NIH Grantspersonship Overview

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National Institute of Mental Health

Sexual & Gender Minority Health Research Regional

Workshop in the Deep South

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Outline

- Overview of NIH
- Developing a Study Concept and Communicating with NIH Program Officers
- Moving from Concept to Application
- Q&A/Discussion



Take home points



✓ Contact Program Staff early!

- ✓ Review Institute/Center priorities and goals ... each has different research training and career development programs
- ✓ Identify the specific grant programs offered by each Institute/Center
- ✓ Learn the NIH application and review process
- ✓ Make early contact with program officers
- ✓ Find innovative, well-respected mentors and collaborators
- ✓ Study successful grant applications



Overview of NIH



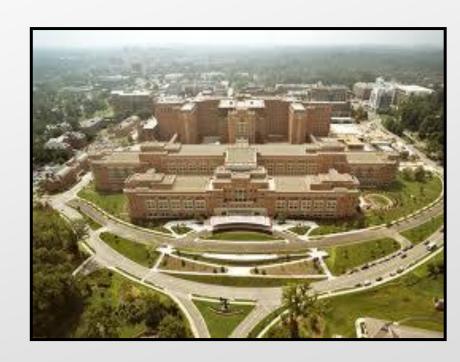


National Institutes of Health

Mission

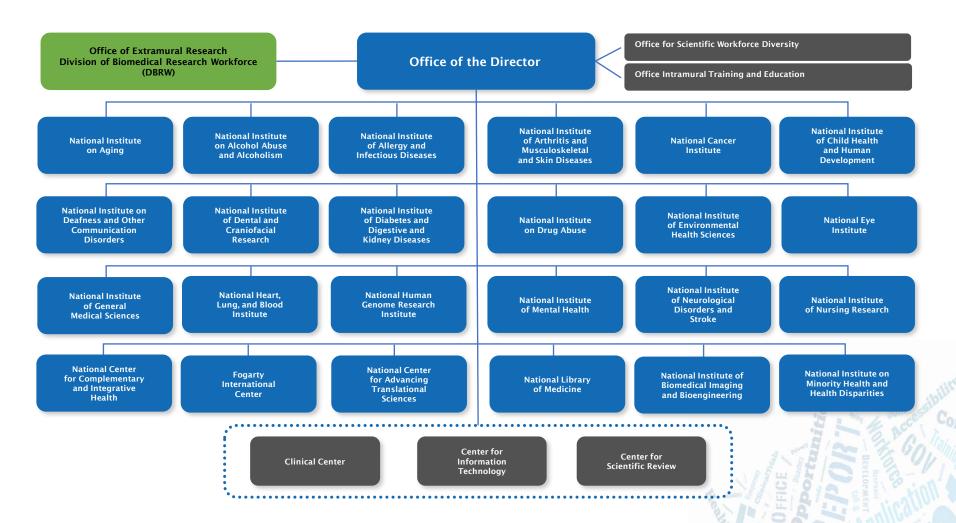
NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability

- Conducting research in NIH laboratories (intramural)
- Supporting research in research institutions globally (extramural)





NIH includes 27 Institutes and Centers (IC)





Developing a Study Concept and Communication with NIH Program Officers



The Applicant's Mantra



NOFOs and NOSIs

Notices of Funding Opportunity (NOFOs)

- Program Announcement (PA)
 - Identify an area of scientific interest
 - Typically uses standard receipt dates
 - PAR: a PA with special receipt, referral, and/or review considerations
 - Parent Announcement
 - Type of PA that is very broad
 - Generally for "investigator-initiated" or "unsolicited" applications
- Request for Application (RFA)
 - More narrowly defined priority area, single receipt date
 - Set aside funds and anticipated number of awards
 - Usually reviewed by a special review panel

Notices of Special Interest (NOSIs)

- Describes a specific topic of interest to ICs
- Refer to active NOFOs that are relevant to the NOSI



Finding Funding Opportunities

GRANTS & FUNDING

The National Institutes of Health is the largest public funder of biomedical research in the world. In fiscal year 2022, NIH invested most of its \$45 billion appropriations in research seeking to enhance life, and to reduce illness and disability. NIH-funded research has led to breakthroughs and new treatments helping people live longer, healthier lives, and building the research foundation that drives discovery.



Grants Home Page

NIH's central resource for grants and funding information.



Find Funding

NIH offers funding for many types of grants, contracts, and even programs that help repay loans for researchers.



Due Dates

Grant applications and associated documents (e.g., reference letters) are due by 5:00 PM local time of application organization on the specified due date.



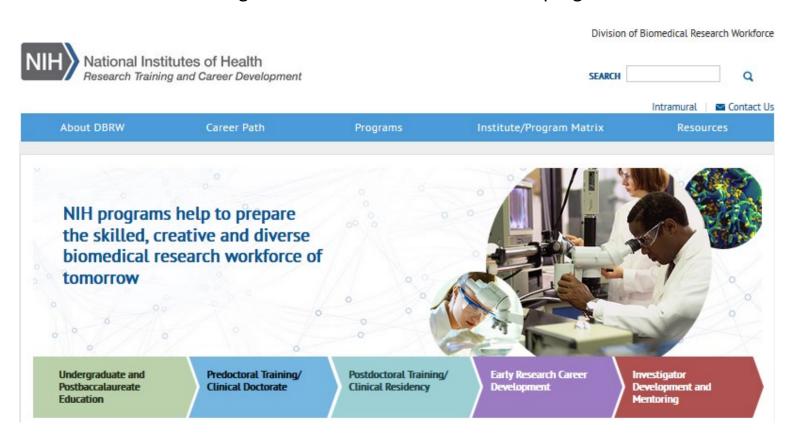
How to Apply

Instructions for submitting a grant application to NIH and other Public Health Service agencies.

NIH Research Training Website

https://researchtraining.nih.gov

- Launched in 2015, one stop for funding opportunities
- Useful resource for trainees and early stage faculty
- Modifications and integration with new DBRW website in progress



NIMH Supported Training Across Career Stages

Graduate/Medical Student

Dissertation Grant: R36

NRSA Fellowships: F30, F31

Institutional Training Grant: T32

Research Residency (MDs): R25

Diversity Supplements

Early Career Faculty

K-Awards: K01, K08, K23, K43

Research Education Grant: R25

Diversity Supplements

Loan Repayment Program

3 Funding Pathways

1. Individual NIMH Awards (R36, F, K)

2. **Institutional** NIMH training awards (T32, R25)

3. **Diversity supplement** to a mentor's NIMH grant

Post-Doctoral Fellow

NRSA Fellowship: F32

K-Awards: K99/R00

Institutional Training Grant: T32

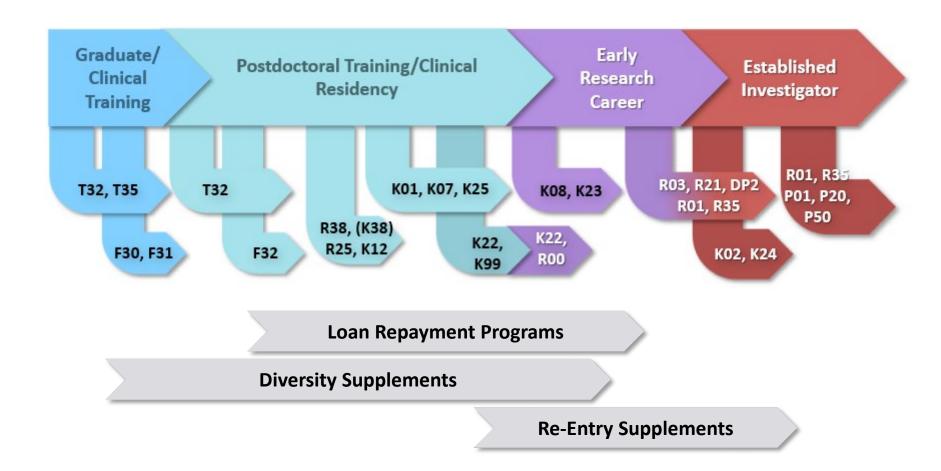
Research Education Grant: R25

Diversity Supplements

Loan Repayment Program



Funding Options Across the Career Path



You've found a FOA, now what? Step 1: Read the FOA

- Components of Participating Organizations
- **≻**Title
- >Activity Code
- ➤ Related Notices
- Companion Funding Opportunity
- **≻**Purpose
- ➤ Key Dates

- Funding Opportunity Description
- **≻**Award Information
- **➤ Eligibility Information**
- ➤ Application and Submission Information
- ➤ Application Revi
- ➤ Agency Contact:

You've found a FOA, now what? Step 2: Write a concept

Be a "problem solver"

- Define a significant health problem and research gap
- Propose a study to address the problem/gap
- Position your study as one step on the path forward
- Underscore how this work advances the field

Write your concept

- Format: 1-2 pages; can be a draft of Specific Aims
- Why is the problem you're addressing important?
- How will you address this problem?



The Study Concept Note

- 1-3 pages
- Depends on your Program Official; ask what they want!
- At a minimum, include:
 - What is the public health problem you are addressing?
 - Why should the I/C care; what I/C priority are you addressing?
 - What is the scientific knowledge gap you aim to fill?
 - How will you go about filling it; what are your study aims?
 - What are your outcomes and mediators/targets?
 - How will your results be broadly applicable?





You've found a FOA, now what? Step 3: Contact a Program Officer

- How do I know which Program Officer to contact?
 - Look at the Scientific Contact on the FOA
 - Look at Institute websites for a listing of Program Officers and the types of research in their portfolios
 - Look in NIH RePORTER to identify Program Officers on similar research projects using Matchmaker
- Can I contact more than one Program Officer? YES In the same IC? Yes but...
- When should I contact a Program Officer? When you have a concept to share and before you have written the entire application
- How should I reach out? Email
- What should I expect when I speak to a Program Officer?





Moving from Study Concept to Application



Main Sections of an NIH Application

- Specific Aims (1 page)
- Research Strategy (12 pages for most)
 - Significance
 - Innovation
 - Approach
- Clinical Trials Forms, if applicable



Main Sections of a Mentored K Application

- Specific Aims (1 page)
- Research Strategy, Candidate Information, Career Development Goals, Training Plan (12 pages total)
- Plans and Statements of Mentors (6 pages)
- Letters of Support from Collaborators/Consultants (6 pages)
- Description of Institutional Environment (1 page)
- Institutional Commitment (1 page)
- Letters of Recommendation (3-5 letters)
- Clinical Trial Forms, if applicable



Don't forget about...

- ProjectSummary/Abstract
- Project Narrative
- Facilities and Other Resources
- Protection of Human Subjects
- Equipment (if applicable)
- Budget, Budget
 Justification, Other
 Support

- Biosketches
- Cover Letter
- Letters of Support
- Resource Sharing, Data Management and Sharing
- Introduction (for resubmissions)
- Etc...! (Be sure to review and confirm the NOFO requirements)

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions² (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes³.

*Check out the link below, to see definitions of the terms "prospectively assigned", "interventions", and "health-related biomedical or behavioral outcomes".



How will NIH Determine if an Application Proposes a Clinical Trial?

- 1. Does the study involve human participants?
- 2. Are the participants **prospectively assigned** to an **intervention**?
- 3. Is the study designed to evaluate the effect of the **intervention** on the participants?
- 4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the Answer is **YES** to all four questions, the application is identified as a **Clinical Trial**

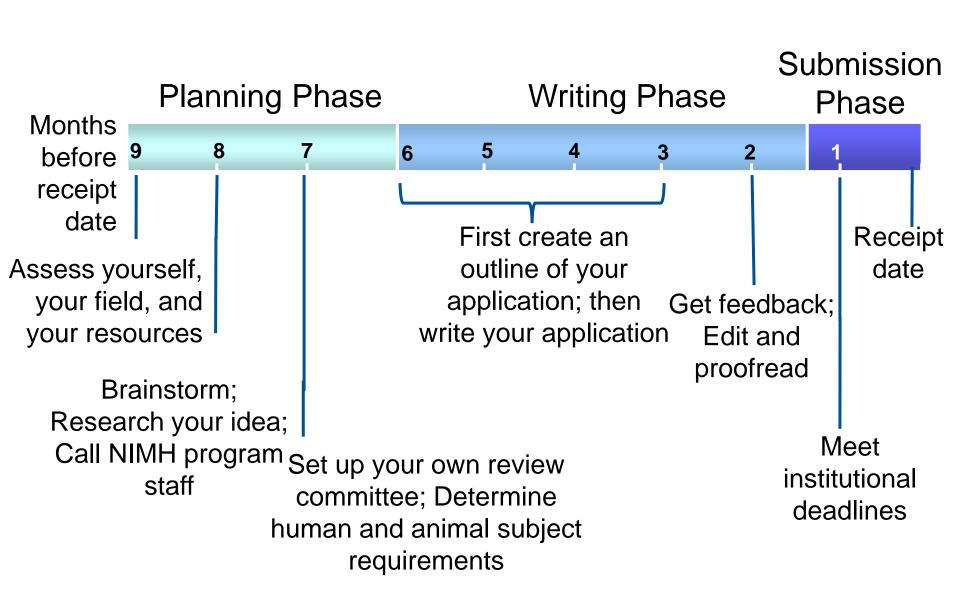


Take home message:

Create a <u>detailed checklist</u> of requirements as early as possible, at least 6 months before submission, and **START EARLY!**



Preparation Timeline



Writing a Grant Avoid these common pitfalls

- Not significant or not new research
- Weak rationale
- Low impact research
- Too ambitious
- Unfocused aims
- Career plan does not match research plan and/or is underdeveloped

- Lacks methodological rigor
- Little feasibility or preliminary data
- Little consideration of mechanisms
- Few publications or collaborators
- Lack of institutional support

Source: https://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications.shtml

Writing Tips

- Write the Aims first....and Last.
- Find <u>examples</u> of successful grants!
- Tell a **story** . . .
 - Build your argument.
 - Help reviewers care.
- Punctuate **key points.**
 - Use subheads/bold key sentences that structure the argument.
 - Don't be afraid of bullets when appropriate.



- Use a <u>conceptual</u> <u>framework</u> and model.
 - Diagram cause-effect or temporal relations.
 - Make the link between aims and products clear.
- Submit to an <u>internal</u> review committee at your institution, if available.

Q&A



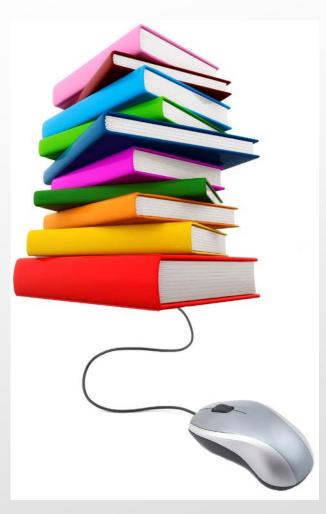
Grant Writing Resources

- NIH Grant Writing Tips Sheets links to different Institute's websites on how to write a grant (grants.nih.gov/grants/grant tips.htm)
- Preparing Grant Applications (<u>deainfo.nci.nih.gov/extra/extdocs/apprep.htm</u>)
- Grant Funding Process (www.niddk.nih.gov/research-funding/process)





Additional Resources: e-newsletters



- NIH Grants Policy
 - https://grants.nih.gov/policy/index.htm
- NIH Electronic Submission
 - https://era.nih.gov/
- Sign up for Inside NIMH
 - Funding news for current and future NIMH awardees
 - Visit the Inside NIMH subscription page: https://www.nimh.nih.gov/news/e-mail-newsletters/index.shtml



Clinical Trial Resources

- NIH Website on Clinical Trials: https://grants.nih.gov/policy/clinical-trials.htm
- NIH Website on Research Involving Human Subjects: https://humansubjects.nih.gov/
- NIH Website on Clinical Trials: https://grants.nih.gov/policy/clinical-trials.htm
- NIH Extramural Intranet Site on Clinical Trials: https://nih-extramural-intranet.od.nih.gov/d/nih/topics/clintrials_main.html
- Annotated Forms E: https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated Forms General FORMS-E.pdf
- Data Entry Fields for Study Record: PHS Human Subjects and Clinical Trials Form: https://nih-extramural-intranet.od.nih.gov/d/sites/default/files/study-record-field-notes-internal-use.docx
- Glossary of Important Clinical Trial-Related Terms: https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm
- New Human Subjects and Clinical Trial Information Form (FORMS-E) <u>Video Tutorial and More</u> https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

