A Peer into the NIH Review Process

A Day with NIH at UTEP
February 19, 2010

Michael A. Sesma, PhD
National Institute of Mental Health
National Institutes of Health
NIH is the steward of **medical and behavioral research** for the Nation. Its 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.
Fulfilling Our Mission

• Support research by non-Federal scientists across U.S. and abroad
• Help train research investigators
• Conduct research in our own laboratories (intramural)
• Foster communication of medical and health sciences information
Research and Training Grant Award Mechanisms

- Individual Fellowships (NRSA) (F30/F31/F32)
- Institutional Research Training Grants (T32)
- Career Development Awards (K-awards)
- Research Grants (R01/R03/R21/R34)
- Program Project & Centers Grants (P01/P50)
- Small Business Awards (SBIR/STTR) (R41/R42/R43/R44)
"Anatomy" of Grant Application Process

Program Staff
Collaborators

Researcher
Idea
INSTITUTION

Program Announcement or RFA

Grant Application (R01, R03, R21, K01, K08, etc.)

National Advisory Council

CSR Referral and Review

Rejection

Revision

Program Staff

Program Staff

Program Staff
Institutional and NIH Team Players in the Grant Application Process
Successful grants require close coordination between all members of the grantee team.

- Grants are awarded to institutions as represented by AORs.
- PD/PIs manage and perform the science.
- Research Administrators support business aspects of the grant.
Responsibilities of the Principal Investigator(s) (PIs)

Designated by the grantee institution

- Responsible for the scientific and technical aspects of project
- Directly manages the project on a day-to-day basis
- Assures scientific compliance by maintaining contact with the NIH Program Officer
- Coordinates with other PDs/PIs on projects with multiple Principal Investigators
The NIH Extramural Team

- Review Staff
- Grants Management
- Program Staff
**Review Staff:**

**Scientific Review Officer (SRO)**

An *Extramural Scientist responsible to NIH for the scientific and technical review of applications*

- Reviews applications for completeness and conformance with application requirements
- Ensure **fair** and **unbiased** evaluation of the scientific and technical merit of the proposed research
- Provide **accurate summaries of the evaluation** to aid funding recommendations made by National Advisory Councils to Institute Directors

Point of contact for applicants during the review process (i.e., after submission, until review is completed)
Program Staff: Program Administrator

(aka Program Officer, Program Director or Program Official)

An Extramural Scientist responsible for the programmatic, scientific, and/or technical aspects of a grant

Role in Pre-submission, Review, Post-Review, Pre-Award, Award and/or Resubmission, Post-Award
Why your Scientific Review Officer or Program Officer Doesn’t Answer E-Mails or the Phone

So, keep trying!
The NIH Grant Process

Investigator initiated research is core to the NIH grant process

WOW! What a great idea
Getting Started: Why Contact a Program Official?

- The program official can:
  - Provide direction to the appropriate **Institute**
    - 24 institutes have granting authority
  - Provide direction to the appropriate **Division/Office**
    - Basic, clinical, behavioral, translational
  - Provide direction to the appropriate **Program Official**
    - Extramural research portfolio
  - Help navigate the **Review** process
  - Provide “application **technical assistance**”
Program Official

Principal liaison between investigators and the NIH

Your most important contact

Call us early ...
Contact us often!
Must I contact NIH *before* applying?

- *Usually it’s just a smart idea*
- When RFA’s request Letter of Intent
- If you have questions about grant mechanisms or budget limitations or eligibility or ...
- When you are considering applying for any grant, if you are a new or experienced investigator -- contact with program staff is always *highly recommended*
  
  **Prior contact with a program officer will always save you time!**
Program Officers ...

Give advice and encouragement!

The cape, Larry! Go for the cape!
New NIH Policy
Encourage New Investigator Applications for the R01

In recent years the use of Small Grants (R03) and the NIH Exploratory/Developmental Research Grant (R21) has increased:

New Investigator policies are limited to applications for Traditional Research project grant (R01) support. Accordingly, the NIH is strongly encouraging New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding.
Are You a “New Investigator”? 

- **Definition:** New Investigator (NI) is a PD/PI who has not yet *competed successfully* for a substantial NIH research grant (Except for R03, R15, R21 or mentored K awards)

- **Definition:** Early Stage Investigator (ESI) is a NI who is within 10 years of completing the terminal research degree or is within 10 years of *completing medical residency* (or equivalent)

- Get special considerations during peer review and IC funding decisions

- Resource web site with further information

grants1.nih.gov/grants/new_investigators
grants.nih.gov/grants/guide/notice-files/NOT-OD-08-121.html
New/Early Stage Investigators

New and Early Stage Investigator Policies

- ESI/NI Applications will be identified to reviewers so that appropriate consideration of career stage can be applied during review.
- Apprise NIH staff of ESI/NI status, which will be considered when applications are selected for award
- Support New Investigators (majority expected to be ESIs) at success rates equivalent to that of established investigators submitting new applications
- For multiple PD/PI applications, all PD/PIs must meet requirements for ESI status to receive consideration during review
- ESIs/NIs are eligible for the Shortened Review Cycle option
The NIH Peer Review Process

NIH Peer Review System

• Two-tiered:
  ▪ Initial peer review
    ▪ Scientific Review Groups (SRGs)
    ▪ I/C Advisory Council or Board (Council)

• Per year:
  ▪ Nearly 80,000 applications
  ▪ Over 18,000 reviewers
The NIH Peer Review Process

Overview

Application received
Assignments made

Initial peer review
Scientific Review Group
(Study section, SRG)
Scientific Review Officer

Funding considerations
Institutes or Centers (ICs)
(Dual assignment possible)
Program Officer

Second level of review
Advisory Council

Funding decisions
IC Director ➔ Award!
The NIH Peer Review Process

Division of Receipt and Referral - CSR

- Check for completeness
- Determine area of research
- Assign an identification number
- Assign a grant number
- Assign application to specific NIH IC for possible funding
- Assign a Scientific Review Group

The Center for Scientific Review = Central receiving point for all competing applications
The NIH Peer Review Process

Referral for Review

CSR Review
- Most R01s, fellowships, and small business applications
- Some Program Announcements (PAs, PARs), Requests for Applications (RFAs)

Institute/Center Review
- IC-specific features
- Program projects/Centers
- Training grants
- Career development awards
- RFAs

Can I influence the Referral Process?
To Request a Scientific Review Group

- Cover letter of application
  - Application title
  - FOA # and title
  - Request:
    - Assignment to particular SRG or study section
    - Assignment to particular IC for funding consideration
    - Disciplines involved, if multidisciplinary
    - Explanation for late application

*Not all requests can be honored.*
The NIH Peer Review Process

Cover Letter of Application

- List one request per line
- Place SRG & IC review requests on separate lines
- Place positive & negative requests on separate lines
- Include name of IC or SRG, followed by a dash and acronym
- Provide explanations for each request in a separate paragraph

Inclusion of a Cover letter is not required. Be proactive!
The NIH Peer Review Process

Information on Review Groups

- **Center for Scientific Review:**
  http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/
  http://www.csr.nih.gov/committees/rosterindex.asp
- **Institutes and Centers:**
  http://era.nih.gov/roster/index.cfm
- **Areas of IC interest:**
The NIH Peer Review Process

Scientific Review Officer (SRO)

- Designated Federal Official for the review
- Extramural scientist
- Identifies and recruits reviewers
- Manages conflicts of interest
- Oversees arrangements for review meetings
- Presides at review committee meetings
- Prepares and releases summary statements
The NIH Peer Review Process

Scientific Review Group (SRG)

“Study Section” Reviewers:
- Expertise
- Stature in field
- Mature judgment
- Impartiality
- Managed conflicts of interest
- Balanced representation
  - Gender
  - Geography
  - Diversity
  - Seniority
The NIH Peer Review Process

Scientific Review Group (SRG)

• Membership
  – Sometimes includes lay members
  – May include foreign reviewers
  – Not more than one-quarter may be federal staff

• Types of SRGs
  – “Chartered”
    ▪ Multiyear terms
    ▪ Formal appointment process
  – Special Emphasis Panel (SEP)
    ▪ Ad hoc membership
    ▪ Often meet only once
The NIH Peer Review Process

Scientific Review Group (SRG) Meeting

First level of review: SRG Meeting

- A standing study section has 15-20 members primarily from academia
- Each study section will review 60-100 applications at a meeting 3X/yr

- For each application:
  - Score (10-90)
  - Human subject concerns
  - Inclusion criteria
  - Vertebrate animal concerns
  - Budget/duration recommendation
The NIH Peer Review Process

Reviewer Assignments

- ≥ Three qualified reviewers (2 + 1)
- Assigned based on scientific content of application
- Expertise of reviewer
- Suggestions from PI on types of expertise – *not names! (cover letter)*
- Suggestions from Program staff
- Managing conflicts of interest
- Balancing workload
The NIH Peer Review Process

Conflicts of Interest (COI)

- Financial
- Employment
- Personal
- Professional
- SRG membership
- Other interests

Two COI vouchers submitted by each SRG member
- Pre-meeting
- Post-meeting
The NIH Peer Review Process

Scientific Review Groups (SRGs)

**Recommendations:**
- Scientific and technical merit
- Budget and project duration
- Bars to award – human subjects, vertebrate animals, biohazards
- Resource Sharing Plans
- Other administrative factors

- Impact/priority scores
- Criterion scores
- Written critiques

*Study Sections do not make funding decisions!*
The NIH Peer Review Process

Scientific Review Groups (SRGs)

Confidentiality
- All materials, discussions, documents (except those in the public domain)
- Reviewers sent guidance with applications
- All questions referred to SRO
- Closed to the public
- Program staff may observe

Reviewers must sign two Confidentiality Certifications!
The NIH Peer Review Process

NIH Scoring System

- Private scoring at SRG meeting
- Numerical scores – new system
  - 1.0 (exceptional) to 9.0 (poor)
  - Final impact/priority score = average of individual scores x 10
  - New feature - individual criterion scores
    - Ranked by percentile for certain mechanisms
- Not Discussed - streamlining
- Other designations (NR, DF, AB, NP, etc.)
The NIH Peer Review Process

Streamlining

• Allows discussion of more meritorious applications
  – Research projects ~ 50%
  – Shared instrumentation ~ 40%
  – Fellowship applications ~ 30%
  – RFAs – pre - arranged limits
• Requires full concurrence of SRG
• Not discussed at SRG meeting, designated “ND”
• Streamlined applications receive a Summary statement:
  – Reviewer critiques
  – Individual criterion scores
  – No final overall impact/priority score
The NIH Peer Review Process

SRG Meeting Procedures

• Call to Order - Chairperson
• Policy and instructions - SRO
• Discuss each application, where feasible:
  – In score order
  – Cluster New Investigator applications
  – Cluster clinical applications
• Scoring
• Discuss other considerations
  – Budget
  – Resource Sharing Plans
  – Foreign institutions
The NIH Peer Review Process

SRG Meeting Procedures

Discussion format

- Members with conflicts excused
- Initial levels of enthusiasm stated (assigned reviewers and discussants)
- Primary reviewer - explains project, strengths, weaknesses
- Other assigned reviewers and discussants follow
- Open discussion (full panel)
- Levels of enthusiasm (assigned reviewers) re-stated
- Individual SRG members vote
- Other review considerations discussed (budget)
The NIH Peer Review Process

SRG Meeting Procedures

Reviewer workload
\sim 6 - 8 as "reviewer"
\sim 2 - 3 as "discussant"

**HINT:** Don’t assume reviewers will
- See the unstated
- Grasp nuances
- Understand your lingo
- Look things up
- Read your mind!
The NIH Peer Review Process

SRG Meeting Procedures

• If 60 applications/SRG meeting
  ~ 50% streamlined
  30 applications to discuss and score
• If 9 hour SRG meeting (8:00 AM – 5:00 PM)
  ~ ½ hour introduction, streamlining
  ~ 1 hour lunch, 2 x 15 minute breaks

Review Implications:
  ~ 14 minutes/application
  ~ 3 - 4 minutes/reviewer

Clarity and brevity are essential!
The NIH Peer Review Process

SRG Meeting Procedures

• Internet Assisted Review
  (http://era.nih.gov/nih_and_grantor_agencies/review_and_decisio
  n_making/internet_assisted_review.cfm)
  – Reviewer critiques/preliminary scores
  – Due several days before SRG meeting
• Acceptance of supplementary material at discretion of
  SRO
  – Correcting errors or omissions
  – New data or newly accepted publications
  – Additional letters of commitment
• Cannot modify application
The NIH Peer Review Process

eRA Commons  http://era.nih.gov/commons/index.cfm

- Final Impact/Priority Score available three days after conclusion of SRG meeting
- Summary statement available 4 – 8 weeks after meeting
  - Available to Program Officers at that time
  - Confidential document
- Available to
  - PD/PIs
  - NIH officials
  - Advisory Council members
The NIH Peer Review Process

Alternate Styles of Review

- Teleconferences
- Editorial-style review
- Video-enhanced discussions
- Asynchronous electronic discussions
The NIH Peer Review Process

Summary Statement

First page
- Program Officer (upper left corner)
  - Name
  - Contact information
- Final Impact/Priority Score or ND
- Percentile (if applicable)
- Codes
  - Human subjects
  - Vertebrate animals
  - Inclusion plans
- Budget request
The NIH Peer Review Process

Summary Statement - continued

Subsequent Pages

- Description (provided by applicant)
- Resumé and Summary of Discussion (if discussed)
- Reviewer critiques – essentially unedited
  – Follow review criteria for mechanism
  – Now formatted in bullet points
  – Protections for Human Subjects
  – Inclusion Plans
  – Vertebrate Animals
  – Biohazards
  – Budget
- Administrative Notes
The NIH Peer Review Process

After the Review

- Program Officer = Point of Contact
- Wait for summary statement
- Read summary statement carefully, several times before calling!

Remember: A favorable score is not a guarantee funding!
The NIH Peer Review Process

Appeals Process

Consider options program if outcome is unfavorable
- Revise and resubmit application
  - Consider critiques in summary statement
  - Address critiques in introduction and text
- Appeal review outcome
  - Lack of reviewer expertise
  - Procedural deficiencies
  - Factual errors
  - May result in re-review of same application by different SRG

Discuss with your Program Officer first!
The NIH Peer Review Process

Advisory Council/Board

Second level of review

Advisory to NIH or IC Director


- **Schedule:** [http://www1.od.nih.gov/cmo/committee/index.html](http://www1.od.nih.gov/cmo/committee/index.html)
The NIH Peer Review Process

Advisory Council/Board

Make recommendations to IC Director:
- Research priority areas
- Policy
- Appeals
- Funding
- Quality of SRG review
  - Concur with SRG recommendations
  - Modify SRG recommendations
  - Deferral for re-review
  - Cannot change final impact/priority score from SRG
The NIH Peer Review Process

Advisory Council/Board

- Scientists from the extramural research community
- Public representatives
- Appointed to terms
- Appointed as Special Government Employees

- Expertise
- Stature in field
- Mature judgment
- Impartiality
- Managed conflicts of interest
- Balanced representation
  - Gender
  - Geography
  - Diversity
  - Seniority
• The NIH Peer Review Process

Funding Considerations

The Institute director will consider:
• Scientific and technical merit (initial peer review)
• Council recommendation
• Relevance to IC program priorities
• Number of meritorious applications received
• Availability of funds
The NIH Peer Review Process

Additional Information

- Enhancing Peer Review Initiative
  http://enhancing-peer-review.nih.gov/

- Office of Extramural Research Peer Review Process
  http://grants.nih.gov/grants/peer_review_process.htm

- Peer Review Policies & Practices
  http://grants.nih.gov/grants/peer/peer.htm

- Center for Scientific Review
  http://cms.csr.nih.gov/AboutCSR/Welcometo+CSR/
Changes in Peer Review are here

http://enhancing-peer-review.nih.gov/
The NIH Peer Review Process *has changed*

New Aspects in Review

- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Clustering of New Investigator Applications
- Score order of review
- No more A2 submissions (2nd revision)

* These changes were implemented for applications considered for FY2010 funding and for ARRA FOAs
Review has Changed: Enhanced Review Criteria

Overall Impact/Priority Score

Reflects the reviewers’ assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

In consideration of:
- Core criteria
- Additional review criteria (RFA or PAR)
- Additional review criteria – as applicable
### Enhanced Review Criteria

<table>
<thead>
<tr>
<th>Overall Impact ➔ Overall Impact/Priority Score</th>
</tr>
</thead>
</table>

- **Core review criteria order:**
  - Significance*
  - Investigator(s)*
  - Innovation*
  - Approach*
  - Environment*

  *Will receive individual criterion scores*

- **Additional review criteria & considerations expanded**

- **Side-by-side comparison available**

  [http://grants.nih.gov/grants/peer_review_process.htm](http://grants.nih.gov/grants/peer_review_process.htm)
Enhanced Review Criteria

Overall Impact ➔ Overall Impact/Priority Score

- Core review criteria for Career Award:
  - Candidate* *Will receive individual criterion scores*
  - Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring *
  - Research Plan*
  - Mentor(s), Consultant(s), Collaborator(s)*
  - Environment and Institutional Commitment*

- Additional review criteria & considerations
- Side-by-side comparison available

http://grants.nih.gov/grants/peer_review_process.htm
**Enhancing Peer Review at NIH: Enhanced Review Criteria**

### Additional Review Criteria

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Resubmission Applications
- Renewal Applications
- Revision Applications
- Biohazards
- Budget and Period Support
- Select Agent Research
- Applications from Foreign Organizations
- Resource Sharing Plans

- As applicable for the project proposed
- Reviewers will consider in the determination of scientific and technical merit
- Reviewers will not give separate scores for these items.

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59
Enhancing Peer Review at NIH: New Scoring System

9-Point Scale

1 = Exceptional
9 = Poor

- Reduces number of rating discriminations
- Provides rating descriptors
  - To improve reliability
  - To encourage use of the entire range
- Scores rounded to fewer digits
## Enhancing Peer Review at NIH: New Scoring System

### New Score Descriptors

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>
Structured Critiques

- Bullet comments on Strengths/Weaknesses
- Decrease variability of review
- Increase quality of information in critiques
- More succinct, better organized
- Encourage evaluative statements
- Scores for five review criteria
- Ensure that reviewers address all review criteria and considerations

Required comments:
- Protections for Human Subjects
- Inclusion Plans
- Vertebrate Animal Welfare
- Biohazards
- Budget
Enhancing Peer Review at NIH

Clustering of New Investigator Applications

- Where feasible, NI applications will be clustered
- NI and ESI applications will be identified for reviewers
- Expectations for preliminary data or track record should not be the same as for established investigators
- Where feasible, discussion order based on:
  - Clustering of New Investigator applications
  - Clustering of clinical applications
  - Clustering of similar activity codes
  - Preliminary overall impact/priority scores
Enhancing Peer Review at NIH

Additional Information

- Enhancing Peer Review Website: (http://enhancing-peer-review.nih.gov/index.html)
- Side-by-side comparison of enhanced and former review criteria (http://grants.nih.gov/grants/peer_review_process.htm)
Enhancing Peer Review at NIH

Major Changes in the Application
(Implemented with Submissions after January 25, 2010*, FY2011 funding)

• Alignment of applications & review criteria
• Restructured Applications
• Shorter Research Plans: new page limits

http://enhancing-peer-review.nih.gov/restructured_applications.html

*Stay Tuned for updates
### Alignment of Application with Review Criteria

<table>
<thead>
<tr>
<th>Enhanced Review Criteria</th>
<th>Section of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>(for research grants and cooperative agreements)</td>
<td></td>
</tr>
<tr>
<td><strong>Significance</strong></td>
<td>Research Plan (restructured)</td>
</tr>
<tr>
<td><strong>Investigator(s)</strong></td>
<td>Biographical Sketch (revised)</td>
</tr>
<tr>
<td><strong>Innovation</strong></td>
<td>Research Plan (restructured)</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td>Research Plan (restructured)</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td>Resources (revised) and Research Plan (restructured)</td>
</tr>
</tbody>
</table>
# Restructuring the Research Plan: Significance, Innovation, Approach

<table>
<thead>
<tr>
<th>Previous Application</th>
<th>New Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background and Significance</strong></td>
<td>Research Strategy</td>
</tr>
<tr>
<td></td>
<td>a. Significance</td>
</tr>
<tr>
<td></td>
<td>b. Innovation</td>
</tr>
<tr>
<td></td>
<td>c. Approach</td>
</tr>
<tr>
<td></td>
<td>• Preliminary Studies for New Applications</td>
</tr>
<tr>
<td></td>
<td>• Progress Report for Renewal/Revision</td>
</tr>
<tr>
<td><strong>Research Design and Methods</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Preliminary Studies/Progress Report</strong></td>
<td></td>
</tr>
</tbody>
</table>
Revisions to Biographical Sketch: Investigator(s)

- **Personal Statement added:**
  - Briefly describe why your experience and qualifications make you particularly well-suited for your role in the project

- **Publications revised:**
  - Limit the list of publications or manuscripts to no more than 15
  - Make selections based on recency, importance to the field, and/or relevance to the application

- **Page limit remains at 4 (except DP1/DP2)**
Revisions to Application:

Environment

- *Instructions added to Resources:*
  - Provide a description of how the scientific environment will contribute to the probability of success of the project
  - For ESIIs describe the institutional investment in the success of the investigator
- *Instructions added to Research Plan*
  - In Select Agent Research section, describe the biocontainment resources available at all performance sites
# Page Limit Revisions

## Shorter Research Plans

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
<td>1 page</td>
</tr>
<tr>
<td>(to Resubmission or Revision)</td>
<td></td>
</tr>
<tr>
<td><strong>Specific Aims</strong></td>
<td>1 page</td>
</tr>
<tr>
<td><strong>Research Strategy</strong></td>
<td>6 pages</td>
</tr>
<tr>
<td>(R03, 13, 21, 36, 41, 43; SC1, SC2; Fellowships (F))</td>
<td></td>
</tr>
<tr>
<td><strong>Research Strategy</strong></td>
<td>12 pages</td>
</tr>
<tr>
<td>(R01, 10, 15, 18, 21/33, 24, 25, 33, 34, 42, 44)</td>
<td></td>
</tr>
<tr>
<td><strong>Combined Candidate Info &amp; Research Strategy</strong></td>
<td>12 pages</td>
</tr>
</tbody>
</table>
What do the changes mean for the Applicants and Grant Administrators?

Applicants must check for new or reissued FOA or Parent Announcement to download new forms.

Forms will be available by December 1.

Applications submitted using incorrect forms will be delayed and may not be reviewed!

A SINGLE UPLOAD for the Research Strategy (previously a 3-file upload) increases applicant control over the look and feel of the application

- Simpler preparation for applicants
- Easier reading for reviewers
Identifying New Application Forms

- New forms are required for both paper PHS 398 and electronic SF 424 (R&R)
  - Funding opportunity announcement (FOA) or Parent Announcement
- Be sure to choose the correct application package:
  - SF 424 (R&R): ADOBE_FORMS_B
  - PHS 398: Revision date “June 2009”
General Information Sources

Enhancing Peer Review at NIH Webpages
http://enhancing-peer-review.nih.gov/index.html

Overview of Peer Review Enhancements Video
http://enhancing-peer-review.nih.gov/video_overview.html
Who Actually Makes the Funding Decisions?

The Institute Director!

Factors Considered:
- Scientific Merit
- Contribution to Institute Mission
- Advisory Council Recommendation
- Program Balance
- Availability of Funds
Yippee!!
Now I only have to worry about getting tenure.
The NIH Peer Review Process

Additional Information

- Enhancing Peer Review Initiative
  http://enhancing-peer-review.nih.gov/

- Office of Extramural Research Peer Review Process
  http://grants.nih.gov/grants/peer_review_process.htm

- Peer Review Policies & Practices
  http://grants.nih.gov/grants/peer/peer.htm

- Center for Scientific Review
  http://cms.csr.nih.gov/AboutCSR/Welcome+to+CSR/
Strategies for “Breaking In” to the NIH System

- Understand the NIH process including the review process
- Understand the ICs and their goals
- Get to know your program officers
- Bounce ideas off established investigators
- Look at successful grant applications
- Find Collaborators
- Put forward your best, creative ideas
  - Appropriate number of goals
  - Impact – now more important than ever
  - Preliminary data if you have it
Path to Success at NIH

Step #1: Do your homework; learn a bit about the grant process and the options.

Office of Extramural Research:

IC priorities: http://www.nih.gov/icd/index.html

NIH Guide Provides Weekly Updates on Funding Opportunities: http://grants.nih.gov/grants/guide/

Step #2: Contact us because… We’re from the Government, we’re here to help you!
New/Early Stage Investigators

Information Sources

- NOT-OD-08-121 (09/26/2008) - Encouraging Early Transition to Independence: Identifying ESIs

- NOT-OD-09-013 (09/31/2008) – Revised New and Early Stage Investigator Policies


- FAQs:
Other NIH Award for New Investigators


- Fund exceptionally innovative research with potential for significant impact
- Launched in 2007
  - Open to new investigators within ten years of their terminal degree
  - Appointment at US institutions
  - Commit at least 25% effort
- Up to $1.5 million over 5 years (direct costs)
- Abbreviated application
  - Preliminary data optional
- Review focus on innovation and creativity, scientific impact
- Number of Applications and awards
  - 2007  2150  30
  - 2008  579  31
  - 2009  419  ? + ARRA
Human Subjects Protection

- Safeguarding the rights and welfare of individuals who participate as subjects in research based on DHHS regulations and established, internationally recognized ethical principles.

- DHHS Office of Human Subjects Research Protections (OHRP) oversees all issues for Federally-funded research involving people.

- Refer to website for information and resources.

www.hhs.gov/ohrp
Humane Animal Research

- Grantees are responsible for the humane care and treatment of animals under NIH-supported activities.
- NIH Office of Laboratory Animal Welfare (OLAW) oversees policies for humane animal care and use.
- Refer to website for information resources

grants.nih.gov/grants/olaw