

Fundamentals of the NIH Grant Process & Need to Know Resources

FALL 2021



GRANTS & FUNDING

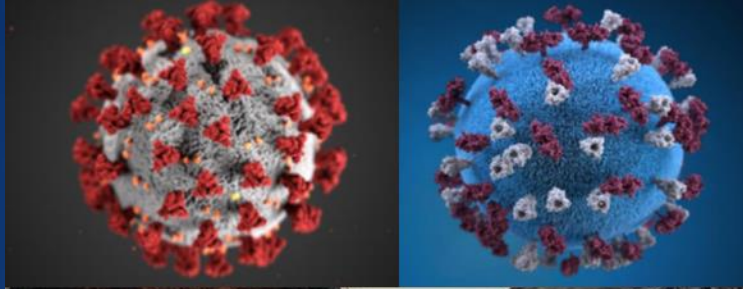
NIH Central Resource for Grants and Funding Information

Who We Are

Largest public
funder of
biomedical
research in
the world.



Clinical Center (Building 10), NIH Campus



NIH Mission

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.

NIH FY2020 By The Numbers

56,169 extramural
grant awards
totaling \$30.761
billion

Supported
research at 2,650
organizations



- Where do I start?
- Where's the funding?
- Where do I turn when I need help or advice?
- What opportunities are available & how can I find them?
- What's the application process & how long does it take?



Where do I start?



CORONAVIRUS DISEASE 2019 (COVID-19)

Search this Site

ABOUT GRANTS

Navigate the NIH grants process.

- [Grants Process Overview](#)
- [Get Started](#)
- [How to Apply](#)
- [Application Referral and Review](#)
- [Pre-Award and Post-Award Processes](#)
- [Forms Library](#)

POLICY & COMPLIANCE

Learn about obligations of your grant award.

- [NIH Grants Policy Statement](#)
- [Notices of Policy Changes](#)
- [Compliance and Oversight](#)
- [Select Policy Topics](#)

INFORMATION FOR...

Find key resources just for you.

- [Researchers](#)
- [Research Administrators](#)
- [Reviewers](#)
- [Small Businesses](#)
- [Foreign Applicants](#)
- [Media and the Public](#)

[How to Apply](#)

[News](#)



CORONAVIRUS DISEASE 2019 (COVID-19)

Application Guide

NIH Guide for Grants & Contracts

RePORT Tools

[Learn More >>](#)



How to Apply



Find Funding



Funded Research
(RePORT)



[Open Mike Blog](#)



[News](#)

ABOUT GRANTS

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CORONAVIRUS DISEASE 2019 (COVID-19)

General grants process information

Policy & Compliance

[Learn More >>](#)



[How to Apply](#)



[Find Funding](#)



[Funded Research \(RePORT\)](#)



[Open Mike Blog](#)



[News](#)

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- [Media and the Public](#)

Questions





Where's the funding?

National **Institutes** of Health

- ▶ 27 Institutes and Centers (ICs)
- ▶ Each IC has its own
 - mission,
 - priorities,
 - budget, and
 - funding strategy.

Related resource ... [NIH Institutes, Centers, and Offices](#)

NCI

NEI

NHLBI

NHGRI

NIA

NIAAA

NIAID

NIAMS

NIBIB

NICHD

NIDCD

NIDCR

NIDDK

NIDA

NIEHS

NIGMS

NIMH

NIMHD

NINDS

NINR

NLM

CC

CIT

CSR

FIC

NCATS

NCCIH

Quick Search

Search

Enter just about anything to find NIH projects and funding information: text, PI names, project numbers, fiscal year, agency

Welcome to the new NIH RePORTER

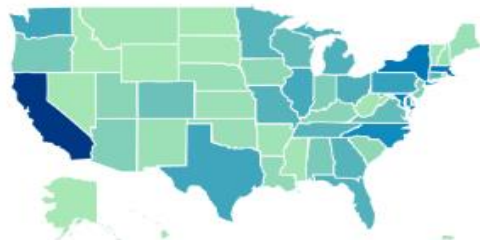
Rebuilt from the ground up, leveraging the latest technologies, to bring you an enhanced experience. Faster performance, mobile ready, and an intuitive, all-new Quick Search brings the power of NIH RePORTER to your fingertips.

Guided Tour

Feedback

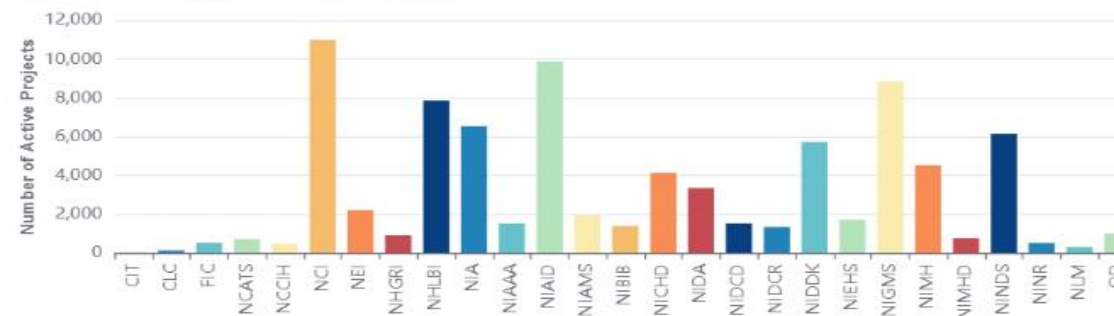
Active Funding by State

Select a state to view projects



Active Projects by Institute/Center

Select a bar to view projects for an Institute/Center



Advanced Projects Search

Fiscal Year ?

Active Projects

Current FY is 2021

Principal Investigator (PI) ?

PI Names or Profile IDs, semicolon ";" separated

Organization ?

Enter at least 3 characters to search

Matchmaker

Find potential Program Officials, ICs, and review panels for your research.

Get Started >

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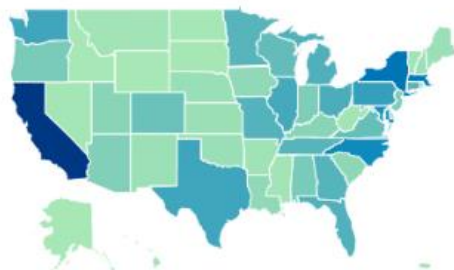
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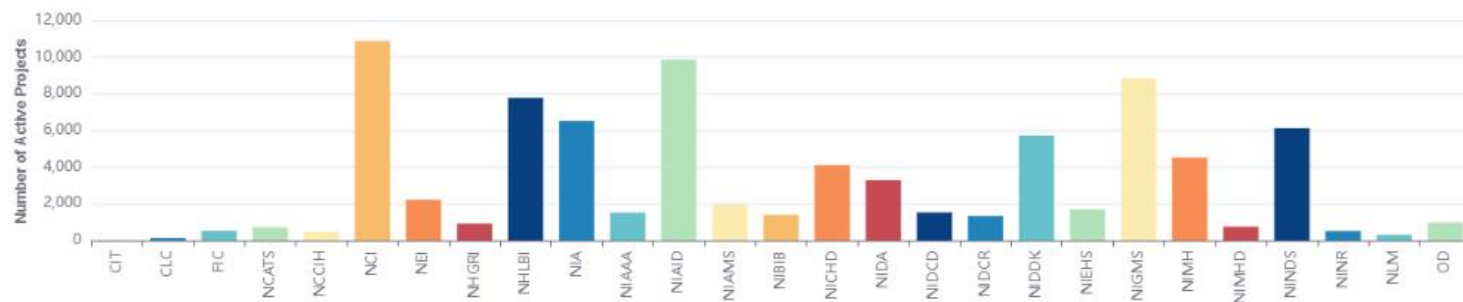
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Matchmaker

Enter abstracts or other scientific text to find potential Program Officials, ICs, and review panels for your research. ?

15,000 characters left

Similar Projects

Similar Program Officials

Reset

Search

Advanced Projects Search

Search using specific criteria to find NIH projects and funding information.

[Get Started >](#)

Publications Search

Find publications associated with extramural or intramural funded projects using PubMed IDs (PMID)

RePORTER - Matchmaker

Matchmaker

Enter abstracts or other scientific text to find potential Program Officials, ICs, and review panels for your research. ?

vaccination and (ii) HIV reactivation. We will (a) evaluate the efficacy of targeted CD25+ cell depletion as a vaccine adjuvant prior to BCG vaccination and (b) evaluate the impact of targeted CD25+ cell depletion on HIV reactivation in PBMCs from patients with controlled HIV infection.

11,780 characters left

- Similar Projects
- Similar Program Officials

Reset

Search

RePORTER – Matchmaker Results

Matchmaker Results

Top 500 Projects

Export

PROJECT SUMMARY Tregs and MDSCs have emerged as key suppressor cells that inhibit effector immunity in the TB granuloma. In addition, Tregs have been implicated in the maintenance of HIV latency. We have generated two selective biologic agents for potent depletion of Tregs and and MDSCs using diphtheria toxin

Search

Projects

Program Officials

Filters

Active Projects

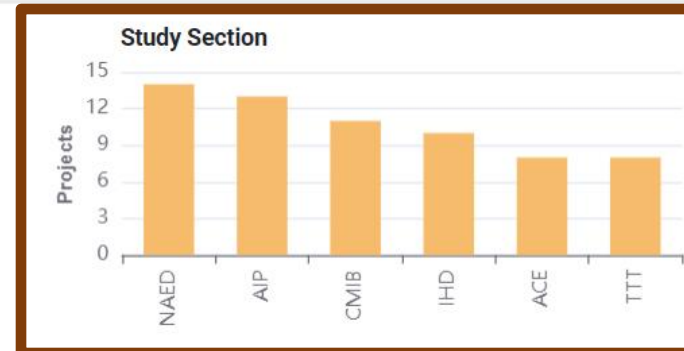
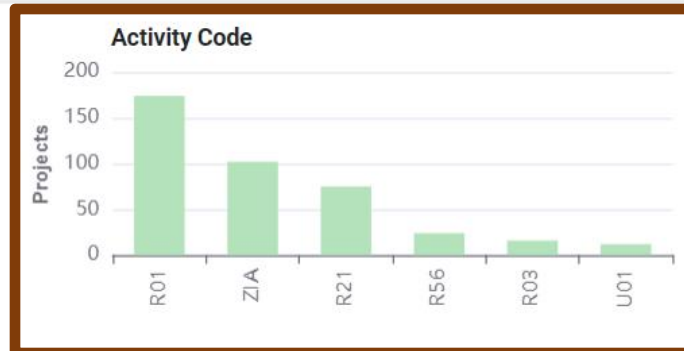
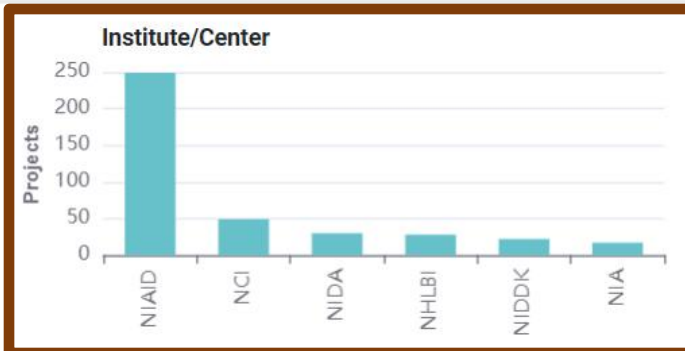
> Fiscal Years

> Agencies

> Activity Codes

> Program Officials

> Study Sections



T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects	Match
Regulation Of Immunopathology In Bacterial And Parasitic Disease										
1ZIAAI000843-22			SHER, ALAN	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2020	NIAID	NIAID	\$619,403	View >	537
Effect of HIV infection on M.tuberculosis granuloma formation and evolution										
5R21AI145539-02			SCHLESINGER, LARRY S.	TEXAS BIOMEDICAL RESEARCH INSTITUTE	2020	NIAID	NIAID	\$243,750	View >	532

PROJECT SUMMARY Tregs and MDSCs have emerged as key suppressors of the TB granuloma. In addition, Tregs have been implicated in the maintenance of granuloma structure. We have generated two selective biologic agents for potent depletion of Tregs and MDSCs. (PMID: 27111111, PMID: 27111112, PMID: 27111113, PMID: 27111114, PMID: 27111115, PMID: 27111116, PMID: 27111117, PMID: 27111118, PMID: 27111119, PMID: 27111120)

Projects

Program Officials

Filters

Active Projects

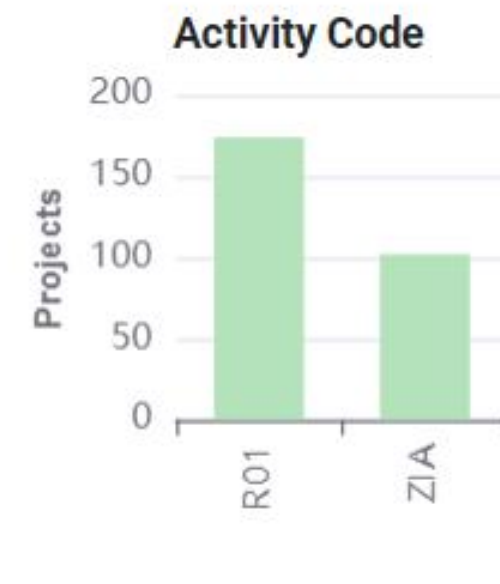
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T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization
---------------	------	-----	--	--------------

Regulation Of Immunopathology In Bacterial And Parasitic Disease

[1ZIAAI000843-22](#)

[SHER, ALAN](#)

NATIONAL INSTITUT

RePORTER – Filtered Results

Matchmaker Results

249 Projects

Export

PROJECT SUMMARY Tregs and MDSCs have emerged as key suppressor cells that inhibit effector immunity in the TB granuloma. In addition, Tregs have been implicated in the maintenance of HIV latency. We have generated two selective biologic agents for potent depletion of Tregs and and MDSCs using diphtheria toxin

Search

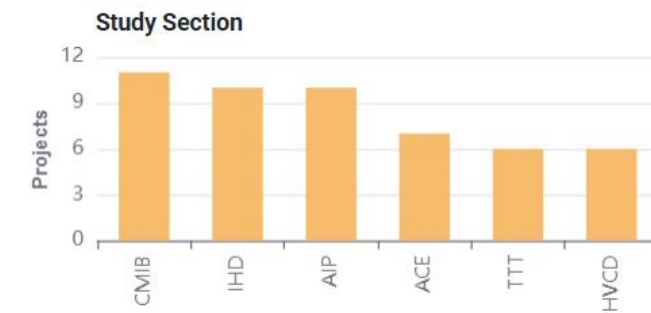
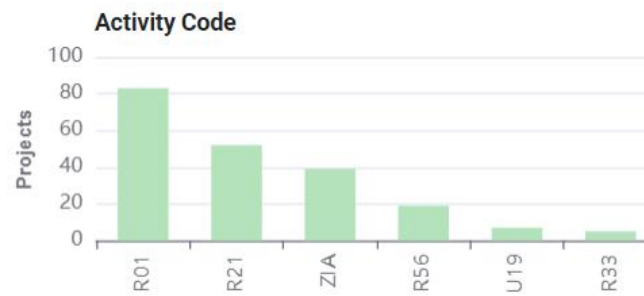
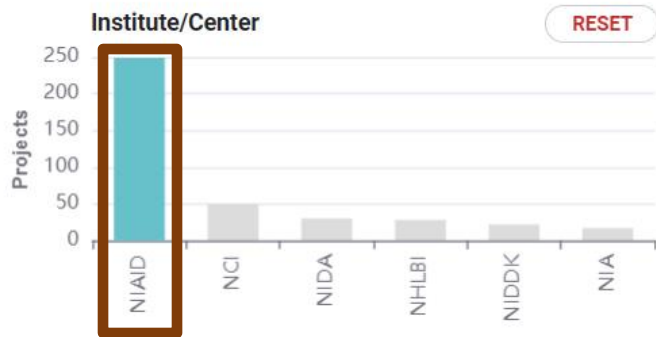
Projects

Program Officials

Filters

Active Projects

CLEAR



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RePORTER – Program Officials

Matchmaker Results

59 POs

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Search

Projects

Program Officials

Filters

Active Projects

> Fiscal Years

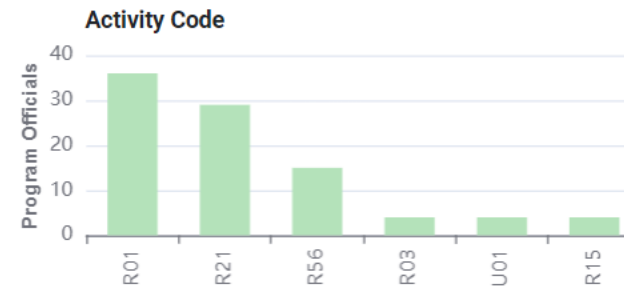
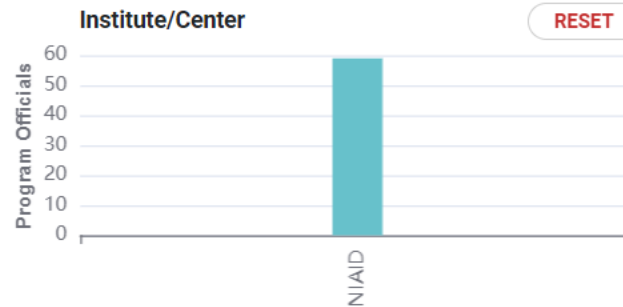
> Agencies

CLEAR

> Activity Codes

> Program Officials

> Study Sections



Program Official	IC	Contact Information	Projects
EICHELBERG, KATRIN	NIAID	View Email Contact info is hidden by default for privacy	23
LACOURCIERE, KAREN A	NIAID		16
SRINIVASAN, SUDHA	NIAID		15
LAWRENCE, DIANE M	NIAID		13
MENDEZ, SUSANA	NIAID		11
BOYCE, JIM P	NIAID		11

Program Officials

Questions



Related sessions ...

- Using RePORT to Understand Who and What NIH Funds – Wednesday, Nov. 3 at 2 PM



**Where do I turn
when I need
help or advice?**

The NIH Extramural Team

Program
Official (PO)

Scientific
Review Officer
(SRO)

Grants
Management
Officer (GMO)

Related resource ... [Understand Staff Roles](#)

Program Official

- ▶ Scientific portfolio of awards within the mission of an institute
- ▶ Initiative development
- ▶ Provides programmatic, scientific, and/or technical guidance pre-application, submission, and post-review
- ▶ Recommends applications to be considered for award to the IC director
- ▶ Post-award oversight by monitoring research progress

Scientific Review Officer

- ▶ Responsible for scientific and technical review
 - Ensures fair and unbiased evaluation of scientific and technical merit
 - Provides a summary of the evaluation
 - Reviews applications for completeness and conformance with application requirements
- ▶ Point of contact for applicants during the review process

Grants Management Officer

- ▶ Responsible for completion of business management requirements
 - Evaluates reviewed applications for administrative content and compliance with policy
 - Negotiates and prepares grant Awards
 - Post-award oversight by monitoring grant activity
 - Interprets grants administration policies

Questions



Related sessions ...

- Roles, Responsibilities and Partnerships Throughout the Life Cycle –
Monday, Nov. 1 at 3 PM



**What opportunities
are available &
how can I find
them?**

Funding Opportunity Announcements (FOAs)

- ▶ Used to advertise grant opportunities
- ▶ Contain information needed for successful application submission

Related resource ... [Understand Funding Opportunity Announcements](#)

FOAs Include

- ▶ Opportunity description
- ▶ Participating ICs
- ▶ Key dates
- ▶ Award information
- ▶ Eligibility
- ▶ Submission requirements
- ▶ Review criteria
- ▶ Award administration
- ▶ Agency contacts

Find Opportunity of Interest

▶ NIH Guide for Grants & Contracts

The screenshot shows the NIH Grants & Funding website. The header includes the NIH logo and the text 'GRANTS & FUNDING NIH Central Resource for Grants and Funding Information'. The navigation menu has tabs for HOME, ABOUT GRANTS, FUNDING (selected), POLICY & COMPLIANCE, and NEWS. The main content area is titled 'Find Funding' and includes a sub-header 'NIH Guide for Grants and Contracts'. Below this, there is a paragraph explaining the guide and a link to learn more. A sidebar on the left lists various organizations, with 'All' selected. The main content area shows a search bar with 'Active FOAs and Notices' selected and a search term. Below the search bar, it says 'Displaying: 1 to 25 of 13181 results' and 'Results Per Page: 25'. A table of results is shown with columns for Title, FOA Number, and Organization. The first row shows a notice of intent to publish the Reissuance of a Funding Opportunity Announcement for Biological Measures for Prognosing and Monitoring of Persistent Concussive Symptoms in Early and Middle Adolescents: Center Without Walls (U54).

Title	FOA Number	Organization
Notice of Intent to Publish the Reissuance of a Funding Opportunity Announcement for Biological Measures for Prognosing and Monitoring of Persistent Concussive Symptoms in Early and Middle Adolescents: Center Without Walls (U54)	NOT-NS-20-014	NINDS

▶ Grants.gov

The screenshot shows the Grants.gov website. The header includes the Grants.gov logo and the text 'GRANTS.GOV FIND. APPLY. SUCCEED.'. The navigation menu has tabs for HOME, LEARN GRANTS, SEARCH GRANTS (selected), APPLICANTS, GRANTORS, SYSTEM-TO-SYSTEM, and FORMS. The main content area is titled 'SEARCH GRANTS' and includes a sub-header 'GRANTS.GOV > Search Grants'. Below this, there is a search bar with 'Keyword(s)', 'Opportunity Number', and 'CFDA' fields. A 'SEARCH' button is located below the search bar. To the right of the search bar, there is a 'SORT BY:' dropdown menu set to 'Posted Date (Descending)' and an 'Update Sort' button. Below the search bar, there is a section for 'OPPORTUNITY STATUS:' with checkboxes for 'Forecasted (231)', 'Posted (2,231)' (checked), 'Closed (3,059)', and 'Archived (51,364)'. Below the search bar, there is a section for '1 - 25 OF 2231 MATCHING RESULTS:' with a table of results. The table has columns for Opportunity Number and Opportunity Title. The first row shows 'F20AS00018' and '2020 National Fish Habitat Act'.

Opportunity Number	Opportunity Title
F20AS00018	2020 National Fish Habitat Act
EPA-OLEM-OBLR-19-05	FY20 GUIDELINES FOR BROAD-BASED ASSESSMENT GRANTS
72061120RFA00001	Service Delivery for Vulnerable Adolescents (SDVCA)
NPS-19-NFRO-0133	Lackawanna Valley National Park

Grants.gov

The screenshot shows the Grants.gov search page. At the top, there is a navigation bar with links for HOME, LEARN GRANTS, SEARCH GRANTS (highlighted), APPLICANTS, GRANTORS, SYSTEM-TO-SYSTEM, and FORMS. Below the navigation bar, the page title is "GRANTS.GOV > Search Grants". The main heading is "SEARCH GRANTS".

BASIC SEARCH CRITERIA:

Keyword(s):

Opportunity Number:

CFDA:

OPPORTUNITY STATUS:

- Forecasted (231)
- Posted (2,231)
- Closed (3,059)
- Archived (51,364)

SORT BY: Posted Date (Descending)

1 - 25 OF 2231 MATCHING RESULTS:

Opportunity Number	Opportunity Title
F20AS00018	2020 National Fish Habitat Ac
EPA-OLEM-OBLR-19-05	FY20 GUIDELINES FOR BRO ASSESSMENT GRANTS
72061120RFA00001	Service Delivery for Vulnerabl Adolescents (SDVCA)
NPS-19-NFRO-0133	Lackawanna Valley National H

► FOAs for all federal grant-making agencies

Related resource ... [Grants.gov Search Grants](#)

NIH Guide

NIH GRANTS & FUNDING
NIH Central Resource for Grants and Funding Information

HOME ABOUT GRANTS **FUNDING** POLICY & COMPLIANCE NEWS

Find Funding

NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts is NIH's official publication of notices of grant policies, guidelines and funding opportunity announcements (FOAs). We publish daily and issue a [table of contents](#) weekly. [Learn more](#) about the NIH Guide and [subscribe to receive updates today!](#)

Organizations

- Issuing Only
- All
- AHRQ
- CDC
- CSR
- DHHS
- FDA
- FIC
- HRSA
- NASA
- NCATS
- NCBDDD
- NCCIH

Active FOAs and Notices Search Terms

Displaying: 1 to 25 of 13181 results Results Per Page: 25

Title	FOA Number	Organizational
Notice of Intent to Publish the Reissuance of a Funding Opportunity Announcement for Biological Measures for Prognosing and Monitoring of Persistent Concussive Symptoms in Early and Middle Adolescents: Center Without Walls (U54)	NOT-NS-20-014	NINDS

Related resource ... [NIH Guide](#)

▶ FOAs

▶ Notices

➤ Notices of special interest

➤ Policy updates

➤ Changes to FOAs

➤ Webinars and training events

NIH Funding Opportunities

- ▶ FOA Types
 - Requests for Applications (RFAs)
 - Parent Announcements
 - Program Announcements (PAs)
- ▶ Notices of Special Interest (NOSIs)

Requests for Applications (RFAs)

- ▶ Narrowly defined scope
- ▶ Set-aside funds
- ▶ Often a single receipt date

Parent Announcements

- ▶ Many NIH institutes and centers participate
- ▶ No science specified
- ▶ For “investigator initiated” or “unsolicited” research
- ▶ Use standard due dates

Related resource ... [Standard Due Dates](#)

Program Announcement (PA)

- ▶ Highlights areas of focus
- ▶ Usually ongoing (3 yrs)
- ▶ Use standard receipt dates
- ▶ Special types
 - PAR – PA with special receipt, referral or review considerations
 - PAS – PA with set-aside funds

Notices of Special Interest (NOSIs)

- ▶ Increasingly used instead of program announcements
- ▶ Highlight areas of scientific interest
- ▶ Designate existing FOAs to use for application submission

Related resource ... [Notices of Special Interest – Video \(5 min\)](#)

Types of Grant Programs

- ▶ Research Grants (R series) E.g., R01, R03, R21, R15
- ▶ Career Development Awards (K series) E.g., K01
- ▶ Institutional Research Training & Individual Fellowships (T & F)
E.g., T32, F30
- ▶ Program Project/Center Grants (P series) E.g., P01
- ▶ Resource Grants (various series)

Related resource ... [Types of Grant Programs](#)



[Home](#) » [About Grants](#) » [Get Started](#) » [Grants Basics](#) » [Types of Grant Programs](#)

FUNDING

[Find Funding: NIH Guide to Grants and Contracts](#)

[Contracts](#)

[Research Training and Career Development](#)



[Loan Repayment Programs](#)



[Extramural Diversity](#)

[NIH Funding Strategies](#)

Types of Grant Programs

NIH uses activity codes (e.g. R01, R43, etc.) to differentiate the wide variety of research-related programs we support. [NIH Institutes and Centers \(ICs\)](#) may vary in the way they use activity codes; not all ICs accept applications for all types of grant programs or they apply specialized eligibility criteria. Look closely at [Funding Opportunity Announcements \(FOAs\)](#) to determine which ICs participate and the specifics of eligibility.

A [comprehensive list of extramural grant and cooperative agreement activity codes](#) is available, or you can search for specific codes below:

Search Activity Codes: (e.g. R01, P01, T, K, F, etc.)

Search All Text: (e.g. Mentored, Training, etc.)

Select from List:

The following groupings represent the main types of grant funding we provide:

- [Research Grants \(R series\)](#)
- [Career Development Awards \(K series\)](#)
- [Research Training and Fellowships \(T & F series\)](#)
- [Program Project/Center Grants \(P series\)](#)
- [Resource Grants \(various series\)](#)
- [Trans-NIH Programs](#)
- [Inactive Programs \(Archive\)](#)

RELATED RESOURCES



Find Opportunities by Career Stage

Select your educational or career level to find a funding opportunity to support your training or career development goals.



Questions



Related sessions ...

- Navigating NIH Programs: An Overview – Monday, Nov. 4 at 4 PM
- After-Hours Conversation: Planning Your Career Path: NIH Experts Share Their Perspectives – Monday, Nov. 4 at 5 PM

Related on-demand videos ...

- [Finding and Understanding Funding Opportunities](#) (12:35)
- [NIH Grants Administration Take 5: Notices of Special Interest](#) (4:59)



**What's the
application
process & how
long does it take?**



CORONAVIRUS DISEASE 2019 (COVID-19) Information for Applicants and Recipients

Grants Process Overview

[Learn More >>](#)



[How to Apply](#)



[Find Funding](#)



[Funded Research \(RePORT\)](#)



[Open Mike Blog](#)



[News](#)

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Related resource ... [Grants Process Overview](#)

Grant Process Overview



GET STARTED

Learn the Basics

Learn how NIH approaches grant funding and how your research fits into our research portfolio. Make sure to explore the different types of grant programs offered at NIH, along with the eligibility requirements.

Plan Your Approach

Find and understand funding opportunities, ensure your research is original, understand your organization's internal procedures, and prepare to write a competitive application.



APPLY FOR GRANT FUNDING

Prepare to Apply

Ensure all registrations are in place, get familiar with requirements, and choose which of the available submission options you will use.

[>6-8 WEEKS BEFORE SUBMISSION]

Write Application

Obtain and complete application forms following provided instructions. Find information on developing your budget and formatting attachments.

Submit

Submit your application to NIH. Track and view your application to verify receipt and to confirm that the assembled document correctly reflects your submission.

[SUBMIT EARLY!]



APPLICATION REFERRAL & REVIEW

Receipt & Referral

Applications compliant with NIH policies are assigned to an NIH Institute or Center and to a scientific review group for evaluation of scientific and technical merit.

[MONTH 1 AFTER SUBMISSION]

Peer Review

Applications undergo a rigorous two-stage review. The first level is carried out primarily by non-federal scientists, while the second is performed by Advisory Councils or Boards.

[MONTHS 2-8 AFTER SUBMISSION]



PRE-AWARD & AWARD PROCESS

Pre-Award & Award Process

Applicants who have scored well submit "just-in-time" information. Final administrative reviews are conducted and Notice of Award documents are sent to successful applicants.

[MONTHS 7-10 AFTER SUBMISSION]

Post-Award Monitoring & Reporting

NIH monitors grants carefully. Active monitoring includes reports and correspondence from the grantee, audit reports, site visits, and other information.

[DURATION OF AWARD]



Plan

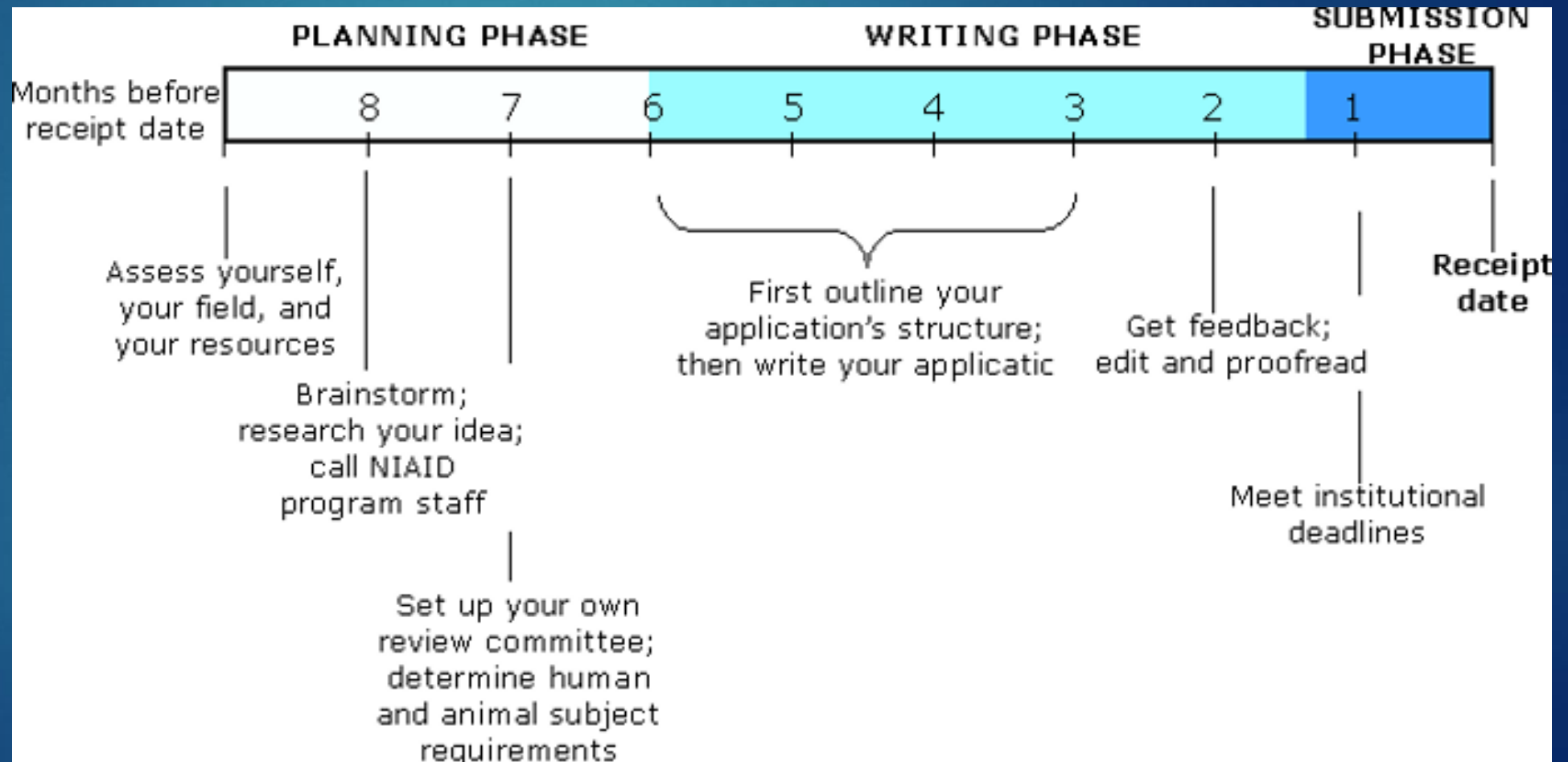
- ▶ 6+ months prior to due date
- ▶ Refine your research idea
- ▶ Reach out to NIH staff
- ▶ Build your team & internal plan





How much time does it take to write a grant application?

It varies, but two weeks before the receipt date is not enough.



Your Team

▶ Members

- Authorized Organization Official (AOR)/ Signing Official (SO)
- Project Directors/Principal Investigators (PD/PI)
- Others

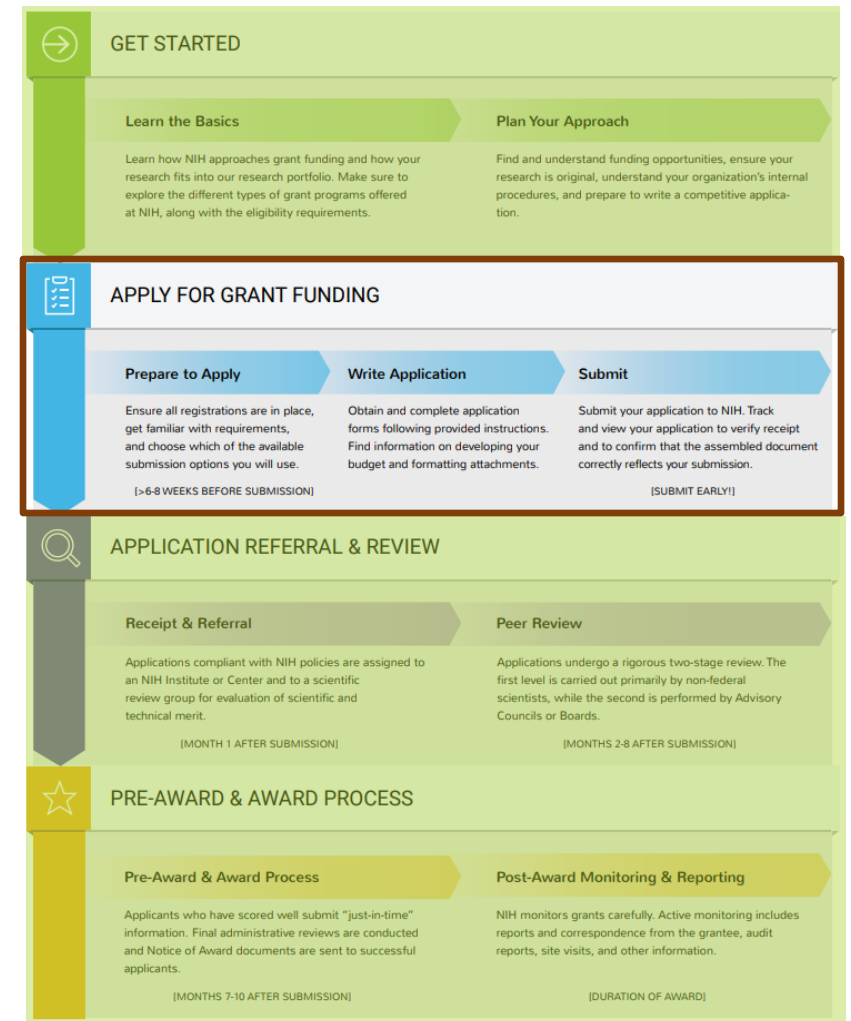
▶ Discuss roles, process & timelines

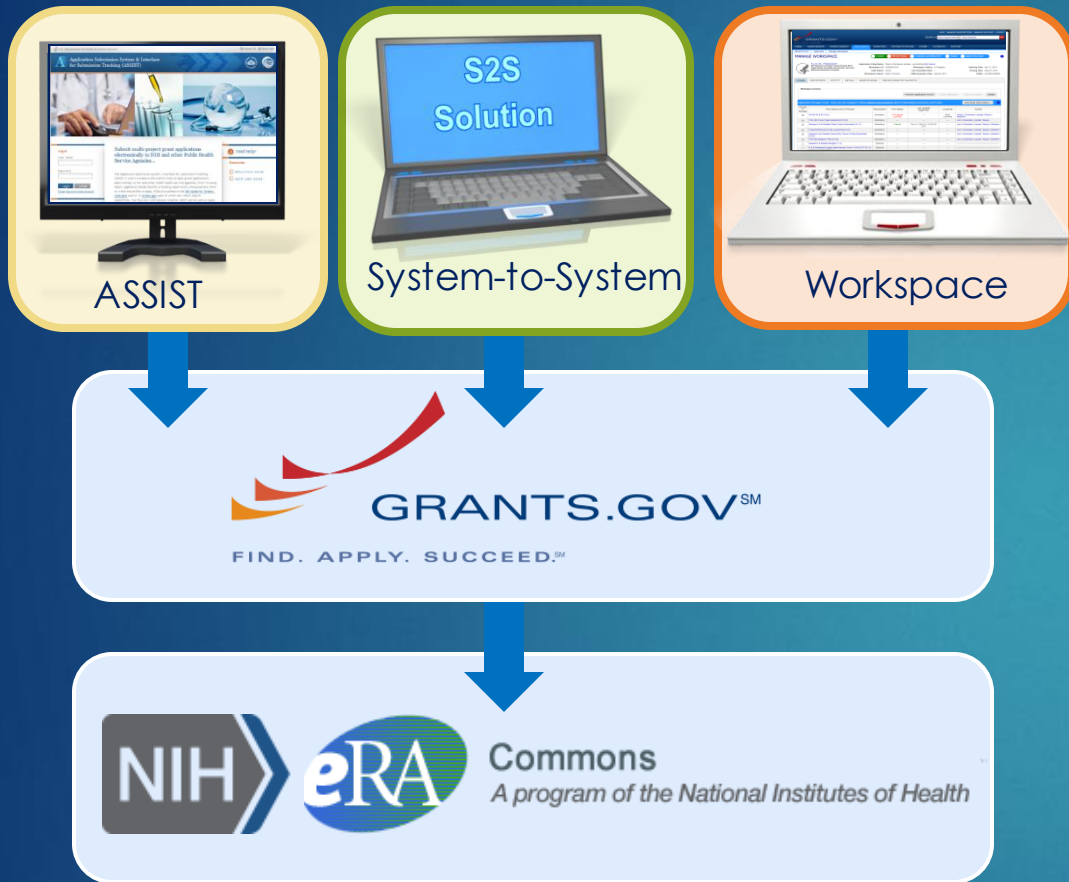




Prepare to Apply

- ▶ Confirm registrations
 - 6+ weeks to complete
- ▶ Confirm funding opportunity
- ▶ Identify submission method
- ▶ Include the institutional timeline in your plans





Access & prepare application forms using one of these submission options.

Related resource ... [Submission Options](#)



Write Application

- ▶ Complete application forms and attachments
- ▶ Write strong proposal that addresses review criteria
- ▶ Read & follow all instructions

Related resource ... [Write Your Application](#)





CORONAVIRUS DISEASE 2019 (COVID-19)

Information for Applicants and Recipients

- [How to Apply](#)
- [Find Funding](#)
- [Funded Research \(RePORT\)](#)
- [Open Mike Blog](#)
- [News](#)

How to Apply –
Application
Guide

ABOUT GRANTS

Navigate the NIH grants process.

- [Grants Process Overview](#)
- [Get Started](#)
- [How to Apply](#)
- [Application Referral and Review](#)
- [Pre-Award and Post-Award Processes](#)

Learn about obligations of your grant award.

- [NIH Grants Policy Statement](#)
- [Notices of Policy Changes](#)
- [Compliance and Oversight](#)
- [Select Policy Topics](#)

INFORMATION FOR...

Find key resources just for you.

- [Researchers](#)
- [Research Administrators](#)
- [Reviewers](#)
- [Small Businesses](#)
- [Foreign Applicants](#)

<https://grants.nih.gov/grants/how-to-apply-application-guide.html>

How to Apply - Application Guide

Use the application instructions found on this page along with the guidance in the funding opportunity announcement to submit grant applications to NIH, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality.

Prepare to Apply

- Systems and Roles
- Register
- Find Funding
- Understand Funding Opportunities
- Types of Applications
- Submission Options
- Obtain Software

Write Application

- Write Your Application
- How to Find Forms
- Develop Your Budget
- Format Attachments
- Rules for Text Fields
- Page Limits
- Data Tables
- Reference Letters
- Biosketches

Submit

- How to Submit, Track, and View
- How We Check for Completeness
- Changed/Corrected Applications
- Standard Due Dates
- Submission Policies
- Dealing with System Issues



[FAQs](#)

RELATED RESOURCES

- [NIH FORMS-F Application Forms Update \(video, 8 min\)](#)
- [Application Submission Presentations](#)
- [Tips for Success Video Series](#)
- [Annotated Form Sets](#)
- [Samples: Applications, Attachments, and other Documents](#)
- [News - Items of Interest](#)
- [Contacting NIH Staff](#)
- [Contacting Staff at Other PHS Agencies](#)

SYSTEMS

- [ASSIST](#)
- [eRA Commons](#)
- [Grants.gov](#)

Application Form Instructions

Need help selecting the right instructions?

Application Instructions	Description	SF424 (R&R) - Version F	SF424 (R&R) - Version G
G General Instructions	Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications	HTML / PDF	HTML / PDF
Filtered Application Instructions			
R Research Instructions	Guidance for research only	PDF	PDF
K Career Development Instructions	Guidance for career development only	PDF	PDF
T Training Instructions	Guidance for training only	PDF	PDF
F Fellowship Instructions	Guidance for fellowship only	PDF	PDF
M Multi-Project Instructions	Guidance for multi-project only	PDF	PDF
B SBIR/STTR Instructions	Guidance for small business only	PDF	PDF

Follow All Instructions Carefully

General Guidance

[How to Apply - Application Guide](#)

NIH National Institutes of Health Grants & Funding

How to Apply - Application Guide

Use the application instructions found in this page along with the questions in the Funding Opportunity Announcement to submit grant applications to NIH. Use the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality.

Application Yarns Instructions

Application Yarns Instructions	Description	SP2A (R01) - Version 3
1. General Instructions	Comprehensive guidance for research, training, fellowship, career development, and career development only.	NIH, F, FSP
2. Research Instructions	Evidence for research only.	FSP
3. Career Development	Evidence for career development only.	FSP
4. Training Instructions	Evidence for training only.	FSP
5. Fellowship Instructions	Evidence for fellowship only.	FSP
6. Career Development	Evidence for career development only.	FSP

FOA-specific Guidance

Funding Opportunity Announcement

- Section IV. Application and Submission Information

Department of Health and Human Services
Part 1. Overview Information

Participating Organizations: National Institutes of Health (NIH)

Components of Participating Organizations: National Inst. Lung and Blood (NIH) (NIH), National Institute on Aging (NIH), National Institute on Alcohol Abuse and Alcoholism (NIH), National Institute on Child Health and Human Development (NIH), National Institute on Drug Abuse (NIH), National Institute of Environmental Health Sciences (NIH), National Institute of General Medical Sciences (NIH), National Institute of Health (NIH), National Institute of Mental Health (NIH), National Institute of Neurological Disorders and Stroke (NIH), National Institute of Nursing Research (NIH), National Institute of Standards and Technology (NIH), National Institute of Standards and Technology (NIH).

Funding Opportunity Title: NIH Research Project Grant (Parent R01 Clinical Trial Required)

Activity Code: R01 Research Project Grant

Assessment Type: New

Related Notices: December 16, 2015 - Notice of NIDDK Policy for Submission of Applications and Participation in P4-16-161 See Notice NIH-16-161
NIH-16-161 Notice of NIDDK Policy for Submission of Applications and Participation in P4-16-161 See Notice NIH-16-161
NIH-16-161 Notice of NIDDK Policy for Submission of Applications and Participation in P4-16-161 See Notice NIH-16-161

FOA-specific & New Policy Updates

Notices in NIH Guide for Grants & Contracts

NIH Policy for Review and Resubmission of New Investigator R01 Applications

Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and

NIH Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule)

Notice Number: NOT-OD-19-050

Key Dates
Release Date: January 2, 2019

Related Announcements
NOT-OD-19-051
NOT-OD-19-052

Issued by: National Institutes of Health (NIH)

Purpose
The purpose of this notice is to provide guidance to the extramural research community regarding the NIH implementation of the Final Rule amending the Federal Policy for the Protection of Human Subjects (Common Rule) (FRS), along with other Common Rule requirements and agencies, published the Final Rule in the Federal Register on January 19, 2017 and subsequently amended the Final Rule to delay the general compliance date until January 21, 2019.

Several provisions in the Revised Common Rule may result in changes to NIH policies and procedures, including: 1) removal of the requirement for Institutional Review Boards (IRBs) to review grant applications and certain proposals funded by research; 2) a new requirement for IRBs that informed consent documents to be posted on a public Federal government website; 3) changes to categories of research that qualify for an exemption; and 4) removal of the requirement for annual IRB reviews for certain categories of research. Additional details, including requirements and processes for adapting to the new provisions, can be found in the Final Rule.

As of January 21, 2019, studies initiated on or after that date, ongoing studies that voluntarily transitioned to the Revised Common Rule, and studies that voluntarily implemented the three four-month review provisions during the delay period (July 19, 2018 through January 20, 2019), are expected to comply with all Revised Common Rule requirements for the remainder of the study. For these studies, the following NIH provisions will apply:

- NIH will no longer require IRB review and approval of the entire grant application or contract proposal. Instead, the IRB must review and approve the research or a research protocol for all NIH supported non-emergent human subjects research studies. Researchers must provide certification to NIH that the IRB has reviewed and approved the research or research protocol.
- For non-emergent or approved clinical trials, informed consent documents must be posted on a public Federal website after recruitment closes and no later than 60 days after the last study visit. More information about these requirements is available at <https://grants.nih.gov/grants/ohrt/irb/irbnotices.html>.
- Applications or proposals that include studies to which the Revised Common Rule applies should take note of changes to categories of research qualifying for exemption and take care to select the appropriate category. Questions and answers about changes to exemptions may be found at <https://www.fda.gov/oc/ohrt/irb/irbnotices.html>.
- For applications submitted for due dates on or after January 23, 2019, NIH will transition from "1" to "2" on the "IRB" codes (e.g., 101) to reflect categories of exempt research. These exempt categories and program reports. For contracts, the option of selecting exemption "1" or "2" applies to all solicitations issued on or after January 23, 2019.
- NIH will no longer require annual IRB reviews unless such review is required by the Revised Common Rule or other Federal, state, or local regulation or policy, or otherwise specified in the Funding Opportunity Announcement or grant application.

The Protection of Human Subjects (FRS) is the revised strategy that is expected to succeed review and certification that NIH that an IRB has reviewed and approved the research or research protocol. IRB approval is the only change to NIH of Justice. IRB approval is the only change to NIH of Justice. IRB approval is the only change to NIH of Justice.



Precedence / Importance

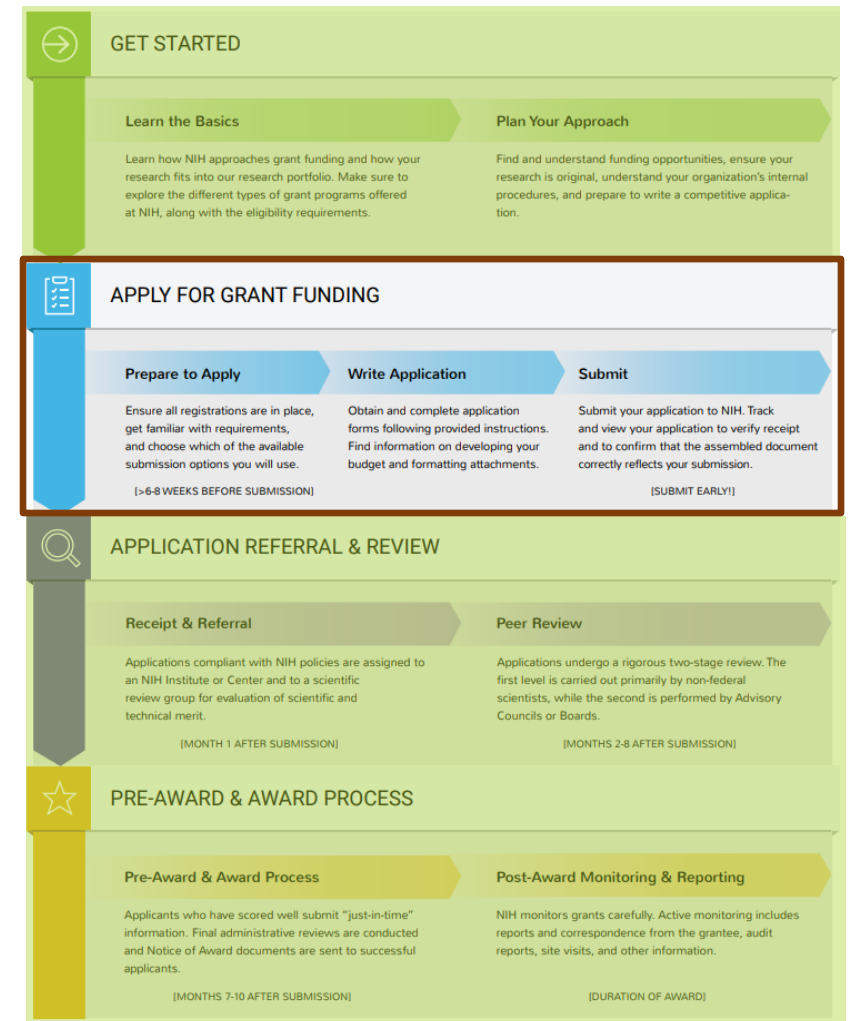




Submit Early!

- ▶ Applications routed through Grants.gov to NIH's eRA Commons
- ▶ Days before due date
 - Allow time to check application image in eRA Commons and address any unforeseen issues

Related resource ... [How to Submit, Track and View Your Application](#)

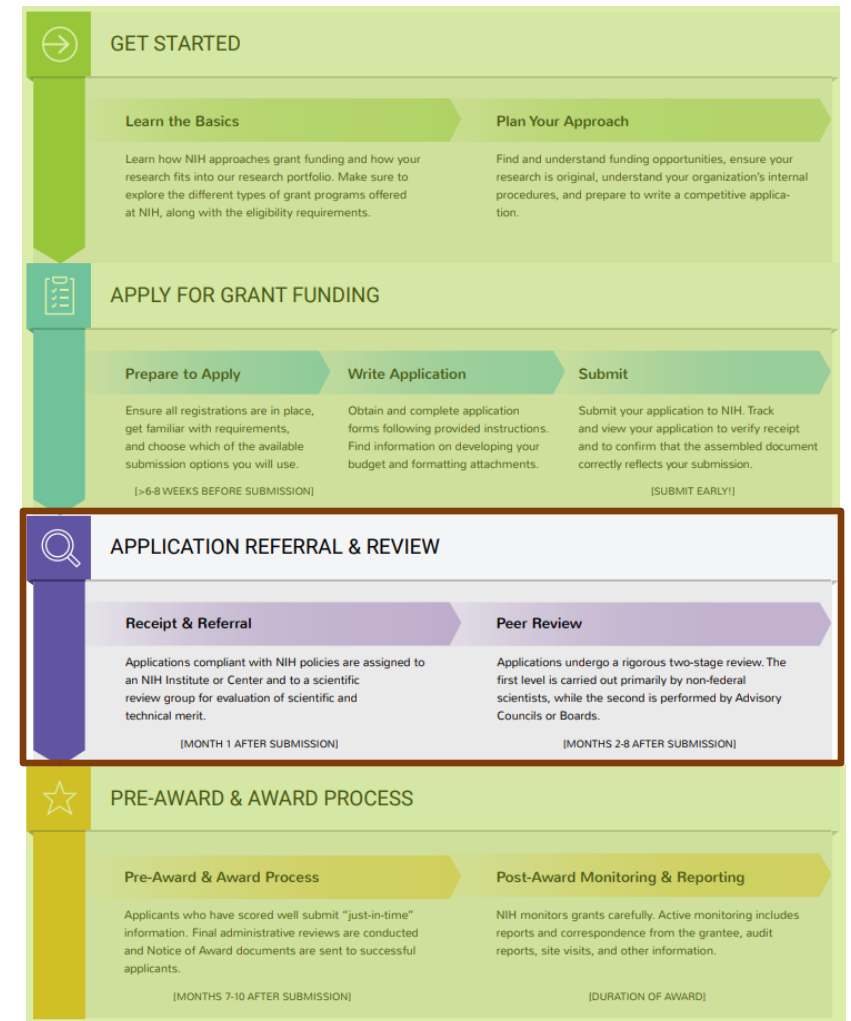




Receipt & Referral

- ▶ Additional application checks
- ▶ Application Number assigned
- ▶ IC assignment
- ▶ Assignment to Integrated Review Group (IRG)
 - IRG Chief assigns study section
- ▶ Assignment details placed in eRA Commons (~2 weeks)
- ▶ It's all on your Commons Page

Related resource ... [Submission & Assignment](#)

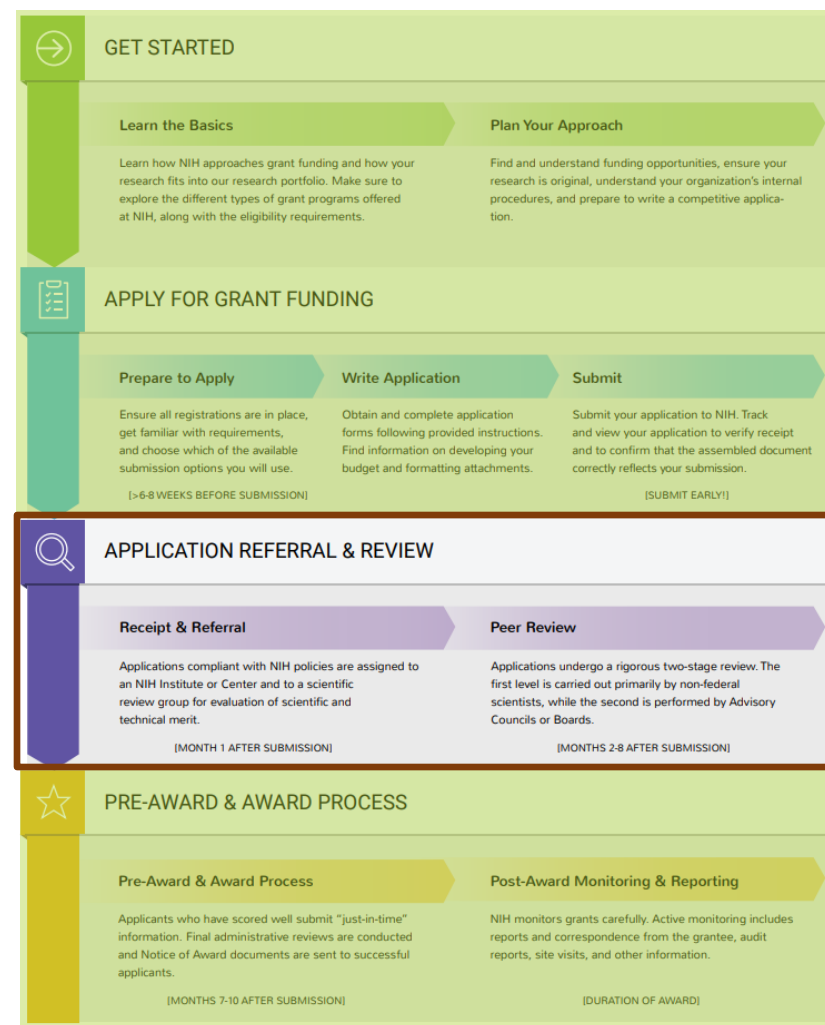




Peer Review

- ▶ Key contact – SRO
- ▶ Study section reviews for scientific merit
- ▶ Priority score & percentile ranking in eRA Commons (2-3 days after meeting)
- ▶ Summary statement in eRA Commons (~1 month)

Related resource ... [Initial Review, Results, and Appeals](#)

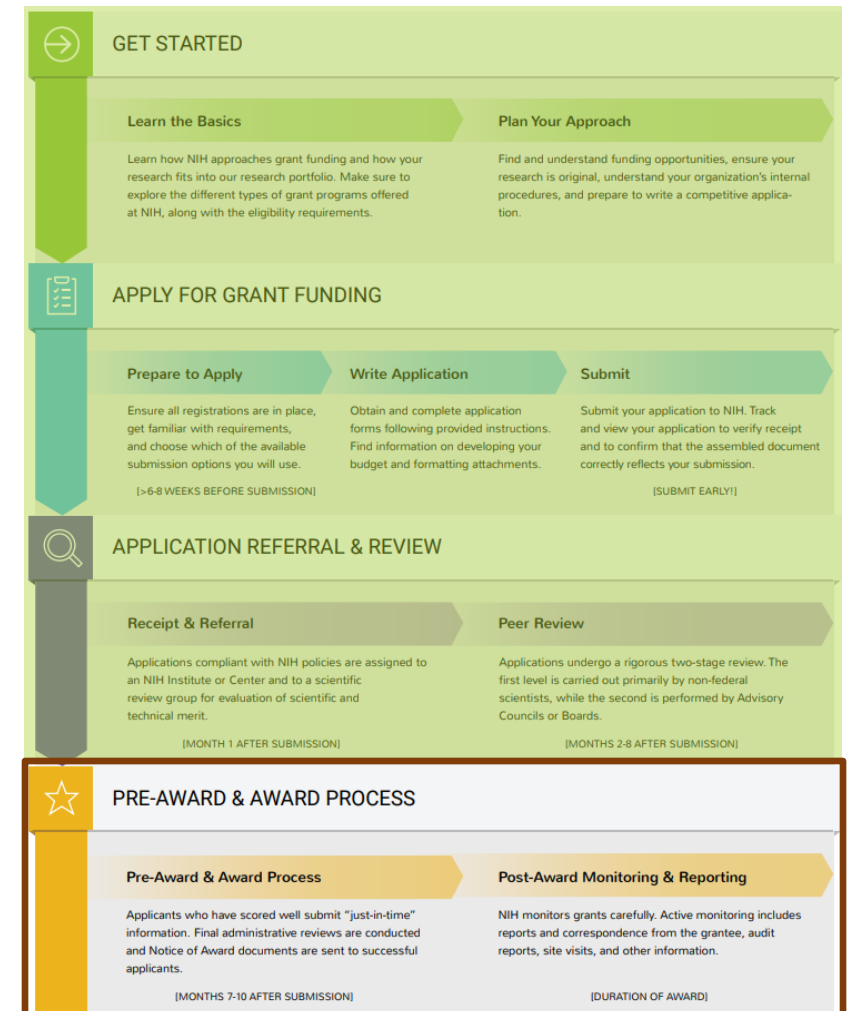




Post-Review, Pre-Award & Award Process

- ▶ Key contacts – PO & GMO/GMS
- ▶ IC review
- ▶ Just-in-time information may be requested

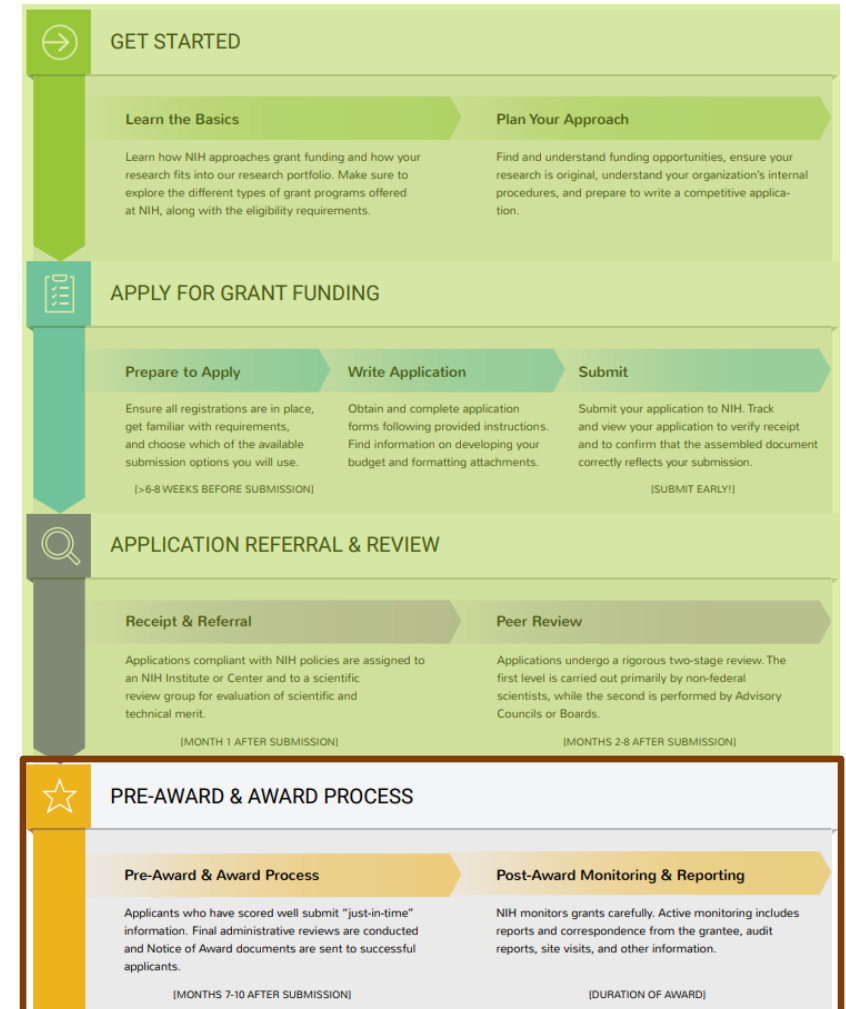
Related resource ... [Pre-Award and Award Process](#)





Pre-Award & Award Process

- ▶ Council – funding recommendations
- ▶ IC Director – funding decisions
- ▶ Notice of Award (~9 months)
- ▶ Or Try again



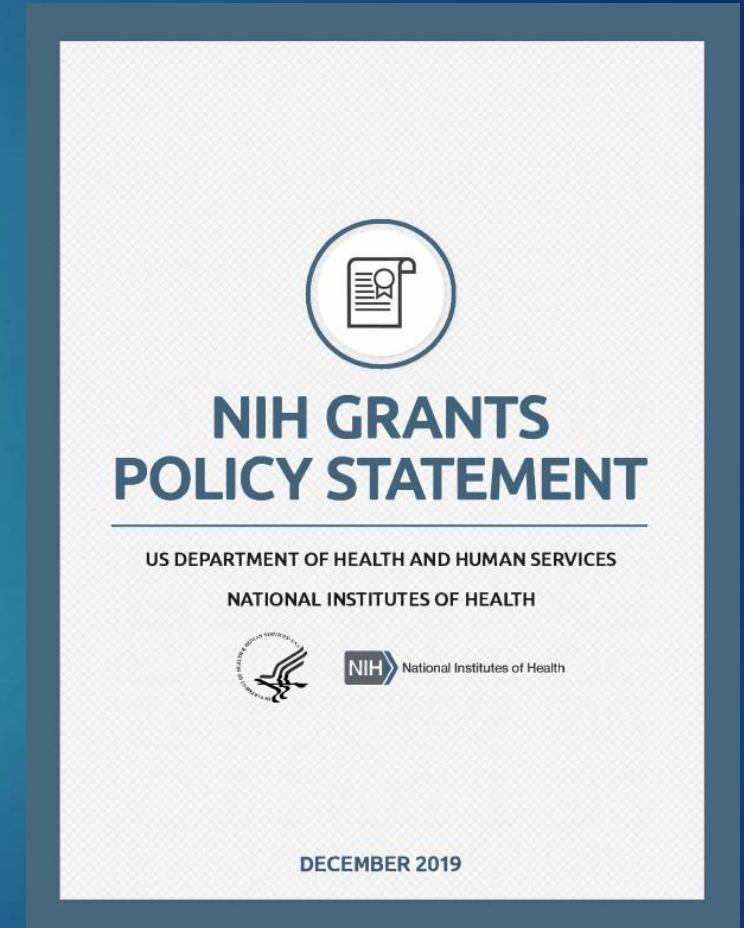
Notice of Award (NoA)

- ▶ Legally binding document
 - Award data and fiscal information
 - Grant payment information
 - Terms and conditions of award
- ▶ Grantee accepts terms and conditions of award as soon as funds are drawn down

NIH Grants Policy Statement

- ▶ Term and condition of grant awards
- ▶ Explicitly defines roles, responsibilities
- ▶ Updated each fall

Related resource ... [NIH Grants Policy Statement](#)

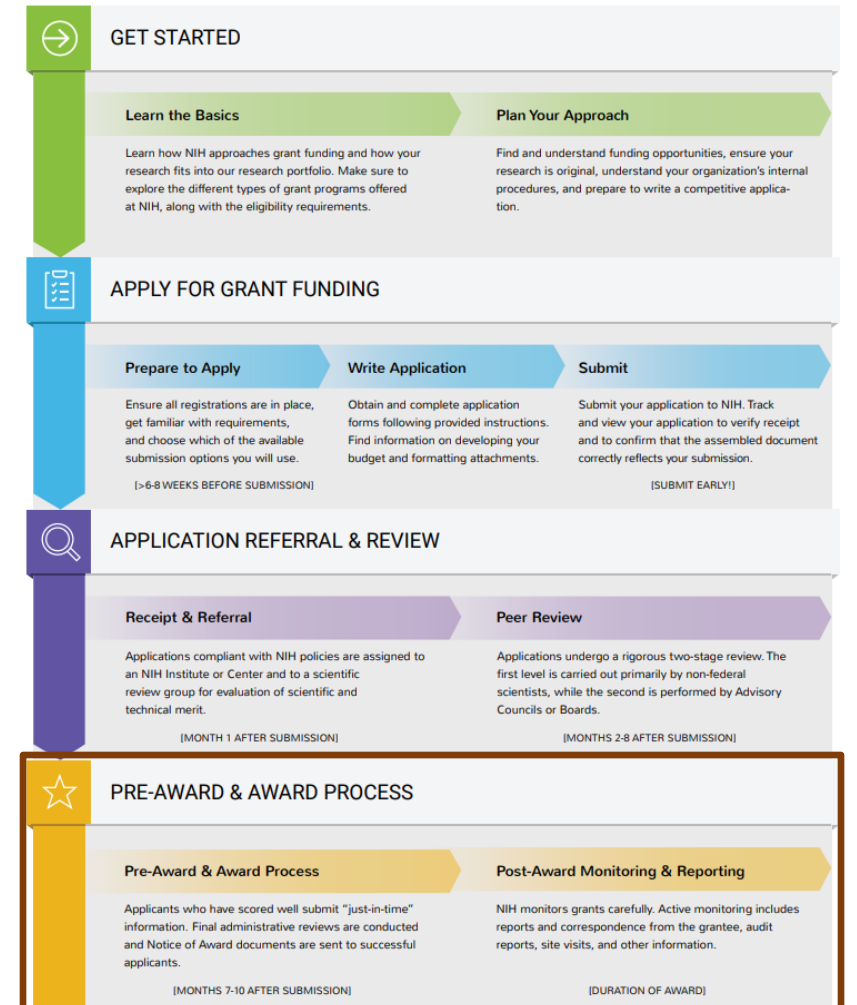




Post-Award Monitoring & Reporting

- ▶ Reports on research progress
- ▶ Prior approval requests
- ▶ Audits
- ▶ Site visits

Related resource ... [Post-Award Monitoring and Reporting](#)



Questions

Related sessions ... all of them!





Stay
Connected

Stay Connected – News & Events



GRANTS & FUNDING

NIH Central Resource for Grants and Funding Information

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Discovery

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[NIH Regional Seminars on Program
Funding & Grants Administration](#)

[SBIR-STTR Engage & Connect](#)

[Loan Repayment Program \(LRP\)
Contact & Engage](#)

[Office of Laboratory Animal Welfare
\(OLAW\)](#)

[Workshops and Conference](#)

[Events Calendar](#)



Consolidated Resource List

Resources: General

- **NIH Grants and Funding**
<https://grants.nih.gov/grants/oer.htm>
- **NIH Grants Policy Statement**
<https://grants.nih.gov/policy/nihgps/index.htm>

Resources: ICs & Staff

- **NIH Institutes, Centers, and Offices**
<https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices>
- **Understand Staff Roles**
<https://grants.nih.gov/help/ic-staff-roles>
- **Grants & Funding – Need Help?**
<https://grants.nih.gov/help>

Resources: Funding Opportunities & Programs

- **Understand Funding Opportunity Announcements**
<https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm>
- **NIH Guide for Grants & Contracts**
<https://grants.nih.gov/searchGuide/>
- **Grants.gov Search Grants**
<https://www.grants.gov/web/grants/search-grants.html>
- **Types of Grant Programs**
https://grants.nih.gov/Grants/funding/funding_program.htm

Resources: Application Preparation

- **How to Apply – Application Guide**
<https://grants.nih.gov/grants/how-to-apply-application-guide.htm>
- **Submission Options**
<https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options.htm>
- **Write Your Application**
<https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm>
- **Standard Due Dates**
<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm>

Resources: Application Process

- **Grants Process Overview**
https://grants.nih.gov/grants/grants_process.htm
- **How to Submit Track and View Your Application**
<https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm>
- **Submission & Assignment**
<https://public.csr.nih.gov/ForApplicants/SubmissionAndAssignment>
- **Initial Review, Results, and Appeals**
<https://public.csr.nih.gov/ForApplicants/InitialReviewResultsAndAppeals>
- **Pre-Award and Award**
<https://grants.nih.gov/grants/pre-award-process.htm>
- **Post-Award Monitoring and Reporting**
<https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm>

Resources: Tools

- **RePORTER**
<https://reporter.nih.gov/>
- **Matchmaker**
<https://reporter.nih.gov/matchmaker>

Thank you!