

Working with
NIH Program Officials:
PreAward & PostAward

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and

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2009 NIH Regional Seminars, Las Vegas

Take-Home Message

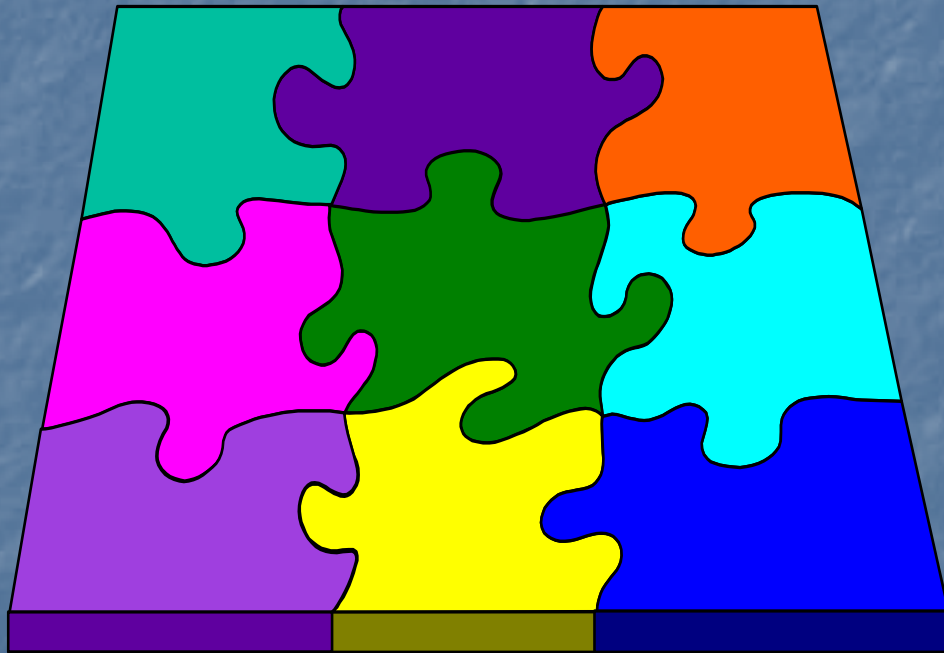
■ Communicate

- with NIH staff
- with Fellow Investigators
- with Institutional Administrators

<http://www.nih.gov>

There are many people at NIH
whose job it is to help YOU!

Finding Your Way at NIH

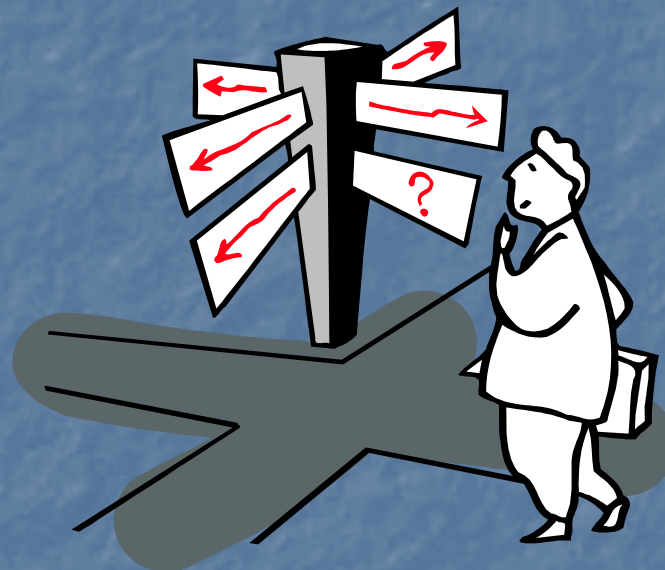


- Comprised of 27 Institutes and Centers
- Similar in some ways - **some common elements** - but not all ways

NIH Research Programs

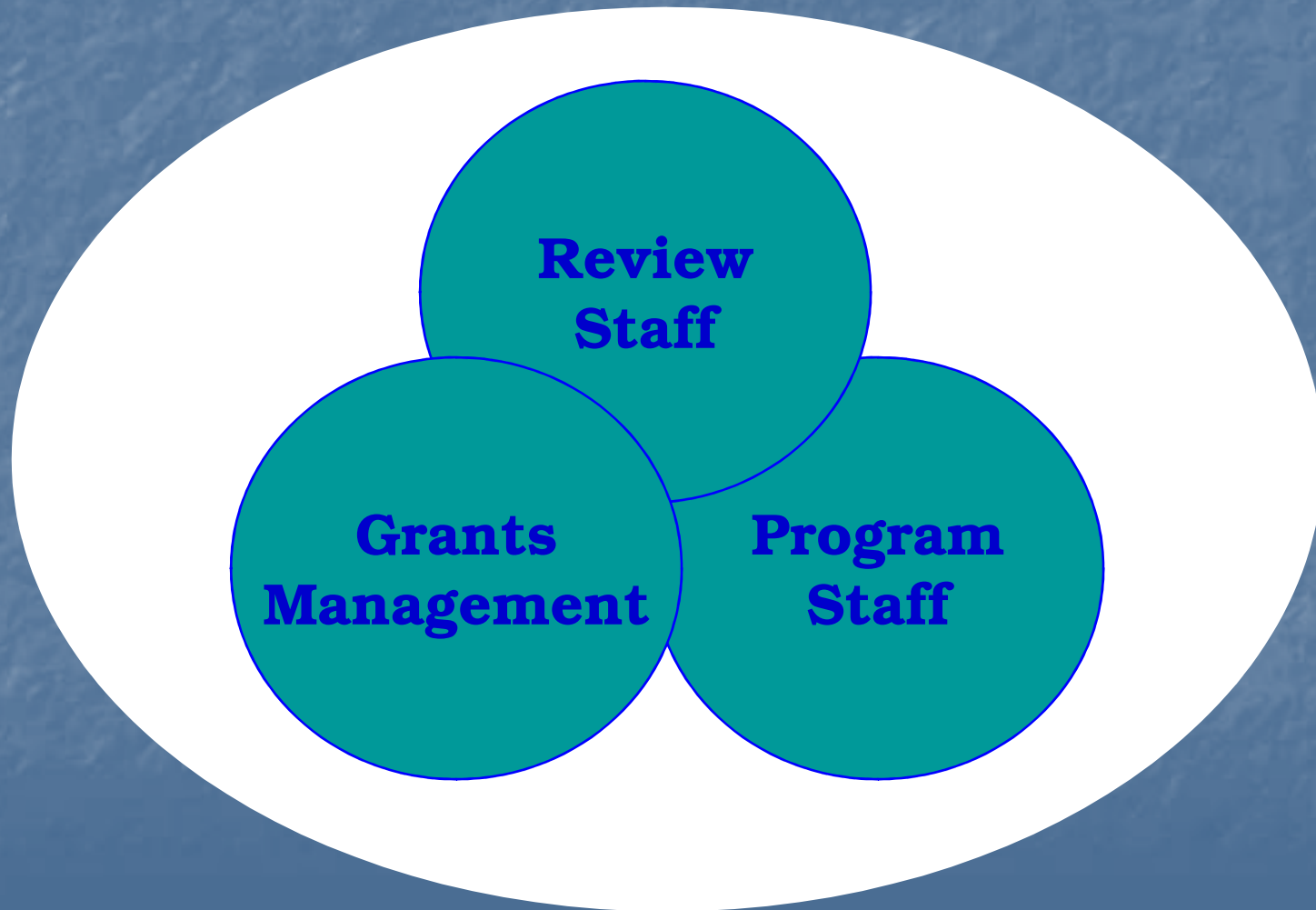
Institutes and Centers

- Divisions
- Branches
- Programs



Where do I find a guide?

The NIH Extramural Team



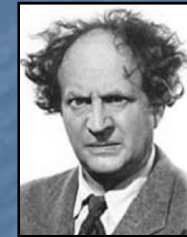
Three Government Officials...

You Should Know!

Program Official



*Scientific Review
Officer*



Grants Specialist



NIH Program Staff: *Your Guide to Success*



Program Official

[*aka* Program Director *or* Project Officer]

**Responsible for the
programmatically, scientific, and
technical
aspects of a grant**

Who/What is a Program Official?



The Program Official is both:

a **Scientist**
and an **Administrator**

Responsibilities of the Program Official

- Manages scientific research portfolio of grants, contracts, and cooperative agreements
- Identifies opportunities and needs of science specific to an Institute's mission
- Stimulates interest in scientific areas of emphasis for each Institute
- Communicates program priorities
 - Program Announcements (PA)
 - Request for Applications (RFA)

Responsibilities of the Program Official

- Provides technical assistance to applicants
- Observes scientific review meetings
- Discusses review issues with applicant
- Evaluates the programmatic merit and mission relevance of applications
- Prepares funding recommendations
- Reviews annual research progress of grantees
- Reports on scientific progress and program accomplishments

Responsibilities of the Program Official

***An Important Resource for
Applicants & Investigators***

Program Official

Principal liaison between investigators and the NIH

Your most important contact

***Call us early ...
Contact us often!***

Getting Started: Contact a Program Official

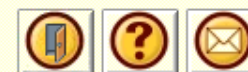
- ***At Your Favorite **Scientific or Professional Meeting*****
 - *Institute Booths*
 - *Mingling thru the Crowds*
 - *Institute sponsored workshops*
- ***Ask a **Colleague*****
 - *Surely somebody knows a Program Contact*
- ***Search **NIH Institute Websites or Directory*****

CRISP

- *Computer Retrieval of Information on Scientific Projects*
- Searchable database of federally supported biomedical research
- Locate experienced NIH-funded investigators in your area of interest
 - Potential mentors/collaborators
- Identify the IC(s) that supports research you want to do
- Analyze current IC portfolio
 - Research areas with few funded projects
 - Research areas with many funded projects



CRISP



ERA Commons *Computer Retrieval of Information on Scientific Projects*

... Searches and displays have been upgraded to handle Multiple PI data ...

CRISP (Computer Retrieval of Information on Scientific Projects) is a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. The database, maintained by the Office of Extramural Research at the National Institutes of Health, includes projects funded by the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Health Care Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH). Users, including the public, can use the CRISP interface to search for scientific concepts, emerging trends and techniques, or identify specific projects and/or investigators. Below you will be able to access additional general information about the CRISP database, as well as obtain answers to questions frequently asked about CRISP. In addition, this home page serves as the gateway to interactive searching of Award Information. From here, you may select from the following list to acquire further information about CRISP:

- [General CRISP Description and Information](#)
- [Frequently-Asked-Questions \(FAQ\)](#)
- [CRISP Release Notes](#)
- [Using CRISP](#)

crisp.cit.nih.gov



CRISP wins 1999 Best Feds On The Web Award!



CRISP has been chosen as a Scout Report selection!

Getting Started: Contact a Program Official

Why?

We can Direct You to:

- *The appropriate **Institute***
 - *24 institutes have granting authority*
- *The appropriate **Division/Office***
 - *Basic, clinical, behavioral, translational*
- *The appropriate **Program Official***
 - *Extramural research portfolio*

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

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
 - whether you are a new or experienced investigator
 - contact with program staff is always **highly recommended**

Prior contact with a program official will always save you time!

Contact before submission has benefits

Two more important reasons:

- Develop a relationship with a potential program official
- Assure that your application has a home (appropriate Institute)

Your Program Official Can Help ...



*During Application Development
and Preparation*

During Scientific Review



After Peer Review

After the Grant Award



Developing the Application: Your Idea



Your Research Needs and Interests

- *My research interests focus on the link between widgets and type II diabetes*
- *My need is for additional research training or career development*

Develop Your Application: For NIH

A Program Official can discuss

➤ *Your ideas*

- *Match your scientific interests with the mission and focus of NIH Institutes*

➤ *NIH ideas*

- *Research initiatives and priorities already established by ICs*

Developing the Application: NIH Interests

NIH Institute Program Priorities

- Search CRISP to learn what research is supported
 - <http://crisp.cit.nih.gov/>
- Search Institute Web Sites
 - www.nih.gov/icd/
- Contact Institute Staff
 - <http://ned.nih.gov/>
- Identify Relevant RFA or PA in NIH Guide
 - <http://grants.nih.gov/grants/guide/index.html>

Program Officials ...

can help During Application Preparation



- Concept paper
- Budget issues
- NIH requirements
- “Technical Assistance”

What's a Concept Paper?

Organize your thoughts for productive discussion with a Program Official

- **Grant Purpose** Briefly, you want a grant from which institute/agency to do what?
- **Problem/Background** Explain why you to think this topic needs study. Demonstrate you know the institute priorities.
- **Significance** Explain why this is important to the field.
- **Question** What hypotheses will you test and what model will guide your hypotheses?
- **Design/Analysis** What is the study design that will enable testing your hypotheses? What statistical approach?
- **Team** Who will be the key participants (co-investigators and organizations) on the project?
- **Miscellaneous** Other issues that may be relevant to your plans

Develop Your Application

What is "Technical Assistance"?

- **Advice on Grant Writing and Preparation**
- **Clarification of Policies and Regulations**
- **Confirm Applicant Eligibility**
- **Determine Responsiveness to Program Initiative**
- **Development of**
 - **Scientific concepts**
 - **Scientific aims & objectives**

Develop Your Application

*Guidance to **Appropriate Grant Mechanism***

- Training Grant
- Career Development Award
- Research Project Grant

Explain the difference between PAs, RFAs, RFPs

NIH Award Mechanisms

R01

K08

R21

F33

R03

T32

K23

R43

Grant Award Mechanisms

- Individual Fellowships (NRSA)
- Institutional Research Training Grants
- Career Development Awards
- Research Grants
- Program Project & Centers Grants
- Small Business Awards (SBIR/STTR)

Types of Awards

Different Interactions

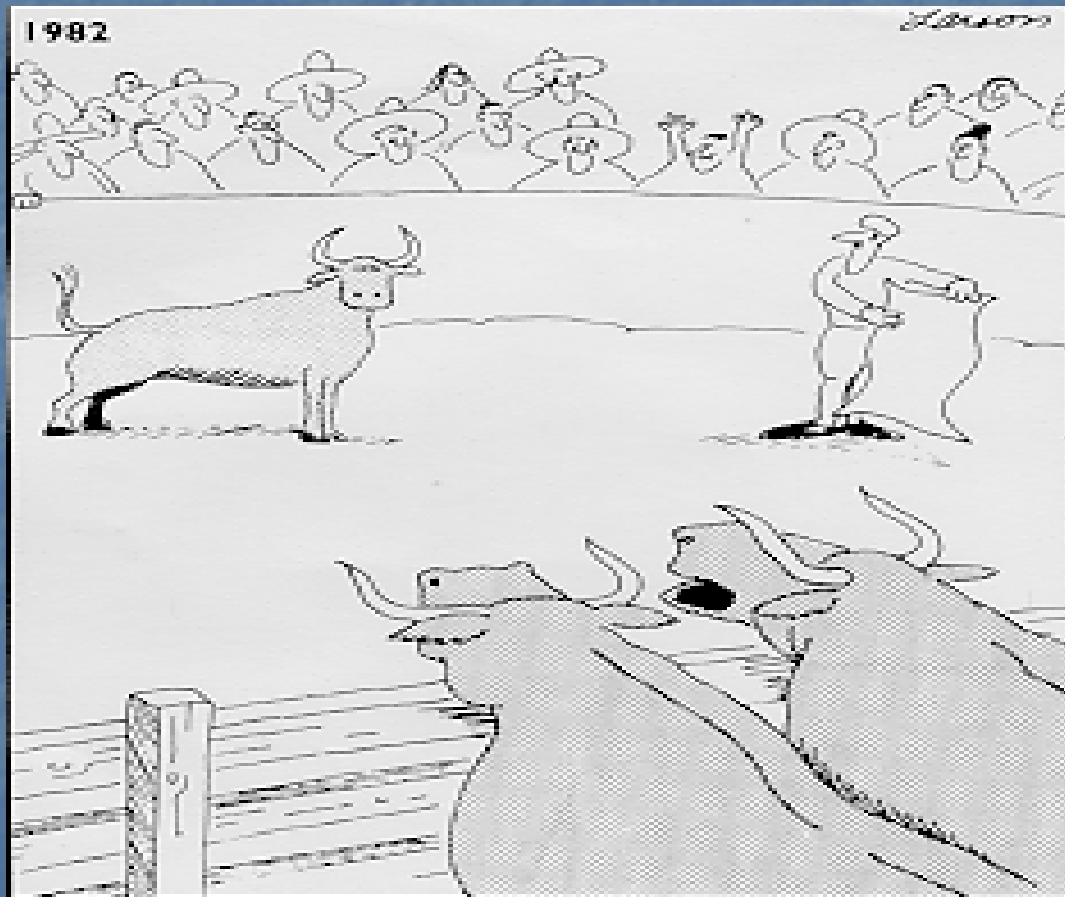
- Grant
 - Financial assistance to carry out approved activities (e.g., research, training)
- Contract
 - Acquisition of goods or services
- Cooperative Agreement
 - Grant support that includes substantial Federal involvement

What Determines Which Applications Become Grants?

- Scientific merit (Review Group)
- Program Considerations
(Program Official, Advisory Council, IC Director)
- Availability of funds

Program Officials ...

Give advice and encouragement!



The cape, Larry! Go for the cape!

Program Officials ...

**... are not done after
you submit your
application**

Program Officials ...

can help **During Scientific Review**

- Answer your questions about grant review
- Be a Liaison to the SRO
- Observe review group meeting



As You Submit Your Application

We can answer your questions about review of applications

SRO is in charge of review process

but the Program Official can:

Discuss and explain grant assignments

- *Institute and Study Section*

We help you navigate peer review process

As You Submit Your Application

We can be a Liaison to the SRO

*SRO is in charge of review process
but the Program Official can:*

Convey to the SRO

- *Requests to submit additional data*
- *Missing elements of your application*
- *Notifying of accepted papers*

As You Submit Your Application

We Can Observe Study Section Review

***SRO is in charge of review process
but the Program Official can:***

- ***Listen to panel discussion of your grant***
- ***Listen to panel discussion of other grants***
 - ***Helpful when an application is unscored***
- ***Provide clarification of Program Initiatives (RFA, PA) if requested by SRO***

Program Officials ...

can help After Peer Review

- Priority Scores and Percentiles
- Study Section Review
- National Advisory Council Review
- Prepare Funding Recommendations

After Peer Review

**Do Priority Score and Percentile Indicate ...
... I Will Get Funding?**

**Important: Nothing is Official Until You
Receive the Notice of Award**

After Peer Review

Your Job

- Read summary statement
- Reread summary statement
- ***Talk with your Program Official***
- Wait for the AWARD, or
- Revise and Resubmit the Application
- Listen to advice from Program Official

After Peer Review

Discuss Study Section Review

- What is **written** in the Summary Statement
- What was **said** during the review
- Do you really want to **appeal**
 - Scientific errors
 - Evidence of bias

After Peer Review

Attend National Advisory Council Review

- Clarify **Scientific Objectives** of Applications to Council
- Present **Appeal** Letters
- Get **Program Priorities** from Council

After Peer Review

Prepare Funding Recommendations to Institute Director

- Priority **Score** and Percentile
- Areas of **Scientific** Emphasis
- Council/Institute **Program Priority**
- **Portfolio** Balance

Remember ...

... the **INSTITUTE DIRECTOR**
makes the final Funding
Decisions

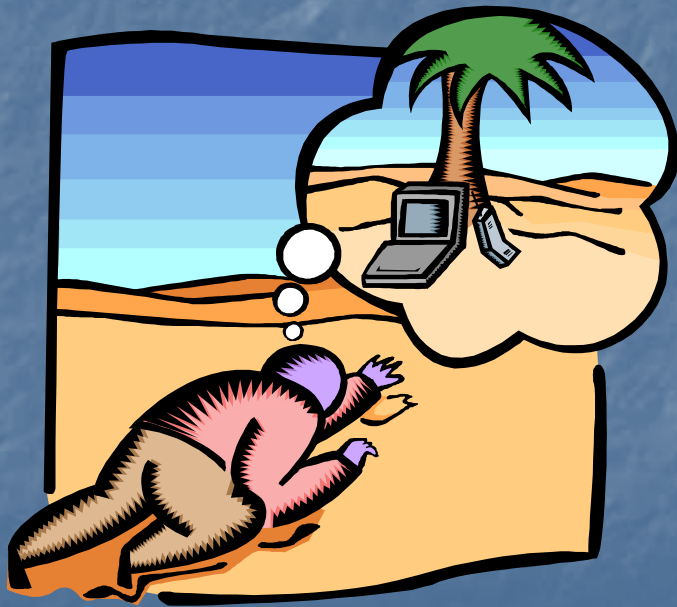
Program Officials ...

can help After Peer Review

If funding seems unlikely:

Consult with applicant on possible next steps:

- Responding to reviewer concerns
- Revisions and resubmission



After The Review - Revisions

Responding to Reviewer Concerns

- What is **written** in the Summary Statement
- What was **discussed** during Peer Review

Please be responsive to reviewer concerns!

Q: What if you know that you are **"Right"** and the reviewers are **"Wrong"**, is it appropriate to argue your position in your resubmission?

A: NO!

Remember

- An application for funding is not about the facts of your completed research.
- It is about ideas and potential research
- **Never be Argumentative !**
- **Never be Abrasive !**
- **Do not do long term damage to yourself**

After The Review - Revisions

Changes to Application

- Develop Your Hypothesis
- Revise Specific Aims & Objectives
- Describe Experimental Approach & Design
- Should you request change in Reviewers or Study Section
- Should you change mechanism

Revise and Resubmit

- **Update Preliminary Results**
- **Remember that Properly Revised applications can receive fundable scores and subsequent**
\$\$
 - **Score can inform degree of revision necessary**
- **Maintain communications with Scientific Review Officer and Program Official**

Revise and Resubmit

- Write A Clear Introduction Section
- Address All Criticisms Thoroughly
- Respond Constructively
- Acknowledge and Accept the Help of Reviewer Comments
- **Don't Be Argumentative !**
- **Don't be Abrasive or Sarcastic !**

Revise and Resubmit

Prepare a REVISION COVER LETTER

- For Revisions, Indicate Review History
- Request Same Or Different Study Section
- Provide Justification for your request
- **Don't be Argumentative ! Never!**
- **Don't be Abrasive ! Never!**

Program Officials ...

can help After Peer Review

If funding seems likely:

Consult with applicant on key issues:

- Budget
- Human subjects
- Administrative requirements



After The Review - Award

Assist Grants Management

Document Policy Compliance

- Animal and Human Subjects Approvals
 - Animal Welfare
 - Women, Minorities, Children Inclusions
 - Check Required Human Subjects Training
- Data and Safety Monitoring Plan
- Review Other Support
- Address Foreign Institution Requirements

After The Review - Award

Discussions with Investigator

- Negotiate Funding Amounts
 - Study Section Recommendations
 - NIH and Institute Guidance
- Request Responses to Reviewer Concerns

Program Officials ...

can help **During Grant Oversight**



- Serve as resource and liaison
- Answer technical questions
- Provide information about funding opportunities
- Monitor progress of study

Grant Oversight

Annual Non-competing Renewal Applications *Progress Reports*

- Monitor scientific progress
- Confirm policy adherence
- Evaluate changes in key personnel or levels of effort
- Communicate your exciting results

Grant Oversight

Provide Technical Assistance to Grantees

- Process grant transfer to another institution
- Evaluate administrative supplement requests
- Facilitate collaborations
- Address tools or resource needs
- Explain grant policy
- Respond to emergency situations

Help Prepare Your Competing Renewal Application

Post-Award Issues and Actions

- ▶ Delay of First Year Award
- ▶ Annual Progress Report
- ▶ Delays of Non-Competing Continuation Award
- ▶ Actions Requiring Prior Approval
- ▶ Administrative Supplements
- ▶ Grant Termination

Delay of the First Year Award

- **Lack of Just-in-Time Information**
- **IRG Comments and Recommendations**
 - IRG recommends design changes or a reduction of scientific scope, budget, or time
 - Human subjects or animal welfare concerns
 - NIH requests a response to an administrative note
- **Data Safety Monitoring Plan requires NIH approval**
- **Lack of Data Sharing or Model Organism Sharing Plan**
- **Renegotiations of specific aims in response to NIH administrative reductions**
- **Foreign component needs State Department clearance**

Annual Progress Report

Due

- ◆ 60 days prior to budget period start date
- ◆ 45 days prior for eSNAP

Submit

Preferred via NIH eRA Commons

<https://commons.era.nih.gov/commons/index.jsp>

or to

Centralized NIH Receipt Point

see NIH Guide Notice [NOT-OD-04-063]

<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-04-063.html>

How NIH staff may use information from the progress report?

- Monitor developments of a specific project
- Monitor evolution of a specific field
- Highlight and publicize important research progress
- Brief the Institute Director
- Prepare reports for Congress
- Respond to inquiries

We keep unpublished information confidential until the day of publication and honor embargoes on journal articles.

Annual Progress Report

A clear and concise presentation of major highlights and/or problems encountered and possible resolutions

- Summary of accomplishments
 - Specific aims – as funded
 - Results – during reporting period
 - Significance
 - Plans for next budget period
- List of publications generated by project
- Explain any changes in Human Subjects or Vertebrate Animal Research
- Report on gender and minority inclusion
 - Inclusion Enrollment Report

Grant Checklist for the Program Official

Program Signoff Notes

1. Is progress satisfactory? (If no, explain.) [Add Comment](#)
2. Is there a change in the scope, goals, or objectives of the project?
3. If yes, does this change benefit the project and is it approved? (If not, explain.)
4. Is there a change in key personnel or their level of effort? (If yes, describe.)
5. If there are changes/concerns in the Multiple PI leadership plan, is the new plan acceptable?
6. Is there evidence of scientific overlap? (If yes, explain.)
-
13. If a progress report for a supplement is required, is progress reported and acceptable?
14. Are there other issues that should be resolved prior to issuing an award? (If yes, provide details.)
15. If any issues have not been resolved, should a restricted award be made?

Delay of Non-Competing Continuation Award

- Late submission of application
- Little or no progress with no discussion of problems and potential solutions
- Changes in Scope not approved in advance
- Inclusion Enrollment Report missing

Contact your program official early.

Actions Requiring Prior Approval

Change in Scope

- Significant change in aims, methodology, approach, or other aspects of project objectives
- Reflects significant change from the project as reviewed and approved

Examples:

- Change in **specific aims**
- Change to a **different animal** model
- Any change from the **approved use of animals or human subjects**
- Shift of research emphasis to a **different disease area**

Final approval of a change in scope requires concurrence of the NIH Program Official and Grants Management Specialist.

Actions Requiring Prior Approval

Change of Grantee Institution

Program Official assesses:

- Progress to date
- Adequacy of new resources and environment
- Availability of expertise (key personnel)
- Potential problems (e.g., equipment)

Contact NIH Program and Grants Management Staff early!

Actions Requiring Prior Approval

Change in Status of PI

- Change of PI
- $\geq 25\%$ change in PI effort
- PI absence of 90 days or more

Note: A project cannot be converted from a single PI to a Multiple PI project during a non-competing phase.

Types of Administrative Supplements

- Increase diversity in researcher community
- Cover unanticipated expenses of work within scope of grant
- Maintain lab or team during funding hiatus during competing continuation phase
- Closeout of grant

Supplements to Promote Diversity

- ▶ Research Supplements to Promote **Diversity** in Health-Related Research (PA-05-015)
 - Individuals from underrepresented racial and ethnic groups
 - Individuals with disabilities
 - Individuals with disadvantaged backgrounds
- ▶ Supplements to Promote **Reentry** into Biomedical or Behavioral Research Careers (PA-04-126)
 - Individuals with high potential to reenter research after taking time off to care for children or attend to other family responsibilities

Supplements: Unanticipated Expenses of Work Within Scope of Grant

- Catastrophes or natural disasters
- Critical equipment breakdowns
- Loss of source for critical reagents

Generally one-time supplement

- **Cannot be used for changes in scope.**
- **Not intended to cover inflationary increases in supplies, animal care, etc.**

Supplements: Bridge or Interim Funding

2008 NIH Director's Bridge Awards

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-037.html>

Interim Funding (Institute specific)

- High likelihood that amended application will improve enough to be funded
- Avoid disruption caused by loss of personnel or scientific momentum
- Maintain a unique or critical resource

Supplements: Closeout of Grant

VERY RARE!

- Finish work that would be of clear benefit to NIH and research community
- R01 Clinical Trials where termination without completion of studies is particularly undesirable

Quick quiz

The PI's recent productivity is down. The PI does not feel ready to apply for a competing continuation R01 award. The PI needs more time to complete and publish new manuscripts (*at least 9 months*).

What are the option(s)?

No Cost Extension:

- Grantee may extend at the end of the project period *up to 12 months* without prior approval
- Notify NIH
 - Within 90 days prior to the expiration date of the project period
 - Up to the last day of the project period
 - Submit via the NIH Commons

See NIH GPS Summary of Expanded Authorities

http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm

Grant Termination

Early Termination

PI leaves research project without qualified and willing replacement

PI changes research direction or takes on new projects

After Termination

Grantee legally bound to submit

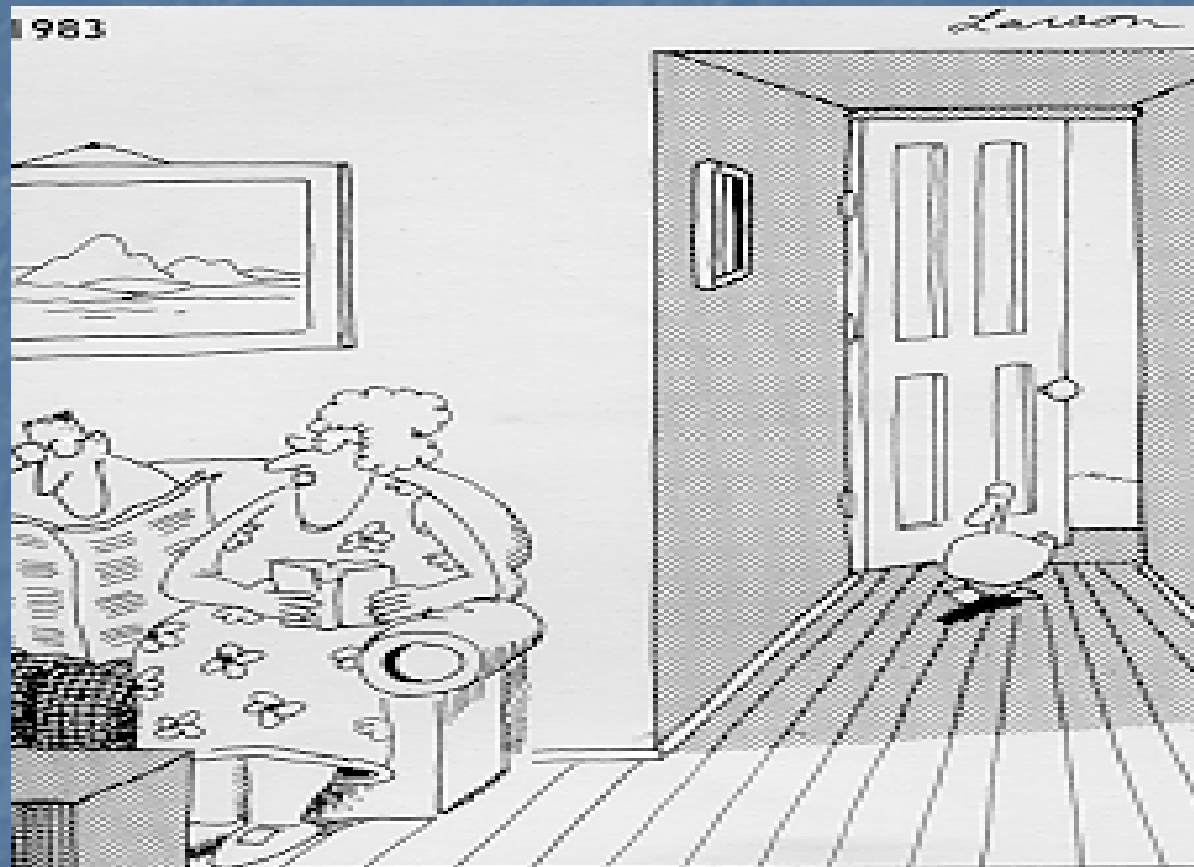
- Final Financial Status Report
- Final Invention Statement and Certification
- Final Progress Report

**Failure to submit timely final reports
may affect future funding**

RESOURCE WEB LINKS

- Office of Extramural Research Grants Home Page:
<http://grants.nih.gov/grants/oer.htm>
- NIH Grants Policy Statement (12/03):
http://grants.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Guide: <http://grants.nih.gov/grants/guide/index.html>
- PHS 398 Application (form pgs are PDF-fillable):
<http://grants1.nih.gov/grants/funding/phs398/phs398.html>
- PHS2590 Progress Report (form pgs are PDF-fillable):
<http://grants.nih.gov/grants/funding/2590/2590.htm>
- Handy Reference: Activity Code, Organization Codes and Definitions Used In Extramural Programs:
<http://grants.nih.gov/grants/funding/ac.pdf>

*We try to be helpful, but ...
we do have our limits*



Here he comes, Earl. Be gentle but firm. We are absolutely, positively not driving him south again this winter.

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>

