

# National Institutes of Health 101

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## National Institutes of Health (NIH)



Pre-Application Meeting for PAR-09-120 Biomedical Research  
on the International Space Station (BioMed-ISS)  
NASA/Johnson Space Center, Houston, TX  
June 16, 2009



# National Institutes of Health (NIH)

- The primary Federal agency for conducting and supporting medical research. Composed of 27 Institutes and Centers (ICs), the NIH provides leadership and financial support to researchers in every state and throughout the world.
- **Public Health Mission:** To uncover new knowledge that leads to better health for everyone by:
  - Supporting peer-reviewed scientific research at universities, medical schools, hospitals, and research institutions throughout United States and overseas and in its own laboratories.
  - Training research investigators.
  - Developing and disseminating credible health information based on scientific discovery.



# NIH SCOPE

- More than **80%** of the NIH's funding (\$30.6 billion FY2009) is awarded through almost **50,000** competitive grants to more than **325,000** researchers at more than **3,000** universities, medical schools, and other research institutions in every state in the U.S. and around the world.
- About **10%** of the NIH's budget supports projects conducted by nearly **6,000 scientists** in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.



# Memorandum of Understanding (MOU) 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 witness.



# 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. Space-related research 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)
- Peer review panel organized by National Institute of Biomedical Imaging and BioEngineering (NIBIB)
- Pre-funding consultation with NASA, and funding decision by participating NIH Institutes & Centers (ICs)
- UH2 to UH3 transition consultation with NASA, and decision by funding NIH ICs



# Pre-Review: Working with NIH

- Prepare NIH and ISS “feasible” applications by:
  - Attending the pre-application meeting at NASA/Johnson Space Center, Houston, TX on **June 16, 2009**
  - Communicating with NIH staff listed in the FOA
- For help with your application, please 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](http://www.grants.gov/applicants/get_registered.jsp))
  - the NIH eRA Commons (Electronic Research Administration) (<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 Application Key Elements

- Cover Letter and Title Page
- Abstract
- Budget with Justification
- Biosketches of Investigators
- Environment and Resources
- **Research Plan**
  - Specific Aims
  - Significance and Background
  - Preliminary Studies
  - Research Design / Methods
- Human / Animal Subjects
- Literature Cited



# ***Specific Aims: What do you intend to do?***

- **Single and most important page of the application**
- **Capture the vision with a**
  - **Strong, solid, testable hypothesis, or**
  - **Discrete, finite technology development goal**
- **State clear research objectives**
  - **Exploit unique environment of space to discover ways to improve health on earth**
  - **Must fall within the mission of a participating institute**
  - **UH2 and UH3 aims must be separate and distinct**
- **Be focused**
  - **Aims independent yet related to overall goal**
  - **Avoid dense and acronym overload text**
- **Add sub-aims as needed**
  - **Experiments support aims, aims test hypothesis**



# Specific for the BioMed-ISS FOA

- ***Specific Aims:*** Applicants should address the scientific questions to be answered, what specifically will be done during the proposed funding periods, and how the proposed research is relevant to the mission of a participating NIH institute. Specific aims should be scientifically appropriate for the relevant phases of the BioMed-ISS project. Include separate aims for both the UH2 and UH3 Phase in this attachment and clearly label them as “UH2 specific aims and UH3 specific aims”.



# **Significance and Background: Why is this important?**

- Does the study address an important health-related problem?
- Define existing knowledge base via evaluating relevant literature. What are the knowledge gaps?
- Will my solution matter?
- How will the results direct / inform future earth-based research?
- Is the proposed work new? Creative?
- What is the value added by using the unique environment on ISS?



# Specific for the BioMed-ISS FOA

- ***Background and Significance:*** Applicants should 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. They should clarify how the proposed fundamental research, technologies, or approaches will enhance and direct the current and/or future Earth-based research. And, they should clearly identify how the BioMed-ISS project, if successful, would result in an improved understanding of human physiology and human health on Earth. Applicants should also describe why the conditions on the ISS are required for these experiments and why the conditions cannot be simulated on Earth.



# Preliminary Studies: What has already been done?

- Data should lead to the current proposal
- 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 required to look anything up!  
Provide sufficient details for an informed judgment.



# Specific for the BioMed-ISS FOA

- ***Preliminary Studies/Progress Report:*** Applicants should focus on how the unique environment of the ISS may be useful for their research and should be able to address how the reduction of gravity or the unique radiation environment on the ISS furthers the research aims and long term goals. Applicants should also address what has been done to demonstrate the feasibility of the proposed research. The narrative should demonstrate creative thinking and knowledge of the field to reinforce the feasibility of the application.



## **Approach / Methods: How will it be done?**

- **Do experiments relate to the *Specific Aims*?**
  - Provide an overview and conceptual framework
- **Are the experiments logical?**
  - 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
- **Are the end-points / milestones clearly defined?**
- **Is the appropriate statistical analysis included?**
- **Is there a sensible timeline?**



# Specific for the BioMed-ISS FOA

- ***Research Design and Methods:*** Address how the specific aims will be accomplished, the practical feasibility of conducting the proposed experiments on the ISS, and their strategy for packaging their experiments for the ISS.
- Experiments conducted and equipment available on the ISS can be found at  
[http://www.nasa.gov/mission\\_pages/station/science/experiments/Expedition.html](http://www.nasa.gov/mission_pages/station/science/experiments/Expedition.html)  
and [http://www.nasa.gov/mission\\_pages/station/science/experiments/Discipline.html](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-10-020.html>.
- The ***Research 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.



# Specific for the BioMed-ISS FOA

- A specific heading labeled “*Milestones*” in the *Research 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.**
- All other sections should be completed as normal. There is a **25-page limit** for the entire *Research Plan* that encompasses the combined sections (Research Plan attachments 2-5) for both UH2 and UH3 phases.
- All applicants are required to use the detailed Research & Related Budget component, regardless of the amount of annual direct costs requested.



# 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.

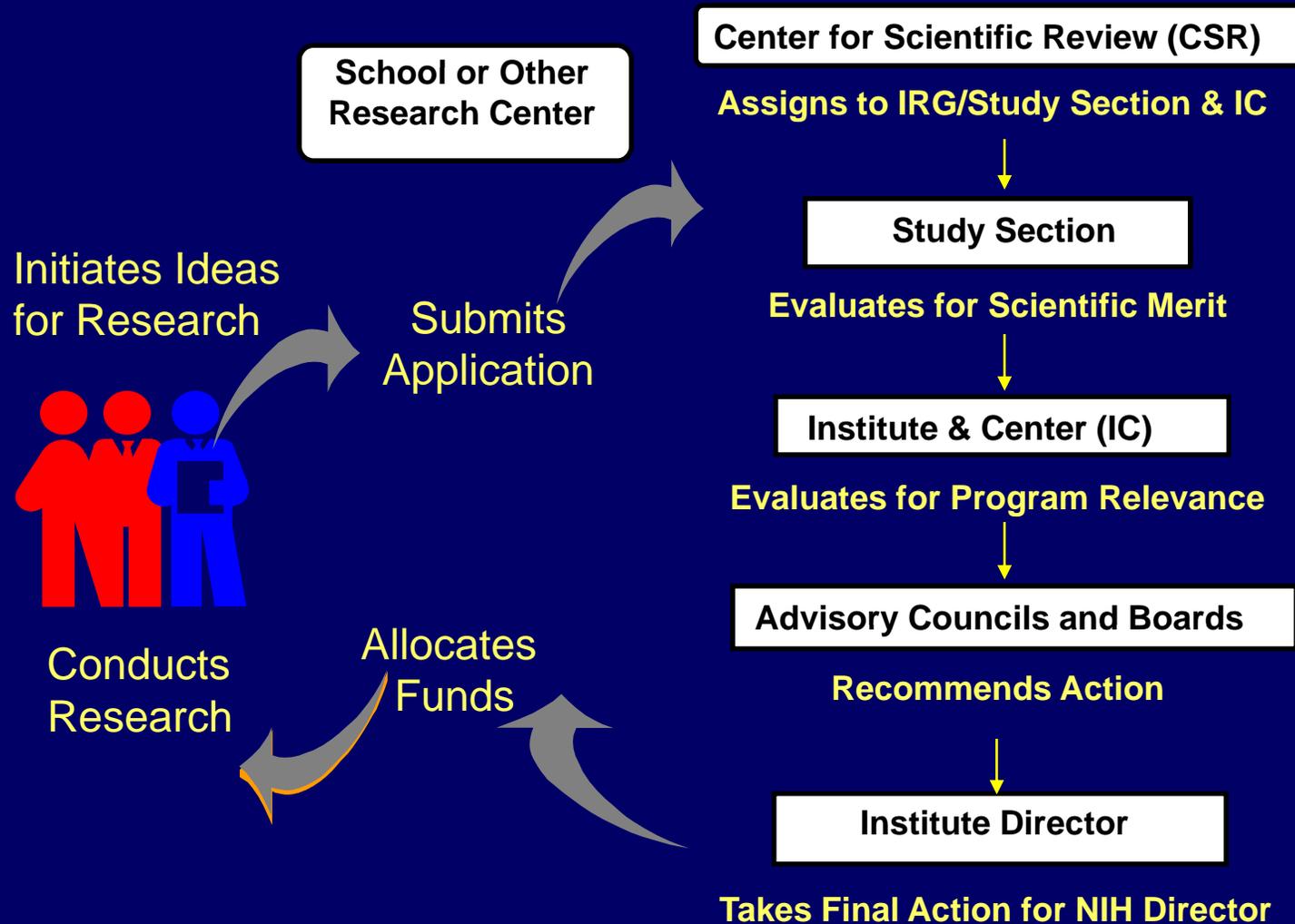


# Ways to Win NIH Grant Awards

- Know your destination (envision the end point application)
- Use the correct vehicle (align the research with the needs and resources of the target funding organization)
- Map the route (define the R&D in technical details)
- Be realistic in goals, time and budget
- Deal with detours (build in contingencies)
- Heed the road signs (know the difference between regulations and guidelines)
- Follow directions
- Good grantsmanship always goes a long way!



# NIH Application Cycle



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



# 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 payload developers / principal investigators (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?**



# UH2 Milestones for UH3 Transition

- The application must have a section labeled "Milestones" that 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?



# 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**



# 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 **met the scientific milestones and feasibility requirements** necessary to conduct research on the ISS.



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**And the Agency Contact in the FOA**

(<http://grants.nih.gov/grants/guide/pa-files/PA-09-120.html#SectionVII>)

