

**How The NIH Program  
Official Works With  
Investigators**

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and  
Roger Sorensen, NIAAA

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**Take-Home Message**

- Communicate
  - with NIH staff
  - with Investigators
  - with Institutional Administrators

<http://www.nih.gov>

There are many at NIH whose job it is to help applicants <sup>2</sup>

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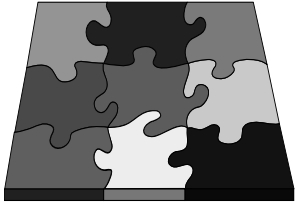
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**Finding Your Way at  
NIH**



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

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## NIH Research Programs

Institutes and Centers

- Divisions
- Branches
- Programs



Where do I find a guide?

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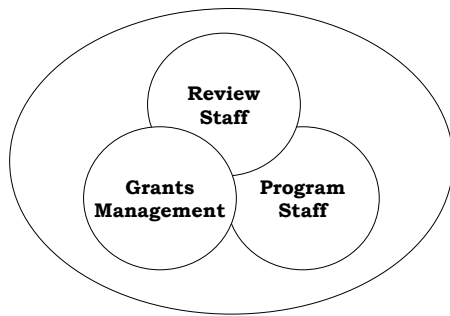
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## The NIH Extramural Team



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## NIH Program Staff: *Your Guide to Success*



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

Responsible for the  
programmatic,  
scientific,  
technical  
aspects of a grant

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**Who/What is a Project Officer/Program Director?**



The Project Officer/Program Director is both  
a Scientist and an Administrator

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**Responsibilities of the Program Official**

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

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## Responsibilities of the Program Official

- Provide technical assistance to applicants
- Observe scientific review meetings
- Discuss review issues with applicant
- Evaluate the programmatic merit and mission relevance of applications
- Prepare funding recommendations
- Review annual research progress of grantees
- Report on scientific progress and program accomplishments

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## Responsibilities of the Program Official

*An Important Resource for Applicants & PIs*

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## Program Official

*Principal liaison between investigators and the NIH*

Your most important contact

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

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**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*

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**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*

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**Must I contact NIH before applying?**

*Yes ... under certain circumstances*

- 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)
- RFA's request Letter of Intent
- Contact with program staff is always **highly recommended**

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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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## Your Program Officer Can Help ...



*During Application Development  
and Preparation*



*During Scientific Review*



*After Peer Review*

*After the Grant Award*



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## Developing the Application: Your Idea



**Your Research Needs and  
Interests**

- *My research interests focus on  
the link between widgets and  
type II diabetes*
- *My thesis advisor told me to  
apply for a fellowship grant*

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## Develop Your Application For NIH

*A Program Officer can discuss*

➤ *Your ideas*

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

➤ *NIH ideas*

- *Research Initiatives and Priorities*

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## Developing the Application: NIH Ideas

### 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/](http://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>

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## Program Officers ...

*can help* **During Application Preparation**



- Concept paper
- Budget issues
- NIH requirements
- "Technical Assistance"

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## 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 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** (*Nice to know if you have gone this far*)

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## 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

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## Develop Your Application

*Suggest the Appropriate Grant Mechanism*

- Training
- Career Development
- Research Project

*Explain the difference between PAs, RFAs, RFPs*

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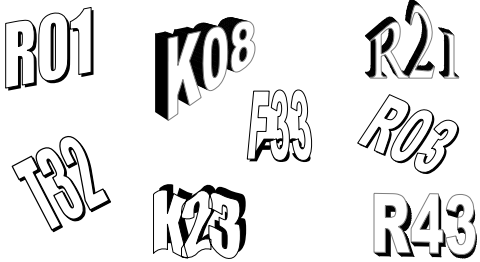
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## NIH Award Mechanisms



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## Grant Award Mechanisms

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

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## 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

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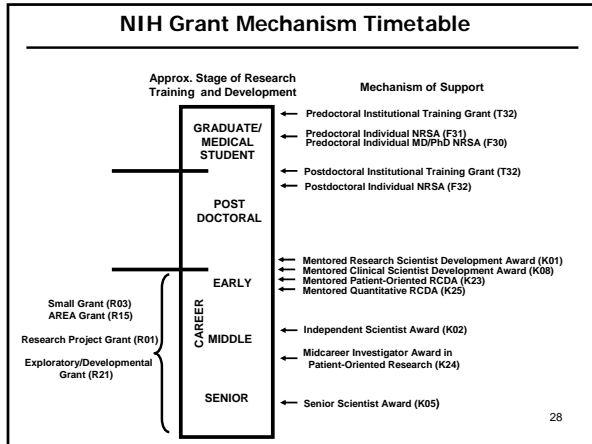
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*What will make your grant application experience unpleasant?*

The Failure to take care of things under your control will lead to frustration and lack of success!

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### When Preparing an Application

- Read instructions and read them again
- Read the Program Announcement again
- Never assume that reviewers "will know what you mean"
- Refer to literature thoroughly, make sure it is current
- State rationale of proposed investigation
- Include well-designed tables and figures
- Present an organized, lucid write-up
- Obtain pre-review from faculty at your institution
- Understand what aspects of the application process you have some control over

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***Problematic Applicant Behavior***

- Submitting an application without prior contact and discussion with program staff
- Submitting a poor, inappropriate or undeveloped research idea (e.g., idea or approach is dated, ignores newer research, doesn't address prevailing opinion in scientifically constructive fashion)
- Poor follow through/missed deadlines
- Not sensitive to NIH staffer's time, expects instant access, immediate feedback
- Overly defensive/resistant to suggestions or criticisms related to your ideas and plans

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***More problematic behavior***

- Resistant to suggested revisions offered by peer reviewers
- Unreasonable requests, e.g, money, override review procedures/decisions, allowable expenses
- Wanting NIH staff to solve applicant's institutional problems
- Rude/Snide comments about government or government employees

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**What/Who Determines which applications become grants?**

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

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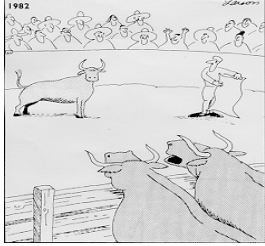
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## Program Officers ...

*Give advice and encouragement!*



**The cape, Larry! Go for the cape!**

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## Program Officers ...

*can help During Scientific Review*

- Answer your questions about grant review
- Be a Liaison to the SRA
- Attend review group meeting



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## Submit Your Application

*Answer your Questions about  
review of applications*

*SRA is in charge of study section review  
but the Program Official can:*

*Discuss and explain grant assignments*

- *Institute and Study Section*

*– Helps to navigate peer review process*

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## Submit Your Application

### *Be a Liaison to the SRA*

*SRA is in charge of study section review  
but the Program Official can:*

- *Convey to the SRA*
  - *Requests to submit additional data*
  - *Missing elements of your application*
  - *Notifying of accepted papers*
  - *Concerns of study section and reviewers*

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## Submit Your Application

### *Attend Study Section Review*

*SRA is in charge of study section review  
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 purpose of Program Initiatives when requested by SRA*

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## Program Officers ...

can help After Peer Review

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

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## After Peer Review

What does the Priority Score and Percentile Indicate .... Funding?

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

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## 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

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## After Peer Review

### Attend National Advisory Council Review

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

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## After Peer Review

### Prepare Funding Recommendations to Institute Director

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

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## Program Officers ...

can help After Peer Review



If funding seems likely:

Consult with applicant on key issues:

- Budget
- Human subjects
- Administrative requirements

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## 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

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## After The Review - Award

### Discussions with Investigator

- Negotiate Funding Amounts
  - Study Section Recommendations
  - NIH and Institute Guidance
  
- Request Rebuttal of Reviewer Concerns

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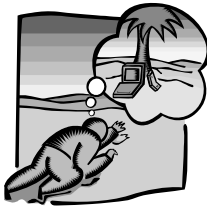
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## Program Officers ...

can help **After Peer Review**

If funding seems **unlikely**:



- Consult with applicant on possible next steps:
- Responding to reviewer concerns
  - Revisions and resubmission

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## 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!*

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## After The Review - Revisions

### Changes to Application

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

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## Program Officers ...

can help During Grant Oversight



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

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## 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

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## 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*

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*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.

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## 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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