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

Mission: research, training, education
— 27 Institutes & Centers (I/C)
FY17 Budget = $33.3 billion
$2 billion increase over FY16

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

NIH provides funding for career development at different stages

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 doctorate or residency
- status defined in your eRA Commons profile by
  — date of doctoral degree
  — date completed residency

Make sure that your profile is current!
NIH has programs to assist New and Early Stage Investigators

Specific award mechanisms:
- K99/R00 Pathway to Independence Award
- Director’s New Innovator Award

Early Stage Investigators receive special consideration for R01 applications:
- some Institutes define increased paylines
  - NCI: 12% vs 10%
  - NHLBI: 10% above the R01 payline

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

Contact your Office of Research to set up account!

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

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
Version E coming in 2018

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

Application Form for your Award
(e.g., K08)

Changes in Forms E focus on Human Subjects and Clinical Trials

- Consolidation of information on Human Subjects & Clinical Trials into a new form
- Additional review criteria for proposals involving clinical trials

Applies to all applications submitted on or after January 25, 2018

see: NIH Notice NOT-OD-17-199
NIH restricts what can be included in the Appendix

For all applications submitted on or after January 25, 2018, the only allowable appendix materials are:
- Blank data collection forms, blank survey forms and blank questionnaire forms -- or screenshots thereof.
- Simple lists of interview questions
- Blank informed consent/assent forms
- Other items only if they are specified in the FOA as allowable Appendix materials

Applications that do not follow the appendix requirements will not be reviewed!

See: NIH Notice NOT-OD-17-098

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!

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

Three ways to submit an NIH application:

1. Use the NIH ASSIST system to prepare, submit and track your application online

Apply Online Using ASSIST

2. Use an institutional system-to-system (ST2) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your Institutional offices regarding availability.

3. Go to Grants.gov to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov; and track your application in eRA Commons.

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!

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

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

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

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

NIH Study Sections and membership rosters are listed on the NIH website

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

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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

Each assigned reviewer recommends an impact 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>1 Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2 Outstanding</td>
<td>Strongly strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3 Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4 Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5 Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6 Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7 Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8 Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9 Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Non-normative score options: NR = Not Recommended for Further Consideration,
CR = Conflict, SI = Insufficient, TR = Not Reviewed, SD = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Major Weakness: A weakness that severely limits impact

See: NIH Notices NOT-OD-17-121 & NOT-OD-17-122

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

For applications submitted on or after January 25, 2018

Fellowship Awards:
- Do the sponsors have the necessary skills in clinical trials?
- Will the experience add to the training of the candidate?

Career Development Awards:
- Does the candidate have necessary skills and/or training?
- Will the experience add to the training of the candidate?
- Is the study justified and feasible?
- Is the study designed appropriately?
- Do the sponsors have the necessary skills in clinical trials?

see: NIH Notices NOT-OD-17-121 & NOT-OD-17-122

There will be additional review criteria for proposals involving Clinical Trials

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. reviewers present their critiques
4. open discussion among panel
5. reviewers recommend final scores
6. all panel members score application
7. SRO writes summary of discussion

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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

15 Steps to the Payline: Checklist

Steps 1-5

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?

Afternoon session: “Writing Effective Specific Aims”

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Step 5 Define the Training Goals

Research Plan  
Training Program

What you’ll accomplish  
What you’ll learn

The proposal must tell a coherent story about you and your research career and goals

Step 6 Plan the proposal

An application typically has two parts  
— make a plan to complete both

Proposal
- specific aims
- research plan
- candidate
- career goals
- training plan

Front pages
- cover page
- budget
- human subjects
- animal welfare
- biosketches

Start early and allow time to get feedback!  
Comply with your Research Office!

Allow enough time to prepare!

Step 7 Contact references & collaborators

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 mentor or collaborators
- at least one referee not in applicant’s current department

The mentors cannot be referees.

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!


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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

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 . . .”

A funded proposal is a successful act of communication

Above all, remember . . .

Keep it simple, concise & logical!

The NIAID website has excellent resources on Grant Writing . . .

https://www.niaid.nih.gov/grants-contracts/apply-grant

Step 9 Build a model

Step 10 Get feedback

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

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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!

NIH 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

You must include plans for instruction in Responsible Conduct of Research

Follow NIH guidelines for Instruction in 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.”

Step 13  Proof and spell check

Submit the proposal

Step 14

The Decision

Reject
Reapply
Funded

Step 15  Receive and respond to reviews

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