

NIH Grant Workshop

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Panelists

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NIH Mission and Structure

- NIH “mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge **to extend healthy life and reduce the burdens of illness and disability.**”
- The NIH mission is not to support university research programs or to train students or postdocs – those are just possible mechanisms to achieve its mission.
- Understand the NIH structure and review system
<http://grants.nih.gov/grants/oer.htm>
- Read the Roadmap documents <http://nihroadmap.nih.gov/>
- Think about applications - translational science
- Talk to program officers – they are there to help and they do
- Weekly email of Guide to Grants – RFAs, etc.
 - <http://grants.nih.gov/GRANTS/guide/listserv.htm>



- Try multiple agencies and approaches
- Can co submit same/similar proposals to >1 federal agencies if have not been PI on previous fed funding
- But be sure that proposal is relevant and tailored
- Consider other agencies as well as NIH
 - DOD, DOE, NSF, USDA, NASA/NSBRI
 - Funding available: NIH > DOD > DOE > NASA > NSF > USDA
 - Charities and foundations

TABLE 2. Federal obligations for research, by agency: FY 1990–2007

| Fiscal year | All agencies | HHS ^a | DOD | DOE | NASA ^b | NSF | USDA | Other |
|--------------------|--------------|------------------|-------|-------|-------------------|-------|-------|-------|
| Current \$millions | | | | | | | | |
| 2005 | 48,032 | 25,578 | 5,302 | 5,098 | 3,333 | 3,345 | 1,790 | 3,585 |
| 2006 preliminary | 47,658 | 24,891 | 5,589 | 5,030 | 3,395 | 3,279 | 1,883 | 3,590 |
| 2007 projected | 46,587 | 24,356 | 5,454 | 5,107 | 3,477 | 3,424 | 1,515 | 3,254 |

DOD = Department of Defense; DOE = Department of Energy; HHS = Department of Health and Human Services; NASA = National Aeronautics and Space Administration; NSF = National Science Foundation; USDA = Department of Agriculture.

^a In FY 2000 the National Institutes of Health (NIH), part of HHS, reclassified as research the activities that it had previously classified as development; NIH data for FY 2000 forward reflect this change.

^b In FY 2000 NASA reclassified Space Station as a physical asset, reclassified Space Station Research as equipment, and transferred funding for the program from R&D to R&D plant; NASA data for FY 2000 forward reflect these changes.

NOTES: Gross domestic product implicit price deflators for 2000 were used to convert current to constant dollars. Agencies reported preliminary obligations for FY 2006 and projected obligations for FY 2007 during FY 2006.

SOURCE: National Science Foundation/Division of Science Resources Statistics, Survey of Federal Funds for Research and Development: FY 2005–07

Proposal Preparation and Grantsmanship

- Start early
- R01 versus R21 versus R15...
 - *Idaho State is eligible for R15 AREA grants*
- Understand NIH rules and follow them
 - they are stricter than most agencies
 - They see 1000s of grants so you must stand out in positive ways
- Understand institutional rules and timelines
- Understand how to do an electronic submission – get the software and do a dummy run to see if you can assemble the final package
- Understand new rules for Early Stage Investigator (ESI) status

- Do the budget first
 - Calculate what you need
 - Ask for 5 years funding
 - Have it checked by the Office of Sponsored Programs
- Summary and Specific Aims pages are very important
- Make the document readable
- Follow font rules
- Break up text-dense sections with tables and figures
- Start important sections on new pages - may be required
- Use **Endnote** or similar
 - Pediatric Pulmonology³⁶

Specific Aims Page

- Very important – should read well and look good
- State long term goals of the research program
- State disease relevance
- State overall hypothesis
- Include how approach and findings are innovative
- If possible, broaden the impact to other areas of medicine and science
- Aims not interdependent
- State specific hypothesis tested by each aim as you delineate the aim
- Use the word “*proposal*” and not the word “*grant*”

Summary/Abstract

- Very important – should read well and look good
- This will shape the reviewer's, program officer's, panel manager's, first and perhaps final opinions
- Follow the rules about content
- What is innovative?
- What is broadly relevant to science (and not just the area/discipline that you are investigating)?
- What is the potential impact on U.S. medicine?
 - Respond to NIH RFAs

- Have your colleagues read your proposals
 - Choose experienced, preferably NIH funded reviewer
 - Give them adequate time so that they can give you honest feedback and so that you have time to make corrections
 - > 1 colleague
 - Just Specific Aims page?
- Submission letter** – polite and respectful
 - A few sentences about the proposal and its disease relevance
 - Request institute (or request dual assignment)
<http://www.nih.gov/icd/index.html>
 - Request study section - do your homework
<http://www.csr.nih.gov/committees/rosterindex.asp>
- Resubmissions are routine these days
 - Address the issues and describe and show how you have done so
 - Polite and respectful – you can disagree but do it in a careful and data-driven way and don't do it too much
 - Request new study section? – even if granted, there may be pros and cons
 - Shorter turnaround for new investigators

- Have interesting and easy to read content in all sections of the proposal
- Bring out your own work in the introduction as well as other sections but be balanced

- Who is on the likely Study Section?
 - Cite their work if relevant and possible
 - Don't overdo this
 - Note that the members will change

- **Preliminary data** – you can have published stuff here
- Spread figures and tables and your data throughout the application

• **Methods** section

- I prefer a methods section for each Aim rather than one comprehensive section.
- You can cite published methods to save space (especially your own pubs – it is good to say “we have successfully used this approach^{x,y,z}”) but include enough detail of the method that shows that you really can do it and that you understand the critical points, the controls, the appropriate statistical methods, and the limitations of the approach.
- Expected outcomes and alternate approaches
 - Include these!
 - Write this constructively: “*an alternate strategy to test this hypothesis is...*”, rather than “*If this approach does not work...*”.

•Letters from collaborators

- Appropriate letters from collaborators or from colleagues willing to share reagents, equipment, or expertise are valuable.
- Shows that you are willing to take whatever approaches are required to answer the scientific question.
- Shows that you are collaborative and science community-oriented.
- Shows that your team has all necessary expertise, especially if you are venturing into a new area
- Another way to emphasize the key Aims of the proposal.
- Give them enough time and information to generate letters.
- You may need their NIH biosketch as well.

- In addition to the data and the project, what else is unique about you and your lab?

- Unique resources? – environment or reagents

- Additional benefits – training of undergrads that go onto science grad school, training of grad students, etc.

- This stuff should not be the major thrust but it is important because reviewers are human and see the big picture.

- **Human Subjects** and **Animal** research

- Important – a specific part of the review

- Just in Time – may not need IRB or IACUC approval in advance of the NIH proposal submission, but it may be helpful to get their initial feedback or advice

NIH Grant Review

- Review process

http://grants.nih.gov/grants/peer_review_process.htm

- Panel composition and meeting dates available on line
<http://cms.csr.nih.gov/PeerReviewMeetings/>
- Conflict of interest policies
- Scoring system and triage; each panelist scores all proposals
 - An unscored application can be improved, resubmitted, and scored more favorably if reviewer concerns are effectively addressed
 - Scoring system changing from 1-5 to 1-7
- Written summary and critiques from each reviewer, whether or not application is scored

- Reviewer perspectives
 - Characteristics of an outstanding/fundable NIH proposal
 - Addresses important health problem – needs to be done
 - Logical, well organized, well justified
 - Preliminary data
 - Experienced team of investigators with complimentary expertise
 - Innovative ideas and methods
 - Describes alternative approaches
 - Common mistakes
 - No/unclear relevance to human health
 - Serious human subjects or animal welfare concerns
 - Repeats or only modestly advances beyond published work
 - Disorganized proposal
 - Insufficient preliminary data

UNDERSTAND THE NIH GRANT REVIEW CHANGES THAT ARE UNDERWAY...

Priority Area 1 – Engage the Best Reviewers

Improve Reviewer Retention: In 2009, new reviewers will be given additional flexibility regarding their tour of duty, and other efforts will be undertaken to improve retention of standing review members.

Recruit the Best Reviewers: A toolkit, incorporating best practices for recruiting reviewers, will be made available to all ICs in 2009.

Enhance Reviewer Training: In spring 2009, training will be available to reviewers and SROs related to the changes in peer review.

Allow Flexibility through Virtual Reviews: Pilots will be conducted in 2009 on the feasibility of using high-bandwidth support for review meetings to provide reviewers greater flexibility and alternatives for in-person meetings.

Priority Area 2 – Improve the Quality and Transparency of Review

Improve Scoring Transparency and Scale: Review criteria-based scoring on 1 to 7 scale commences in May 2009. Reviewers will provide feedback through scores and critiques for each criterion in a structured summary statement.

- What is the “grading rubric”?
- Have you adequately addressed each of these review criteria ?

Provide Scores for Streamlined Applications: In 2009, streamlined applications will receive a preliminary score.

Shorten and Restructure Applications: Shorter (12-page research plan) R01 applications (with other activity codes scaled appropriately) will be restructured to align with review criteria for January 2010 receipt dates.

Priority Area 3 – Ensure Balanced and Fair Reviews across Scientific Fields and Career Stages, and Reduce Administrative Burden

Fund the Best Science Earlier and Reduce Need for Resubmissions: To ensure that the largest number of high quality and meritorious applications receive funding earlier and to improve system efficiency, NIH is considering **separate percentiling** of new and resubmitted applications and permitting one amended application.

Review Like Applications Together: NIH is establishing an Early Stage Investigator (ESI) designation. In 2009, NIH will evaluate clustering ESI applications for review. The same approach will be considered for clinical research applications.

Updates and details will be posted at <http://enhancing-peer-review.nih.gov> and published in the monthly Extramural Nexus (subscribe at <https://list.nih.gov/cgi-bin/wa?SUBED1=extramuralnexus&A=1>) as they are known. Also, several notices will be posted in the *NIH Guide* detailing specific elements of this implementation.

Review Criteria and Proposal Structures

- Significance
 - Approach
 - Innovation
 - Investigator
 - Environment
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- Proposals may be cut to 12 pages
 - The above criteria may become the new sections