The National Institutes of Health is an Agency of the US Public Health Service

**Mission:** research, **training**, education
- 27 Institutes & Centers (I/C)

**Budget:** FY14 = $30.08 billion

Dr. Francis Collins
NIH Director

Dr. Francis Collins
NIH Director

Dividing up the $30 billion NIH pie . . .

NIH provides funding for career development at different stages

©2014 Robert J. Milner, Ph.D. & Joan M. Lakoski, Ph.D.
K99/R00 Awards combine elements of K and R (research) awards

- student
- post doc
- resident
- junior
- faculty
- senior
- faculty
- F31
- F30
- F32
- K Awards
- K99/R00 Award
- R01

NIH has several programs targeted to New & Early Stage Investigators


Definition of New & Early Stage Investigators

New Investigator:
- has not been PI on a significant NIH research grant (e.g., R01)
- can have held small research grants (e.g., R03, R21), K awards, Fellowships

Early Stage Investigator (ESI):
- a new investigator within 10 years of doctorate or completing residency
Status defined in your eRA Commons profile

Make sure that your profile is current!
You must have an eRA Commons username to submit applications to NIH

Contact your Office of Research to set up account!

Extramural Research in each NIH Institute is organized into Programs

Each Program covers an area of research

Program Officers:
• administer funded grants in their area

Each NIH Institute has a Program Officer for training & career development

*Cultivating the interest and support of program officers is essential*

Before applying you must obtain & be familiar with three sources of information

SF424 (R&R)
Application Guide
*For Adobe Forms Version C*

Program Announcement (PA) for your Award
(e.g., K01, K08)

Application Form for your Award
(e.g., K01, K08)
Application Package: PHS SF424 (R&R)
Download instructions for application
Version C is current!

Read the Program Announcement (PA)
— link to application package & download

Your institution may use a software system to interface with Grants.gov

The interface may be more user-friendly but the components you need to write are the same
— contact your Grants Office for more details
The application consists of electronic forms + attachments (pdf)

Format for attachments is defined:
- single-spaced
- specific fonts & sizes
- single column
- minimum margins

Applications that do not conform may be returned without review!

The electronic submission system assembles the separate pdfs & forms into a single application

You attach pdfs & upload the forms

eRA system assembles a single application

Your grant

The NIAID website has excellent resources on Grant Writing

http://www.niaid.nih.gov/researchfunding/grant/Pages/applying.aspx
The Grant Triangle defines the relationship between you, your institution, and NIH

The Grant Review Process — Important Concepts

Applications must be submitted from a recognized institution

Each application has two independent reviews within NIH: “Dual Review”

Funding goes to the investigator’s home institution not the investigator

Most grant reviews at NIH are managed by the Center for Scientific Review (CSR)

Independent unit within NIH separate from Institutes

Administers review panels (Study Sections)

Receives & assigns applications:
  • to Study Sections for review
  • to Institutes for funding

Some types of proposals are reviewed by panels within NIH institutes

NIH Study Sections usually meet for 1–2 days, 3 times per year

Members:
- working scientists (~15-30)
- one member serves as Chair

Scientific Review Officer (SRO):
- NIH staff person
- assigns grants to reviewers, collates reviews etc

Each proposal is reviewed by 2–3 reviewers

The review criteria are defined for each application type

Each assigned reviewer provides written critiques submitted before the meeting

Each proposal gets an Impact Priority score:
- scale: 10 (exceptional) to 90 (worst)
- bottom 50% of applications may be unscored

Each reviewer gives a score on a range of 1 (exceptional) to 9 (poor)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Non-numerical score options: NR = Not Recommended for further consideration; IF = Inferred; D = Data not available; OF = of Concern; SP = of Substance; NA = Not Available; ND = Not discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lowers impact
Major Weakness: A weakness that severely limits impact

For K awards 5 individual criteria are also reviewed & scored on the 1-9 scale

- Candidate
- Career Development Plan
- Research Strategy
- Mentor
- Environment & Institutional Commitment

*These criteria are applied differently for different K award types*

Other criteria are reviewed for adequacy

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Select Agents
- Education in Responsible Conduct in Research (RCR)
- Budget and Period of Support
- Resource Sharing Plans

A typical sequence of review . . .

1. process moderated by Chair
2. reviewers indicate preliminary enthusiasm
3. primary & secondary reviewers present
4. tertiary reviewer comments
5. open discussion among panel
6. reviewers recommend final scores
7. all panel members score application
8. SRO writes summary of discussion
What happens next . . .

Written reviews & scores (summary statements or “pink sheets”) are collated by SRO & distributed to applicant via the eRA Commons.

The Institute Advisory Council determines the payline based on available funding:
• approves grants for funding

Notice of Award sent to applicant & institution

---

Step 1  Start the Application

An Idea
A Mentor
An Institution

---

Step 2  Start with the right attitude

---
**Step 3**  Find Information & Make Connections

**Step 4**  Frame the Question

Define the specific aims of your proposal

↓

**A Testable Hypothesis**

_Funded_  
*Good research is hypothesis driven*

**Step 5**  Define the Goals

- Research Plan
- Training Program

What you’ll accomplish  ↔  What you’ll learn

©2014 Robert J. Milner, Ph.D. & Joan M. Lakoski, Ph.D.
Justify the proposal by describing how it fits into your career development

Consider your long-term career goals
Describe your previous scientific history
Describe how the award will enable you to enhance your career objectives

Contact References

K Award & Fellowship applications require at least 3 letters of reference

3–5 letters from individuals other than those involved in the application
i.e., not sponsor/mentor or collaborators
The letters should address the candidate’s competence & potential as an independent investigator

The list of referees (including name, departmental affiliation, and institution) is included in Other Attachments on the Other Project Information Form AND in the Cover Letter Attachment.
Reference letters are submitted by your referees through the eRA Commons

Instructions for referees:
— Fellowships:
  see Fellowship SF424 Instructions (Section 5.4)
— Career Awards:
  see SF424 Instructions (Section 7.3)

Send instructions to each referee

*Letters must be submitted* by the application deadline*

Tips for Best Reference Letters

Develop effective working relationships with potential referees
Keep your referees updated on your progress
Make your referees’ job easy, provide:
  – current CV, reprints
  – draft of proposal

*Remember: this is a personal & professional relationship that may last your entire career*

Step 7  Stock the Reservoirs

*Specific Aims*  *Background Significance*  *Experimental Plan*
Step 8 | Draft the proposal

Research Plan “should be appropriate to develop skills needed by a researcher”

- should be hypothesis-driven
- not overly ambitious or routine

**Format of the Research Plan:**
Specific Aims (1 page)
Research Strategy:
  a) Significance
  b) Innovation*
  c) Approach

*Innovation Section not required for Fellowship applications unless specified

To communicate effectively your proposal should answer these questions:

**Significance:**
- Why is this study important?
- How will it change the field?

**Innovation:**
- What is novel about the proposed research?

**Approach:**
- Are the experiments feasible?
- What will be accomplished?

*Keep it simple, concise & logical!*

©2014 Robert J. Milner, Ph.D. & Joan M. Lakoski, Ph.D.
Crafting a successful proposal requires good communication skills

*Know your audience:*

“The Reviewer at Work”

Design a clear experimental plan

- have a clearly stated, testable hypothesis
- keep the proposal focused
- indicate outcomes: what will you learn?
- anticipate pitfalls; outline alternatives
- provide a timeline: limit the experiments to what can be accomplished within the time period

Write the review for the reviewer . . .

“The outcome of these experiments will be . . .”
“The significance of the results is . . .”
“The feasibility of this approach is demonstrated by . . .”
“This proposal will advance knowledge of . . .”

*Keep it simple, concise & logical!*
Above all, remember . . .

A funded proposal is a successful act of communication

Step 9 Build a Model

Specific Aim # 1

Specific Aim # 2

Specific Aim # 3

Step 10 Get feedback!

Mentor

Advisor

Applicant

Chair

Colleague

Ask someone who is not in your field to read your proposal!
Step 11: Comply with the regulations (in good time!)

Assurances/Certifications
- Human Subjects
- Animal Welfare
- [ ]
- [ ]
- [ ]

You must include plans for instruction in Responsible Conduct in Research

NIH has defined guidelines for Instruction in Responsible Conduct in Research (RCR)

“Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process or not reviewed.”

NIH now has very specific requirements for RCR instruction

Instruction must recur at each career stage (student, postdoc, faculty)
Face-to-face instruction is required (min. 8 hours)
(online courses alone are not sufficient)
Your application must address
5 Instructional Components:
   1. Format of Instruction
   2. Subject Matter
   3. Faculty Participation
   4. Duration
   5. Frequency

©2014 Robert J. Milner, Ph.D. & Joan M. Lakoski, Ph.D.
Step 12  Manage your Mentor

- Sponsor's Checklist
- Mentor's Statement
- Environment & Institution
- Feedback on draft

Step 13  Proof & spell check

Step 14  Submit the proposal
Plan ahead for resubmission!

18 months

Step 15 Receive & respond to reviews

The Decision

Reject

Reapply

Funded