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

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

**Budget:** FY16 = $31.3 billion

<table>
<thead>
<tr>
<th>Intramural (10%)</th>
<th>Extramural Research &amp; Training (81%)</th>
<th>( \text{FY2016 NIH Budget} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>\text{Dr. Francis Collins}</td>
<td>\text{NIH Director}</td>
<td>\text{Research Projects (53%)}</td>
</tr>
</tbody>
</table>

NIH provides funding for career development at different stages

- **student**
- **post doc**
- **residents**
- **junior faculty**
- **senior faculty**

**career development awards**

- F31
- F32
- K Awards

**K99/R00 Awards combine elements of K and R (research) awards**

- **student**
- **post doc**
- **residents**
- **junior faculty**
- **senior faculty**

**K99/R00 Award**

- F31
- F32
- K Awards
- R01

NIH has several programs targeted to New & Early Stage Investigators

- **New Investigator (NI)** has not received a substantial NIH research grant (e.g., R01)
  - can have held small research grants e.g., R03, R21, R00, or K awards, Fellowships
  - but not major research awards: R01, P01

- **Early Stage Investigator (ESI)** is a New Investigator within 10 years of completing research training
  - within 10 years of completing doctoral or residency
  - status defined in your eRA Commons profile by:
    - date of doctoral degree
    - date completed residency

  *Make sure that your profile is current!*

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You must have an eRA Commons username to submit applications to NIH

[Image: https://commons.era.nih.gov/commons]

Contact your Office of Research to set up account!

NIH has a newly-designed website for career development and training

[Image: https://researchtraining.nih.gov]

Extramural Research in each NIH Institute is organized into Programs

- Each Program covers an area of research or training
- Program Officers administer funded grants in their area
- There are program officers for training and career development programs

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

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

- **SF424 (R&R) Application Guide**
  - Currently Version D
- **Program Announcement (PA)**
  - for your Award (e.g., K08)
- **Application Form**
  - for your Award (e.g., K08)

SF424 (R&R) Instructions have recently been revised and are more user-friendly

Specific Instructions for different award mechanisms:

- General Instructions
- Fellowship Awards
- Career Awards


Read the Program Announcement (PA) — make sure you have the most current!

[Image: PA-16-191]

Use the “parent” program announcement only for unsolicited applications.

Use the appropriate Funding Opportunity Announcement (FOA) for institute-specific awards.
The Program Announcement or Funding Opportunity Announcement will have a link for applications.

| Apply online using ASSIST: Application Submission System & Interface for Submission Tracking | Download forms for submission through Grants.gov |

The application consists of electronic forms + attachments (pdf)

- 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

system assembles a single application

Your grant

The Grant Triangle defines the relationship between you, your institution, and NIH

Investigator

Home Institution

NIH

Study Section

Council

Program Council

Program Institute

1. application

2. home institution

3. NIH Institute

4. Council

5. funding

6. home institution administers the grant for the investigator

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
Receives & assigns applications:
- to Study Sections for review
- to Institutes for funding
Administers review panels (Study Sections)

Some proposals are reviewed 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 typically reviewed by 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

For K awards 5 individual criteria are also reviewed and 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 Define the specific aims

What you expect to accomplish:
- should be a test of your hypothesis

At this point get a reality check:
- consult colleagues/mentors:
  - is the question important?
  - is the approach logical?
  - are the experiments feasible?

Step 5 Define the Training Goals

Research Plan

Training Program

What you’ll learn

What you’ll accomplish

Afternoon session: “Writing Effective Specific Aims”
The proposal must tell a coherent story about you and your research career and goals

- Past history
- Your proposal
- Future career

What have you done already?
How are you going to get there?
Where do you want to be?

Step 6 Plan the proposal

Front pages:
- Budget
- Human subjects
- Animal welfare
- Biosketches

Proposal:
Specific aims

Research plan:
A. Significance
B. Innovation
C. Approach

Allow enough time to prepare!

Step 7 Contact references & collaborators

Fellowship and career development applications require at least 3 letters of reference

Letters should address candidate’s competence & potential as an independent investigator
- 3–5 letters from individuals other than those involved in the application — i.e., not sponsor/mentor or collaborators
- Thesis advisor for postdoc fellowships (or explain why not)
- At least one referee not in applicant’s current department

The sponsor (mentor) cannot be a referee.

Reference letters are submitted by your referees through the eRA Commons

The referees (name, department, institution) must be listed in the Cover Letter Attachment
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
Crafting a successful proposal requires good communication skills

**Know your audience:**

“The Reviewer at Work”

Your goal is to excite and persuade your reviewer

How do you want the reviewer to react to your proposal?

To communicate effectively your proposal must answer these questions:

- Why is this study important?
- What will be accomplished?
- Are the experiments/approaches feasible?
- What obstacles might be encountered?
- What alternative strategies will be used?

*Keep it simple, concise & logical!*

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

The NIAID website has excellent resources on Grant Writing

http://www.niaid.nih.gov/researchfunding/grant/Pages/aag.aspx

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 Manage your mentors & colleagues

Checklist
- Mentor’s Statement
- Environment & Institution
- Feedback on draft

Step 11 Comply with the regulations

Assurances/Certifications
- Human Subjects
- Animal Welfare
- 
- 
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Respect the work of your Office of Research and submit materials in good time!

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You must include plans for instruction in Responsible Conduct of Research

Follow NIH guidelines for Instruction in Responsible Conduct of Research

NIH has very specific requirements for RCR instruction

Instructions 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

Step 13 Proof and spell check

Step 14 Submit the proposal

Use the new Assignment Request Form to request assignment to a NIH Institute and/or Review Panel

Step 15 Receive and respond to reviews

The Decision

Reject
Reapply
Funded

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