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

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

Budget: FY15 = $30.31 billion

| Intraural (10%) | Extramural Research & Training (81%) |

Dividing up the $30 billion NIH pie . . .

Research Projects (53%)
Career Development Awards ~$615 million (~2%)

NIH provides funding for career development at different stages

student → post doc → resident → junior faculty → senior faculty

F31 → F32 → K Awards
R01

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

student → post doc → resident → junior faculty → senior faculty

F31 → 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

Extramural Research in each NIH Institute is organized into Programs

Contact your Office of Research to set up account!

Cultivating the interest and support of program officers is essential!

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

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

Application Package: PHS SF424 (R&R)

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

Version C is current

(Version D is coming in 2016)

Read the Instructions!

Watch for changes in forms and instructions for applications submitted in 2016!

Use the “parent” program announcement only for unsolicited applications

Use the appropriate Funding Opportunity Announcement (FOA) for institute-specific awards

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)
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

ASSIST is a new NIH system for online grant application

http://grants.nih.gov/grants/ElectronicReceipt/assist.htm

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

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
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 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

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

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

<table>
<thead>
<tr>
<th>Impact Score</th>
<th>Description</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>Poor</td>
<td>Weaknesses but with at least one major weakness</td>
</tr>
</tbody>
</table>

Non-numerical score options:
- NA = Not Recommended for Further Consideration
- DF = Deferred
- AD = Abortion
- CF = Conflict
- IP = In Progress
- ND = Not Discussed
- Minor Weakness: An easily addressable weakness that does not substantially lessen impact
- Moderate Weakness: A weakness that adversely limits impact
- Major Weakness: A weakness that severely limits impact


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

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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

A summary of your proposal
— What is the research question?
— What is the hypothesis?
— What are the outcomes?

Get feedback from experienced colleagues (reality check!):
• 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 accomplish  
What you’ll learn

**Step 6** Plan the proposal

Front pages:
- budget
- human subjects
- animal welfare
- biosketches

Proposal:
- Specific Aims
- Career Goals
- Training Plan
- Research Plan

*Allow enough time to prepare!*

**Step 7** 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*

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**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*

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**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

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**Crafting a successful proposal requires good communication skills**

*Know your audience:*

“*The Reviewer at Work*”

---

**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!*

---

**Your goal is to excite and persuade your reviewer**

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

!!!

#%&

*ZZZZZZZ*
You must communicate:

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

[Image: https://www.niaid.nih.gov/researchfunding/grant/Pages/applying.aspx]

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

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**Step 10** Get feedback!

Ask someone who is not in your field to read your proposal!

**Mentor** ➔ **Advisor** ➔ **Applicant** ➔ **Chair** ➔ **Colleague**

**Step 11** Comply with the regulations

**Assurances/Certifications**
- Human Subjects
- Animal Welfare
- 
- 
- 

*Respect the work of your Office of Research and submit materials in good time!*

**You must include plans for instruction in Responsible Conduct in Research**

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

Update on the Requirement for Instruction in the Responsible Conduct of Research

**NOT-OD-10-019**

“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

**For all grant submissions on or after May 25 the biosketch must be in the new format**

*new section: Contributions to Science*

Briefly describe up to five of your most significant contributions to science

Include a link (URL) to a complete bibliography in a public database (SciENcv or My Bibliography)

You can use SciENcv to generate your CV online:


**Step 12** Manage your Mentor

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

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Step 13  
Proof & spell check

Step 14  
Submit the proposal

There are three deadlines per year for submission of NIH Awards

K awards:

<table>
<thead>
<tr>
<th>Receipt</th>
<th>Review</th>
<th>Council</th>
<th>Start</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 12</td>
<td>June-July</td>
<td>Sept-Oct</td>
<td>December</td>
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<tr>
<td>June 12</td>
<td>Oct-Nov</td>
<td>Jan-Feb</td>
<td>April</td>
</tr>
<tr>
<td>Oct 12</td>
<td>Jan-Feb</td>
<td>May-June</td>
<td>July</td>
</tr>
</tbody>
</table>

Applications must be received electronically at NIH on or before the receipt date.

Your Office of Research will require proposals to review before the NIH deadline.

Plan ahead for resubmission!

18 months

The Decision

Reject

Reapply

Funded