provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html) with the information requested on inclusion of women and minorities if your proposal involves research on human subjects.

NASA will require current IRB certification prior to each year's award.

Additional Requirements for Research Employing Animals

**Specific information describing and justifying the use of animal subjects must be included in the proposal.**

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) identifying the proposal submitted to NASA by title and certifying approval of the proposed animal research protocols and procedures should be included with each copy of the proposal. The institution's Public Health Service Animal Welfare Assurance Number must be included on the IACUC certification and entered in the IRB/IACUC section of the Proposal Cover Page. IACUC certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IACUC certification is pending on the proposal due date, select "pending" from the IRB/IACUC selection menu on the Proposal Cover Page, and include with each copy of the proposal a letter signed by the IACUC Chair identifying the proposal by title and indicating the status of the IACUC review process at the time of submission. IACUC certification must be received no later than 90 days after the proposal due date. An application lacking the required IACUC certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review. NASA will require current IACUC certification prior to each year's award.

(11) Detailed Budget and Supporting Budgetary Information

For detailed budget information, you must use the forms provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). Sample copies of these forms are also available as attachments to this NRA. These forms cannot be electronically submitted. Fill out the forms and attach them to your proposal.

NASA is expected to be operating on the basis of full cost accounting as soon as possible, including all Civil Service salaries with overhead. In the interim period, proposals should use the accounting method authorized at their institutions at the time proposals are due and for the entire proposed period of performance. Funds to support the Resident Research Assistant (RRA) Postdoctoral Program costs (e.g., stipend, travel, computer time, supplies, etc.) are to be budgeted within the NASA intramural Principal

Investigator budget.

If travel is planned, the proposal budget should include appropriate travel funds for visits to NASA field centers (as appropriate) and presentation of findings at professional society meetings.

In this solicitation, the terms “cost” and “budget” are used synonymously. Sufficient proposal cost detail and supporting information are required; funding amounts proposed with no explanation (e.g., Equipment: \$1,000, or Labor: \$6,000) may cause delays in evaluation and award. Generally, costs will be evaluated for realism, reasonableness, allowability, and allocation. The budgetary forms define the desired detail, but each category should be explained. Offerors should exercise prudent judgment in determining what to include in the proposal, as the amount of detail necessarily varies with the complexity of the proposal.

The following examples indicate the suggested method of preparing a cost breakdown:

#### Direct Labor

Labor costs should be segregated by titles or disciplines with estimated hours and rates for each. Estimates should include a basis of estimate, such as currently paid rates or outstanding offers to prospective employees. This format allows the Government to assess cost reasonableness by various means including comparison to similar skills at other organizations.

#### Other Direct Costs

Please detail, explain, and substantiate other significant cost categories as described below:

- Subcontracts: Describe the work to be contracted, estimated amount, recipient (if known), and the reason for subcontracting.
- Consultants: Identify consultants to be used, why they are necessary, the time they will spend on the project, and the rates of pay.
- Equipment: List separately. Explain the need for items costing more than \$5,000. Describe basis for estimated cost. General-purpose equipment is not allowable as a direct cost unless specifically approved by the NASA Grant Officer. Any equipment purchase requested as a direct charge must include the equipment description, how it will be used in the conduct of the basic research proposed, and why it cannot be purchased with indirect funds.
- Supplies: Provide general categories of needed supplies, the method of acquisition, and estimated cost.
- Travel: Describe the purpose of the proposed travel in relation to the grant, and provide the basis of estimate, including information on destination and number of travelers (if known). **Note: Investigators are required to include travel to an annual PI meeting in their budget.**

- Other: Enter the total of direct costs not covered by a) through e). Attach an itemized list explaining the need for each item and the basis for the estimate.

### Indirect Costs

Indirect costs should be explained to an extent that will allow the Government to understand the basis for the estimate. Examples of prior year historical rates, current variances from those rates, or an explanation of other basis of estimates should be included. Where costs are based on allocation percentages or dollar rates, an explanation of rate and application base relationships should be given. For example, the base to which the General and Administrative (G&A) rate is applied could be explained as: application base equals total costs before G&A less subcontracts.

All awards made as a result of this NRA maybe funded as grants. However, while proposals submitted by “for profit” organizations are allowed, they cannot include a “fee.”

(12)Other Support: You must provide information on other support for specific sources of other support for the principal investigator and each Co-Investigator (not consultants). A sample form is provided at:

[http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html). A sample copy of the form is also available as attachment to this NRA

(13)Appendices, if any (**reviewers are not required to consider information presented in appendices**).

## 5. Submission Dates and Times

One (1) signed original cover page and proposal and twenty (20) copies of the proposal cover page and proposal **must be received by 4:30 p.m. Eastern Time, September 8, 2004.**

Proposals shall not be submitted electronically, except for parts specified in this NRA. Proposals mailed through the U.S. Postal Service by express, first class, registered, or certified mail are to be sent to the following address:

NASA Peer Review Services  
SUBJECT: **Biomedical Research and Countermeasures Program**  
500 E Street SW  
Suite 200  
Washington, DC 20024

Proposals that are hand delivered or sent by commercial delivery or courier services are to be delivered to the above address between 8:00 a.m. and 4:30 p.m. Proposals must be received by 4:30 p.m. Eastern time on the proposal due date. The telephone number (202) 479-9030 may be used when required for reference by delivery services. NASA Peer Review Services (NPRS) cannot receive deliveries on Saturdays, Sundays, or federal holidays. NPRS will send notification to the investigator confirming proposal receipt within 5 business days of the

proposal receipt date; however, there will not be a response from the Office of Biological and Physical Research.

The following items apply only to this Announcement:

<b>Solicitation Announcement Identifier:</b>	<b>NRA NNH04ZUU003N</b>
<b>Number of Copies Required:</b>	<b>Original + 20 copies</b>
<b>Proposals Due:</b>	<b>September 8, 2004</b>
<b>Estimated Selection Announcement:</b>	<b>February 2005</b>
<b>Selecting Officials:</b>	<b>Guy Fogleman, Ph.D. Bioastronautics Research Division</b>

## 6. 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 Guidebook for Proposers.
- 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.
- U.S. research award recipients may directly purchase of supplies and/or services that do not constitute research from non-U.S. sources, but award funds may not be used to fund research carried out by non-U.S. organizations. However, subject to possible export control restrictions, foreign nationals may conduct research while employed by a U.S. organization.
- Profit for commercial organizations is allowed under contract awards only.
- 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.
- 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/fulcost/>.

## V. Proposal Review Information

The following information is specific to this NRA and **supersedes** the information contained in the Guidebook for Proposers.

### A. Intrinsic Scientific or Technical Merit Review and Evaluation Criteria

The overall evaluation process for proposals submitted in response to this Announcement will include review of relevance, cost criteria, and merit criteria. All of the following merit criteria, of equal consideration, will be used in determining the merit score of the proposal:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field? Is there a significant societal or economic impact?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Does the project employ appropriate novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and any co-investigators? Is the evidence of the investigator's productivity satisfactory?
- **Environment:** Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

### B. Review and Selection Process

#### 1. Compliance Matrix

All proposals must comply with the general requirements of the Announcement as described in both this solicitation and the Guidebook for Proposers. Upon receipt, proposals will be reviewed for compliance with these requirements including:

1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
2. Submission of appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) certification for all proposals using human or animal test subjects.

3. Submission of a budget that is within the guidelines specified in this Announcement and is for a funding period not exceeding that described in the Announcement.
4. Proposals that are revised versions of proposals previously submitted to NASA must be clearly designated as such on the proposal cover page and must contain an explanation of how the revised proposal has addressed criticisms from previous NASA review. This explanation should be presented at the beginning of the project description in a separate section of no more than two pages, and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
5. Submission of gender and minority inclusion data as appropriate.
6. Submission of all other appropriate information as required by this Announcement.

***Note: At NASA's discretion, non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.***

Compliant proposals submitted in response to this Announcement will undergo an intrinsic scientific or technical merit review. Only those proposals most highly rated in the merit review process will undergo additional reviews for program relevance and cost.

## 2. Review and Selection

The overall evaluation process for proposals submitted in response to this Announcement will include the following reviews:

**First Tier Merit Review:** A review for intrinsic technical or scientific merit and overall impact will be conducted for all proposals.

**Second Tier Review for Relevance and Cost:** Relevance to NASA, program balance and proposed project cost.

The **first review tier** will be a merit review by a panel of scientific or technical experts. The number and diversity of experts required will be determined by the response to this NRA and by the variety of disciplines represented in the proposals relevant to the research emphases described in Appendix A. The merit review panel will assign **a score from 0-100** based upon the intrinsic scientific or technical merit of the proposal. This score will reflect the consensus of the panel.

The score assigned by this panel ***will not be affected by the cost of the proposed work nor will it reflect the programmatic relevance of the proposed work to NASA.*** The panel will be asked to include in their critique of each proposal any comments they may have concerning the proposal's budget and relevance to NASA. In addition to the above, in accordance with the NIH policy that NASA and NSBRI have adopted, all applications will be reviewed with respect to:

- Adequacy of plans to include genders, members of minority groups, and their subgroups, as appropriate for the scientific goals of the research
- Plans for the recruitment and retention of subjects

- Reasonableness of the proposed budget and duration in relation to the proposed research
- Adequacy of the proposed protection for humans, animals or the environment to the extent they may be adversely affected by the project proposed in the application

The **second review tier** will evaluate the programmatic relevance, balance and cost of all proposed work. This review will be conducted by NASA Program Scientists and Managers. Evaluation of the cost of a proposed effort includes consideration of the realism and reasonableness of the proposed cost and the relationship of the proposed cost to available funds. Programmatic relevance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks required by critical research issues faced by NASA and OBPR.

In order to optimize resources, NASA is pursuing the intentional formation of investigator partnerships between individual investigators whose experiments will leverage resources by addressing different facets of the same critical question. NASA anticipates that such intentional teaming arrangements will result in better utilization of available resources to resolve specific enabling questions. NASA strongly encourages individual investigators submitting applications in response to this NRA to consider identifying collaborations between individual investigators as part of the development of their individual proposals and to identify this pre-coordination in their management plan.

The information resulting from these two levels of review, as described above, will be used to prepare a **selection recommendation** developed by NASA program scientists and managers for each of the program elements described in this Announcement. This recommendation will be based on:

1. The scientific or technical merit review score from the peer review panel.
2. The programmatic relevance.
3. The cost of each proposal.

This **selection recommendation** is the responsibility of the NASA program scientist(s). Selection for funding will be made by the selecting official identified in the Submission Dates and Times Section of this NRA. There will be one selection.

## **VI. Award Administration Information**

### **A. Award Notices**

At the end of the selection process, each proposing organization is notified of its selection or nonselection status. NASA provides debriefings to those investigators who request one. The selection letters will include a statement indicating the selected organization's business office will be contacted by a NASA Contracting or Grant Officer, who is the only official authorized to obligate the Government, and a reminder that any costs incurred by the investigator in anticipation of an award are at their own risk. Selection notification will be made by a letter signed by the selecting official.

The NASA Procurement Office will determine the type of award instrument, request further business data, negotiate the resultant action, and are the only personnel with the authority to obligate government funds.

NASA reserves the right to offer selection of only a portion of a proposal. In these instances, the investigator will be given the opportunity to accept or decline the offer.

## B. Administrative and National Policy Requirements

This solicitation does not invoke any special administrative or National policy requirements, nor do the award(s) that will be made involve any special terms and conditions that differ from NASA's general terms and conditions as given in the Guidebook for Proposers.

## C. Program Reporting/Individual Researcher Reporting

It is expected that results from funded research will be submitted to peer-reviewed journals as the work progresses. Only published papers that acknowledge NASA's support and identify the grant or contract will be counted as resulting from the research project and used to evaluate its productivity.

**Annual Reporting.** The Office of Biological and Physical Research publishes a comprehensive online document titled OBPR Program Tasks and Bibliography (Task Book) which includes descriptions of all current peer-reviewed activities funded by the division. Since its inception, the Task Book has served as an invaluable source of information for OBPR as well as the scientific and technical communities.

Investigators are required to provide NASA with this summary information at a minimum of once per year. This information will be made available to the scientific community and will be used to assess the strength of the Division's programs. It will also serve as the basis for determining the degree of progress of the project. The information provided for the Task Book will meet both the requirements for program annual reporting requirements and the individual researcher task book reporting. Updates can be made throughout the duration of the project at anytime during the year, with a due date of at least once per year 60 days prior to the anniversary date of the grant start date.

The information requested will include:

- an abstract,
- a brief statement of progress during,
- a brief statement of benefits of the research with respect to life on Earth,
- an updated bibliographic list,
- a copy or reprint of each publication listed in the bibliography,
- a listing of presentations or activities conducted at 6-12 educational institutions,
- a listing of interactions, presentations, or other activities with the general public, and
- a statement of potential scientific, technological, economic or societal impact.

Note that although this publication will be made available to the general scientific community, it

is not a substitute for traditional scientific reporting in journals and elsewhere.

All articles submitted for publication must include the following statement: “This research was funded in whole or in part by a grant from the Office of Biological and Physical Research of the National Aeronautics and Space Administration.” Publications not including this acknowledgement will not be considered to be the product of NASA-funded research when NASA assesses the progress of the grant.

**Final Report.** A final report must be provided to the appropriate Division Director at NASA HQ at the end of the funding period, including a detailed listing of all peer-reviewed publications. Information required for inclusion in final reports is:

- summary of the research activities;
- 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 and copies of all publications and reports. Any publications or other public materials containing data are particularly important to include in this section.

## VII. NASA Contacts

Additional technical information for the NASA programs is available from

Guy Fogleman, Ph.D.  
Biastronautics Research Division  
Mail Code UB  
NASA Headquarters  
Washington, DC 20546-0001  
Telephone: (202) 385-0220  
Fax: (202) 358-1468  
E-mail: [gfoglema@hq.nasa.gov](mailto:gfoglema@hq.nasa.gov)

The contracting point of contact will be specified in each selection notification letter.

Potential investigators should read with care the program descriptions that are of interest and focus their proposals on the specific research emphases defined in this Announcement.

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

## **VIII. Additional Forms and Proposal Submission Frequently Asked Questions (FAQs)**

### *(Independent Investigator Research Projects Only)*

#### **A. Frequently Asked Questions (FAQs)**

The information provided here is in response to questions from investigators such as yourself. Additional information regarding submission procedures and requirements can be found in the research announcement to which you are responding, and at the NASA online proposal site:

<http://proposals.hq.nasa.gov/proposal.cfm>

#### **1. What forms should I use when submitting a proposal?**

Currently, the NASA proposal site does not support the uploading of information or forms other than the information gathered while completing the online cover page. Please complete the online cover page early in the process (you can always return and edit the cover page at any time up to the due date). After completing the cover page, any additional information you are required to provide or wish to provide can be submitted in hardcopy in any format you choose.

Please find included in this document several sample forms that you may use when providing additional information. A standard checklist of materials to include is also provided. Information outside of the online proposal cover page can be provided in any format you choose, as long as it adheres to the NRA requirements. Please reference the NRA for information on all material required when submitting your proposal. Please be aware that we ask for copies of the completed proposal package, not just the project description, and must **receive** the copies by the proposal due date. The additional information requested in the NRA does not count towards the 20 page limit of your project description.

#### **2. Where does my authorizing official sign?**

You must include your authorizing official as a team member. When you complete and print the proposal cover page, you will see signature blocks both for yourself and your authorizing official. You are required to submit one original signed (by both you and your authorizing official) cover page with your proposal hardcopies.

To be added as a team member to your proposal, the individual must be registered with the SYS-EYFUS system. If you try and add a team member and they are not found in the database, you must contact and have that individual register as a new SYS-EYFUS user. You will then be able to add them as a team member.

#### **3. Who should I contact if I receive errors or have additional problems while using the NASA proposal site?**

For technical support, please e-mail [proposals@hq.nasa.gov](mailto:proposals@hq.nasa.gov) or call 202-479-9376 (Monday to Friday 8 a.m.-6 p.m. EST/EDT).

## B. Checklist for Proposers and Additional Forms

**Form A**

### **CHECKLIST FOR PROPOSERS** *(Independent Investigator Research Projects Only)*

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Proposal Cover Page (completed online)

Checklist for Proposers (Form A)

Proposal Title Page

Response to previous reviews (if applicable, these 2 pages are not included in the 20 page proposal page limit)

Project Description

Bioastronautics Critical Path Roadmap (BCPR) Form (Form B)

Biographical Sketches (Form C)

Facilities and Equipment Description

IRB or ACUC letter/form (if applicable)

Targeted/Planned Enrollment (FOR HUMAN SUBJECTS ONLY, Form D)

Summary Budget Form/Budget Justification (Form E)

Detailed 12-Month Budget (for each year of support, Form F)

Other Support (Form G)

Letters of Collaboration/Support (if applicable)

Appendices, if any

**Form B**

## BIOASTRONAUTICS CRITICAL PATH ROADMAP (BCPR) FORM

*(Independent Investigator Research Projects and NSBRI Team Research Projects)*

<u>Hypotheses</u>	<u>Risk Number</u> (from BCPR)	Bioastronautic s Critical Question <u>Number</u> (from BCPR)	<u>Enabling Question</u> (from BCPR)	<u>Specific Aim</u>

## Form C

*(Independent Investigator Research Projects Only)*

### **BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel.  
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION(S) AND LOCATION	DEGREE(S) (if applicable)	YEAR(S)	FIELD(S) OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years, and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

**TARGETED/PLANNED ENROLLMENT FORM**  
*for human subjects only*

Principal Investigator/Program Director (Last, First, Middle):

**This report format should NOT be used for data collection from study participants.**

**Study Title:** \_\_\_\_\_

**Total Planned Enrollment:** \_\_\_\_\_

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
<b>Ethnic Category: Total of All Subjects *</b>			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
<b>Racial Categories: Total of All Subjects *</b>			

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

*(Independent Investigator Research Projects Only)*

**BUDGET FOR ENTIRE PROJECT PERIOD  
DIRECT COSTS ONLY**

<i>BUDGET CATEGORY TOTALS</i>		<i>1<sup>st</sup> BUDGET PERIOD</i>	<i>ADDITIONAL YEARS OF SUPPORT REQUESTED</i>		
			<i>2<sup>nd</sup></i>	<i>3<sup>rd</sup></i>	<i>4<sup>th</sup></i>
<b>PERSONNEL (Salary and Fringe Benefits) (Applicant organization only)</b>					
<b>SUBCONTRACTS</b>					
<b>CONSULTANT COSTS</b>					
<b>EQUIPMENT</b>					
<b>SUPPLIES</b>					
<b>TRAVEL</b>	<b>DOMESTIC</b>				
	<b>NON-DOMESTIC</b>				
<b>OTHER EXPENSES</b>					
<b>TOTAL DIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL INDIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL DIRECT + INDIRECT COSTS FOR EACH PERIOD</b>					
<b>TOTAL DIRECT + INDIRECT COSTS FOR ENTIRE PROJECT</b>					

**JUSTIFICATION FOR UNUSUAL EXPENSES :**

**Form F**

*(Independent Investigator Research Projects Only)*

<b>DETAILED BUDGET FOR 12-MONTH BUDGET PERIOD</b>		FROM	THROUGH		
<b>DIRECT COSTS ONLY</b>		FUNDING AMOUNT REQUESTED			
Duplicate this form for each year of grant support requested					
<b>PERSONNEL</b> (Applicant Organization Only)		<b>EFFORT ON PROJECT</b>	<b>SALARY</b>	<b>FRINGE BENEFITS</b>	<b>TOTALS</b>
<b>NAME</b>	<b>ROLE IN PROJECT</b>				
	Principal Investigator				
SUBTOTALS					
		→			
SUBCONTRACTS					
CONSULTANT COSTS					
EQUIPMENT (Itemize; use additional sheet if needed)					
SUPPLIES (Itemize by category; use additional sheet if needed)					
TRAVEL	DOMESTIC				
	NON-DOMESTIC				
OTHER EXPENSES (Itemize by category; use additional sheet if needed)					
<b>TOTAL DIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD</b>					
<b>INDIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD</b>					
<b>TOTAL COST FOR FIRST 12-MONTH BUDGET PERIOD</b>					

**OTHER SUPPORT**

*(Independent Investigator Research Projects Only)*

Please provide information regarding specific sources of other support for the principal investigator and each co-investigator (not consultants). This information should be provided separately for each individual in the format shown below. List all active support for an individual before listing pending support. Include the investigator's name at the top of each page and number pages consecutively.

<b>NAME OF INDIVIDUAL</b>		
<b>ACTIVE/PENDING</b>		
Project Number (Principal Investigator)	Dates of Approved/ Proposed Project	Percent Effort
Source Title of Project (or Subproject)	Annual Direct Costs	
One-sentence description of project goals. (The major goals of this project are...)		
Brief description of potential scientific or commitment overlap with respect to this individual between this application and projects described above (summarized for each individual).		

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**Research Opportunities Soliciting  
Ground-Based Studies for  
Human Health in Space:  
National Space Biomedical Research Institute**

**NASA Research Announcement  
NNH04ZUU003N-NSBRI**

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: National Space Biomedical Research Institute

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# Research Opportunities Soliciting Ground-Based Studies for Human Health in Space: National Space Biomedical Research Institute

## I. Funding Opportunity Description

### A. Introduction

The National Space Biomedical Research Institute (NSBRI) is a non-profit organization competitively selected by NASA that uses an **integrated team approach** to advance biomedical research and countermeasure development. The Institute works in partnership with NASA. Research and development are conducted primarily at **Countermeasure Readiness Levels (CRL) 3-7**, with the goal of ensuring safe and productive long-term human exploration of space. Proposals that lead to the development of operationally relevant countermeasures in high priority areas on the Bioastronautics Critical Path Roadmap (BCPR) are encouraged. The current NSBRI research program consists of approximately 70 research and technology projects organized into research teams. NSBRI's strategic plan is available at [www.nsbri.org](http://www.nsbri.org).

The NSBRI is governed by a consortium of twelve institutions: Baylor College of Medicine; Brookhaven National Laboratory; Harvard Medical School; The Johns Hopkins University School of Medicine and the Applied Physics Laboratory; 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.

**Consortium membership is not a requirement for research program participation.** The management plan for the Institute is based on the model used by the National Institutes of Health. An independent Board of Scientific Counselors (BSC) is responsible for assuring excellence in the Institute's research program through independent external peer review conducted in partnership with NASA. An External Advisory Council (EAC) 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. The 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, safety, and performance. An Industry Forum of representatives from the space and biomedically-related industries advises and assists the NSBRI concerning Earth- and space-based applications for Institute research. In addition to its research program, the NSBRI has developed a vital education and outreach program that takes advantage of the Institute's core research activities. The Institute coordinates its research activities with NASA through several committees and working groups including a joint NASA/NSBRI Steering Committee.

Proposals submitted to the NSBRI in response to this NRA must address one of the ten research areas discussed in section I.B. Proposals that impact more than one area should be directed to only one primary research area, although a secondary research area may be designated if the

proposal has significant overlap with that area. Studies using integrated methods are encouraged.

Cross-disciplinary proposals dealing with the effects of space radiation on aspects of human functioning in space are acceptable, as long as the proposal is aligned with the strategic plan of at least one of the NSBRI teams listed in section I.B. Proposals that synergistically bridge multiple disciplines for the purpose of modeling the effects of microgravity on the human body to aid in the development and testing of countermeasures, or proposals to develop technologies that enable research in one or more NSBRI research area(s), and are potentially applicable for flight, are strongly encouraged. Applications that incorporate innovative bioinformatics approaches to acquisition and assessment of biomedical data are also invited.

It is critical for investigators to read carefully **ALL** of the instructions in this NRA. All proposals will undergo peer review using similar processes and procedures, but procedures and forms for proposal submission differ for the different programs and elements. **All proposal submissions to the NSBRI are electronic and must utilize the NSBRI's Electronic Proposal Submission system.** Programmatic balance is maintained by the selecting official(s) for the program.

The proposer must examine and understand the Bioastronautics Critical Path Roadmap (BCPR), located at [http://research.hq.nasa.gov/code\\_u/bcpr/index.cfm](http://research.hq.nasa.gov/code_u/bcpr/index.cfm), and specify in their proposal the rationale and evidence underlying which risks and enabling questions their proposed research will answer. NSBRI and NASA will perform an assessment to understand how the proposed research addresses the BCPR risks and enabling questions. Proposals that do not identify what BCPR risks and questions are being addressed by the research will be returned to the proposer without review.

Investigators are encouraged to review summaries of the research currently funded by this program by accessing the NASA Office of Biological and Physical Research (OBPR) Tasks and Bibliography (OBPR Task Book) at [http://research.hq.nasa.gov/code\\_u/code\\_u.cfm](http://research.hq.nasa.gov/code_u/code_u.cfm). In order to achieve programmatic balance, specific topics that are currently well represented in the scope of our research be de-emphasized.

The research programs described in this NRA support the utilization of specialized NASA ground-based facilities and the development of special technologies required in the pursuit of its research goals. Investigators can access NASA specialized ground-based facilities for their research. Please refer to the *Space Life Sciences Ground Facilities Information Package* for instructions on how to incorporate the use of these facilities into a proposal is online at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html).

The information pertaining to proposal submission and review is specific to this NRA and supersedes the information contained in the guidebook for proposers, which can be found at: <http://www.hq.nasa.gov/office/procurement/nraguidebook/>.

## B. Research Elements and Emphases

Each of the NSBRI research teams consists of a set of coordinated and complementary projects focused on a common theme. Team Leaders oversee the value added among the projects, to ensure that the integrated team approach leads to more effective outcome-driven research than that obtainable by a single project alone. Proposers are encouraged to look at the team strategic plans and the current composition of the teams in preparation of their proposal. Applicants are also encouraged to define clear milestones for their project and to describe plans of how collaboration with NASA scientists, engineers, flight surgeons, and astronauts, as appropriate, will occur, in order to maximize the likelihood of success and impact of their proposed research. (Contact with astronauts must be arranged through the NSBRI program office.)

### 1. NSBRI Bone Loss Team

The Bone Loss Team studies the mechanisms involved in bone loss related to microgravity, the development of countermeasures to prevent bone loss, and methods for evaluating the rate of loss and the impact on fracture risk. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Bone.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- What nutritional, mechanical or other non-pharmacological treatments, or combinations thereof, effectively diminish the loss of bone mass in weightless or non-weight bearing conditions that simulate microgravity?
- Which procedures will protect against soft tissue injury in-flight and hasten repair of damaged soft tissues?
- Can alterations in the timing and consolidation of fracture callus that forms during disuse/microgravity be normalized, and what pharmacological or mechanical interventions may facilitate this process?
- What modalities that might accelerate fracture healing are practical for spaceflight applications?

### 2. NSBRI Cardiovascular Alterations Team

The Cardiovascular Alterations Team is focused on understanding the mechanisms of, and identifying effective solutions for, conditions whereby astronauts may experience: heart rhythm disturbances; cardiac atrophy; and a drop in blood pressure, causing faintness, reduced exercise capacity, and decreased function following landing. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Cardio.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- Countermeasures to reduce impaired cardiac responses to microgravity.
- Techniques to address the manifestation of previously asymptomatic cardiovascular disease that may present during space missions.
- Individual cardiac susceptibility to the adverse effects of simulated microgravity.

### **3. NSBRI Human Performance Factors, Sleep, and Chronobiology Team**

The Human Performance Factors, Sleep, and Chronobiology Team is developing ways to reduce human mistakes and optimize mental and physical performance during long-duration spaceflight. The loss of 24-hour day/light cycle, weightlessness, a confined environment, and work demands make sleep difficult in space. Cumulative sleep loss increases the risk of accidents and possible mission failure. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Sleep.html>.

Proposals are sought with research that addresses, but is not limited to, the following area and question:

- What are the best methods for monitoring the relationships between altered sleep and metabolic functions relevant to spaceflight?

### **4. NSBRI Immunology, Infection, and Hematology Team**

The Immunology, Infection, and Hematology Team is examining the effects that extended spaceflight might have on virus reactivation and a weakened immune system. Radiation damage to the bone marrow stem cell raises concern of spaceflight-related anemia and other blood cell deficiencies following a mission. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Immune.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- The role of microgravity in injury, including crushes and burns, and the effects of simulated microgravity on hemostasis and wound healing.
- The effect on B-cell responses and bone marrow to spaceflight conditions utilizing ground-based, microgravity analogs.

### **5. NSBRI Muscle Alterations and Atrophy Team**

The Muscle Alterations and Atrophy Team's objective is to develop methods to prevent or reduce muscle loss on space missions. While astronauts exercise in space, current exercise regimens alone are not sufficient to prevent potentially deleterious changes that occur in skeletal muscle during spaceflight. The Team works to identify effective physical countermeasures (i.e., exercise prescriptions) and to combine this strategy with other countermeasures, such as improved nutrition and pharmacological interventions. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and

priorities, are located at <http://www.nsbri.org/Research/Muscle.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- Human studies of resistance training as a countermeasure to muscle alterations and atrophy in simulated microgravity (e.g. altered loading states).
- How does artificial gravity (e.g., gravity-equivalent acceleration and variable-G forces) affect the structure and function of human skeletal muscle in normal and atrophying skeletal muscle?
- Are atrophying skeletal muscle, the myotendinous junctions, tendons, and ligaments in simulated microgravity more prone to injury and how is the course of recovery altered?

## **6. 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 brain functions 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 and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Psycho.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- What objective, unobtrusive methods and approaches, including the tailoring and application of existing evidence-based practices, will permit prevention, detection and treatment of stress, declining cognitive, emotional, and social functions, and changes in operationally relevant performance capabilities during spaceflight?
- What are the effects of culture, gender, personality, leadership, and training on performance, stress, and health in isolated groups in confined environments and ground-based, analog environments for spaceflight?
- What are the major influences on interpersonal actions, communications, and problem-solving in small isolated groups and what techniques can be used to evaluate group processes and optimize group dynamics and performance?

## **7. NSBRI Neurovestibular Adaptation Team**

The Neurovestibular Adaptation Team is developing potential pre-flight and in-flight countermeasures to allow crew members to adjust more rapidly to gravitational changes that can result in disorientation, motion sickness and a loss of sense of direction. These problems have an impact on space motion sickness, landing and post-flight adaptation. Team information and the

Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Neuro.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- Development of improved human microgravity sensorimotor simulation models.
- What spacecraft architectures and interior visual cues minimize disorientation?

## **8. NSBRI Nutrition, Physical Fitness and Rehabilitation Team**

The Nutrition, Physical Fitness, and Rehabilitation Team is addressing the quality and quantity of dietary intake, exercise, and rehabilitation. The Team is also examining countermeasures to reduce the biomedical risks of radiation, circadian alterations, and other factors associated with long duration human space missions. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Nutrition.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas and questions:

- Understanding mechanisms and designing effective nutritional countermeasures to the deficiencies in thirst and nutrient intake, with relevance to changes that may occur during human spaceflight.
- Establishing ground-based clinical measurements of biochemical alterations that may indicate depression of food intake.
- Assessment of simulated spaceflight metabolism and exercise countermeasures that include strict dietary control and contain measures of energy balance.
- Development of accurate methods to assess body composition changes relevant to human spaceflight.

## **9. NSBRI Smart Medical Systems Team**

The Smart Medical Systems Team is developing and applying new technologies for physiological and medical monitoring and clinical care that integrate novel hardware, intelligent algorithms and models, and new therapeutic approaches applicable for remote health care in the space environment and on Earth. The Team works closely with the Technology Development Team and the Space Medicine group at Johnson Space Center, as well as other NASA Centers. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at [http://www.nsbri.org/Research/Med\\_Sys.html](http://www.nsbri.org/Research/Med_Sys.html).

Proposals are sought with research that addresses, but is not limited to, the following areas:

- Develop system architectures to insure integration of a suite of smart medical components.

- Novel diagnostic and therapeutic hardware modalities to reduce risk and problems associated with trauma and acute medical conditions that might occur in the space environment. System design and development should be for non-expert use.
- Innovative strategies with automated, intelligent diagnostic interpretation capabilities.
- Develop expert systems for clinical care in remote settings.
- Develop crew medical training paradigms for clinical care in remote settings.
- Methods to manage and reduce the risk of toxic exposure in a space environment.
- Methods to better understand and reduce risk of altered pharmacodynamics, adverse drug reactions, and drug interactions.

## **10. NSBRI Technology Development Team**

The Technology Development Team develops new devices to improve research techniques and capabilities in support of flight research and space medicine. Projects add value to the enabling scientific and medical technologies already supported by the other teams and by NASA, including technologies to help support the Clinical Status Evaluation for astronaut health. Team information and the Team Strategic Plan for countermeasures research and development, including research goals and priorities, are located at <http://www.nsbri.org/Research/Tech.html>.

Proposals are sought with research that addresses, but is not limited to, the following areas:

- Development of multi-purpose instruments or devices to monitor physiological measures (e.g., vital signs, core body temperature, eye motion, body fluid chemistry, etc.) using sensors and sensor systems that are easy to use, non-invasive (or minimally invasive), comfortable to wear, unobtrusive, and non-interfering with task performance.
- Low mass, compact diagnostic and therapeutic tools and equipment that use minimum spacecraft resources and augment the efforts of the NSBRI Smart Medical Systems Team and NASA Space Medicine to enrich the in-flight clinical status evaluation of crews.

## **C. Education and Public Outreach**

NSBRI has an Education and Public Outreach Program that operates in collaboration with other OBPR programs to enhance and broaden public knowledge, understanding, and appreciation of biological and biomedical research, and the value of this research in the space environment. The NSBRI Education and Public Outreach Program is integrated with the NSBRI Research Program, as well as with collaborative research projects between NSBRI and NASA. Further information about the NSBRI Education and Outreach Program is available at: <http://www.nsbri.org/Education/index.html>.

## D. 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.

## E. Availability of Funds for Award

Funds are not currently available for awards under this announcement. 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 NASA determines are acceptable for award under this announcement.

## II. Award Information

Selected proposals will be funded as research grants in one-year increments for activities lasting up to four years. The anticipated start date for proposals selected in response to this NRA is February 15, 2005. The funding duration will depend on proposal requirements, review panel recommendations, and continuing progress of the activity. All proposals will be evaluated for overall merit by independent peer review panels, and also assessed by NSBRI for relevance and proposed cost.

The total annual cost (direct and indirect costs) for ground research cannot exceed \$450,000. It is expected that the average annual total costs of selected proposals will be approximately \$250,000. Program project type proposals which clearly identify complementary areas while remaining within the funding guidelines for each component project may be submitted.

NSBRI reserves the right to return proposals, without review, that exceed the described award amounts. NSBRI may, in certain cases, elect to fund only a portion of a proposed effort. In this case, the applicant will be given the opportunity to accept or decline such partial funding. It is estimated that the initial selection will be announced by **February 2005** and the grant awarded in a reasonable timeframe thereafter.

## III. Eligibility Information

### A. Eligibility of Applicants

All categories of 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 Announcement. 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 or a competing factor in the selection process.

## B. Cost Sharing or Matching

NSBRI awards require a cost-sharing arrangement with all institutions of higher education, hospitals, other non-profit organizations and commercial organizations consisting of an augmentation of at least 10% of the total annual NSBRI award. This contribution should not be identified in the submitted project budget but will be requested at the time the institutional award is made.

## C. Guidelines for International Participation

**Export Control Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation.** Foreign proposals and 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.pmdtc.org/> and <http://www.bis.doc.gov/>. Investigators are advised that under U.S. law and regulations, spacecraft and their specifically designed, modified, or configured systems, components, and parts are generally considered “Defense Articles” on the United States Munitions List and are subject to the provisions of the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120-130.

## IV. Proposal and Submission Information

### A. Source of Application Materials

**All proposals to join one of the NSBRI’s ten research teams in response to this NRA must be submitted through the NSBRI’s Internet-based Electronic Proposal Submission System (EPSS).** All specific application forms necessary can be found in electronic format in the Downloadable Templates section of the system.

## B. Content and Form of Proposal Submission

### 1. Electronic Submission Procedures

EPSS has been designed to enable investigators to collaborate on the development of a proposal, to retain complete privacy throughout the proposal development process, and to allow fast and accurate proposal submission.

In order to facilitate planning for the review process, proposers are requested to submit a letter of intent using EPSS. **A Letter of Intent to propose must be prepared and electronically submitted through EPSS.** To assure that the notice of intent is submitted by **July 7, 2004**, go to the Web site <http://myportal.nsbri.org/> and register to obtain a personal account on the system. After entering contact information, investigators will receive via email a username and password for entry into EPSS. **To submit a letter of intent proposers should begin by creating a new proposal.** After entering the proposal title, the appropriate NSBRI team(s) and NRA should be selected, after which the PI will be prompted to enter the information required for a letter of intent. (Both the proposal title and selected NSBRI team(s) can be changed at a later date prior to submission.) After this, the above Web address will serve as the entry point for proposal development and modification. All information entered, with the exception of that required for the letter of intent, will remain private until electronic submission is completed. Please note that letters of intent are requested, but not required for submission of a proposal. Failure to submit a letter of intent will not impact the selection process. Letters of intent cannot be submitted after the deadline stated in this NRA.

Proposal information requested in EPSS closely follows the information requested by NIH grant application form PHS 398. This information includes Basic Personal and Institutional Information, Project Description, Performance Sites, Key Personnel, Investigator Budgets with Justifications, Other Support, Biographical Sketches, Laboratory Resources, and Research Plan. Further details and guidelines can be found in the online instructions through EPSS.

A proposal overview screen will guide applicants through the process of completing the required proposal information. EPSS offers a collaborative work environment for the Principal Investigator and Co-Investigators to view and submit various portions of the proposal. For example, the Principal Investigator can enter or upload all information for the proposal. Co-Investigators can view most of the proposal information but are permitted to enter only their specific personal information and their assigned project and budgetary information. All investigators can allow an administrative support person to act on their behalf, to assist in the entry of proposal information; however, electronic submission can only be performed by the Principal Investigator. EPSS also contains an Investigator Profile section, which stores biographical sketches and other support information, for each investigator registered in the system. This information can be used by authorized proposing investigators, eliminating the duplicate entry of such information in multiple proposals.

Please direct any questions concerning this application procedure to the NSBRI by sending your inquiry to [contact\\_us@www.nsbri.org](mailto:contact_us@www.nsbri.org), by calling 713-798-7412, or by faxing your questions to 713-798-7413. The technical requirements to operate EPSS are Internet Explorer 4.0+ or Netscape 4.03+ for Windows, Macintosh, or Unix. EPSS is best viewed using Internet Explorer 6.0.

## 2. Research Certifications

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

Policies for the protection of human subjects in NSBRI sponsored research projects are described in NASA Management Instruction (NMI) 7100.8B (*Protection of Human Research Subjects*). 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*). Both documents are available from the Office of Biological and Physical Research, Code UB, NASA Headquarters, Washington, DC 20546.

### Additional Requirements for Research Employing Human Subjects

A letter signed by the Chair of the Institutional Review Board (IRB) identifying the proposal submitted to NSBRI by title and certifying approval of proposed human subjects protocols and procedures should be included in the appendix of the proposal. IRB certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IRB certification is pending on the proposal due date, select “pending” from the IRB/IACUC section menu on the Proposal Cover Page, and include a letter signed by the IRB Chair identifying the proposal by title in the proposal appendix indicating the status of the IRB review process at the time of submission. IRB certification must be received no later than 90 days after the proposal due date. An application lacking the required IRB certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

With regard to research involving human subjects, NASA and the 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. Please fill in the form provided at [http://research.hq.nasa.gov/code\\_u/nra/current/NNH04ZUU003N/index.html](http://research.hq.nasa.gov/code_u/nra/current/NNH04ZUU003N/index.html) with the information requested on inclusion of women and minorities if your proposal involves research on human subjects.

NSBRI will require current IRB certification prior to each year’s award.

## Additional Requirements for Research Employing Animals

Specific information describing and justifying the use of animal subjects must be included in the proposal.

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) identifying the proposal submitted to NASA by title and certifying approval of the proposed animal research protocols and procedures should be included in the appendix of the proposal. The institution's Public Health Service Animal Welfare Assurance Number must be included on the IACUC certification and entered in the IRB/IACUC section of the Proposal Cover Page. IACUC certifications for other research proposals or grants cannot be substituted (even if they employ the same protocols and procedures).

If IACUC certification is pending on the proposal due date, select "pending" from the IRB/IACUC selection menu on the Proposal Cover Page, and include in the appendix of the proposal a letter signed by the IACUC Chair identifying the proposal by title indicating the status of the IACUC review process at the time of submission. IACUC certification must be received no later than 90 days after the proposal due date. An application lacking the required IACUC certification 90 days after the proposal due date will be considered incomplete and may be returned to the applicant without review.

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

### 3. Data Management Plan

Investigators should plan to supply data from their studies to an NSBRI/NASA bioinformatics initiative, within the time frame of the project funding. If selected, a data management plan including a list of the data products and an anticipated schedule for their delivery, must be prepared and submitted to the NSBRI. Details will be forthcoming as the initiatives are developed. An estimate of reasonable costs for these activities is appropriate to include in the proposed budget.

### 4. Submission Dates and Times

**Electronic proposals and applications must be submitted before 4:30 p.m. Eastern Time, September 8, 2004.** After submission using EPSS, the Principal Investigator must mail the printed proposal cover page that is generated by the system, with the appropriate institutional approvals, to the following address within one week of the submission deadline:

NSBRI  
**Attn: NRA NNH04ZUU003N**  
One Baylor Plaza, NA-425  
Houston, TX 77030-3498  
713-798-7412

The following items apply only to this Announcement:

<b>Solicitation Announcement Identifier:</b>	<b>NRA NNH04ZUU003N</b>
<b>Proposals Due:</b>	<b>September 8, 2004</b>
<b>Estimated Selection Announcement:</b>	<b>February 2005</b>
<b>Selecting Official:</b>	<b>Jeffrey P. Sutton, M.D., Ph.D.</b> <b>Director, NSBRI</b>

## 5. 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 Guidebook for Proposers.
- 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.
- U.S. research award recipients may directly purchase supplies and/or services that do not constitute research from non-U.S. sources, but award funds may not be used to fund research carried out by non-U.S. organizations. However, subject to possible export control restrictions, foreign nationals may conduct research while employed by a U.S. organization.
- Profit for commercial organizations is allowed under contract awards only.
- 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.
- 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/fulcost/>.

## V. Proposal Review Information

### A. Intrinsic Scientific or Technical Merit Review and Evaluation Criteria

The overall evaluation process for proposals submitted in response to this Announcement will include review of merit, relevance, and cost criteria. All of the following merit criteria, of equal consideration, will be used in determining the merit score of the proposal:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field? Is there a significant societal or economic impact?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the proposed

approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics?

- **Innovation:** Does the project employ appropriate novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and any co-investigators? Is the evidence of the investigator's productivity satisfactory?
- **Environment:** Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

## B. Review and Selection Process

### 1. Compliance Matrix

All proposals must comply with the general requirements of the Announcement as described in both this solicitation and the Guidebook for Proposers, as appropriate. Upon receipt, proposals will be reviewed for compliance with these requirements including:

1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
2. Submission of appropriate Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) certification for all proposals using human or animal test subjects.
3. Submission of a budget that is within the guidelines specified in this Announcement and is for a funding period not exceeding that described in the Announcement.
4. Proposals that are revised versions of proposals previously submitted to NASA and/or NSBRI must be clearly designated as such on the proposal cover page and must contain an explanation of how the revised proposal has addressed criticisms from previous NASA review. This explanation should be presented at the beginning of the project description in a separate section of no more than two pages, and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
5. Submission of Gender and Minority inclusion data as appropriate.
6. Submission of all other appropriate information as required by this Announcement.

***Note: At the NSBRI's discretion, non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.***

Compliant proposals submitted in response to this Announcement will undergo an intrinsic scientific/technical merit review. Only those proposals that are highly rated in the merit review process will undergo review for program relevance and cost.

## 2. Review and Selection

The overall evaluation and selection process for proposals submitted in response to this Announcement will include the following:

- A. Review for scientific and technical merit
- B. Review for programmatic relevance and cost
- C. Selection of proposals for funding

Peer review for intrinsic technical and/or scientific merit will be conducted for all proposals. The number and diversity of experts required will be determined by the response to this NRA and by the variety of disciplines represented in the proposals relevant to the research emphases described in Section I.B. The merit review panel will assign a score from 0-100 based upon the intrinsic scientific or technical merit of the proposal. This score will reflect the consensus of the panel. The score assigned by this panel will not be affected by the cost of the proposed work nor will it reflect the programmatic relevance of the proposed work to NSBRI. After the panel has assigned the proposal a merit score, the reviewers will be asked to include in their critique of each proposal any comments they may have concerning the proposal's budget and relevance to the NSBRI. In addition to the above, in accordance with the NIH policy that NASA and NSBRI have adopted, all applications will be reviewed with respect to:

- Adequacy of plans to include genders, members of minority groups, and their subgroups, as appropriate for the scientific goals of the research
- Plans for the recruitment and retention of subjects
- Reasonableness of the proposed budget and duration in relation to the proposed research
- Adequacy of the proposed protection for humans, animals or the environment to the extent they may be adversely affected by the project proposed in the application.

A separate evaluation for relevance, program balance and proposed project cost will be performed. Evaluation of the cost of a proposed effort includes consideration of the reasonableness of the proposed cost. Programmatic relevance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks in alignment with the BCPR and the Institute's mission.

A set of selection recommendations will be developed by the NSBRI External Advisory Council (EAC) based on the merit review scores, programmatic relevance, and costs. The most important element in the evaluation process is the merit review, which carries the highest weight in final evaluation and selection. The other factors are approximately equal in weight to each other. Deficiencies in any one of these factors may prevent selection of a proposal. Proposed selections will be coordinated between the NSBRI and Bioastronautics Research Division at NASA Headquarters to ensure programmatic balance and elimination of duplicate efforts. Final selections for funding of NSBRI proposals will be made by the NSBRI Director.

## VI. Award Administration Information

### A. Award Notices

At the end of the selection process, each proposing organization is notified of its selection or non-selection status. NSBRI provides debriefings to those investigators who request one. The selection letters will include a statement indicating that the selected organization's business office will be contacted by the NSBRI, and a reminder that any costs incurred by the investigator in anticipation of an award are at their own risk. Selection notification will be made by a letter signed by the selecting official. The NSBRI reserves the right to offer selection of only a portion of a proposal. In these instances, the investigator will be given the opportunity to accept or decline the offer.

### B. Administrative and National Policy Requirements

This solicitation does not invoke any special administrative or National policy requirements, nor do the award(s) that will be made involve any special terms and conditions that differ from NSBRI's general terms and conditions as given in the Guidebook for Proposers.

### C. Program Reporting/Individual Researcher Reporting

It is expected that results from funded research will be submitted to peer-reviewed journals as the work progresses. **Only published papers that acknowledge the NSBRI's support and identify the NSBRI Cooperative Agreement will be considered as resulting from the research project and used to evaluate its productivity.**

#### Annual Reporting

The NSBRI requires one annual reporting submission utilizing the NSBRI's online Annual Project Report and Task Book Submission system (APRTS). Both the NSBRI Annual Progress Report and NASA Task Book submission are collected through APRTS. **This submission is due 30 days prior to the end of each funding year of the project.** Updates can be made throughout the duration of the project at any time during the year. The final Annual Project Report and NASA Task Book submission for the project will be due 60 days following the conclusion of the project funding. In addition to these electronic reporting requirements, a signed cover sheet generated by APRTS, a reprint of each publication listed in the bibliography, and a copy of all intellectual property disclosures resulting from the funded research must be sent to the NSBRI.

The Annual Progress Report is used by the Institute's BSC and NSBRI Management to formally evaluate project progress in achieving specific aims, as related to the BCPR.

The Task Book, a publication of the Office of Biological and Physical Research, is a comprehensive online document which includes descriptions of all current peer-reviewed activities funded by the Division. Since its inception, the Task Book has served as an invaluable

source of information for OBPR as well as the scientific and technical communities. The Task Book is made available to the scientific community and can be used to assess the strength of the Division's programs. It will also serve as the basis for determining the degree of progress of the project.

The Task Book information requested will include:

- an abstract,
- a brief statement of progress,
- a brief statement of benefits of the research with respect to life on Earth,
- an updated bibliography,
- a listing of presentations or activities conducted at educational institutions for grades 6-12,
- a listing of interactions with, presentations to, or activities for the general public, and
- a statement of potential scientific, technological, economic or societal impact resulting from the funded work.

Note that although this publication will be made available to the general scientific community, it is not a substitute for traditional scientific reporting in journals and elsewhere.

All articles submitted for publication must include the following statement: "This work was supported by the National Space Biomedical Research Institute through NASA NCC 9-58." Publications not including this acknowledgement will not be considered to be the product of NSBRI-funded research when the NSBRI and NASA assess the progress of the grant.

## **VII. NSBRI Contacts**

Additional technical information for the NSBRI is available from:

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The contracting point of contact will be specified in each selection notification letter.

Potential investigators should read with care the program descriptions that are of interest and focus their proposals on the specific research emphases defined in this Announcement.

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