National Space Biomedical Research Institute

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

Request for Applications
NSBRI-RFA-07-01

RFA Issued: January 3, 2007
Step-1 Proposals Due: February 2, 2007
Step-2 Proposals Due: April 12, 2007

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

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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 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 Roadmap (BR) are encouraged. The current NSBRI research program consists of approximately 70 science and technology projects organized into research teams. NSBRI's strategic plan is available at http://www.nsbri.org/About/StrategicPlan.pdf.

This NSBRI Request for Applications solicits ground-based proposals addressing one of nine research emphases:

1. Bone Loss
2. Cardiovascular Alterations
3. Human Performance Factors, Sleep and Chronobiology
4. Muscle Alterations and Atrophy
5. Neurobehavioral and Psychosocial Factors
6. Nutrition, Physical Fitness and Rehabilitation
7. Sensorimotor Adaptation
8. Smart Medical Systems
9. Technology Development

Proposals solicited through this RFA will use a two-step proposal process. Only proposers submitting Step-1 proposals determined to be relevant with respect to the Research Emphases outlined in Section I.B. of the RFA will be invited to submit full Step-2 proposals.

Proposals that impact more than one emphasis should be directed to 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. 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 RFA. All proposals will undergo peer review using similar processes and procedures. **All proposal submissions to the NSBRI are electronic and must utilize NSBRI's Electronic Proposal Submission System.** Programmatic balance is maintained by the selecting official(s) for the program.

In order to identify and make publicly known the biomedical and health risks of spaceflight and the research and technology questions that must be answered to reduce those risks, NASA, in partnership with NSBRI, has developed the Bioastronautics Roadmap (BR). The BR 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, research and technology questions, tasks, deliverables, and risk mitigation with the intent of directing biomedical research in support of human spaceflight, especially human exploration missions.

The proposer must examine and understand the Bioastronautics Roadmap, located at http://bioastroroadmap.nasa.gov. Based on the BR, proposers must specify in their proposal the rationale and evidence underlying which risks and research and technology questions their proposed research will answer. NSBRI will perform an assessment to understand how the proposed research addresses the BR risks and research and technology questions. Proposals that do not identify what BR risks and questions are being addressed by the research will be returned to the proposer without review.

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

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. 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 the 12 NSBRI Consortium member institutions) advises the Institute concerning program strategy,

tactical implementation, and effectiveness. NSBRI also has a User Panel of former and current astronauts and flight surgeons responsible for assuring that the research program is focused squarely on astronaut health, safety, and performance. The User Panel advises senior management on the operational relevance of science and technology projects. An Industry Forum of representatives from space and biomedically-related industries advises and assists NSBRI concerning Earth- and space-based applications for Institute research. The Institute coordinates its research activities with NASA through several committees and working groups including a joint NASA/NSBRI Steering Committee. 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.

B. NSBRI Teams and Research 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 might be attainable by a single project alone. Proposers are encouraged to look at the team strategic plans and the current composition of the teams in preparing 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 the impact of their proposed research.

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, methods for evaluating the rate of loss and the impact on fracture risk. Team information for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Bone.html. The Strategic Plan for the Bone Loss Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/BoneLoss2003.pdf.

Proposals are sought with research that addresses the following areas:

- Enhance the understanding of the effects of space radiation on bone health and repair;
- Identify the factors affecting the maintenance of bone health and repair during prolonged stays on the lunar surface;
- Determine the effectiveness of procedures to protect against soft tissue injury in flight and on the lunar surface, and that hasten repair of damaged soft tissues during and after missions.

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 for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Cardio.html. The Strategic Plan for the Cardiovascular Alterations Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Cardio2003.pdf.

Proposals are sought with research that addresses the following areas:

- Develop strategies to mitigate serious cardiac events associated with spaceflight or lunar surface exploration;
- Enhance the understanding of individual cardiovascular susceptibility to the adverse effects of spaceflight or partial gravity environments.

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 the 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 for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Sleep.html. The Team Strategic Plan for the Human Performance Factors, Sleep and Chronobiology Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Sleep2003.pdf.

Proposals are sought with research that addresses the following areas:

- Design and testing of lighting systems for space environments, including spacecraft and lunar habitat, to optimize cognitive, sensory and behavioral performance;
- Elucidate methods and effectiveness of countermeasures for altered sleep and workload relevant to spaceflight and lunar surface.

4. 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 for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Muscle.html. The Strategic Plan for the Muscle Alterations and Atrophy Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Muscle2003.pdf.

Proposals are sought with research that addresses the following areas:

- Design and test integrated exercise countermeasures configurable to current and planned mission architectures;
- Elucidate risk of musculoskeletal injury related to spaceflight and lunar surface activities and post-flight recovery.

5. 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 for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Psycho.html. The Strategic Plan for the Neurobehavioral and Psychosocial Factors Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Psycho2003.pdf.

Proposals are sought with research that addresses the following areas:

- Develop and test objective, noninvasive methods to preserve cognitive, emotional, and social well-being relevant to spaceflight and lunar surface activities;
- Assess, monitor, and mitigate adverse effects on critical team performance relevant to spaceflight and lunar surface activities.

6. 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 for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Nutrition.html. The Strategic Plan for the Nutrition, Physical Fitness and Rehabilitation Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Nutrition2003.pdf.

Proposals are sought with research that addresses the following areas:

- Develop effective countermeasures to inadequate fluid, nutrient, and caloric intake, relevant to spaceflight and lunar surface activities.
- Develop and test integrated countermeasures to optimize physical fitness before, during and after flight.

7. NSBRI Sensorimotor Adaptation Team

The Sensorimotor 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 the sense of direction. These problems have an impact on space motion sickness, landing and post-flight adaptation. Team information for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Neuro.html. The Strategic Plan for the Sensorimotor Adaptation Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Sensorimotor.pdf.

Proposals are sought with research that addresses the following areas:

- Design and test display and control systems for space environments, including spacecraft and lunar habitats, to optimize performance and spaceflight human system standards;
- Develop integrated functional tests of sensorimotor performance relevant to spaceflight and lunar surface activities.

8. 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 to 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 NASA Johnson Space Center, as well as other NASA Centers. Team information for countermeasures research and development, including research goals and priorities, is located at http://www.nsbri.org/Research/Med_Sys.html. The Strategic Plan for the Smart Medical Systems Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Med_Sys2003.pdf.

Proposals are sought with research that addresses the following areas:

- Develop a suite of integrated smart medical systems, including non-invasive physiological monitors, relevant to spaceflight and lunar surface activities;
- Design and test critical care systems for emergent conditions relevant to spaceflight and lunar surface activities.

9. NSBRI Technology Development Team

The focus of the Technology Development Team is on 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 for countermeasures research and development, including research goals and priorities, is located at

http://www.nsbri.org/Research/Tech.html. The Strategic Plan for the Technology Development Team can be accessed at: http://www.nsbri.org/Research/StrategicPlans/Technology2003.pdf.

Proposals are sought with research that addresses the following areas:

- Design and test systems for data fusion and clinical decision making relevant to spaceflight and lunar surface activities;
- Develop and validate methods to increase pharmaceutical shelf life in the space environment.

C. Education and Outreach

NSBRI has an Education and Outreach Program that operates in collaboration with other NASA 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 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 NSBRI auspices shall conform to this policy.

E. Availability of Funds for Award

The NSBRI's obligation to make awards is contingent upon the availability of the appropriated funds from which payment can be made and the receipt of proposals that are deemed acceptable for award under this solicitation.

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 RFA is no earlier than August 2007. 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 (section V).

The total annual cost (direct and indirect costs) for ground research cannot exceed $450,000. NSBRI reserves the right to return proposals, without review, that exceed

$450,000 per year. It is estimated that the average annual total costs of selected proposals will be approximately $300,000. Program project type proposals which clearly identify complementary areas while remaining within the funding guidelines for each component project may be submitted.

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. The initial selection will be announced no earlier than July 2007 and the grant awarded in a reasonable timeframe thereafter.

III. Eligibility Information

A. Eligibility of Applicants

All categories of U.S. entities, including private, public and non-profit organizations, are eligible to submit proposals in response to this RFA. 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.

B. Cost Sharing or Matching

NSBRI awards require a cost-sharing arrangement with all non-government entities 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.

IV. Proposal and Submission Information

A. Source of Application Materials and Instructions

All proposals for both Step-1 and Step-2 of the RFA process must be submitted through the NSBRI's Internet-based Electronic Proposal Submission System (EPSS) as detailed in the instructions below. All specific application forms and instructions necessary can be found in electronic format in the Downloadable Templates section of the system.

B. Content and Form of Proposal Submission

1. Step-1 Proposal Content

Proposals will be solicited using a two-step process. The Step-1 proposal will include a synopsis of the intended research, with the total length of the proposal not to exceed five pages using a standard 12-point font and one inch margins. **Required elements** of the five-page, Step-1 application include a proposed NSBRI team assignment, a brief

abstract, a clear indication of the relevance to the research emphases (section I.B), mapping to the BR risks, a plan outline for countermeasure(s) and/or technology development (including approach and key personnel), and the project impact. Budget and detailed program data should not be included with the Step-1 proposal. Project personnel are not considered binding for Step-1 and can be adjusted in an invited Step-2 proposal. **Step-1 proposals must be electronically submitted by 5 PM ET, February 2, 2007**. All submitters of Step-1 proposals will be notified no later than February 20, 2007 that they are, or are not, invited to submit a Step-2 proposal.

2. Step-2 Proposal Content

Step-2 proposals must be electronically submitted by 5 PM ET, April 12, 2007. In addition to the Step-1 proposal elements, the invited Step-2 proposal will include Basic Personal and Institutional Information, Project Description, Performance Sites, Key Personnel, Investigator Budgets with Justifications, Other Support, Biographical Sketches, Laboratory Resources, Research Plan, and additional accompanying information as outlined in the submission procedures below.

Step-2 proposals must be in compliance with the following:

- The proposal project description must not be more than 20 pages in length;
- 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;
- Submission of an appropriate and justified budget for a funding period not exceeding that described in this RFA;
- Revised versions of proposals previously submitted must be clearly designated as such and must contain an explanation of how the revised proposal has addressed criticisms from previous review. This explanation should be presented preceding the research description as part of the main proposal upload and is limited to two pages;
- Submission of the Bioastronautics Roadmap form;
- Submission of all other appropriate information as required by this RFA.

Non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.

3. General Electronic Submission Procedures and Account Registration

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.

To assure that the Step-1 proposal is submitted by the due date of February 2, 2007 at 5 PM ET, investigators are encouraged to register for an EPSS account, if they do not already have one. To register for an account in EPSS, send an email to contact_us@www.nsbri.org with your full name and institution. Investigators will receive

via email a username and initial password for entry into EPSS. Once you have received your login information, go to the web site http://nims.nsbri.org/ to complete creation of your account. Investigators will need to enter basic contact and institutional information to complete their online account setup before proceeding with proposal submission.

4. Step-1 Proposal Format and Submission Process

To submit a Step-1 proposal, proposers should begin by creating a new proposal. After entering the proposal title and selecting the appropriate NSBRI team(s) and Request for Applications NSBRI-RFA-07-01 from the drop-down menu, the PI will be prompted to upload a document for a Step-1 proposal submission.

The PI should prepare a Step-1 proposal document as a PDF file and upload it in EPSS as outlined above (section IV.B.1).

5. Step-2 Proposal Format and Submission Process

Step-2 proposals will be accepted from invited Step-1 proposers only. Investigators who receive invitations for a Step-2 proposal will be notified no later than February 20, 2007. All Step-2 proposals must be completed and electronically submitted by 5 PM ET, April 12, 2007, to be considered for funding.

The same web address used for Step-1 proposals will serve as the entry point for proposal development and modification for Step-2. Step-1 proposals invited for Step-2 submission will automatically be created in the user profile for the PI with the same title as the Step-1 proposal. The proposal title and selected NSBRI team(s) from the submitted and selected Step-1 proposal can be changed at any time prior to submission of the Step-2 proposal. All information entered, with the exception of that submitted for Step-1 proposals, will remain private until electronic submission is completed.

Step-2 proposal information requested in EPSS closely follows the information requested by the National Institutes of Health and other funding agencies. 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 or by calling 713-798-5676.

6. 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, uploaded in the Appendices, from the applicant institution certifying that the proposed work will meet all Federal and local human subject 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).

a. 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 that may be related to the work proposed 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 in the proposal appendix signed by the IRB Chair identifying the proposal by title 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 Step-2 proposal due date. An application lacking the required IRB certification will be considered incomplete and may be returned to the applicant without review. NSBRI requires current IRB certification prior to each year’s award.

With regard to research involving human subjects, NSBRI has adopted the National Institutes of Health (NIH) policy. Women and members of minority groups and their subpopulations must be included in NSBRI-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale 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.

b. Additional Requirements for Research Employing Animals

A letter signed by the Chair of the Institutional Animal Care and Use Committee (IACUC) identifying the proposal submitted to NSBRI 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.

7. Submission Dates and Times

Step-1 Proposals Due: February 2, 2007, 5 PM ET
Step-2 Proposals Due: April 12, 2007, 5 PM ET
Estimated Selection Announcement: July 2007
Selecting Official: NSBRI Director

8. Funding Restrictions

The construction of facilities is not an allowed activity unless specifically stated so in the program description. For further information on allowable costs, refer to the cost principles cited in the NASA Federal Acquisition Regulations (FAR) Supplement Provision.

Travel, including foreign travel, is allowed as may be necessary for the meaningful completion of the proposed investigation, as well as for presenting results at an appropriate professional meeting.

V. Proposal Review Information

A. Step-1 Proposal Relevancy Review

Each Step-1 proposal will be reviewed by NSBRI's Executive Science and Medicine Council (ESMC). The ESMC will incorporate advice from the NSBRI User Panel and NASA. Recommendations will be made as to "relevant" or "not relevant" based upon the research emphases outlined in this RFA, section I.B. Only those Step-1 proposals having a final evaluation of "relevant" will be invited to submit a full Step-2 proposal.

B. Step-2 Proposal Scientific/Technical Merit Review and Evaluation Criteria

The overall evaluation process for Step-2 proposals submitted in response to this RFA 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? Is current and appropriate literature cited to support the assertion of problem importance? 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?

C. Review and Selection Process

Upon receipt, proposals will be reviewed for compliance as outlined in section IV.B of this RFA. 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 RFA 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.

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

- Review for scientific/technical merit
- Review for programmatic balance and cost

- Selection of proposals for funding

Peer review for intrinsic technical and/or scientific merit will be conducted for all compliant Step-2 proposals. The number and diversity of experts required will be determined by the response to this RFA 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 balance 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 balance to the NSBRI. In addition to the above, in accordance with the NIH policy that NSBRI has adopted, all applications will be reviewed with respect to:

- Adequacy of plans to include males and females, 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 program balance and proposed project cost will be performed by the NSBRI. Evaluation of the cost of a proposed effort includes consideration of the reasonableness of the proposed cost. Programmatic balance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks in alignment with the BR and the NSBRI mission.

A set of selection recommendations will be developed by the NSBRI External Advisory Council (EAC) based on the merit review scores, programmatic balance, and costs. These recommendations will be reviewed with NASA prior to selection by the NSBRI Director.

VI. Award Administration Information

A. Award Notices

At the end of the selection process, each proposing organization and Principal Investigator is notified of the selection or non-selection status. The selection letters will include a statement indicating that the selected organization's business office will be contacted by 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. Selection notification will also include proposal reviews generated during the peer-review process. NSBRI reserves the right to offer selection of only a portion of a proposal. In these instances, the organization/Investigator

will be given the opportunity to accept or decline the offer. NSBRI provides debriefings to those Investigators who request one.

B. 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 NSBRI support and identify the NSBRI Cooperative Agreement (NCC 9-58) will be considered as resulting from the research project and used to evaluate its productivity.

NSBRI requires an annual reporting submission utilizing the 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 reprint of each publication listed in the bibliography and a copy of all intellectual property disclosures resulting from the funded research must be uploaded in APRTS with the annual online submission. The NASA Task Book includes descriptions of all peer-reviewed activities funded by the NASA Exploration Systems Mission Directorate (ESMD).

The Annual Progress Report is used by NSBRI Management to formally evaluate project progress in achieving specific aims, as related to the BR.

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 NSBRI Team and Research Emphases information is available from:

Associate Director
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