Steps to a Competitive Application
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The National Institutes of Health is an Agency of the US Public Health Service

Mission: research, training, education

FY19 Budget = $39 billion
$2 billion increase over FY18

Intramural (10%)
Extramural Research & Training (81%)
Admin (9%)

Dr. Francis S. Collins
NIH Director

Research Projects (53%)
Career Development Awards
$688 million* (~2%)

*FY2017 NIH Budget (data not available for FY2018)

NIH provides funding for career development at different stages

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

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!

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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

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

SF424 (R&R)
Application Guide
Currently Version E

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

see: NIH Notice NOT-OD-17-119

NIH restricts what can be included in the Appendix

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 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.
   - ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
   - custom software

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

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

- The CAYUSE system 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

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

1. An application is initiated & prepared by an investigator.
2. Application is submitted to NIH through the investigator’s home institution.
3. A NIH study section reviews the proposal & the score is sent to a NIH Institute.
4. The Institute Council decides whether to fund the grant.
5. An Institute Program sends funding for the grant to the home institution.
6. The home institution administers the grant for the investigator.

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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

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

Request NIH Institute
Request review panel
List individuals who should not review

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

Standing membership and rosters for last three meetings

Roster will also be listed on a summary statement (grant review)

https://public.csr.nih.gov/StudySections

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

Each assigned reviewer recommends an impact score on a range of 1 (exceptional) to 9 (poor)

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*

There are additional review criteria for proposals involving Clinical Trials

**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-17-122](#) [NOT-OD-18-109](#)

Note NIH requirements on “Implementing Rigor and Transparency”

Four areas must be addressed:

1. strengths & weaknesses in the **rigor of the prior research**
   - In Significance Section of Research Strategy
2. rigorous experimental design for robust and unbiased results
   - In Approach Section of Research Strategy
3. consideration of relevant biological variables
4. authentication of key biological and/or chemical resources
   - Attachment: Item 15 Other Research Plan

see: NIH Notice NOT-OD-16-011

*NEW* see: NIH Notice NOT-OD-18-229

What was previously called “scientific premise” will be replaced by “rigor of the prior research”

For all submissions on or after January 25, 2019

In the **Significance** section of the Research Plan:
- Describe the strengths and weaknesses in the **rigor of the prior research** (both published and unpublished) that serves as the key support for the proposed project

In the **Approach** section of the Research Plan:
- Describe plans to address weaknesses in the **rigor of the prior research** that serves as the key support for the proposed project

Review criteria will be revised to address these changes

**You must critically review and evaluate all data (including preliminary data) that you use to justify your project.**

see: NIH Notices: [NOT-OD-18-227](#) [NOT-OD-18-229](#)

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
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

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Step 1  Start the Application

An Idea
A Mentor
An Institution

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Step 2  Start with the right attitude

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Step 3  Find information & make connections

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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

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

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

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

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!

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

Crafting a successful proposal requires good communication skills

*Know your audience:*

“The Reviewer at Work”

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

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

**Step 9** Build a model

Specific Aim # 1

Specific Aim # 2

Specific Aim # 3

**Step 10** Get feedback

Mentor

Advisor

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!

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.”

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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

Step 13 Proof and spell check

Step 14 Submit the proposal

Step 15 Receive and respond to reviews

The Decision
Reject
Reapply
Funded