Navigating the NIH and the Peer Review Process

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Some slides adapted from NIH Regional Grants Presentations and NIH Data Book
National Institutes of Health

Office of the Director
(Common Fund “Roadmap”)

21 Institutes
(NCI, NIDDK, NHLBI, NIMH etc)

6 Centers
(CSR, NCRR, CC, etc)
National Institutes of Health

Grant → CSR Center for Scientific Review → SEP (F32) Program → $
NIH Institutes and Centers

NIH is one of 11 agencies in the Department of Health and Human Services (HHS)

NIH includes 27 Institutes and Centers (ICs)
63 years of Study Sections

The First NIH Study Section

1946

A NIH Study Section Today

2010
Why Has U.S. Biomedical Research Been So Successful?

- It is not the money but the way it is spent

% of Nobel Prizes
% of Major Discoveries

Global Federal Expenditure for Biomedical Research in Developed Countries

- USA 9%
- The Rest 91%
30 Years of Medical Innovation

- MRI and CT Imaging
- ACE inhibitors
- Angioplasty
- Statins
- Mammography
- Coronary Interventions
- H inhibitor and H2 Blockers
- Antidepressant
- Cataract and Lens Replacement
- Ultrasound Imaging

- Asthma Treatment
- Cardiac Enzymes
- Fluoroquinolones
- Hypoglycemic Agents
- HIV Testing and Intervention
- Tamoxifen
- PSA
- H. Pylori Test and Treatment
- Cephalosporins
- Calcium Blockers
- Conscious Sedation

Fuchs and Sox, Health Affairs, 20, 30-42
The Fundamental Tenets for NIH (1946)

1. The only possible source for adequate support of our medical research is the taxing power of the federal government.

2. The federal government and politicians must assure complete freedom for individual scientists in developing and conducting their research work.

3. Reviews should be conducted by outside experts essentially without compensation.

4. Program management and review functions should be separated.

Surgeon General Thomas Parran, Jr.
The Basic Operating Principles of NIH Peer Review

NIH has ownership of the process

- The Scientific Review Officer nominates the review panel, assigns applications and is responsible for the meeting.

The study section (SRG, review panel) has ownership of the science.

- Is composed of the best and most experienced scientists in the field. Usually 20 are permanent members, serving 4 years 3 times/year and 10 are ad hoc.

- CSR has over 800 study sections reviewing different biomedical science.
The Rules and the Results of the Process

• NIH Pays Science not directly Scientists or Institutions

• Researchers are “Contractors” who bid in an open competition

• Peer Review is the judge of the competition

• Universities and Research Institutions receive funds only to the extent they have competitive Faculty
NIH Review Process

Initiate Research Idea

Submit Application

Revise/Resubmit

Allocate Funds

National Institutes of Health
Center for Scientific Review

Assign to IC IRG (Study Section)

Study Section

Review for Scientific Merit

Institute

Evaluate for Relevance

Advisory Councils and Boards

Recommend Action

Institute Director

Takes final action
The NIH Peer Review Process

Scientific Review Group (SRG)

“Study Section”
- Expertise
- Stature in field
- Mature judgment
- Impartiality
- Geographical balance
- Diversity

“Chartered” Permanent or membership

“Special Emphasis Panel” (SEP) – ad hoc membership
The NIH Peer Review Process

Reviewer Assignments

• At least three qualified reviewers per application (2 + 1)
• Based on scientific content of application
• Expertise of reviewer
• Suggestions from PI on types of expertise – *not names!*
• Suggestions from Program staff
The Study Section

• 15 to 18 regular members and as many as 5 or 6 ad hoc members
  – Members have their own R01s
• Meets 3 to 4 times a year
• Review from 50 to 120 proposals per session
• Reviewers are paid ~$200 per day
The Meeting

• SRA introduces the grant
• Those with conflict leave the room
• Primary, secondary and tertiary reviewers verbalize their priority scores
• Reviewers provide their comments
• Reviewers recapitulate their scores
• Study section members mark vote (may be asked to announce if they are outside the range)

Video of a mock study section: http://www.youtube.com/watch?v=fBDxI6I4dOA&feature=youtu.be
What determines the score

• The quality of the grant
• The reviewers

What determines the reviewer:

• The Study Section
• Luck
Enhancing Peer Review
Major Complaints About NIH Peer Review

• The process is too slow
• There are not enough senior/experienced reviewers
• The process favors predictable research instead of significant, innovative, or transformative research
• Clinical research may not fare as well as other research
• The time and effort required to write, submit, resubmit, review and re-review is a heavy burden on applicants and reviewers
Enhancing Peer Review

1. Reorganizing CSR and Recruiting Staff
2. Improving Study Section Alignment
3. Assigning Applications More Accurately
4. Addressing Review and Funding for New Investigators
5. Shortening the Review Cycle
6. Advancing Additional Review Platforms
7. Recruiting the Best Reviewers
The reorganized CSR

Neuroscience, Development and Aging
- Brain Disorders & Clinical Neuroscience
- Molecular, Cellular & Developmental Neuroscience
- Integrative, Functional & Cognitive Neuroscience
- Emerging Technologies & Training in Neuroscience
- Biology of Development & Aging

AIDS, Behavioral, Population
- Biobehavioral & Behavioral Processes
- Risk, Prevention & Health Behavior
- Population Sciences and Epidemiology
- Healthcare Delivery & Methodologies
- AIDS & Related Research

Basic- Integrative Biological Sci
- Biological Chemistry & Macromolecular Biophysics
- Bioengineering Sciences & Technologies
- Cell Biology
- Genes, Genomes & Genetics
- Oncology 1 – Basic Translational
- Interdisciplinary Molecular & Training

Physiological Pathological Sci
- Endocrinology, Metabolism, Nutrition & Reproductive Sciences
- Immunology
- Infectious Diseases & Microbiology
- Digestive, Kidney & Urological Systems

Translational and Clinical Sci
- Cardiovascular and Respiratory Sciences
- Surgical Sciences, Biomedical Imaging and Bioengineering
- Musculoskeletal, Oral And Skin Sciences
- Oncology 2 – Translational Clinical
- Vascular and Hematology

Brain Disorders & Clinical Neuroscience

Molecular, Cellular & Developmental Neuroscience

Integrative, Functional & Cognitive Neuroscience

Emerging Technologies & Training in Neuroscience

Biology of Development & Aging

Biobehavioral & Behavioral Processes

Risk, Prevention & Health Behavior

Population Sciences and Epidemiology

Healthcare Delivery & Methodologies

AIDS & Related Research

Biological Chemistry & Macromolecular Biophysics

Bioengineering Sciences & Technologies

Cell Biology

Genes, Genomes & Genetics

Oncology 1 – Basic Translational

Interdisciplinary Molecular & Training

Endocrinology, Metabolism, Nutrition & Reproductive Sciences

Immunology

Infectious Diseases & Microbiology

Digestive, Kidney & Urological Systems

Cardiovascular and Respiratory Sciences

Surgical Sciences, Biomedical Imaging and Bioengineering

Musculoskeletal, Oral And Skin Sciences

Oncology 2 – Translational Clinical

Vascular and Hematology
Enhancements to peer review at study section

New investigators are reviewed first

Then applications are reviewed based on their priority score

Some institutes add 5 or 10% to the percentile score for first-time investigators
New and Experienced Investigators on R01 Equivalent Grants and New Investigators as a Percentage of All Competing R01 Awardees (FY 1962 - 2010) preliminary

Fiscal Year

Established Investigators  New Investigators  Percent New

0.0% 10.0% 20.0% 30.0% 40.0% 45.0%

0 5,000 10,000 15,000 20,000 25,000 30,000 35,000 40,000 45,000 50,000

2. Funding the Most Promising Research Earlier

![Graph showing time-to-award for new and established PIs from 2006 to 2010.](image-url)
Focusing More on Impact and Significance and Less on Approach

• Shorten Applications (13 or 7 pages instead of 25 or 12)
• Scoring Significance
• Discussed applications receive additional overall impact score
• Training of Reviewers and Chairs
NIH Funding
NIH Budget in Current and Constant Dollars

- With Supplemental Appropriation (ARRA)
- Current Appropriation ($ Millions)
- Constant 2010 ($ Millions)
FY 2007 Estimate
Total NIH Budget Authority
$28.578 Billion

- Training 2.7% $760.5 Million
- Research Mgmt. & Support 3.9%
- All Other 5.5%
- Other Research (inc Ks) 5.9%
- Research Centers 9.9%
- Intramural Research 9.7%
- R&D Contracts 9.6%
- All Other 5.5%

Research Project Grants 52.9% $15.122 Billion

RPG = R01, R23, R37, DP1, P01, P42, PN1, R03, R15, R21, R22, R23, R33, R34, R35, R36, R37, R55, R56, UC1, U01, U19
Competing RPG # of Awards
FY 1996 - 2006

- % of Competing RPG Awards from PA's
- % of RPG Awards from RFA's
- % of Competing RPG Awards from Unsolicited

Year
Percentage
90.0% 80.0% 70.0% 60.0% 50.0% 40.0% 30.0% 20.0% 10.0% 0.0%
Success Rates for New (Type 1) Applications, Including First-time R01 Award

- Research Project Grants (Type 1)
- R01 Equivalent (Type 1) Awards
- First-time R01 Equivalent Award
How to find your way through the NIH funding process

seek out mentors and advice
NIH Training and Career Development Timetable

**Career Stage**
- Graduate/Medical Student
- Postdoctoral
- Early Career
- Middle Career
- Senior Career

**Activity Codes**
- Predoctoral Institutional Training Grant (T32)
- Predoctoral Individual NRSA (F31)
- Predoctoral Individual MD/PhD NRSA (F30)
- Postdoctoral Institutional Training Grant (T32)
- Postdoctoral Individual NRSA (F32)
- NIH Pathway to Independence (PI) Award (K99/R00)
- Mentored Research Scientist Development Award (K01)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented RCDA (K23)
- Mentored Quantitative RCDA (K25)
- Independent Scientist Award (K02)
- Midcareer Investigator Award in Patient-Oriented Research (K24)
- Senior Scientist Award (K05)

**Exploratory/Development Grant (R21)**

**Small Grant (R03)**
Funds go to research priorities

Mission

The NIMH mission is to reduce the burden of mental illness and behavioral disorders through research on mind, brain, and behavior. **To fulfill its mission, the Institute is committed to the following priorities:**

- support the integrative science of brain and behavior providing the foundation for understanding mental disorders;
- define the genetic and environmental risk architecture of mental disorders;
- develop more reliable, valid diagnostic tests and biomarkers for mental disorders;
- develop more effective, safer, and equitable treatments that have minimal side-effects to reduce symptoms, and improve daily functioning;
- support clinical trials that will provide treatment options to deliver more effective personalized care across diverse populations and settings; and
- create improved pathways for rapid dissemination of science to mental health care and service efforts.

To reach these goals, the NIMH divisions and programs are designed to emphasize translational research spanning bench, to bedside, to practice. For targeted priorities and funding initiatives, please visit our division websites.

**Directors Corner**
Director's Updates, Institute news, articles, and links of interest from NIMH Director, Dr. Thomas Insel

**Strategic Planning Reports**
Priorities and strategic plans for achieving the NIMH mission

**Budget**
Annual budget requests to Congress for research funding
Success rates for Career Development

- F30: MD-PhD Fellowships (33%)
- F32: Postdoctoral Fellowships (30%)
- K22: Postdoctoral → Faculty (23%)
- K99: Postdoctoral → Faculty (23%)
- K01: Research Scientist (39%)
- K08: Clinician Scientist (44%)
- K23: Patient-Oriented (38%)
Kirschstein-NRSA pre-doctoral fellowships (F31s)
Applications, awards, and success rates
Understanding the Institute’s Mission

• Mission of each NIH Institute is based and defined in law
  • Authorizations (periodic)
  • Appropriations (annual)

• ICs establish specific research emphases
  • Legislative mission
  • Current state of science

• Use the Web to find out!
Not every institute funds all types of NRSAs!

Read the program announcement (PA)

Trends in funding individual NIH K awards by institute or center
Planning a grant

• What type? - training vs. research

• What agency?
  – NIH – F, K, R type awards
  • RFA, PA
  – Private Foundations
  – Other government agencies - DOD, etc
Know what the agency wants

• What is more important for this grant - training or research?
• Gear the grant to address the specific issues the agency is trying to address
• Consider submitting the grant to more than one agency (only if appropriate!!)
  – Note: More is not necessarily better!!
The NIH grant

• PHS Form 398 - FOLLOW THE DIRECTIONS!
• www.nih.gov go to CSR for study sections
  – Ask for advice
• “NIH Peer Review Revealed” and “NIH Tips for Applicants” videos
• Don’t be afraid to contact the NIH staff
  – Scientific Review Administrator/Scientific Review Officer - CSR
  – Program Officer - Institutes
Program Announcement (PA)

Institutes that fund this mechanism:

- National Institutes of Health (NIH)
- Agency for Healthcare Research and Quality (AHRQ)
- National Cancer Institute (NCI)
- National Center for Complementary and Alternative Medicine (NCCAM)
- National Center for Research Resources (NCRR)
- National Eye Institute (NEI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Child Health and Human Development (NICHD)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- Office of Dietary Supplements (ODS)

Title: Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research

Announcement Type
This Program Announcement (PA) revises and replaces PA-08-487 that was previously released on July 21, 2008. This revision changes the application receipt dates, amends the submission requirements as described in NOT-OD-07-025, and updates the Tuition Fees, and Institutional Allowance as detailed in NOT-OD-08-033.
## K Kiosk - Information about NIH Career Development Awards

- **Career Award Wizard** - Helps you select the right career award
- **Visual Guide to NIH Career Development Awards**
  - For individuals with a research doctorate
  - For individuals with a health-professional doctorate
- **Career Award Data and Administrative Information**
  - Funded Career Development Awards
  - Career Award Application Success Rates

<table>
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<th>Program</th>
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| **K01** | **Mentored Research Scientist Development Award**
Career development in a new area of research.
3-5 yrs; Salary determined by the sponsoring Institute. |
|         | **International Research Scientist Development K01 Award (IRSDA)**
Provides US scientists with the opportunity to embark/enhance research careers related to global health. |
|         | **Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research (K01)** - NHLBI (RFA-HL-05-015) |
|         | **Mentored Career Award for Faculty at Minority Institutions (K01)** - NHLBI (RFA-HL-05-016) |
Components: Research Grant

• Abstract
• Specific aims
• Research strategy (+ preliminary data)
  – Significance (overall or for each aim)
  – Innovation (overall or for each aim)
  – Approach
Components: Training Grant

• Often same as research grant PLUS
  – Career development plan
    – Past accomplishments and training (breaks?)
    – Future goals
    – Deficiencies in training - plan to correct

• Sponsor information
  – Track record in training
  – Current support for research in this area
How career development awards are assessed

• Candidate
  • Evidence of commitment
  • Evidence of research experience

• Career development plan
  • Specificity

• Proposal
  • Reflects on applicant and mentorship

• Mentor
  • NIH funded
  • Mentorship experience

• Evidence of institutional commitment
Gathering Information

• Monitor Institute websites and the NIH Guide.
• Get to know the Program Officer for your scientific area.
• Contact a PO about your research ideas.
  – Fit with Institute mission and priorities
  – Best grant mechanism or program
  – Appropriate study section for review
• Participate in workshops and symposia.
• Participate in review of grant applications.
• Talk with mentors, collaborators, & peers about ideas for your application.
Research Portfolio Online Reporting Tool (RePORT)

- A searchable database of federally supported biomedical research – replaced CRISP.
- Access reports, data, analyses, expenditures, results of NIH supported research activities.
- Identify, analyze IC(s) research portfolios, funding patterns, funded investigators.
- Identify areas with many or few funded projects.
- Identify NIH-funded investigators and their research.
- Identify potential mentors/collaborator.

Remember ... *Before you start*

- Talk to program official at appropriate IC
  Find program officers through mentors, colleagues, and the program staff at the Institute or Center that matches your scientific area. Info at [http://writedit.wordpress.com/nih-paylines-resources/](http://writedit.wordpress.com/nih-paylines-resources/)

- Read instructions for application form

- Know your audience
  - Which study section is most likely to review your application?

- Propose research about which you are **passionate** and totally committed to doing
Dual Review System for Grant Applications

First Level of Review
Scientific Review Group (SRG)
• Provides Initial Scientific Merit
• Review of Grant Applications
• Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award

Second Level of Review
Council
• Makes Recommendation to Institute Staff on Funding
• Evaluates Program Priorities and Relevance
• Advises on Policy
Principles of Success

• Understand the agency mission
  – *Every IC is different!*

• Secure collaborators (mentors) to complement your expertise and experience
  – Don’t compete ... *collaborate!*

• Learn and practice the skills of writing applications for grant funds

• Understand the peer review process

• *Take control of your life and career!*