

NIH Application Submission and Review Changes: *Insights from NIH*

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Take-Home Message

Communicate

- with NIH staff
- with other investigators
- with institutional administrators

Use your Resources wisely

Learn about the application process

<http://www.nih.gov>

NIH in 2010

One agency of 11
within U.S.
Department of
Health and Human
Services (HHS)

Comprises 27
Institutes and
Centers (IC)



Mission

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



Understand the Dual Nature of NIH



NIH is an institution (Intramural Research)

- ~ Approx. 6,000 scientists
- ~ Approx. 10% of NIH budget

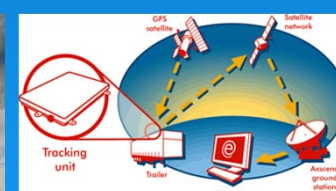


NIH supports institutions & people (Extramural Research)

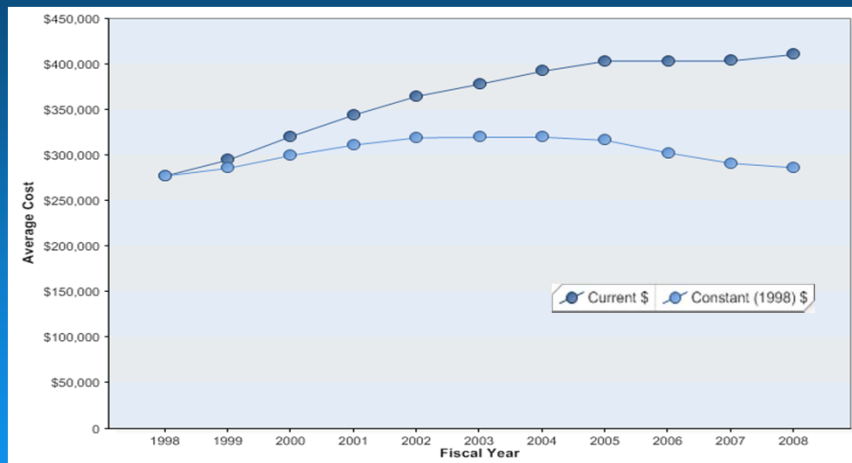
- > 4,000 institutions
- > 300,000 scientists & research personnel
- ~ Approx. 80% of the NIH budget

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 Project Grants (RPGs): Average Size



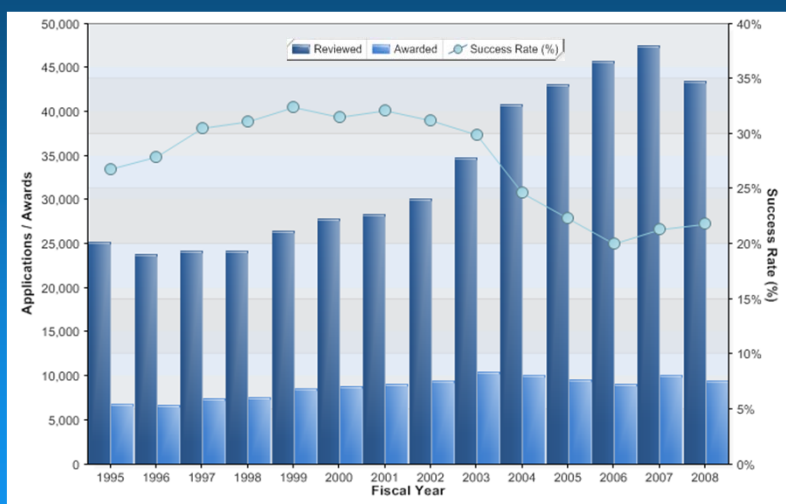
Constant (1998) \$ is the inflation-adjusted average size, in 1998 dollars.

- Research Project Grants (RPGs) include R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RL1, RL5, RL9, P01, P42, PN1, UC1, UC7, U01, U19, U34, DP1, DP2, RL1, RL2, RL5, RL9.

More info available at: <http://www.report.nih.gov>

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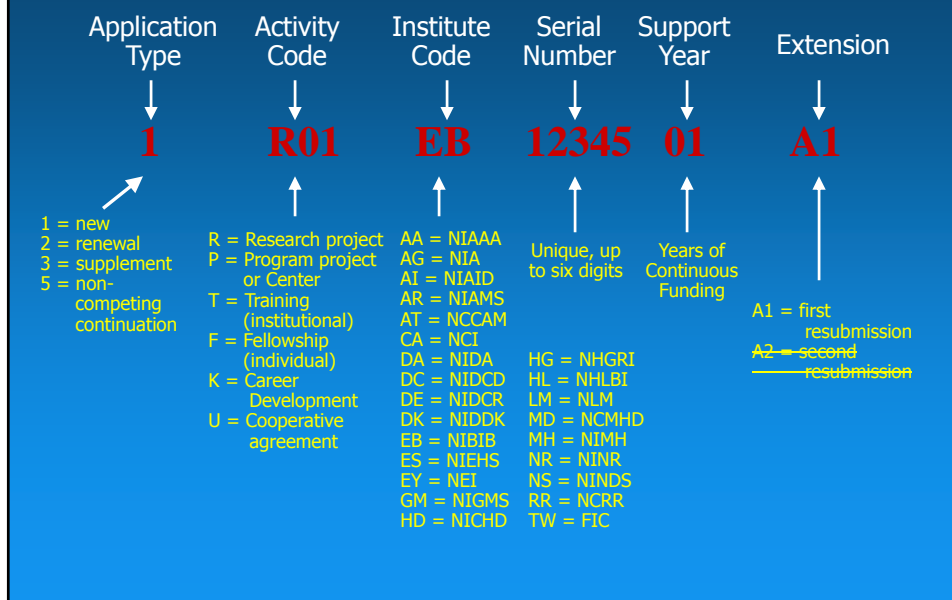
Research Project Grants (RPGs): Applications, Awards, and Success Rates



More info available at: <http://www.report.nih.gov>

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Decoding Your NIH Grant Number



NIH Award Mechanisms

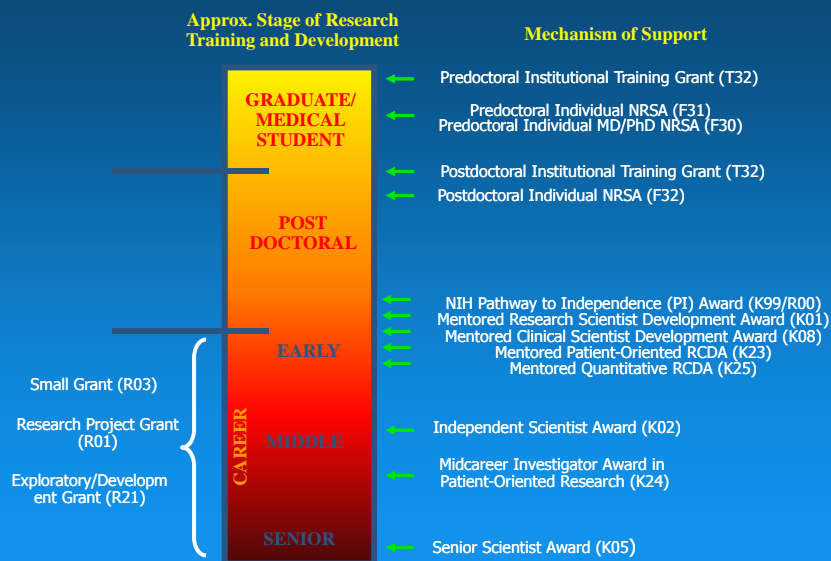


Research and Training Grant Award Mechanisms

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

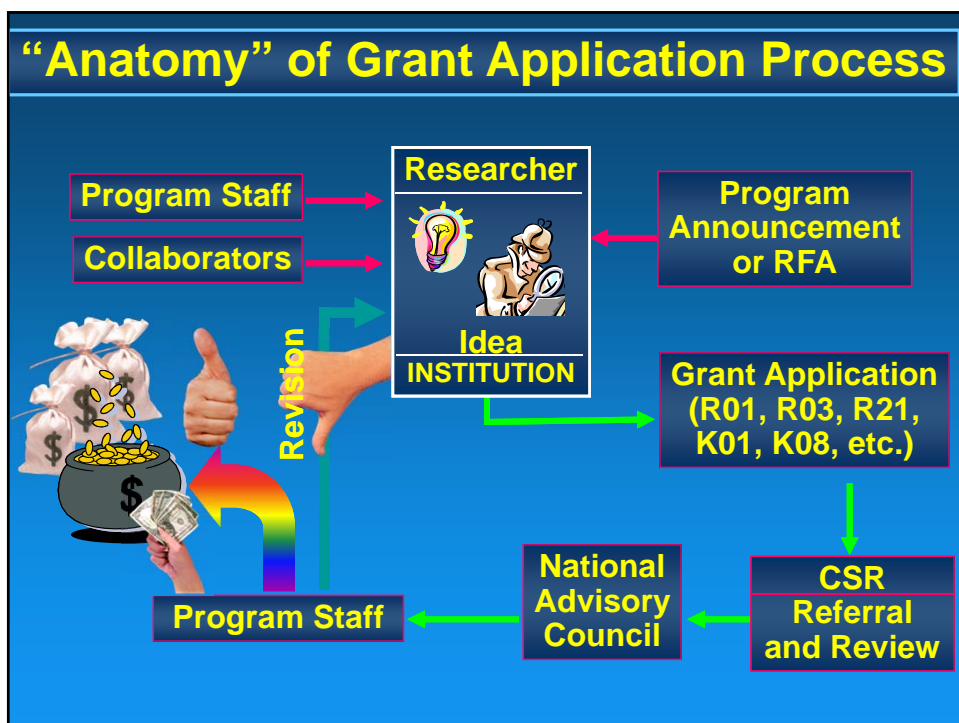
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NIH Offers Funding Programs to Support Scientists at Every Stage of Their Career



*Graph represents a small sample of NIH funding mechanisms available.

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Enhancing Peer Review

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 concerning level of support and duration of award

Mandated by law – PHS Health Act
Defined in federal regulation – 42 CFR 52h
Further defined in NIH policy

Per year:

Nearly 80,000 applications
Over 18,000 reviewers



Second level of review

Advisory Council

- Makes recommendations to IC staff concerning funding
- Evaluates program priorities and relevance
- Advises on policy

Enhancing Peer Review: Summary of Recommendations

Priority 1: Engage the Best Reviewers

Increase Flexibility to Better Accommodate Reviewers
Recruit Reviewers
Acknowledge Reviewers more formally
Compensate Reviewers Time and Effort
Improve Review Quality with Training

Priority 2: Improve the Quality & Transparency of Review

Modify Rating System to Focus on Specific Review Criteria
Align Summary Statement with Review Criteria
Shorten and Align Application with Review Criteria

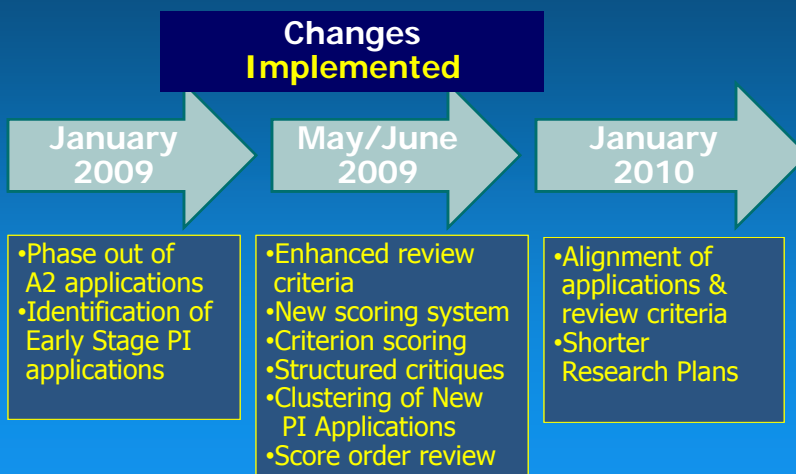
Priority 3: Ensure Balanced & Fair Reviews Across Scientific Fields and Career Stages

Support for Early Stage Investigators
Review of Established Investigators
Enhanced Review of Clinical Research
Expand Awards Encouraging "Transformative Research"
Reduce Need for Resubmissions

Priority 4: Continuous Review of Peer Review

More at: <http://enhancing-peer-review.nih.gov>

Enhancing Peer Review at NIH: Timeline



More at: <http://enhancing-peer-review.nih.gov>

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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
 Restructured Applications



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
 - *Significance
 - *Investigator(s)
 - *Innovation
 - *Approach
 - *Environment
- Additional review criteria (RFA or PAR)
- Additional review criteria – as applicable

**Will receive individual criterion scores*



http://grants.nih.gov/grants/peer/guidelines_general/comparison_of_review_criteria.pdf

Enhanced Review Criteria

Overall Impact → Overall Impact/Priority Score

- Core review criteria for Career Award:
 - Candidate*
 - 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

**Will receive individual criterion scores*

Enhanced Review Criteria

Scored Review Criteria

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?

Enhanced Review Criteria

Scored Review Criteria

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project?

If Early Stage Investigators or New Investigators, or in the early stages of independent careers, 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?

Enhanced Review Criteria

Scored Review Criteria

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?

Innovation

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?

Enhanced Review Criteria

Scored Review Criteria

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Approach

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?

Enhanced Review Criteria

Scored Review Criteria

Approach

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Enhanced Review Criteria

Scored Review Criteria

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?

Enhancing Peer Review at NIH: Enhanced Review Criteria

Additional Review Criteria

- FOA Specific 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.**

Enhancing Peer Review at NIH: New Scoring System

9-Point Scale, New Score Descriptors

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Moderate Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

Overall Impact
Score:
SRG Average
X 10
e.g., 2.2 x 10 = 22

Enhancing Peer Review at NIH

Structured Critiques

- Bullet comments on Strengths/Weaknesses
- More succinct, evaluative statements
- Scores for core review criteria



Clustering of New Investigator Applications

- NI/ESI applications identified and clustered for review
- Different expectations for preliminary data or track record from established investigators
- When feasible discussion order based on:
 - Clustering of NI/ESI, clinical applications, activity code
 - Preliminary overall impact/priority score

Restructured Applications and Instructions

- Implementation of goal: *Align the structure and content of applications with review criteria, and shorten the length of applications*
- Three sections of application instructions revised:
 - Research Plan
 - Biographical Sketch
 - Resources and Facilities
- Shorter Page Limits
- *For additional information see NIH Guide Notice NOT-OD-09-149 issued 09/16/09.
(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html>)

More at: <http://enhancing-peer-review.nih.gov>

Alignment of Application with Review Criteria

Enhanced Review Criteria (for research grants and cooperative agreements)	Section of Application
Significance	Research Plan (restructured)
Investigator(s)	Biographical Sketch (revised)
Innovation	Research Plan (restructured)
Approach	Research Plan (restructured)
Environment	Resources (revised) and Research Plan (restructured)

Research Plan Changes

Research Strategy has 3 subsections:

- **Significance**
- **Innovation**
- **Approach**
 - Progress report for renewal/revision applications
 - Preliminary studies for new applications (can be placed anywhere in the Research Strategy Section)
- **Research Strategy** section replaces 3 sections of the previous application Research Plan
 - Background and Significance,
 - Preliminary Studies/Progress Report
 - Research Design and Methods

More at: <http://enhancing-peer-review.nih.gov>

Page Limit Revisions

Shorter Research Plans

Introduction (to Resubmission or Revision)	1 page
Specific Aims	1 page
Research Strategy (R03,13, 21, 36, 41, 43; SC1, SC2; Fellowships (F))	6 pages
Research Strategy (R01 , 10, 15, 18, 21/33, 24, 25, 33, 34, 42, 44)	12 pages
Combined Candidate Info & Research Strategy (Career Development Award (K) Applications)	12 pages

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*FOA page limits should be followed if they differ from application instructions.
http://grants.nih.gov/grants/forms_page_limits.htm

Biographical Sketch: Investigator(s)

- *Personal Statement:*
 - Briefly describe why your experience and qualifications make you particularly well-suited for your role in the project
 - Does not apply to participating faculty on Ts
- *Publications:*
 - 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)*

More at: <http://enhancing-peer-review.nih.gov>

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 ESIs 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

More at: <http://enhancing-peer-review.nih.gov>

Restructured Application Forms/Instructions

- Implemented changes for Peer Review initiative
- Resubmissions must use new application forms and instructions (and shorter page limits)
- Amended NIH Policy on submission of late grant application materials prior to initial peer review (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-070.html>)
 - Page limits for supplemental information
 - Must have concurrence of Authorized Organization Representative

More at: <http://enhancing-peer-review.nih.gov>

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
 - NIH Forms & Applications Page:
<http://grants.nih.gov/grants/forms.htm>
- Be sure to choose the correct application package:
 - SF 424 (R&R): ADOBE_FORMS_B
 - PHS 398: Revision date "June 2009"

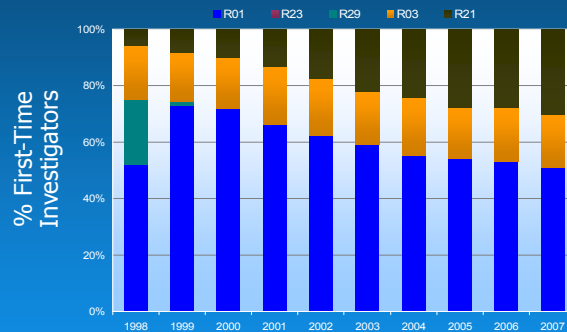
EARLY STAGE & NEW INVESTIGATORS

NIH fosters research independence of
early career investigators.



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.

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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)
- Receive 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

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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
(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html>)

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New/Early Stage Investigators

Information Sources

- NOT-OD-08-121 (09/26/2008) - Encouraging Early Transition to Independence: Identifying ESIs
<http://grants1.nih.gov/grants/guide/notice-files/not-od-08-121.html>
- NOT-OD-09-013 (09/31/2008) – Revised New and Early Stage Investigator Policies
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html>
- NOT-OD-09-034 (12/31/2008) – ESI Policies: Requesting an Extension of the ESI Period
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-034.html>
- FAQs:
http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.html
- NIH Director's New Innovator Award:
<http://commonfund.nih.gov/newinnovator/index.asp>

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Changes in Application and Submission continue

- As of 9/25/2010 - Every submission must be in response to an active FOA
- As of 1/25/2011 - New 37 month Time Limit for Resubmissions after the initial submission
- As of 1/25/2011 - Elimination of Error Correction Window
- Clarification of On-Time submission and Late Application

Changes in Application and Submission continue

- After 1/7/2011 - New page limits for F and K award applications
- New Reference Letter due dates for F and K applications
- New Rules on Post-Submission Materials
- Clarification of what is considered a NEW or Resubmission application

Biosketch Update

- As of 5/25/11 and beyond, all biosketches in the PHS398, PHS2590 and SF424 R& R forms may include:
 - A description of personal issue that may have reduced productivity.
 - Instructions ask you to: briefly describe factors such as family care responsibilities, illness, disability and active duty military service that may have affected your scientific advancement or productivity
- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-045.html>

Relevant links to information about changes to Application or Submission policies

FOA Submissions: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-134.html>

Time Limit: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html>

Error Correction: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-123.html>

New App Definition: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html>

Automatic New App: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html>

Reference Letters: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-036.html>

K Page limits: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-027.html>

Post-submission material: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html>

Inappropriate material: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-077.html>

On-time submission: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>

Institutional and NIH Team Players in the Grant Application Process

Grantee Institution Team

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

Responsibilities of the Research Administrator

Acts as an agent of the Principal Investigator and the Authorized Organizational Representative

- Gathers information needed to ensure compliance with Federal regulations, as well as organization-wide requirements
- Provides essential grant-related support
- Cannot assume responsibilities assigned to the Authorized Organizational Representative or the PI

The NIH Extramural Team



Grants Staff: Chief Grants Management Officer (CGMO)

Responsible for ensuring that all required business management actions are performed by the grantee and the federal government in a timely and appropriate manner both prior to and after award.

Assistance with business and fiscal aspects of the application

Grants Staff: Grants Management Specialists

- Assist GMOs/CGMOs in managing and awarding grants
- Answer questions about completing application forms
- Provide guidance on the administrative and fiscal aspects of an award
- Help navigate NIH grants management information on the Web

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
- Appoints members to scientific review groups/study sections/special emphasis panels
- Provide **accurate summaries of the evaluation** to aid funding recommendations made by National Advisory Councils to Institute Directors

SRO is applicant contact during the review process (i.e., after submission, until review is completed)

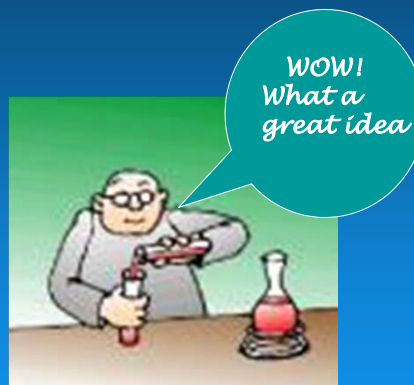
Program Staff: Program Administrator

(aka Program Officer, Program Director or
Program Official)

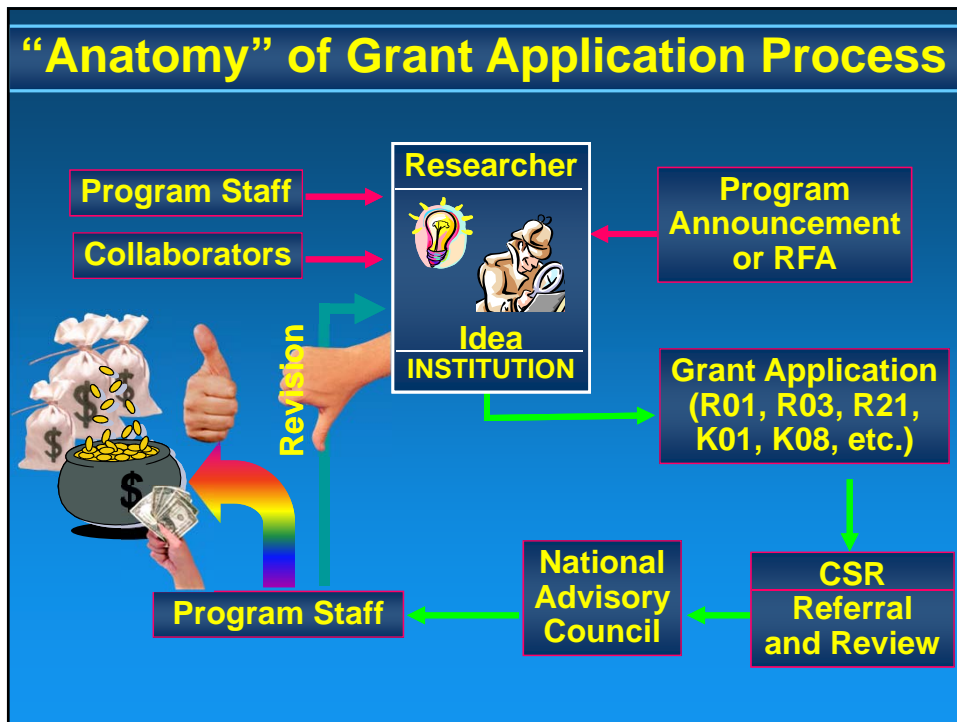
*An Extramural Scientist responsible for
the programmatic, scientific, and/or
technical aspects of a grant*

Role in Pre-submission, Review, Post-
Review, Pre-Award, Award and/or
Resubmission, Post-Award

The NIH Grant Application Process



Investigator initiated research is core
to the NIH grant process



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**”
- The Program Official is the Principal liaison between investigators and the NIH

Must I contact NIH *before* applying?

- **Yes ...under certain circumstances it is MANDATORY**
- Applications with budgets \geq \$500,000 (direct cost) for any single year
 - IC must agree to accept the application
 - Request must be **six weeks** before receipt date
 - NIH Guide NOT-OD-02-004 (10/16/2001)
- R13 Conference Grant Applications
 - IC must agree to accept the application

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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!

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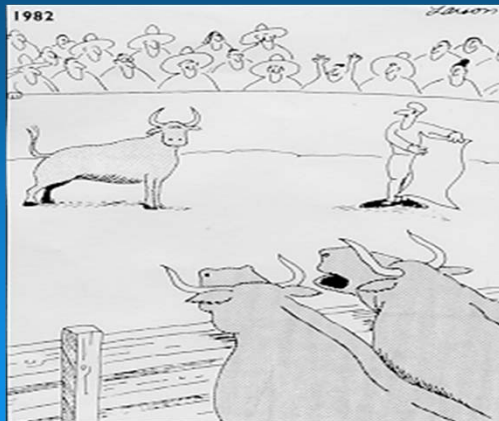
Contact before submission has benefits

- Two more important reasons
- Develop a relationship with a potential program officer
- Assure that your application has a home

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Program Officers ...

Give advice and encouragement!



The cape, Larry! Go for the cape!

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The NIH Peer Review Process

Receipt and Referral to Scientific Review Group (SRG)

- **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
 - Training grants
 - Career development awards
 - RFAs



The NIH Peer Review Process

Role of Scientific Review Groups (SRGs)

Make recommendations:

- Scientific and technical merit
- Budget and project duration
- Bars to award – human subjects, vertebrate animals, biohazards
- Resource Sharing Plans
- Other administrative factors
- ✓ Priority scores or UN
- ✓ Written critiques (summary statements)



**Study Sections
do *not* make
funding decisions!**

The NIH Peer Review Process

To Request a Scientific Review Group

- Include Cover letter with 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.*

SRG rosters are posted 30 days before the SRG meeting:

<http://era.nih.gov/roster/index.cfm>

<http://www.csr.nih.gov/committees/rosterindex.asp>

Who are the Peer Reviewers?

- Demonstrated Scientific Expertise
- Doctoral Degree or Equivalent
- Mature Judgment
- Work Effectively in a Group Context
- Breadth of Perspective
- Impartiality
- Interest in Serving
- Adequate Representation of Women and Minority Scientists

The NIH Review Process



First level of review: SRG Meeting



- A standing study section has 15-20 members primarily from academia and a Scientific Review Officer
- Each standing 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

SRG Meeting Procedures

- Call to Order - Chairperson
- Policy and instructions – SRO
 - Conflicts of Interest
 - Confidentiality
- Review order based on initial scores
- Discuss each application separately
- Scoring
- Discuss other considerations
 - Resource Sharing Plans
 - Foreign institutions
- Applications in lower half not discussed



The NIH Peer Review Process

SRG Meeting Procedures

Discussion format

- Members with conflicts excused
- Initial levels of enthusiasm (assigned reviewers)
- Primary reviewer explains project, strengths/weaknesses
- Other assigned reviewers follow
- Open discussion (full panel)
- Levels of enthusiasm (assigned reviewers)
- Reviewer workload
 - ~ 6 – 8 as “reviewer”
 - ~ 2 – 3 as “discussant”



The NIH Peer Review Process

SRG Meeting Procedures

- Score order of review
 - SRG discusses most meritorious applications first
 - Entire SRG decides when to stop, which applications will not be discussed in panel
- Other order of review (e.g., IC assignment, grant mechanism)
 - SRO prepares a list of average preliminary scores
 - Distributes to SRG
 - Entire SRG decides which applications to discuss



The NIH Peer Review Process

Streamlining

- Allows discussion of more meritorious applications
 - Less meritorious applications tabled at the SRG meeting, designated Not Discussed (ND)
 - Requires full concurrence of the entire SRG
 - ND applications receive a Summary statement:
 - Reviewer critiques
 - Individual criterion scores
 - No numerical, overall impact/priority score



The NIH Peer Review Process

SRG Meeting Procedures

- If 60 applications/SRG meeting
 - ~ 50% streamlined/not discussed
 - 30 applications to discuss and score
- If 9 hour SRG meeting (8:00 AM – 5:00 PM)
 - ~ ½ hour introduction, orientation
 - ~ 1 hour lunch, 2 x 15 minute breaks



Review Implications:

- ~ 14 minutes/application
- ~ 3 - 4 minutes/reviewer

Clarity is essential!

Timeline: New Applications



Receipt
Date

February 5

June 5

October 5



Scientific
Review

July

October

March



Council
Review

October

January

May



Award
Date

December

April

July

<http://grants.nih.gov/grants/funding/submissionschedule.htm>

The NIH Peer Review Process

eRA Commons Post Review

- Overall Impact/Priority Score availability
 - ✓ Three days after conclusion of SRG meeting
- Summary statement
 - ✓ 4 – 8 weeks after conclusion of SRG meeting
 - ✓ Available to Program Officers at that time
 - ✓ Confidential document
- Available to
 - ✓ PD/PIs
 - ✓ NIH officials
 - ✓ Advisory Council members



Summary Statement

- Overall resumé and summary of discussion (for discussed applications)
- Reviewer critiques/criterion scores - essentially unedited
- Overall Impact Score and percentile rank
- Budget recommendations
- Administrative Notes
- Animal/Human Subjects Concerns
- Concerns about Gender, Minority, Child Inclusion
- Program Officer, Contact information

The NIH Peer Review Process

After the Review

- Program Officer is the Point of Contact
- Wait for summary statement
- Read summary statement carefully, several times, take notes, then contact program officer to discuss the next step

The impact score/percentile rank is not a guarantee of funding!

The NIH Peer Review Process

After the Review

- Consult Program Officer
- Consider options if outcome unfavorable
 - Revise and resubmit application
 - ✓ Consider critiques in summary statement
 - ✓ Address critiques in introduction and text
 - Appeal review outcome
 - ✓ Procedural deficiencies
 - ✓ Factual errors
 - ✓ May result in re-review of same application by different SRG



The NIH Peer Review Process

After the Review

- Consult Program Officer
- If an award is likely the program officer will
- Discuss responses to issues raised by reviewers
 - Budget
 - Human subjects or animal welfare issues
 - Inclusion issues
 - Administrative requirements
 - Discuss Funding and Duration
 - Study Section Recommendations
 - NIH and Institute Guidance



The NIH Peer Review Process

Advisory Council/Board

Panel of scientific experts and lay members
provide advice to Institute Director
Members appointed for 3-4 year term

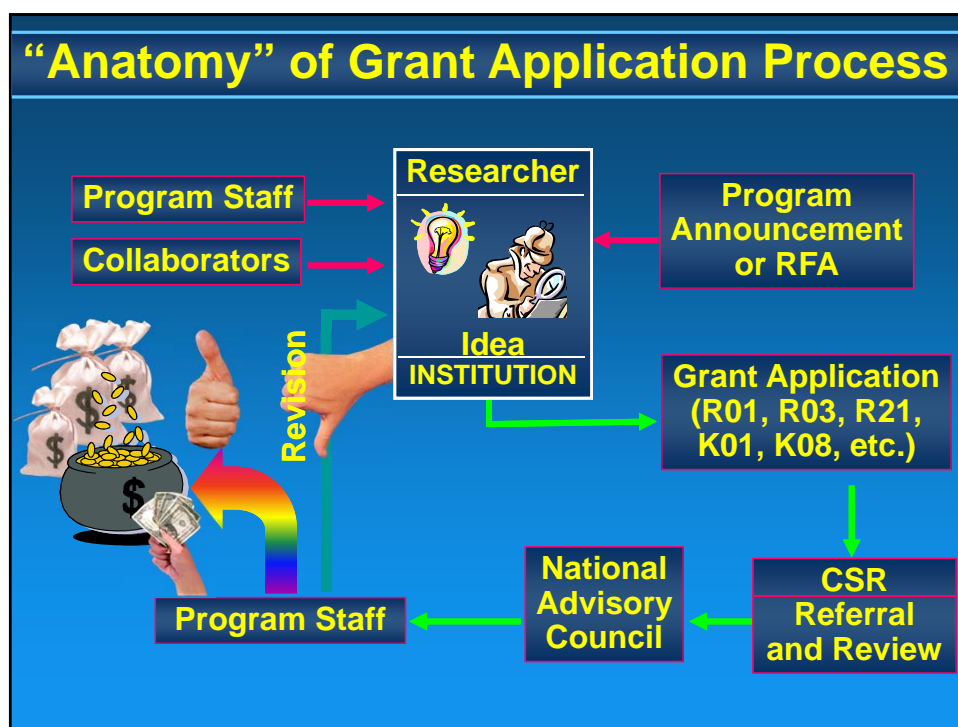
Second level of review

- Advice on Funding Applications, Research Priority Areas, Policy, Program Development, Appeals, Quality of SRG review
- Rosters: <http://www1.od.nih.gov/cmo/committee/index.html>
- Schedule: <http://www1.od.nih.gov/cmo/committee/index.html>

Who Actually Makes the Funding Decisions?

The Institute Director!

- Factors Considered:
 - Scientific Merit
 - Contribution to Institute Mission
 - Advisory Council Recommendation
 - Program Balance
 - Compliance with policies
 - Number of meritorious applications received
 - Advice of IC Program Staff
 - 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/Welcome+to+CSR/>



Path to Success at NIH

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

Office of Extramural Research:

Basics - http://grants.nih.gov/grants/grant_basics.htm

Overview - http://grants.nih.gov/grants/grants_process.htm

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, and we're here to help you!

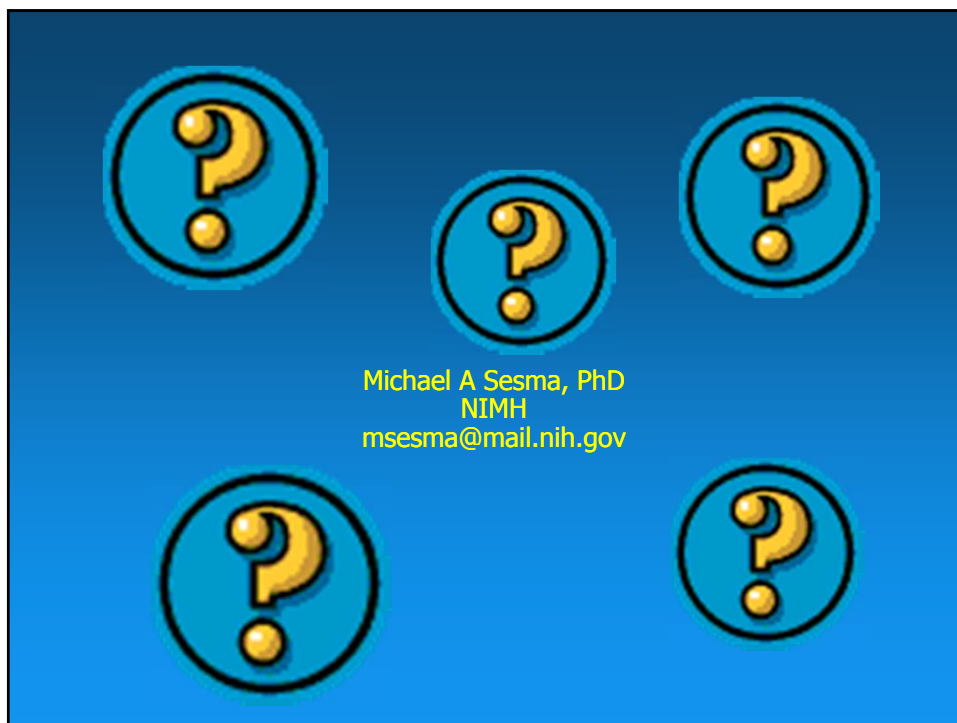


Take-Home Message

- Never hesitate to ask questions about the process
- Communicate
 - with NIH staff
 - With other investigators
 - with institutional administrators

<http://www.nih.gov>

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The NIH Grant Application Becomes an NIH Grant

Grants Management
After the Review
Pre- and Post-Award



Award Negotiation & Issuance

- There are still many steps after a funding decision is made before a grant is awarded.
- Grants management staff work closely with grantee and NIH program staff to complete this final process.



Grants Management Issues

- Assurances in Place
 - Office of Human Research Protections (humans)
 - Office of Laboratory Animal Welfare (animals)
- Financial Status Report (FSR)
 - (SF 269-long form)
 - if applicable
- Human Subjects Education
- Performance Site(s)/Consortium(s) information
- Checklist completeness
- Just-In-Time Information



Just-In-Time Information

Information not required to review the application which is necessary to implement the grant.

- Certification of Education on Human Subjects
- Institutional Review Board (IRB) approval
 - Required within 1 year and before any human subjects research begins.
- Institutional Animal Care and Use Committee (IACUC) Approval
 - Required within 3 years and before animal research begins.
- Information on "Other Support" received by Key Personnel



Budget Issues

- Correctly apply modular and categorical budgets
 - Modular budgets reduce burden by eliminating the need for specific budget numbers
 - Available for grants at or below \$250,000 per year
 - Grantees awarded grants in “modules” of \$25,000
- Budget Justification
- Adjustments may be applied to individual grant awards based on IC financial policies
 - Caps on certain types of costs specific to that funding opportunity
 - Limits on overall grant funding due to NIH budget constraints.



Notice of Award (NoA): Overview

LEGALLY BINDING DOCUMENT

- Award Data & Fiscal Information
- Grant Payment Information
- OIG* Hotline Information
- Terms and Conditions

* Office of the Inspector General



Grantee Acceptance



The grantee indicates acceptance of the terms and conditions of the award by **drawing down funds against the grant** from the Payment Management System.



After the Award...



Administrative and Fiscal Monitoring Requirements



Annual Progress Report (PHS 2590)



Annual Financial Status Reports (FSR)



Invention Reporting

Yearly Audits (as applicable)



Final Closeout Reports

