How The NIH Program Official Works With Investigators

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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

Finding Your Way at NIH

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

NIH Research Programs

- Institutes and Centers
- Divisions
- Branches
- Programs

Where do I find a guide?

The NIH Extramural Team

Program Official

[aka Program Director or Project Officer]

Responsible for the programmatic, scientific, technical aspects of a grant
Who/What is a Project Officer/Program Director?

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

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)

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

Responsibilities of the Program Official

An Important Resource for Applicants & PIs

NIH Program Staff: Your Guide to Success

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**

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

Your Program Officer Can Help ...

- During application preparation and submission
- During scientific review
- After the review
- After the grant award

Program Officers ...

Can help during application preparation

- Idea development
- Institute emphasis areas
- Selection of grant mechanism
- Contact with other investigators

Program Officers ...

Can help during application preparation

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

Develop Your Application

**Discuss Scientific Ideas**

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

- **NIH ideas**
  - Research Initiatives and Priorities
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

Developing the Application: NIH Ideas

NIH Institute Program Priorities
- Search CRISP to learn what research is supported
- Search Institute Web Sites
- Contact Institute Staff
- Identify Relevant RFA or PA in NIH Guide

NIH GUIDE for Grants and Contracts
U.S. Department of Health and Human Services

- Announces NIH Scientific Initiatives
- Provides NIH Policy and Administrative Information

What is a RFA and PA?

RFA: Request for Application
- Stimulates research in understudied areas
- Grant proposals target well-defined scientific area
- A one-time competition for set aside funds

PA: Program Announcement
- Communicates new, continuing, or expanded research interests of an Institute/Center
- Announces the availability of a new mechanism of support
- Remains active for 3 years

Develop Your Application

Suggest the Appropriate Grant Mechanism
- Training
- Career Development
- Research Project

NIH Award Mechanisms
Types of Awards

• **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

Grant Award Mechanisms

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

NIH Grant Mechanism Timetable

<table>
<thead>
<tr>
<th>GRADUATE/ MEDICAL/ STUDENT</th>
<th>MECHANISM OF SUPPORT</th>
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<tr>
<td>POST DOCTORAL</td>
<td>Predoctoral Training Grant (T32)</td>
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Who is Eligible for an NI H Grant?

• A qualified scientist at an institution that can provide the needed resources.
• Awards to foreign institutions for projects not having comparable research in the U.S.
• For most training and career awards, person needs U.S. permanent residency by the time of award.
• Grants are awarded to institutions, not individuals (Except for fellowships).

Must I contact NI H before applying?

Yes ... under certain circumstances

- Applications with budgets ≥$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

Contact before submission has benefits

Two more important reasons

- Develop a relationship with a potential program officer
- Assure that your application has a home
Develop Your Application

Obtain 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

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

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!

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

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

What/Who Determines which applications become grants?
- Scientific merit (Review Group)
- Program Considerations (Program Officer, Advisory Council, IC Director)
- Availability of funds
Program Officers ...
Give advice and encouragement!

The cape, Larry! Go for the cape!

Program Officers ...
can help during scientific review
- Answer your questions about grant review
- Be a Liaison to the SRA
- Attend review group meeting

Submit Your Application
Answer your Questions
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

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

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

Program Officers ...
can help after the review
- Priority Scores and Percentiles
- Study Section Review
- National Advisory Council Review
- Prepare Funding Recommendations
After The Review

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

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

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

Attend National Advisory Council Review

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

Prepare Funding Recommendations to Institute Director

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

Program Officers ...

*can help after the 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 Rebuttal of Reviewer Concerns

**Program Officers ...**

*can help after the 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!*

**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

**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

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.

Need Help with Your Application?...
Who Ya’ Gonna’ Call?

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