# International Space Station Research Opportunities: National Institutes of Health

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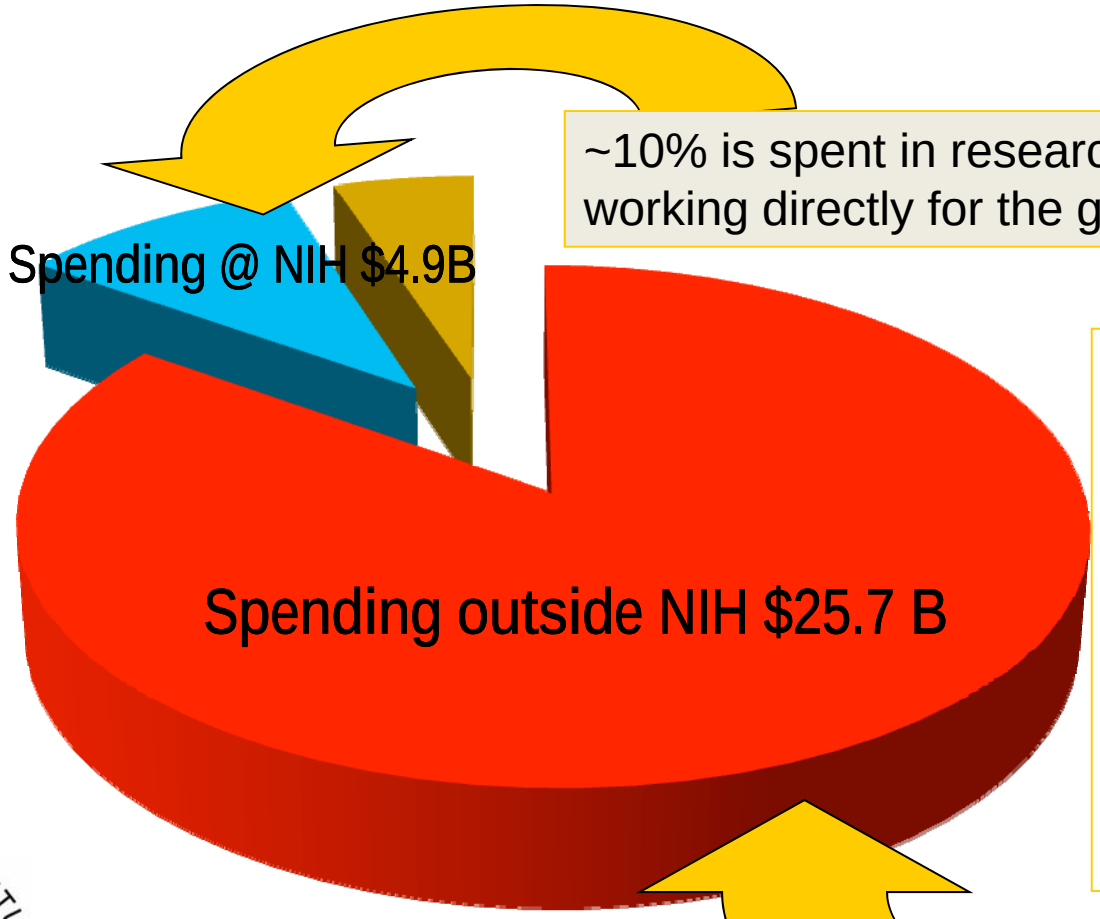
# National Institutes of Health (NIH)

http://www.nih.gov/about/

- NIH is the largest source of funding for medical research in the world. Composed of 27 Institutes and Centers (ICs), the NIH provides leadership and financial support to researchers in every state and throughout the world.
- NIH Public Health Mission: Seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

# NIH Budget in FY 2009: $30.6 Billion




~10% is spent in research conducted by scientists working directly for the government at NIH.

~ 84% of the total NIH budget supports over 325,000 scientists at more than 3,000 private non-governmental universities and research centers.

# NIH's Major Opportunities


- Applying high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases
- Translating basic science discoveries into new and better treatments
- Putting science to work for the benefit of health care reform
- Encouraging a greater focus on global health
- Reinvigorating and empowering the biomedical research community

# Finding NIH Grant Opportunities

- All applications must be submitted in response to a *Funding Opportunity Announcement* (FOA)
- Many NIH funding opportunities are posted online in the NIH Guide for Grants & Contracts and at www.Grants.gov (under "Find Grant Opportunities")
  - All of the NIH FOAs (parent and solicited) can be found at the NIH Guide http://grants.nih.gov/grants/guide/index.html
  - All of the NIH parent FOAs

  http://grants.nih.gov/grants/guide/parent_announcements.htm
  - **Weekly NIH Funding Opportunities and Notices**

  **Sign up at** http://grants.nih.gov/grants/guide/listserv.htm

# Memorandum of Understanding Between the NIH and NASA

NIH will use reasonable efforts to

- Publicize, to the intramural and extramural communities, the availability of the ISS as a research environment...
- Give careful consideration through the standard review process to well-developed, investigator-initiated extramural applications and potential intramural activities related to space-related health research...


September 12, 2007: NIH Director Dr. Elias A. Zerhouni and NASA Administrator Dr. Michael D. Griffin shake hands after signing the MOU at the U.S. Capitol while Senators Kay Bailey Hutchison and Barbara Mikulski stand by.

# NIH BioMed-ISS Program

- The Biomedical Research on the International Space Station (BioMed-ISS) Program was developed to facilitate research relevant to the NIH mission on the ISS to benefit human health on Earth.
- An NIH Funding Opportunity Announcement (FOA) was released on March 17, 2009 to support molecular- or cell-based studies and to be complementary to NASA's Human Research Program. Research for space exploration will not be conducted under this FOA.
- Investigator-initiated biomedical research that will use the unique microgravity and radiation environment and resources of the ISS to test innovative hypotheses to benefit human health **on Earth** is encouraged.

# BioMed-ISS FOA Synopsis

http://grants.nih.gov/grants/guide/pa-files/PAR-09-120.html

The FOA (**PAR-09-120**) is active for 3 years:

- UH2/UH3 Cooperative Agreement for up to 5 years
- Once a year receipt (September 30, 2009, 2010, 2011)
- "Letter of intent" strongly encouraged (August 31, 2009, 2010, 2011)
- Pre-application meeting organized by NASA/NIH (June 16,2009 and August 4, 2010)
- Peer review panel organized by NIBIB
- Pre-funding consultation with NASA, and funding decision by participating NIH Institutes and Centers (ICs)
- UH2 to UH3 transition based on the successful completion of milestones, consultation with NASA, available fund and decision by funding NIH ICs

# Pre-Submission: Working with NIH

- **Prepare NIH and ISS "feasible" applications by**
  - Attending the pre-application meeting at Johnson Space Center, Houston, TX on 8/3-5/2010
  - Communicating with NIH staff listed in the FOA
  - Working with your implementation partners
- **For help, contact**
  - Program director about the scientific and technical aspects of the application
  - Scientific Review Officer for questions about the review
  - Grants Management Specialist with the business aspects of the application

# Before Sending in an Application

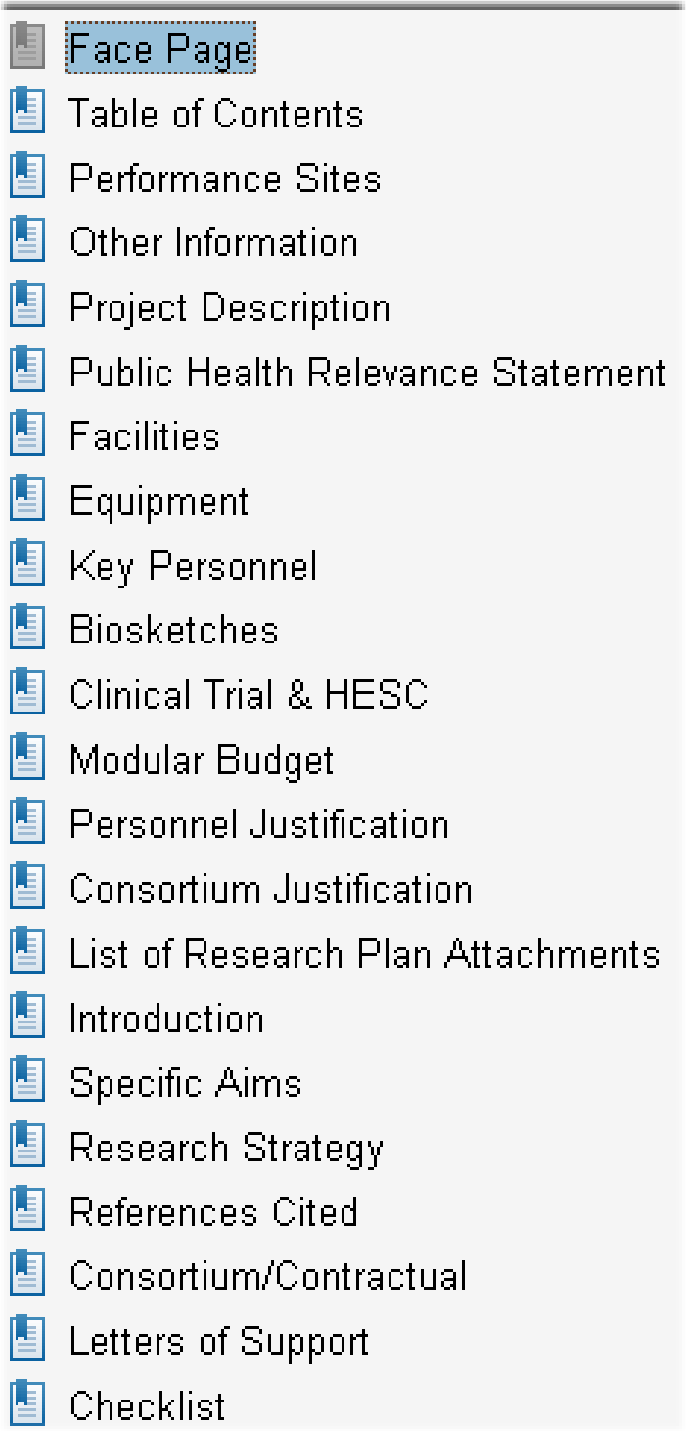
- Register to submit/track the application (at least one month prior to submission)
  - grants.gov (http://www.grants.gov/applicants/get_registered.jsp)
  - the NIH eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)
- Understand the FOA

  (http://grants.nih.gov/grants/guide/pa-files/PAR-09-120.html)
  - Phase I (UH2) and Phase II (UH3) are separate but contingent awards
- Time management is critical
  - Roles of implementation partners must be clear. Take the time to get it right.
  - Contact collaborators early and document their participation.
  - Give colleagues a week to review final draft.
  - Build in time to obtain institutional signatures.

# NIH Applications

Key Elements:

- ❑ Cover Letter and Title Pages
- ❑ Abstract (1 page synopsis)
- ❑ Budget with Justifications
- ❑ Biosketches of Investigators (4 pages)
- ❑ Resources and Facilities
- ❑ Introduction (resubmission/revision! 1 page)
- ❑ Specific Aims (1 page)
- ❑ Research Strategy (30 pages for BioMed-ISS FOA)
  - ▪ Significance
  - ▪ Innovation
  - ▪ Approach
  - ➢ Preliminary Studies/Progress Report
  - ➢ Experimental Design and Methods: UH2, Milestones, UH3
- ❑ Bibliography and References
- ❑ Human Subjects if any
- ❑ Other (animals, consortium, multi-PI, select agents, other support, resource sharing) if any



# SPECIFIC AIMS: What do you intend to do?

## Single and most important page of application

- **Introductory paragraph should**
  - Capture the vision with a broad goal justifying the research question and the impact of success
  - Engage the reader with
    - strong, solid, testable hypotheses, or
    - discrete, finite technology development goal
  - Summarize relevance and feasibility of the approach(es)
- **Succinctly state each research objective in a topic phrase or sentence**
  - Follow with a brief outline of specific experiments
- **Add sub-aims as needed**
  - Experiments support aims, aims test hypothesis
- **Be focused**
  - aims independent yet related to overall goal
  - avoid dense text and acronym overload
  - consider MILESTONES for UH2

# RESEARCH STRATEGY - Significance:

## Why is this important?

- Amplify initial paragraph of the Specific Aims.
- Does the study address an important health related problem or critical barrier in the field? How do you know?
- Define existing knowledge base via evaluating relevant literature. Where are the gaps?
- Will my solution matter? Assuming success, quantify and qualify the impact on:
  - Scientific knowledge
  - Technical capacity
  - Clinical practice
- A picture (figure or graph) is worth a thousand words, but be selective to emphasize (not divert from) the point.

# Specific for the BioMed-ISS FOA

- Address why the proposed BioMed-ISS research is important, explain how it potentially impacts improving human health and reducing the burdens of illness and disability **on Earth**, and elaborate on the innovative nature of the proposed BioMed-ISS research.
- Clarify how the proposed fundamental research, technologies, or approaches will enhance and direct the current and/or future **Earth-based** research.
- Identify how the BioMed-ISS project, if successful, would result in an improved understanding of human physiology and human health **on Earth**.
- Describe why the conditions on the ISS are required for these experiments and why the conditions cannot be simulated **on Earth**.
- But also insure that the biological changes in space are relevant or occur on earth.

# RESEARCH STRATEGY – Innovation:

## How is this game changing?

- How will this effort shift current research or clinical practice paradigms?
- Is the proposed work new? Creative? Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions(s) to be developed.
- How will the results direct/inform future research?
- How will it be disseminated?
- Will success improve the “State-of-the-art”, or establish new research directions?

# RESEARCH STRATEGY – Approach:

## Preliminary Studies/Progress Report: What has already been done?

- Data should lead to the current proposal, supporting the feasibility of the proposed work
- Demonstrate that the investigator has:
  - mastery of (and/or access to) the required techniques
  - ability to manage and work with collaborators/partners
  - sufficient attention to important details (i.e. accurate, carefully assembled figures, tables, graphs)
- Reviewers are NOT expected to looking anything up so don't presume they will – the application must be self-contained
- Provide sufficient, *relevant* details for an informed judgment but keep the message simple

# Specific for BioMed-ISS FOA

- Emphasize how the unique environment of the ISS is required for your research
- Specifically address how microgravity or the unique radiation environment on the ISS furthers the your research aims and long term goals
- Also address what has been done to demonstrate the feasibility of the proposed research
- Demonstrate creative thinking and knowledge of the field to reinforce the feasibility of the application to reviewers

# RESEARCH STRATEGY – Approach:

## Experimental Design and Methods: How will it be done?

- Do experiments relate to the Specific Aims?
  - Provide an overview and conceptual framework
- Are the experiments logical, grounded, and well-integrated?
  - Why are the proposed methods the best way to go? Be sure this study is not "a technology looking for a problem"
  - Less detail needed for established techniques
  - Alternatives for high risk elements add to the feasibility
  - Biohazards identified here, then fully discussed in a subsequent section
- Are end-points/milestones clearly defined, with appropriate benchmarks? Is there a sensible timeline?
- Is the appropriate statistical analysis included?

# Specific for BioMed-ISS FOA

- Experiments conducted and equipment available on the ISS can be found at http://www.nasa.gov/mission_pages/station/science/experiments/Expedition.html and http://www.nasa.gov/mission_pages/station/science/experiments/Discipline.html
- Applicants who require assistance in identifying an implementation partner to assist them in preparing their experiments for space should participate in the Pre-Application Meeting announced in http://grants.nih.gov/grants/guide/notice-files/NOT-AR-10-041.html
- The *Experimental Design and Methods* attachment should include 3 separate major divisions – UH2 phase, Milestones (to be achieved at the end of the UH2), and a UH3 phase
- 30 page limit for the entire Research Strategy
- Use the detailed Research & Related Budget component, regardless of the amount of annual direct costs requested

# Milestones for UH2 to UH3 Transition

- A specific heading labeled "*Milestones*" in the *Experimental Design and Methods* attachment should be included.
- Milestones should be well described, quantifiable, and scientifically justified and not simply a restatement of the specific aims.
- A discussion of the milestones relative to the success of the UH2 phase, as well as implications for successful completion of milestones in the UH3 phase should be included. Applications lacking this information will likely be non-competitive.
- Milestones are metrics to measure the success of UH2 Phase. UH2 to UH3 transition, i.e. NIH funding of the UH3 Phase, is not automatic. Successful completion of milestones is required for an application to be considered for transition from ground to flight status. Consider with implementation partner the metrics that assess feasibility of experiment to work in the ISS environment.

# Common Application Weaknesses

- Unrealistically large amount of work; too many variables
- Errors in design, feasibility = fatal flaw
- Diffuse, superficial, or unfocused research plan
- Lack of experimental detail
- Poor feasibility due to skimpy relevant prior studies
- Irrelevant, inconsistent, or insufficient literature review, impact statement
- Low innovation
- Lackluster track record
- Absence of appropriate expertise on the research team
- Serious/unresolvable human or animal subjects concerns
- Weakly documented institutional support; or poor environment.

# Submission & Review Procedures

# Submit to NIH via Grants.gov

## Grants.gov

- Submit your application to Grants.gov
- Grants.gov hosts standardized federal forms SF424 (R&R) and agency-specific forms (PHS 398)
- Electronic application through Grants.gov using these forms is mandatory for most FOAs. Grants.gov checks the application for federal-wide requirements.

## NIH eRA Commons

- NIH will retrieve your application from Grants.gov and check the application against NIH-specific requirements
- eRA Commons allows applicants to electronically track the status of submissions and to receive/transmit application and award information

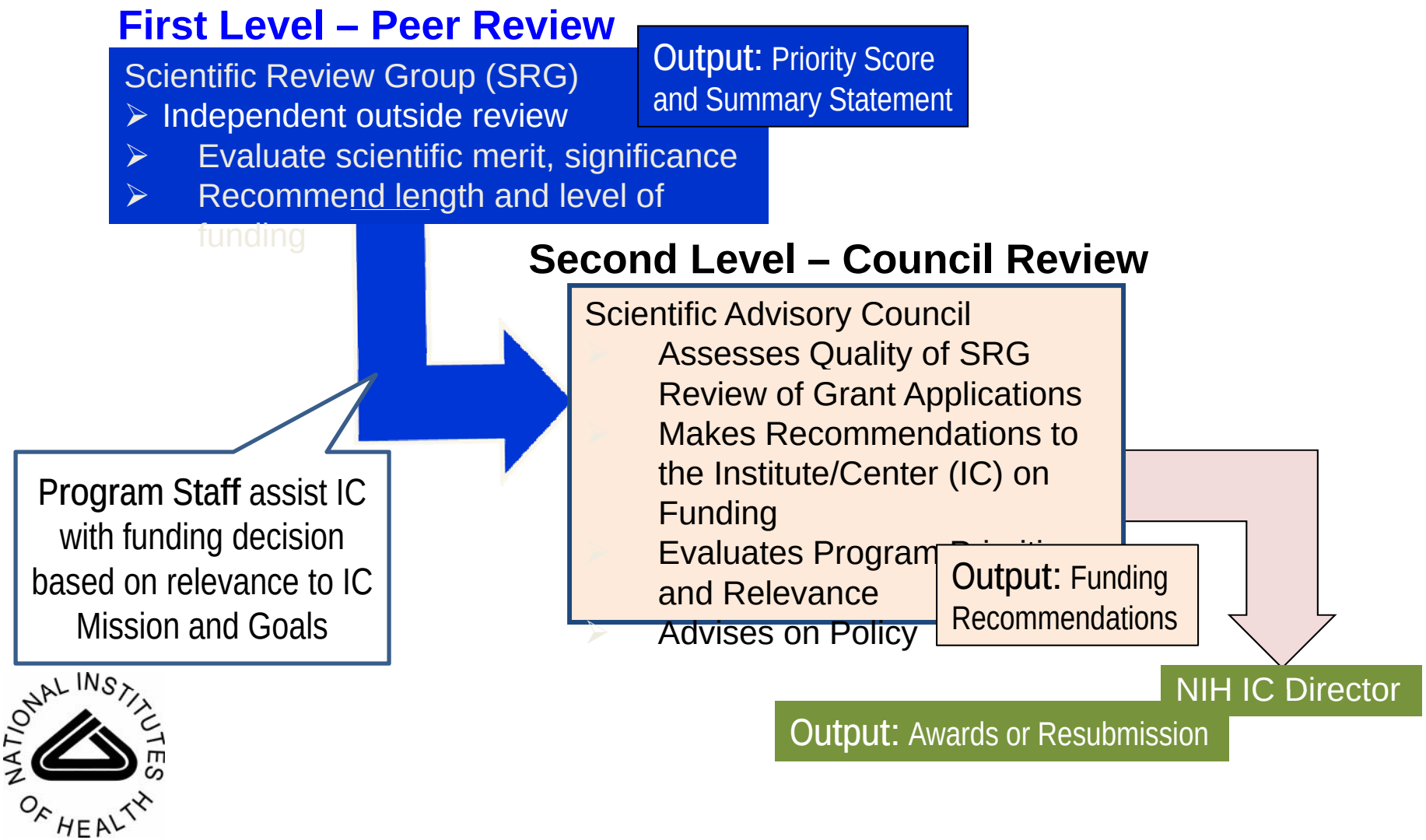
# Check Your Application After Submission

After submission, there is a two-weekday, including holidays, opportunity for you to check your application.

- If problems occur, work with your institutional official to reject the application and submit corrected version.
- After the two-weekday window, you must contact the Scientific Review Officer (SRO) about corrections. Most times, corrections may not be allowed.

**Check Your Application!**

# NIH Dual Level Review System



# NIH Peer Review Criteria

- Overall Impact – Score to reflect reviewer's assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Overall Impact score is **NOT** the average of the five criteria (below) scores

- Core Review Criteria
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment

# NIH Scoring System

| Impact | Full Description | Score – Descriptor |
|---|---|---|
| High | Exceptionally strong with essentially no weaknesses | 1 – Exceptional |
| | Extremely strong with negligible weaknesses | 2 – Outstanding |
| | Very strong with only some minor weaknesses | 3 – Excellent |
| Medium | Strong but with numerous minor weaknesses | 4 – Very Good |
| | Strong but with at least one moderate weakness | 5 – Good |
| | Some strengths but also some moderate weaknesses | 6 – Satisfactory |
| Low | Some strength but with at least one major weaknesses | 7 – Fair |
| | A few strengths and a few major weaknesses | 8 – Marginal |
| | Very few strengths and numerous major weaknesses | 9 – Poor |

Minor weakness: Easily addressable weakness that does not substantially lessen impact.

Moderate Weakness: Impact lessened.

Major Weakness: Impact severely limited.

Overall Impact Score = Panel Average x 10

# Significance

- Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Will conducting this research on the ISS lead to new insights or refinements of the field and further work on Earth? Does it provide better understanding of human physiology and human health on Earth and benefit human health on Earth?

# Investigator(s)

- Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Do the PD/PIs have experience designing experiments collaboratively with other institutions/organizations? Is the implementation partner appropriate and a well integrated part of the research team?

# Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Does the use of the ISS significantly add to the innovation of this research?

# Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

- Is the use of the ISS environment appropriate to this area of research? ***Are the proposed milestones well-defined, quantitative, and appropriate for assessing the success in the UH2 phase of the application?*** Is it clear how the UH3 phase of the study will develop and expand once the UH2 milestones are achieved?

# Environment

- Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

## NIH Peer Review Video

http://cms.csr.nih.gov/ResourcesforApplicants/InsidetheNIHGrantReviewProcessVideo.htm

# Checklist for Preparation of an NIH Application

- ❑ Read instructions
- ❑ Never assume that reviewers "will know what you mean”
- ❑ Refer to literature thoroughly
- ❑ State rationale of proposed investigation
- ❑ Include well-designed tables and figures
- ❑ Present an organized, lucid write-up
- ❑ Obtain pre-review from investigators familiar with NIH applications

# A list of Most Frequent Problems in Applications

- ❑ Lack of new or original ideas
- ❑ Absence of an acceptable scientific rationale
- ❑ Lack of experience in essential methodology
- ❑ Questionable reasoning in experimental approach
- ❑ Uncritical approach
- ❑ Diffuse, superficial or unfocused research plan
- ❑ Lack of sufficient experimental detail
- ❑ Lack of knowledge of published, relevant work
- ❑ Unrealistically large amount of work
- ❑ Uncertainty regarding future directions

**For BioMed-ISS Applications:**

- ❑No clear relevance to human health on Earth
- ❑Not clear on the research needs to be done in ISS

# Funding Process for Institutes and Centers

# UH2 Milestones for UH3 Transition

- The application must have a section labeled "Milestones" which must include:
  - one to three well-defined, objective, quantifiable, scientific milestones for completion of the UH2 phase,
  - a discussion of the suitability of the proposed milestones for assessing success in the UH2 phase, and
  - a discussion of the implications of successful completion of these milestones for the proposed UH3 study.

- Milestones are reviewed in Approach "Are the proposed milestones well-defined, quantitative, and appropriate for assessing the success in the UH2 phase of the application?" and are one of the key factors for later transition.

# Funding BioMed-ISS UH2 Phase

- Awards made through this FOA will initially support milestone-driven, ground based preparatory studies (UH2 ground feasibility phase), with possible rapid transition to the second, ISS-based research phase (UH3 ISS experimental phase).
- NIH Peer Review will only review scientific merit, NOT ISS feasibility.
- Scientifically meritorious applications will be subject to administrative review for ISS feasibility in consultation with NASA
  - If feasible, the participating NIH institute will proceed for funding
  - Otherwise, PI may be given a chance within a short time frame to work with his/her implementation partner to

    make it feasible

# BioMed-ISS UH2 to UH3 Transition

- The ground feasibility phase (UH2) will allow investigators to focus on ground-based preparatory work to meet scientific milestones and technical requirements leading to the ISS experimental phase (UH3).
- The UH3 phase will include preparing the experiments for launch, conducting them on the ISS, and the subsequent data analyses on Earth.
- UH3s will be awarded after administrative review of the eligible UH2s that have successfully met the scientific milestones and feasibility requirements necessary to conduct research on the ISS.

# Thank You and Many NIH Colleagues who Contributed to This Presentation

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**NIH Institute Contacts in the BioMed-ISS FOA**

http://grants.nih.gov/grants/guide/pa-files/PAR-09-120.html#SectionVII