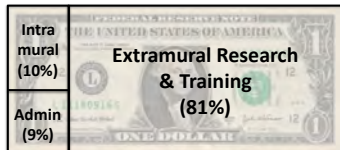
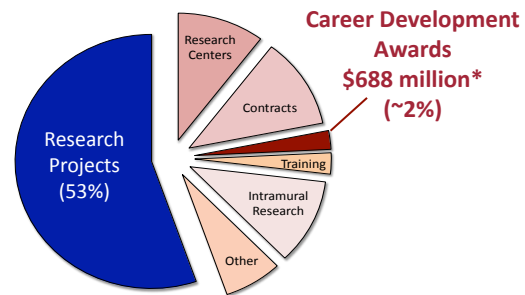


Steps to a Competitive Application

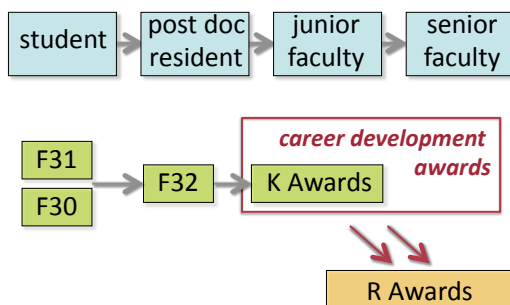
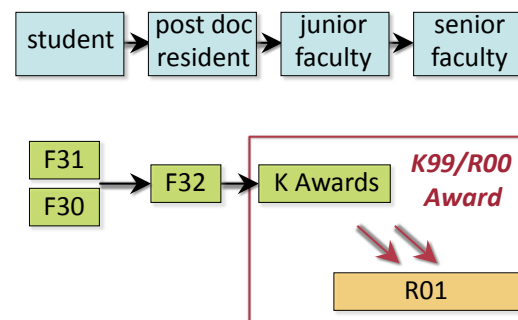
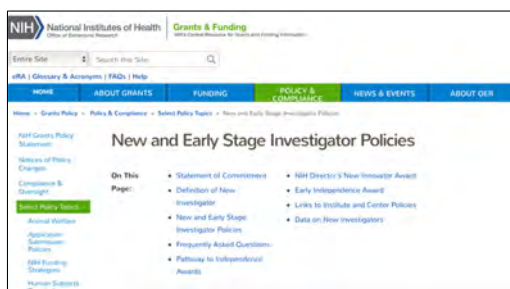
Joan M. Lakoski, PhD • Robert J. Milner, PhD

The National Institutes of Health is an Agency of the US Public Health Service**Mission:** research, training, education

— 27 Institutes & Centers (I/C)

FY19 Budget = \$39 billion*\$2 billion increase over FY18*Dr. Francis Collins
NIH Director<http://www.nih.gov/about/director/images/directorgallery/index.htm>**Dividing up the NIH pie . . .**

*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**http://grants.nih.gov/grants/new_investigators/index.htm**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

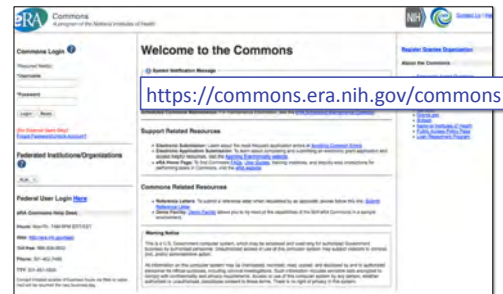
Specific award mechanisms:

- 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



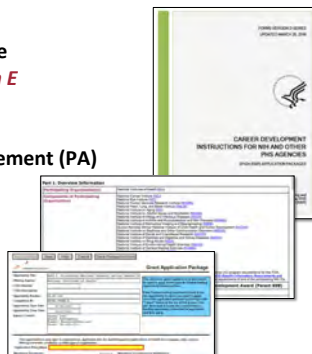
Contact your Office of Research to set up account!

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:



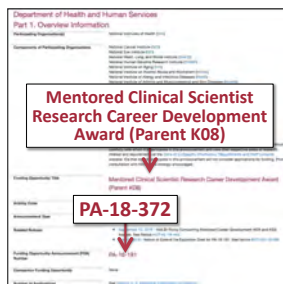
**General
Instructions**

**Fellowship
Awards**

**Career
Awards**

<http://grants.nih.gov/grants/how-to-apply-application-guide.htm>

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



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

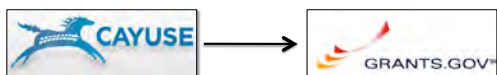
Use the appropriate Funding Opportunity Announcement (FOA) for institute-specific awards

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 → 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 Workspace 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 interface may be more user-friendly but the components you need to write are the same

— contact your Grants Office for more details

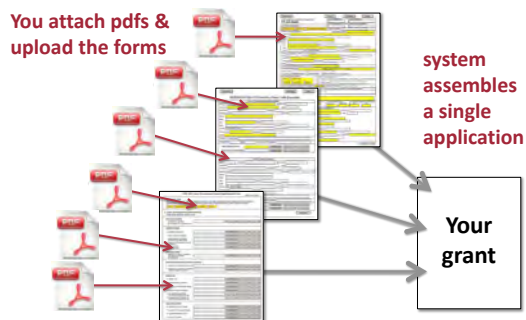
The application consists of electronic forms + attachments (pdf)

Format for attachments is defined:

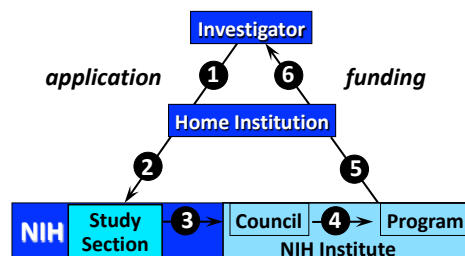
- single-spaced
- specific fonts & sizes
- single column
- minimum margins

Applications that do not conform may be returned without review!

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



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



6. the **home institution** administers the grant for 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

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

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

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

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)

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

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

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

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

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**
 In Approach Section of Research Strategy
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

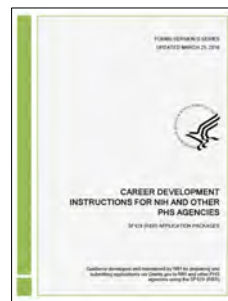
Step 1 Start the Application

**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

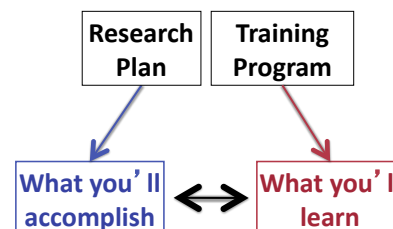
What you expect to accomplish:
— should be a test of your hypothesis

At this point get a reality check:

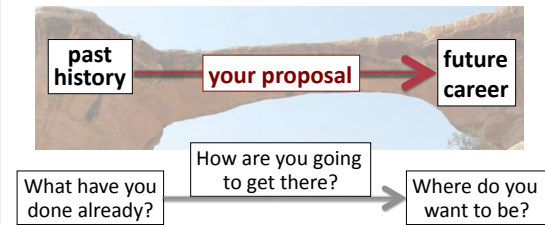
- consult colleagues/mentors:
- is the question important?
- is the approach logical?
- are the experiments feasible?

Afternoon session: **“Writing Effective Specific Aims”**

Step 5 Define the Training Goals



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

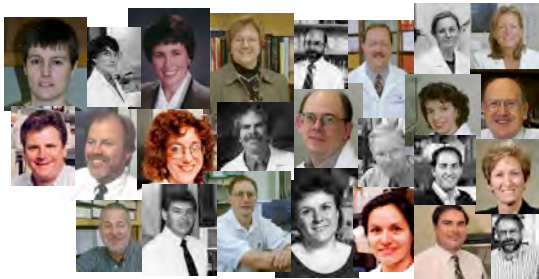
- cover page
- budget
- human subjects
- animal welfare
- biosketches

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!

see: <http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letter.htm>

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 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**

The screenshot shows the top portion of the NIH website. The header includes the NIH logo and the text "National Institute of Mental Health | Intramural Clinicians". A search bar contains the text "Search NIMH QL" and a blue "Search" button. Below the header is a dark navigation bar with white links: "RESEARCH", "ISSUES & CONDITIONS", "GRANTS & CONTRACTS", "CLINICAL TRIALS", "NEWS & EVENTS", and "ABOUT NIAD". The main content area has a light gray background. It features the heading "Apply for a Grant" in large black font, followed by social media icons for Facebook, Twitter, and YouTube. Below this is a section titled "Sample Applications and More:" in bold. Underneath is a quote from a satisfied customer: "I am so grateful and appreciative that you are part of the grant application from NIAD and NIH, receiving sample applications and written documents, data sharing, and model organism sharing plans." Further down is another section titled "Determine Eligibility for NIAD Grants:". The text below explains that before one can consider applying for funding, they need to know if they are eligible. It lists three criteria: being an investigator or part of a research team at the NIH, having access to qualified personnel, and having access to the NIH's "non-expendable" status. It concludes by stating that one can go to the "NIAD Grants" link to see if they qualify as an investigator or organization working outside the United States. On the right side of the page, there is a sidebar with the heading "More resources:" followed by four links: "International Assistance", "Training & Career Development", "Institutional Collaboration Opportunities", and "NIAD Grants". At the bottom of the page, there is a large blue box containing the URL "https://www.niad.nih.gov/grants-contracts/apply-grant" in white text.

Specific Aim # 1

Specific Aim # 2

Specific Aim # 3

A diagram illustrating the roles of different people in a research proposal process. In the center is a purple person icon labeled "Applicant" in red. Surrounding it are four grey person icons, each with an arrow pointing towards the central applicant:

- Mentor** (top left)
- Advisor** (top right)
- Chair** (bottom left)
- Colleague** (bottom right)

Below the diagram, a red text box contains the following instruction:

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

	Checklist
X	Mentor's Statement
X	Environment & Institution
X	Feedback on draft

- Human Subjects
- Animal Welfare
-
-
-
-

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

Follow NIH guidelines for Instruction in Responsible Conduct of Research

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

Notice Number: NOT-OD-10-019

Key Dates
Release Date: November 24, 2009

Issued by:
National Institutes of Health (NIH), <http://www.nih.gov>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

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 has very specific requirements for RCR instruction

Instruction must recur at each career stage (student, postdoc, faculty)

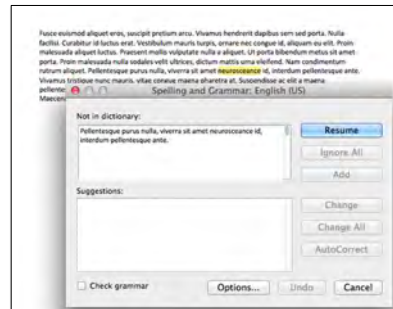
Face-to-face instruction is required (min. 8 hours) (online courses alone are not sufficient)

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

