National Council of University Research Administrators

NCURA
Supporting Research...together™

Integrity • Excellence • Respect • Diversity • Access • Inclusion • Opportunity • Equity • Sharing • Values • Collegiality • Transparency • Service •

65th Annual Meeting

inclUSion

August 6-9, 2023
Washington, DC

WORKSHOP 17

NIH FUNDAMENTALS

Wednesday, August 9, 2023
Live virtual workshop: 1:00 - 4:30 PM

bakertilly

Thank you to Baker Tilly for their support of this live streamed workshop!

Please enjoy these resources, courtesy of Baker Tilly

- Baker Tilly's Internal Audit Resource Center
- Baker Tilly's Academic Medical Centers page
- Baker Tilly's Fiscal Resiliency Resource Center
- Inflation Reduction Act (IRA) Video

NIH Fundamentals

NCURA | Washington D.C.

1pm to 4:30 pm ET | August 9, 2023

National Institutes of Health
Office of Extramural Research

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Meet the Team

Xanthia James

Director, Division of Grants Policy

OPERA, OER

Priyanga Tuovinen

Asst. Grants Policy Officer, Division of Grants Policy

OPERA, OER

Kasima Garst

Deputy Director, Division of Grant Systems Integration

OPERA, OER

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NIH Fundamentals (Description)

This workshop provides a primary basis of understanding of proposals to and awards from the National Institutes of Health (NIH). This workshop will give you the basics and we will walk you through the grants process and give you an overview of key resources and websites you will need to be successful.

The program is perfect for someone new to Research Administration, as well as for Research Administrators seeking to expand their knowledge of federal funding agencies. The curriculum provides an overview of the policies and procedures essential to preparing successful proposals to and managing grant awards from the NIH.

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Learning Objectives

Major content areas covered include:

1. NIH overall structure, culture, and organization
2. Developing and submitting NIH grant applications
3. The peer review process
4. Post-Award administration
5. Tips and tricks

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Learning approaches

- Presentation / slides
- Examples / activities
- Discussion / Q&A

- Break at 2:30pm
- Questions anytime

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Survey: topics for today

- Handout with pre-workshop survey responses
- Hope to cover most of these topics
- Some questions/specifics may be out of scope for today's fundamentals (foreign subaward policy) or addressed in other forums (NIH Updates)
- Some items would be great to hear you all share your experience and practice
- *Feel free to refer to this handoff to check off items you think have been covered or ask about items where you still have questions*

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Let's meet you - *icebreaker*

- Has been in research administration less that a year? Less than 6 months? More than 5 years? More than 10 years?
- In pre-award only? Post-ward only? Pre-to-post award? Accounting or finance? Compliance areas? Other?
- Who here has NOT been involved in NIH grants before?

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ABOUT THE NATIONAL INSTITUTES OF HEALTH

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United States Department of Health And Human Services (HHS)

- The National Institutes of Health is located within the US Department of Health and Human Services (HHS), a Cabinet-level executive agency.
- HHS is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
- The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.
- Agencies of HHS conduct health and social science research, work to prevent disease outbreaks, assure food and drug safety, and provide health insurance.

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HHS Organization

HHS has 11 Operating Divisions, including NIH

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

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THE NATIONAL INSTITUTES OF HEALTH

The Nation's Steward of Medical & Behavioral Research
(2022 budget: $45 billion)

"Science in pursuit of ***fundamental knowledge*** about the nature and behavior of living systems and the ***application of that knowledge*** to extend healthy life and reduce illness and disability."

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HOW DOES NIH FUND RESEARCH?

- NIH provides financial support in the form of ***grants, cooperative agreements, contracts and other transactions*** to support the advancement of the NIH mission to enhance health, extend healthy lives, and reduce the burdens of illness and disability
- 24 of the 27 NIH Institutes and Centers (ICs) fund extramural research, based on their mission and priorities, budget, and funding strategy

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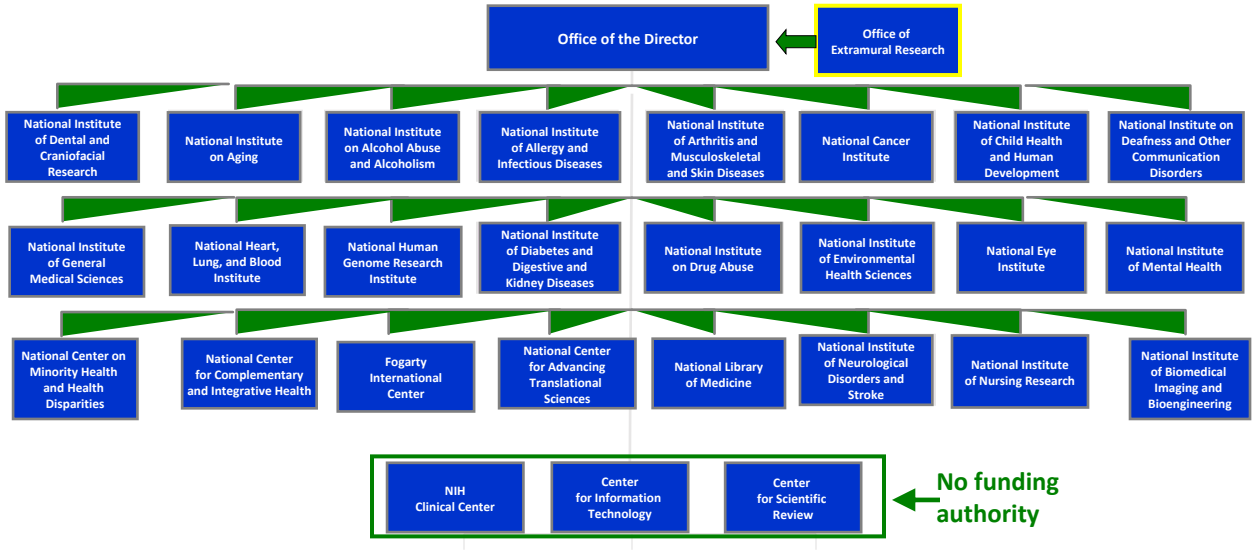
NATIONAL INSTITUTES OF HEALTH



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NIH Funding Institutes and Centers (ICs)

NIH Funding Institutes

Acronym	Full Name	Code
FIC	John E. Fogarty International Center	TW
NCATS	National Center for Advancing Translational Sciences (NCATS)	TR
NCCIH	National Center for Complementary and Integrative Health	AT
NCI	National Cancer Institute	CA
NEI	National Eye Institute	EY
NHGRI	National Human Genome Research Institute	HG
NHLBI	National Heart, Lung, and Blood Institute	HL
NIA	National Institute on Aging	AG
NIAAA	National Institute on Alcohol Abuse and Alcoholism	AA
NIAID	National Institute of Allergy and Infectious Diseases	AI
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	AR
NIBIB	National Institute of Biomedical Imaging and Bioengineering	EB
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development	HD
NIDA	National Institute on Drug Abuse	DA
NIDCD	National Institute on Deafness and Other Communication Disorders	DC
NIDCR	National Institute of Dental and Craniofacial Research	DE
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	DK
NIEHS	National Institute of Environmental Health Sciences	ES
NIGMS	National Institute of General Medical Sciences	GM
NIMH	National Institute of Mental Health	MH
NIMHD	National Institute on Minority Health and Health Disparities	MD
NINDS	National Institute of Neurological Disorders and Stroke	NS
NINR	National Institute of Nursing Research	NR
NLM	National Library of Medicine	LM

Source: https://www.era.nih.gov/files/Deciphering_NIH_Application.pdf

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NIH BY THE NUMBERS – FY22

- **NIH Total Budget FY2022: $45.2 billion**
  - **Grant awards (competing and noncompeting): $33.3 billion (increase 3.1% from prior year)**
  - **Total number of extramural awards (excluding contracts): 58,368 awards (increase 2.8% from prior year)**

- **Research Project Grants (RPG): $24.4 billion**
  - RPG is an award made to an institution/organization to support discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies.
  - *NIH's most commonly used grant program is the Research Project Grant Program (R01).*
    - **Reviewed:** 54,571 competing RPG applications
    - **Awarded:** 11,331 new/renewal competing RPG grants
    - **Success Rate**: 20.7%
    - **Average RPG award:** $592,617

https://nexus.od.nih.gov/all/2023/03/01/fy-2022-by-the-numbers-extramural-grant-investments-in-research/

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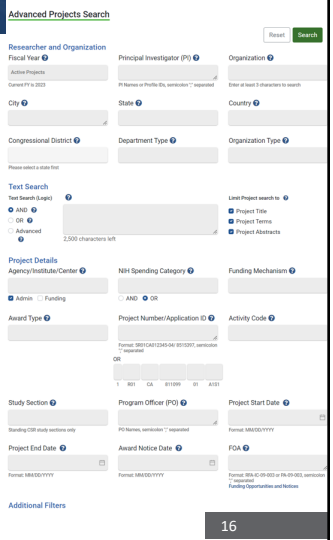
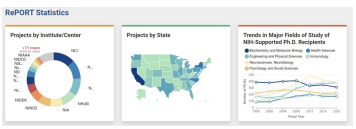
NIH RePORT
Research Portfolio Online Reporting Tools

https://report.nih.gov/



NIH exemplifies and promotes the highest level of public accountability. To that end, the Research Portfolio Online Reporting Tools (RePORT) provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research.

- NIH Data Book: provides basic summary statistics on extramural grants and contract awards, grant applications, and NIH funded organizations
- RCDC: Data on NIH projects by category
- Reporter: Searchable database with detailed NIH award information



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ABOUT THE NIH EXTRAMURAL RESEARCH ORGANIZATION

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OFFICE OF EXTRAMURAL RESEARCH (OER) ORGANIZATION

Office of Laboratory Animal Welfare (OLAW)	Office of Policy for Extramural Research Administration (OPERA)	Electronic Research Administration (eRA)	Office of Research Reporting and Analysis (ORRA)
Division of Human Subjects Research (DHSR)	Division of Biomedical Research Workforce (DBRW)	Division of Communications and Outreach (DCO)	Small Business Education and Entrepreneurial Development (SEED)
Research Integrity Officer	Review Policy Officer	NIH Guide for Grants and Contracts	Program Administration Officer

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OER OVERVIEW

- OER supports the entire NIH extramural research community by providing policy, guidance, systems, and other support to the recipient community as well as to the 24 NIH Institutes and Centers that award grants.
- OER serves as a vital interface for the biomedical research community by guiding investigators and their institutions through the process of attaining grants funding and helping them understand and navigate through federal policies and procedures.

OPERA MISSION

OPERA provides leadership and oversight in grants management policy and compliance, intellectual property, and OMB clearances to the extramural research community and NIH extramural staff through policy development, expert guidance, analysis, outreach, and related information dissemination in order to promote effective stewardship of NIH extramural funds in support of health research.

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OPERA PARTNERS AND STAKEHOLDERS

- Applicants and Recipients
- Congress
- HHS
- OGC
- GAO
- OIG
- DOJ
- OMB
- Professional Societies (NCURA, SRA)
- Recipient Constituent Organizations (e.g. FDP, COGR)
- NIH Office of Management Assessment
- NIH extramural staff
- And more!!

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ABOUT THE NIH FINANCIAL INSTRUMENT TYPES

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Instrument Type - Grants

- Financial assistance mechanism
- ***Direct benefit is to the public***
- Used when the funding IC ***does not*** anticipate having substantial programmatic involvement in the project
- Provide money to an eligible entity to carry out an approved project or activity

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Categories Of Activities Funded With Grants

- Research Projects (Rs e.g. R01, R21)
- Center Grants (Ps e.g. P30)
- Conference Support (R13)
- Training & Fellowships (Ts, Fs)
- Career Development (Ks)
- Small Business Innovation Research (R43/44)
- Construction (C06)
- Shared Instrumentation (S10)
- Clinical Trials (various mechanisms)

Types of Grant Programs:
https://grants.nih.gov/grants/funding/funding_program.htm

Instrument Type – Cooperative Agreements

- Financial assistance mechanism
- ***Direct benefit is to the public***
- Similar to grants, but are used when the funding IC ***will*** have **substantial federal programmatic involvement** in the project
- The Notice of Funding Opportunity (NOFO) will outline the responsibilities of both the NIH staff and the recipient, as well as joint responsibilities and obligations
- U mechanisms (e.g., U01, UM1, U24)

Instrument Type – Contracts

- Unlike grants and cooperative agreements, contracts are an acquisition mechanism, rather than assistance
- ***Direct benefit is to the government***
- The goal is to acquire goods or services for the use of the government or designated third party
- Usually government-initiated
- Contracts make up a small portion of the NIH extramural research portfolio

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Instrument Type - Other Transaction

- Unique type of legal instrument. Not a grant, not a cooperative agreement, not a contract
- Requires Congressional authorizing language, budget
- Used when NIH needs greater flexibility to identify and engage nontraditional research partners, or to engage traditional partners in new ways
- Negotiate terms and conditions that will concentrate their efforts, spur innovation, and facilitate collaborative problem solving

For additional information:
https://grants.nih.gov/funding/other-transactions.htm

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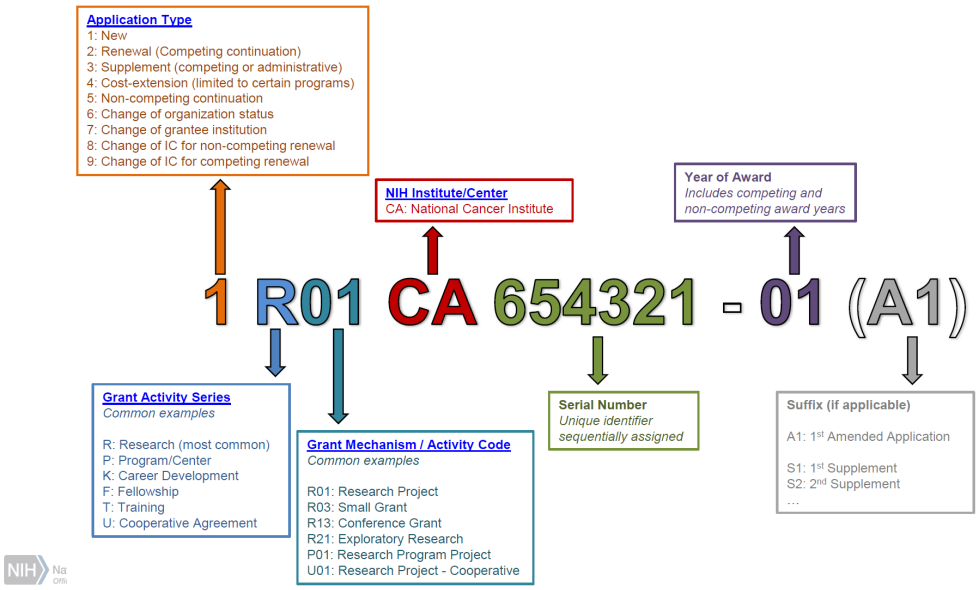
The NIH Grant Number

https://www.era.nih.gov/sites/default/files/Deciphering_NIH_Application.pdf
https://www.era.nih.gov/erahelp/commons/Commons/understandGrantNums.htm



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Questions / Discussion

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GRANT LIFECYCLE OVERVIEW

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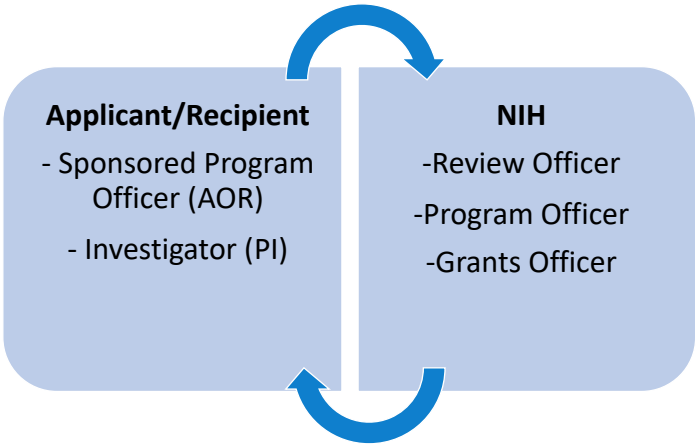
NIH's Birds Eye View: Partners In The Grants Process



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We are in this together!

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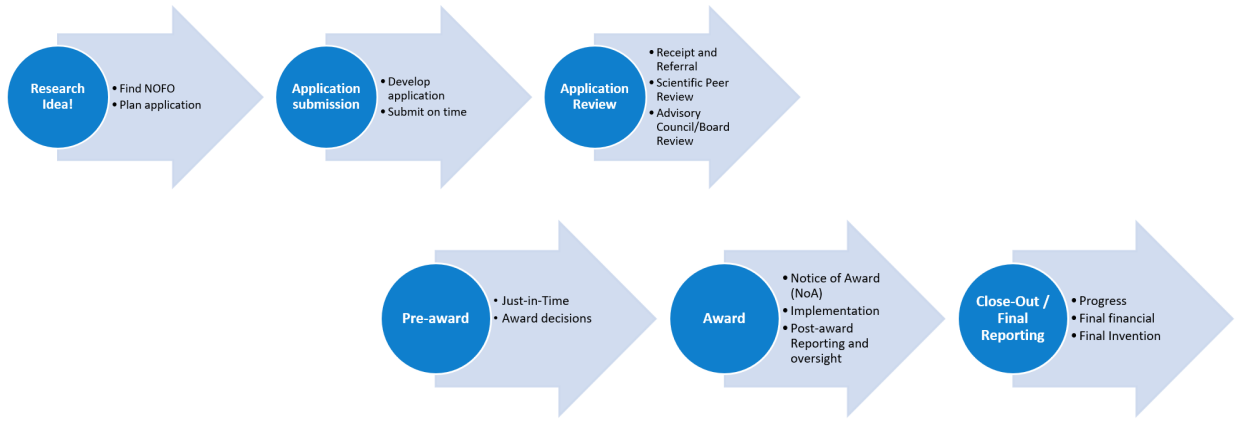
NIH Grants Lifecycle



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WHERE TO I START? PREPARING TO SUBMIT AN NIH GRANT APPLICATION

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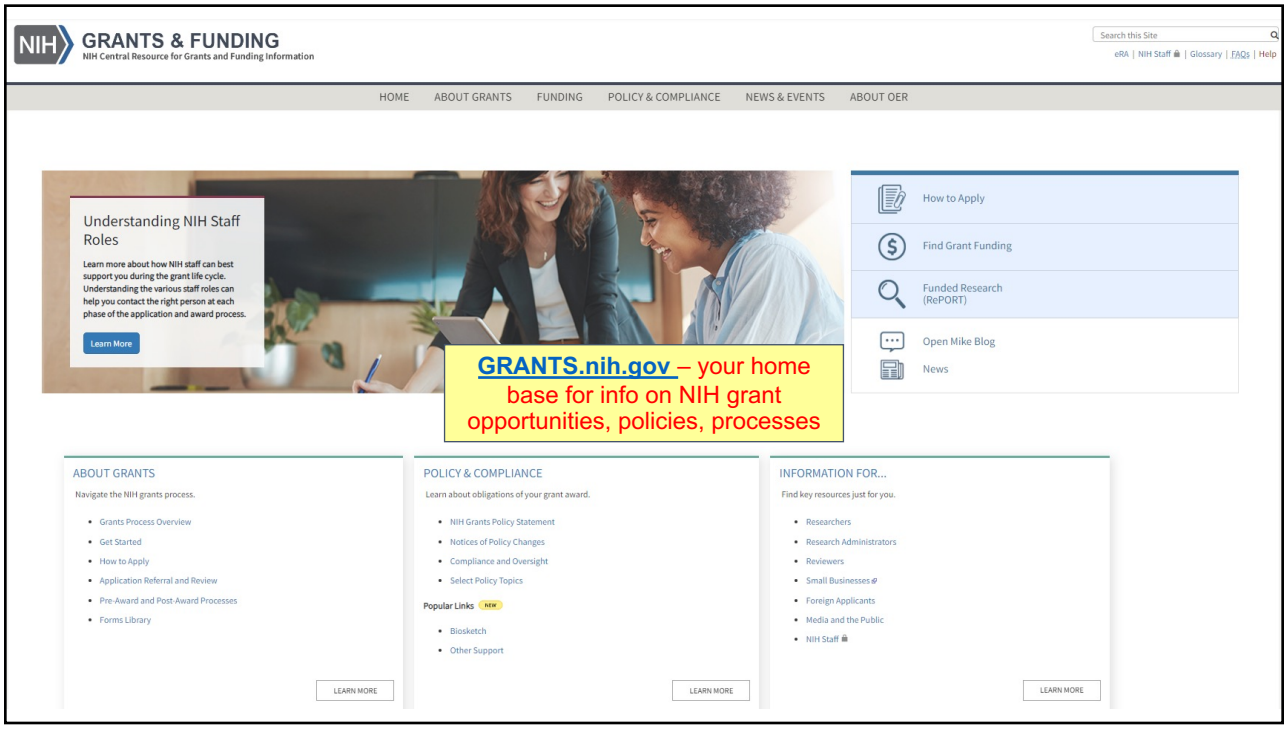

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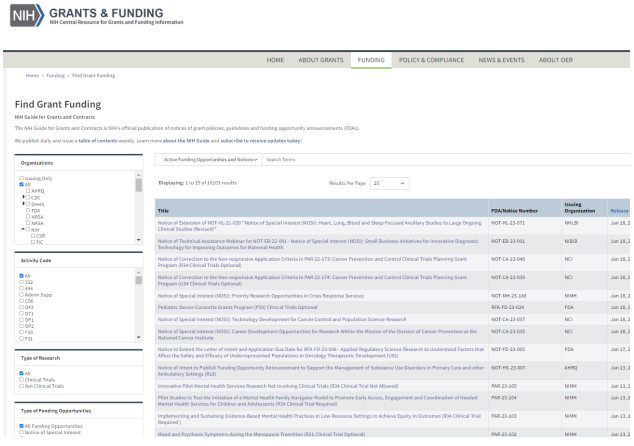
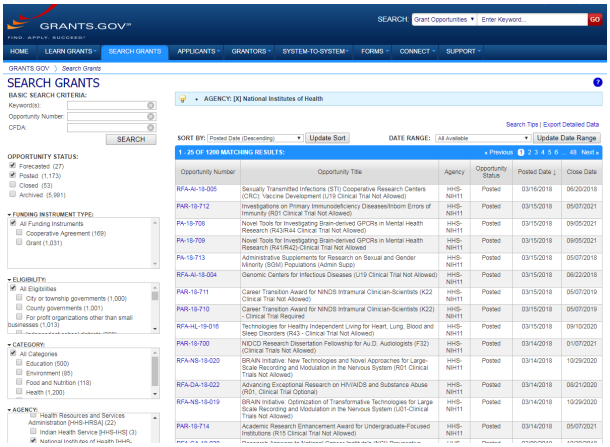
Finding a Notice of Funding Opportunity (NOFO)

- Investigator has an idea for a research project – looks to see if there is a particular NOFO for that area of research



https://grants.nih.gov/funding/searchguide/index.html#/



https://www.grants.gov/web/grants/search-grants.html

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Submitting An Application To NIH

- ***All applications submitted to NIH must be in response to a Notice of Funding Opportunity (NOFO)***
- NOFOs are published in the NIH Guide for Grants and Contracts
- Check out the NIH "Understand Funding Opportunities" Resource
- Types of NOFOs:
  - Program Announcements (PA)
    - Program Announcements with Review Criteria (PAR)
    - Program Announcements with Set-Aside Funds (PAS)
  - Requests for Applications (RFA)
- *Related*:
  - Notices of Special Interest (NOSI)

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Program Announcements (PA)

- Notify the community of a new or expanded interest in a research area.
- They can be specific to an NIH Institute or Center (IC) or general to NIH.
- Applications submitted are reviewed by NIH at the Center for Scientific Review (CSR).
- There are Parent Program Announcements for many grant mechanisms to allow applicants to submit investigator-initiated or unsolicited applications (e.g., Parent R01).
- *Other types of PAs include:*
  - Program Announcements with Review Criteria (PAR)
    - Contain special review criteria.
    - Can be reviewed by IC review branch or CSR.
  - Program Announcements with Set-Aside Funds (PAS)

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Request For Applications (RFA)

- Used to invite applications in a well-defined scientific research area that reflect IC priorities in a specific topic
- Include specific review and eligibility criteria
- Typically reviewed by the funding IC
- Can include specific terms of award requiring participation in networks, attending meetings, etc.
- Always have a set-aside of funds that the IC has committed to support applications submitted in response

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Clinical Trial NOFOs

- All applications involving one or more clinical trials must be submitted through a NOFO specifically designed for clinical trials.
- NOFOs specify the allowability of clinical trials in the NOFO title with the following designations:

Clinical Trial Not Allowed	Only accepts applications that do not propose clinical trial(s)
Clinical Trial Required	Only accepts applications that propose clinical trial(s)
Clinical Trial Optional	Accepts applications that either propose or do not propose clinical trial(s)
Basic Experimental Studies with Humans (BESH) Required	Only accepts applications that propose clinical trial(s) that also meet the definition of basic research

https://grants.nih.gov/policy/clinical-trials.htm

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NIH Eligible Applicant Entities

In general, the following types of organizations may apply for NIH grants

- Non-Profit Organizations
- For Profit Organizations
- Institutions of Higher Education
- Hospitals
- State and Local Governments
- Federal Institutions – with some qualifiers
- Foreign Institutions

Note: RFAs or PARs may further limit eligibility criteria.

Always review the NOFO to confirm your eligibility!

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Questions / Discussion

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HOW DO I APPLY?

APPLICATION PREPARATION AND SUBMISSION

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Required Registrations

- Organization Registrations
  - System for Award Management (SAM) – Required to do business with the federal government
    - Unique Entity Identifier (UEI)
  - Grants.gov – Required to submit grant applications
  - eRA Commons – Required to do business with NIH
  - Small Business Administration (SBA) – Required for SBIR/STTR applications
- Individual Registrations
  - Grants.gov – Authorized Organization Representative (AOR)
    - Additional users for Grants.gov Workspace
  - eRA Commons – Signing Official (SO) and Principal Investigator (PI)
    - Additional users for other roles and privileges

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ERA Commons Profile Maintenance

- PIs have an obligation to keep information in their Personal Profile current.
- Profile maintenance is especially critical for researchers applying for Early Stage Investigator status
- Profile data used in other electronic processes (e.g., Summary Statements, email Notifications)
  - Degrees
  - Position Titles
  - Addresses – e-mail and postal

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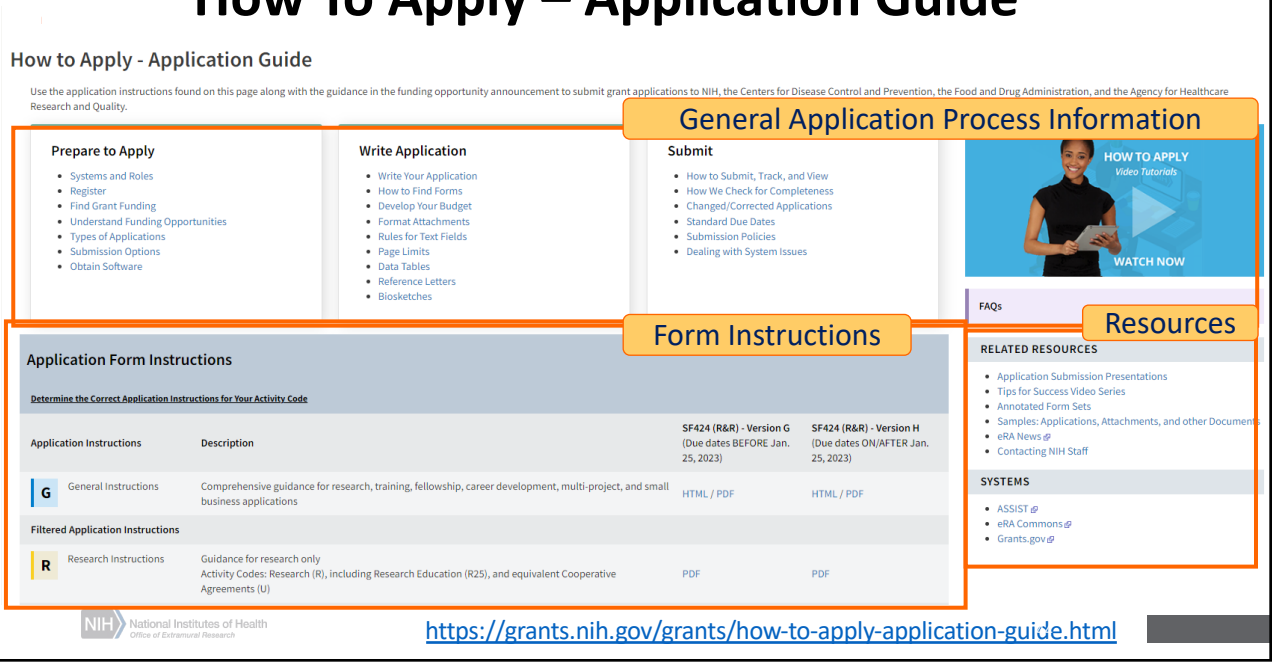
How To Apply – Application Guide



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

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Data Management and Sharing (DMS) Plan

- 2023 NIH Data Management and Sharing (DMS) Policy: See NIH GPS Section 8.2.3.1
- Effective for application due dates on/after January 25, 2023, the DMS Policy requires:
  - researchers to prospectively plan for how scientific data will be preserved and shared through submission of a DMS Plan (*replaces 2003 Data Sharing Policy*).
  - **submission of a DMS Plan** (including a Genomic Data Sharing Plan, if applicable) outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
  - **compliance with the recipient's plan** as approved by the NIH Institute and Center (IC).
- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.
- When required in the NOFO, the DMS plan must be provided in the application "Other Plan(s)" attachment on the PHS 398 Research Plan or PHS 398 Career Development Award Supplemental Form, as applicable.

See NIH Sharing website for additional information: https://sharing.nih.gov/

Application Forms

- There is NOT a universal set of application forms that can be downloaded from our form library or websites.
- You must use the application form package attached to your funding opportunity announcement.
  - Each application form package includes the customized subset of forms supported by NIH which are needed for that opportunity.
- Application forms are accessed using your chosen submission method.

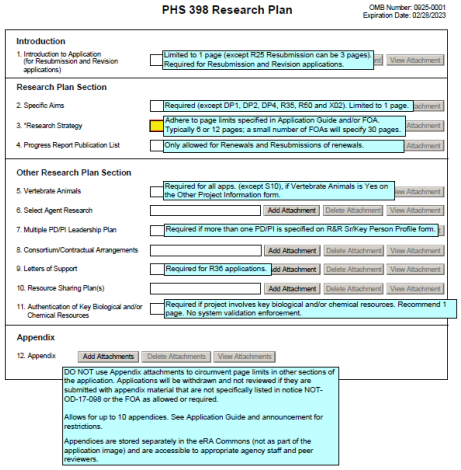
Preparing Application – *Follow All Instructions*

- Follow All Guidance
  - Notices in NIH Guide for Grants & Contracts including Notices of Special Interest (NOSIs)
  - Notice of Funding Opportunity
    - Section IV. Application and Submission Information
  - How to Apply - Application Guide

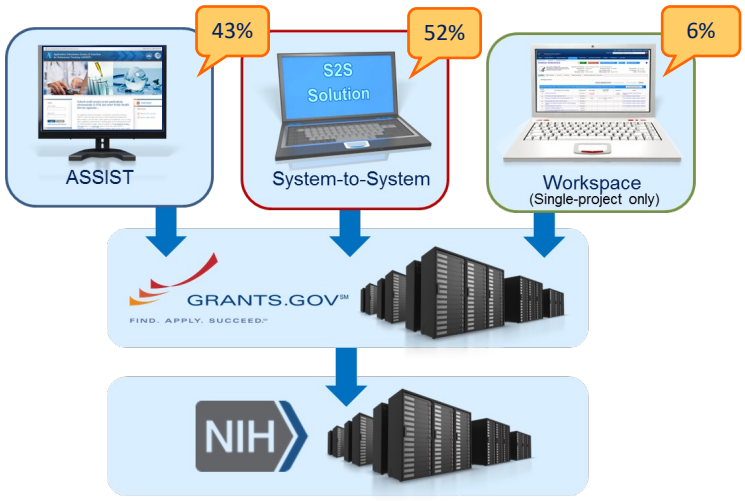
Precedence / Importance

- Handy Resource

Annotated form sets



Application Submission Options



eRA ASSIST

- Managed by NIH
- Leverages eRA Commons accounts
- Pre-population from eRA Commons profiles
- Track application status in single system
- Supports all NIH competing applications
- Pull study information from ClinicalTrials.gov
- Integrated NIH messaging (tips, system alerts)

Grants.gov Workspace

- Managed by Grants.gov
- Requires additional user registrations
- No Pre-population from existing profiles
- Must track application in multiple systems
- Supports all NIH single- project competing applications (no multi-project support)

System2System

- Managed by institution or service provider
- Typically integrate with other internal systems and databases to reduce data entry
- Features vary by solution
- Allowable for single- and multi-project application submission

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Regardless Of Submission Method, All Applications Will Be…

- Subject to the same registration requirements
- Completed with the same data items
- Routed through Grants.gov
- Validated against the same NIH business rules
- Assembled in a consistent format for review consideration
- Tracked in eRA Commons

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Submission Of An Application - Due Dates

- Grant applications and associated documents are due by 5:00 PM local time of applicant organization on the specified due date
  - Application must be free of all federal system-identified **errors** (Grants.gov & eRA)
- Many activity codes use standard due dates (three cycles/year)
- These due date cycles allow NIH to distribute the receipt of applications throughout the fiscal year
- Always check the NOFO to confirm the due date(s)
- Additional information: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm

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Questions / Discussion

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HOW WILL MY APPLICATION BE REVIEWED? THE NIH PEER REVIEW PROCESS

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The Center For Scientific Review (CSR)

- CSR is the gateway for NIH grant applications and their review for scientific merit
- Receives all grant applications for NIH (electronically)
- Conducts peer review for about 75% of NIH applications

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Receipt And Referral

- All grant applications submitted to NIH go to the **Division of Receipt and Referral** (DRR) within the **Center for Scientific Review** (CSR).
- After receiving the application DRR:
  - Checks the application for 'On time' submission and completeness.
  - Determines area of research and which specific IC to assign it to.
  - Assigns a unique NIH grant number to the application.
  - Assigns application to a specific study section, also known as a Scientific Review Group or review committee that has the expertise to evaluate the scientific and technical merit of the application.
- CSR coordinates the reviews for most NIH grants, while ICs coordinate review for applications with institution-specific features.

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What Is Peer Review?

NIH has a two-stage review.

- First level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists with relevant expertise.
- The second level of review is performed by the Institute and Center National Advisory Councils or Boards composed of both scientific and public representatives.
- *Only applications that are recommended for approval by both the SRG and the Advisory Council may be recommended for funding. Final funding decisions are made by the IC Directors*.

https://grants.nih.gov/grants/peer-review.htm

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Initial Review

- Can occur at CSR or at the funding IC.
- Each NOFO specifies all the review criteria and considerations that will be used in the evaluation of applications submitted for that NOFO.
- Reviewers score all applications for which they are present and not in conflict.
- Preliminary impact scores are used to determine which applications will be discussed in full at the meeting.
- Focus of discussion on major strengths and weaknesses relative to review criteria.
- Final scores are recorded for each discussed application.

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Initial Review

- Evaluations and the assigned score (or "Not Discussed") are provided to the investigator (via posting in the eRA Commons) in a Summary Statement
- Individual Reviewers assign scores utilizing a scale of 1 – 9 (1 = exceptional; 9 = poor)
- Overall impact/priority score is the mean score from all eligible reviewer scores, multiplied by 10. Final scores will range from 10 to 90, reported in whole numbers

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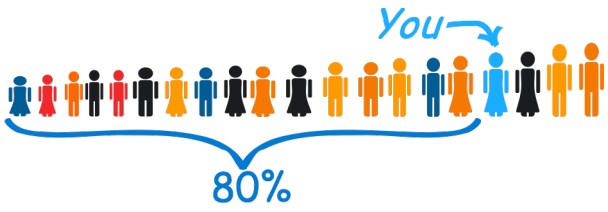
Initial Review

- To account for score compression and inflation with applications reviewed at standing CSR study sections, raw scores are then percentiled
- The Percentile is the relative rank, generally within a review group, but sometimes CSR-wide, for each raw priority score.



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Summary Statement Components

- Overall resume and summary of review discussion (if scored)
- Critiques by the reviewers
- Priority score and percentile ranking (if scored; also not all applications receive a percentile ranking)
- Budget recommendations
- Administrative notes

Although your summary statement gives you critical feedback, it is not an exhaustive critique or a teaching tool containing every point reviewers found to be problematic.

Sample Summary Statement

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Council Review

- Each IC has an Advisory Council or Board
- Composed of scientists from the extramural research community and public representatives
- Provides the second level of review and makes recommendations to the IC Director

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Questions / Discussion

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Case Study: Dr. Munroe

- *Case study activity – see handout*

Instructions:
1. Review the following scenarios
2. Consider the question prompts for each situation
3. Discuss with your table/group

BREAK 2:30 to 2:45pm

- *Brief discussion/report out after break*

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Case Study

Scenario 1: You are a research administrator and Authorized Organization Representative (AOR) at Metropolis University. Dr. Ororo Munroe, a new faculty member, is interested in applying for NIH funding to test a research idea that could improve human health. She asks you for guidance as she considers a grant proposal.

- *How can Dr. Munroe submit her idea to NIH? What questions would you ask her about her proposed project?*
- *What are key considerations for developing an NIH grant application?*

Scenario 2: Dr. Munroe has decided to submit to the parent R01 NOFO and wants to include collaborators from other institutions on the application.

- *For consortium applications, does one institution need to be the lead? How is this handled?*
- *As the prime applicant, how is the application electronically submitted to NIH? Who is does the final application sign-off and submission? What do you do if you receive errors or warnings? Who can you contact for help?*
- *Unfortunately, Hurricane Kitty hit the state around the due date and caused widespread power and disruptions in the region, preventing on-time submission. Dr. Munroe has concerns if her application can be submitted late. What are considerations for late submission?*

Scenario 3: Dr. Munroe's application was submitted, reviewed, and received a score.

- *Where can Dr. Munroe see her score and summary statement after peer review?*
- *What should she do if she has questions about the review?*
- *If the score is within a broad fundable range, what should she expect to hear from NIH?*

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WHAT HAPPENS AFTER REVIEW? PRE-AWARD PROCESS

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Pre- Award Process

- Following peer review, the pre-award process begins
- Just-in-time information will be collected throughout the process, including other support, IRB approval, IACUC approval and any other documents needed to support the award.
- Negotiations may also occur regarding overlap, level of effort, budget, and Facilities and Administrative (F&A) costs
- For non-competing awards the process is streamlined. Recipients submit progress reports which are reviewed and approved prior to funding the new budget year.

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Just In Time (JIT)

- Items that are submitted after initial review when the application is under consideration for funding;
- Minimizes burden to institutions and ensures information is current at time of award.
- Request for or submission of JIT, regardless of priority score, is not an indication of funding.

Comprised of:

- Other Support
- IACUC approval
- IRB approval

Requirements:

- Cannot be over 120 days old
- Must be submitted by authorized official

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Disclosure Requirements: *Other Support*

Includes all resources made available to researchers or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

- The purpose of other support disclosure is to assess scientific, budgetary, and commitment capacity for the PI and Senior/Key Personnel.
- IC scientific program and grants management staff will review disclosure information before award to ensure the following:
  - Sufficient levels of effort are committed to the project.
  - There is no scientific, budgetary, or commitment overlap.
  - All financial resources, domestic or foreign, directly supporting the individuals research endeavors have been reported.
  - Only funds necessary to the approved project are included in the award.

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Negotiation

- Communication after IC review and determination if an award can be made, if special conditions are required, and funding level is appropriate.
- Involves communication between IC and an authorized representative of the applicant organization.
- Could involve adjustments such as IRG recommendations, budget/programmatic modifications, determination of Facilities and Admin. Rate, budget and project start date.
- Confirms a start date, which may be different than the start date requested in the application.

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Notice Of Award (NoA)

- The legally binding document issued to notify a recipient that an award has been made and funds may be requested from the Payment Management System (PMS)
- Issued for initial budget period
- Subsequent budget periods referenced as commitments
- Terms and conditions of award:
  - Standard
  - Specific
- Grants Management and Program Official Contact Information
- Recipient accepts terms by drawing down funds

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THE AWARD HAS BEEN MADE - WHAT'S NEXT? ROLES AND RESPONSIBILITIES

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Recipient Institution

- Awards are made to the recipient institution, not the PI
- The Authorized Organization Representative (AOR) is the designated point of contact for NIH officials
  - Assures compliance with federal regulations, policies and procedures
  - Monitors proper conduct of the project
  - Fiscal management of the project
- PI is responsible for the Scientific and Technical Aspects of the grant and the day-to-day management of the project

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NIH Program Official

Responsible for the programmatic, scientific, and/or technical aspects of grants

- Reviews post-award requests for prior approval and provides scientific input and recommends approval/disapproval
- Reviews annual progress of grants
- In the case of cooperative agreements, program officials are very involved in program design and outcomes.

NIH Grants Management Officer

Monitors administrative and fiscal aspects of the project

- The GMO is the **only** NIH official authorized to obligate NIH to the expenditure of funds - or to change funding amounts, budget/project period dates, or other terms and conditions of a grant award.

NIH Grants Management Specialist

The Grants Management Specialist (GMS) acts as an agent of the GMO.

- Assures compliance with laws and NIH/HHS policies and procedures
- Analyzes grant applications and budgets
- Provides technical assistance, interprets NIH policies and Institute procedures
- Awards grant funds
- Reviews and responds to recipient prior approval and rebudgeting requests

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Questions / Discussion

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POST-AWARD: *MANAGEMENT AND COMPLIANCE*

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Managing Your Award

- NIH Grants Policy Statement
- Expanded Authorities
- Prior Approval
- Reporting Requirements

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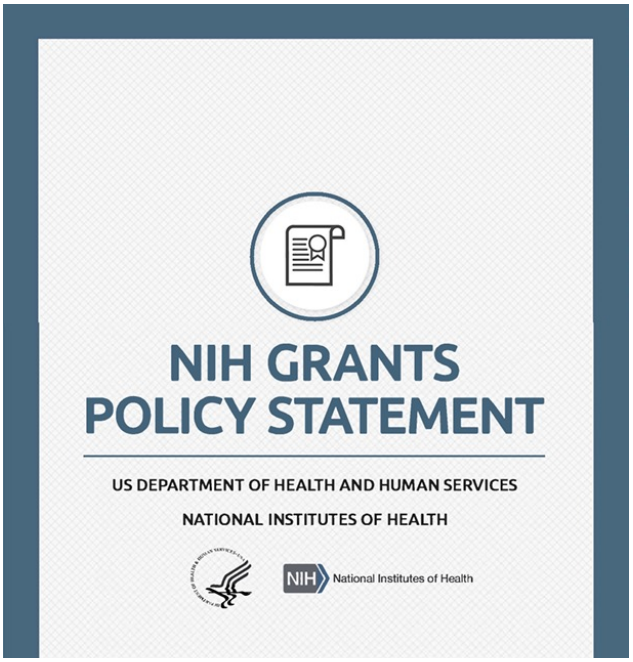
NIH GRANTS POLICY STATEMENT!

https://grants.nih.gov/policy/nihgps/index.htm



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NIH Grants Policy Statement (NIHGPS)

- The NIH Grants Policy Statement (NIHGPS) makes available, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. By accepting an award, recipients agree to comply with the requirements in the NIH Grants Policy Statement except where the notice of award states otherwise.
- Notices of policy changes published in the NIH Guide for Grants and Contracts can supersede information in the NIH Grants Policy Statement. Compliance with these policy updates also becomes a term and condition of award.

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NIH Grants Policy Statement

- **Part I NIH Grants-General Information**
  - Glossary
  - Roles and Responsibilities
  - Application Submission
  - Peer Review
  - Pre-award Process
- **Part IIA Terms and Conditions of NIH Grant Awards**
  - Overview
  - Public Policy Requirements, Objectives, and Other Appropriation Mandates
  - Notice of Award
  - Payment
  - Cost Consideration
  - Administrative Requirements
- **Part IIB Terms and Conditions of NIH Grant Awards**
  - Multiple PD/PI
  - Construction Grants
  - Kirschstein-NRSA (Fs & Ts)
  - Career Awards (Ks)
  - Modular Applications & Awards
  - Conference Grants
  - Consortium Agreements
  - Foreign Institutions
  - Federal Recipients
  - For-Profit Organizations
  - Patient Care Costs
- **Part III:** points of Contact information
- **Target Audience**: Applicants and Recipients, NIH staff

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https://grants.nih.gov/policy/nihgps/index.htm

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Expanded Authorities

- NIH is committed to reducing administrative burden for NIH recipients.
- Under expanded authorities, the recipient institution has the authority to take certain actions on grants without agency prior approval.

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Expanded Authorities

- **NIHGPS** Section 8.1.1 describes "expanded authorities" that waive certain cost-related and administrative prior approvals.
  - 1st No-Cost Extension of a project period (up to 12-months)
  - Rebudgeting unrestricted funds between budget categories, if not an indication of a change in the scope of the project
  - Carryover of unexpended unrestricted funds from one budget period to the next
  - Transferring performance of work to a 3rd party or changing a 3rd party, if not an indication of a change in scope and the third party is not a foreign organization

Prior Approval

- **NIHGPS** Section 8.1.2 describes ***Prior Approval Requirements*** (situations that require prior approval)
- **NIHGPS** Section 8.1.3 describes ***Request for Prior Approvals*** **process** for submitting a request to NIH

Note: All requests for NIH prior approval must be made in writing (including submission by e mail) to the awarding IC GMO **no later than 30 days before the proposed change**, and signed by the AOR.

NIH prior approval is required for, but not limited to, the following:

- Second or subsequent No-Cost Extension
- Change of PI or Change of recipient institution
- Addition of a foreign component
- Undertaking activities disapproved or restricted as a term of award
- Carryover of restricted funds if required by term of award
- Need for additional NIH funds
- *Change in scope*
- *Reduction in effort*

Prior Approval – *Change In Scope*

Potential indicators of a Change in Scope (see NIHGPS Section 8.1.2.5)

- Change in aims
- Shift in research emphasis
- Application of new technology
- Change in use of human subjects or animals
- Significant change in key personnel
- Significant rebudgeting (deviation of a single category committed costs >25% of total costs awarded)

Prior Approval – Effort

Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA (see NIHGPS 8.1.2.6)

- Prior approval is required when there is a change is status of:
  - PI (always defined as key personnel)
  - Other key personnel **specifically named** in the notice of award
- NIH prior approval is required when the change in status involves:
  - 25% or more reduction in effort
  - Absence of 3 continuous months or more from the project

Prior Approval

Request for Prior Approvals process (see NIHGPS Section 8.1.3)

All requests for NIH approval must be:

- Submitted in writing (by email) or via eRA Commons
- Submitted no later than 30 days before the proposed change
- Signed by the AOR
- Sent to both Program and Grants Management
- Only responses to prior approval requests signed by the Grants Management Officers are valid.

A Rule Of Thumb

Whenever you are contemplating post award changes and are uncertain about the need for prior approval, **consult in advance** with:

- Your institution's Office for Sponsored Research
- The NIH Grants Policy Statement
- NIH grants management official (named in the Notice of Award)

Questions / Discussion

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PROGRESS REPORTING AND OVERSIGHT

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Annual Reporting and Compliance Requirements

- Research Performance Progress Report (RPPR)
- Federal Financial Report (FFR)
- Public Access
- Financial Conflict of Interest (FCOI)

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Research Performance Progress Report (RPPR)

- Annual *Research Performance Progress Report* (*RPPR*) Format
- Submission through NIH Commons
- Due Dates
  - Non-SNAP: Approximately 60 days before the start of next budget period
  - SNAP: Approximately 45 days before start of the next budget period
  - Multi-Year Funded: On or before award anniversary date

Searchable list to determine which progress reports are due:
https://public.era.nih.gov/commons/public/quickqueries/progressReportByIpf.era
Note: This query will return a list of progress reports that are listed as "due" within the next 4 months for a selected recipient institution.

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Non-Competing Award (Type 5) Progress Report (RPPR) Review Considerations

- What happened
- What's planned
- Changes
  - Scope
  - Effort
  - Other Support
  - Leadership Plan (MPI)
  - Performance Sites
  - Use of Human or Animal Subjects
  - Significant Budget Changes/Balances

Compliance

- Publications - Compliance with Public Access Policy
- Review Foreign Involvement (existing and new)
- Invention Reporting
- Restrictions and Special Terms
  - E.g. Approved DMS plan

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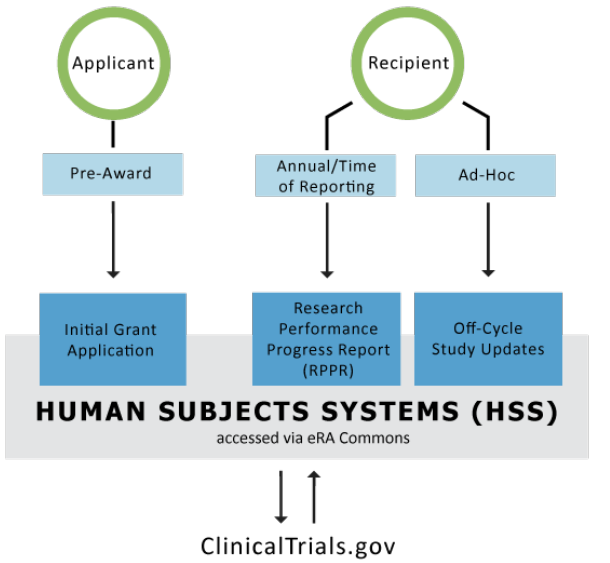
Human Subjects System

UPDATING STUDY INFORMATION WITH HSS



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Federal Financial Report (SF-425 FFR)

- For most NIH awards an FFR is submitted at the end of the competitive segment.
- For complex mechanisms and other awards not subject to the Streamlined Non-Competing Award Process (SNAP), FFRs must be submitted annually.
- Annual FFRs are due no later than 90 days after the end of the calendar quarter in which the budget period ends.
- Since January 1, 2021, all FFRs must be submitted through the NIH Payment Management System (PMS).
- Since April 1, 2022, recipients will no longer complete the quarterly Federal Cash Transaction Report (FCTR).

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Public Access

More information:
https://publicaccess.nih.gov/

Public Access Policy Overview:

- To advance science and improve human health, NIH makes the peer-reviewed articles it funds publicly available on PubMed Central.
- The NIH public access policy **requires scientists to submit final peer-reviewed journal manuscripts** that arise from NIH funds **to PubMed Central immediately** upon acceptance for publication.

- The Public Access Policy applies to any manuscript that:
  - Is peer-reviewed
  - Has been accepted for publication in a journal
  - Has direct funding from an NIH grant or cooperative agreement

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Public Access

- Proposals and Reports must include citations that demonstrate compliance with the NIH Public Access Policy for all applicable papers that are authored by the Principal Investigator (PI) or arose from the NIH grant funding.
- Investigators will need to use My NCBI to enter papers onto progress reports. Papers can be associated electronically using the RPPR
- Additional Information at the ***NIH Public Access site:***
  https://publicaccess.nih.gov/

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Financial Conflict Of Interest (FCOI)

- See NIHGPS section 4.1.10 Financial Conflict of Interest
  - Purpose is to ensure that NIH funded research will be free from bias by any conflicting financial interest of any Investigator or individual who is responsible for the design, conduct, or reporting of research
  - The Financial Conflict Of Interest (FCOI) policy applies to all NIH recipient (prime and sub) institutions and investigators EXCEPT FOR Phase 1 SBIR/STTR applicants and recipients
  - The institution is required to have an up-to-date, written and enforced administrative process to identify and manage FCOI with respect to all research projects for which NIH funding is sought or received; and to identify and manage FCOIs and provide initial and ongoing FCOI reports to NIH.

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CLOSEOUT

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Administrative Grants Closeout

See NIHGPS 8.6 Closeout

- Three closeout reports are required:
  - **Final Research Performance Progress Report (FRPPR)**
    - If a competing renewal application (Type-2) is submitted an Interim Research Performance Progress Report (IRPPR) is required
    - If the Type 2 application is not funded, the IRPPR automatically becomes the FRPPR
  - **Final Federal Financial Report**
    - Not required for NRSA Individual Fellowship awards.
    - Directly impacts financial closeout.
  - **Final Invention Statement**
    - Not required for some activity codes (e.g., Fs, Ts, C06, R13, R25, S10). See NIH GPS 8.6.3.

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Grants Closeout Deadlines (120 days)

See NIHGPS 8.6 Closeout

- Recipients have 120 days after the project end date to submit the required closeout documents through the eRA Commons.
  - After 120 days Unilateral Closeout procedures begin.
  - After 270 days, the award will unilaterally closed by NIH.
    - This is a serious non-compliance action. Depending on the financial status, could put the recipient in a debt status.

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Questions / Discussion

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COMPLIANCE REQUIREMENTS (THE NOT SO SMALL PRINT)

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Compliance Through The Life Cycle

- *Preparing the application:* Respond fully to all requirements in the NOFO
- *Signing the application:* By signing, the AOR certifies that the institution will comply with all applicable assurances and certifications referenced in the application
- *Terms and conditions:* Outlined in the NOA NIH Grants Policy Statement. Terms accepted when funds are drawn down
- *Annual reporting requirements:* programmatic and financial
- *Closeout:* Timely submission of accurate closeout reports

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Common Contributors To Noncompliance

- Failure to ensure that terms and conditions flow down to subrecipients
- Inaccurate and untimely reporting (e.g., closeout)
- Lack of internal controls (e.g., outdated policies) and internal oversight
- Inadequate management systems (e.g., financial management, other support)
- Insufficient knowledge of grant compliance requirements

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HELPFUL NIH RESOURCES

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Office of Extramural Research

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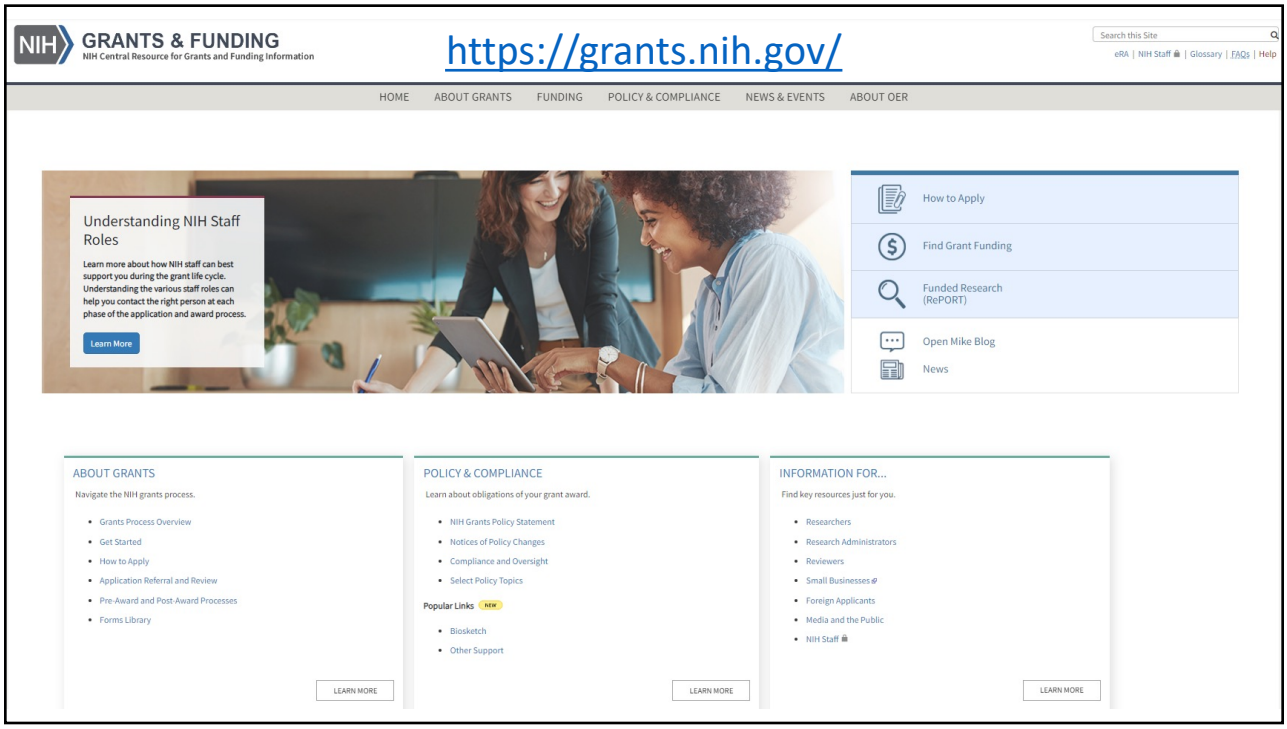

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NIH Grants And Funding News And Events

- Get the Latest News and Events from NIH OER!
  - https://grants.nih.gov/news/news_and_events.htm
- Find opportunities to meet experts from the NIH Office of Extramural Research at upcoming events.
  - NIH Grants Conference and PreCon Events
  - NIH Regional Seminars on Program Funding and Grants Administration
  - OER Webinars
  - NIH Loan Repayment Program (LRP) Contact & Engage Link to External Site
  - NIH Office of Laboratory Animal Welfare Workshops & Conferences
  - SEED Events (for the innovator community)
- Other great On Demand Resources:
  - All About Grants Podcasts
  - NIH Grants YouTube Channel
  - eRA Videos

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NIH Grant-related Listservs

- NIH Grant Seminars
  https://grants.nih.gov/news/contact-in-person/seminars.htm#listserv
- NIH Guide for Grants and Contracts: Official publication for NIH Grant Policies, Guidelines & Funding Opportunities
  http://grants.nih.gov/grants/guide/listserv.htm
- Extramural Nexus: News, updates, and blog posts on extramural grant policies, processes, events, and resources
  https://nexus.od.nih.gov/all/subscribe/
- Office for Human Research Protections (OHRP):
  http://www.hhs.gov/ohrp
- Office of Laboratory Animal Welfare (OLAW):
  https://olaw.nih.gov/resources/list.htm
- eRA News: News and updates on the electronic submission of grant applications (i.e., eSubmission), as well as ASSIST and eRA Commons.
  https://www.era.nih.gov/about-era/get-connected.htm http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm

https://grants.nih.gov/news/subscribe-and-follow/listservs_and_rss.htm

Additional Helpful NIH Web Pages

- NIH Guide for Grants and Contracts:
  https://grants.nih.gov/funding/searchguide/index.html#/
- NIH Grants Policy Statement: https://grants.nih.gov/policy/nihgps/index.htm
  - Notice of NIH Policy Changes: https://grants.nih.gov/policy/PolicyNotices.php
- NIH Extramural Nexus – newsletter for the extramural community:
  http://nexus.od.nih.gov/all/nexus-by-date/
- Grants Basics: http://grants.nih.gov/grants/grant_basics.htm

Additional Helpful NIH Web Pages

- How to Apply - Application Guide: http://grants.nih.gov/grants/how-to-apply-application-guide.htm
- Annotated Application Form Sets (General and Small Business and Multi-project): https://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm
- How we check for application completeness: https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm
- *Do I have the right electronic forms for my application?* Resource: http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf

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Additional Helpful NIH Web Pages

- eRA Commons Web pages: http://era.nih.gov/
- eRA Help & Tutiorials: https://www.era.nih.gov/help-tutorials
- eRA Commons User Guides: https://www.era.nih.gov/help-tutorials/era-commons/user-guide.htm
- Intellectual Property Policy: https://grants.nih.gov/policy/intell-property.htm
- Research Portfolio Online Reporting Tools (RePORT): http://report.nih.gov
- RePORT Expenditures & Results (RePORTER): http://projectreporter.nih.gov/reporter.cfm
- Information for Foreign Grants: https://grants.nih.gov/grants/foreign/index.htm
  - International Collaborations: Policies, Processes, & Partnerships (Materials available from Nov. 2022 Virtual Event)

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RPPR Resources

- NIH Grants & Funding- RPPR webpage: http://grants.nih.gov/grants/rppr/
- eRA RPPR Resource webpages:
  - https://www.era.nih.gov/recipients/submit-reports/rppr.htm
  - https://www.era.nih.gov/help-tutorials/rppr
- Includes links to:
  - RPPR Instruction Guide
  - RPPR Guide Notices
  - Frequently Asked Questions
  - Training

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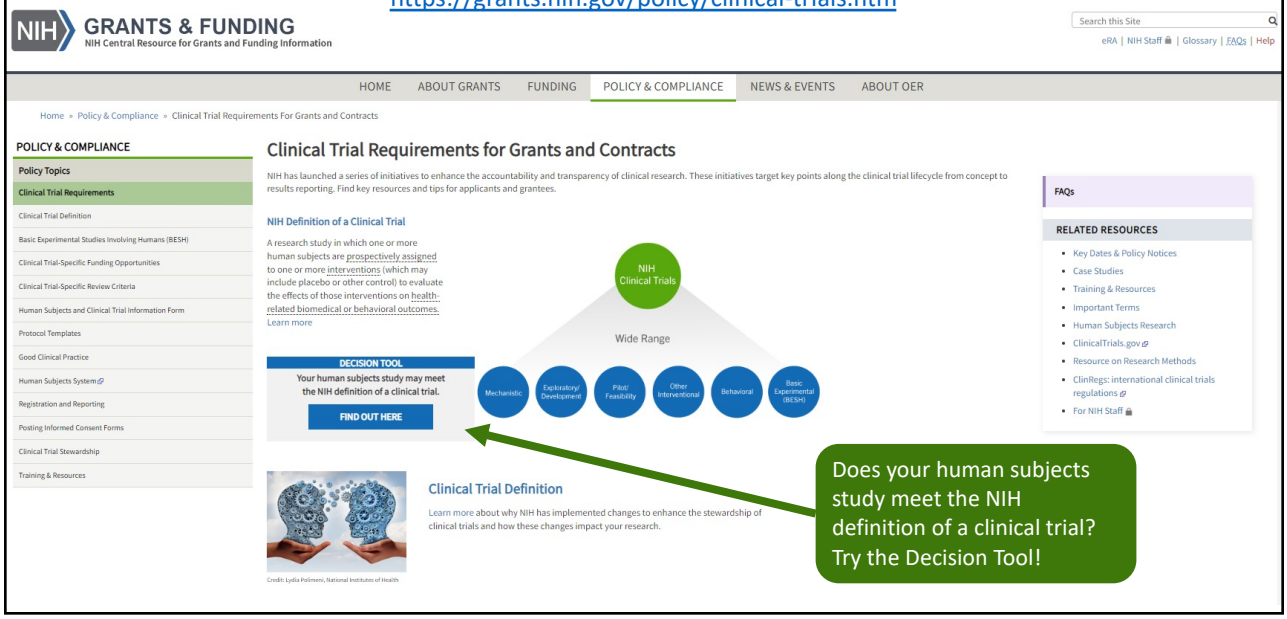
NIH Clinical Trial Resources

https://grants.nih.gov/policy/clinical-trials.htm



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NIH Sharing Research Resources

- NIH Grants Policy Statement:
  - 8.2.3 Sharing Research Resources
    - 8.2.3.1 Policy for Data Management and Sharing
    - 8.2.3.4 Sharing Model Organisms
    - 8.2.3.5 Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)
- NIH Scientific Data Sharing website: https://sharing.nih.gov/
  - Data Management and Sharing Policy Overview: https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview
  - Genomic Data Sharing Policy Overview: https://sharing.nih.gov/genomic-data-sharing-policy
  - Other Sharing Policies (Model Organism, Research Tools): https://sharing.nih.gov/other-sharing-policies
  - Accessing Data: https://sharing.nih.gov/accessing-data

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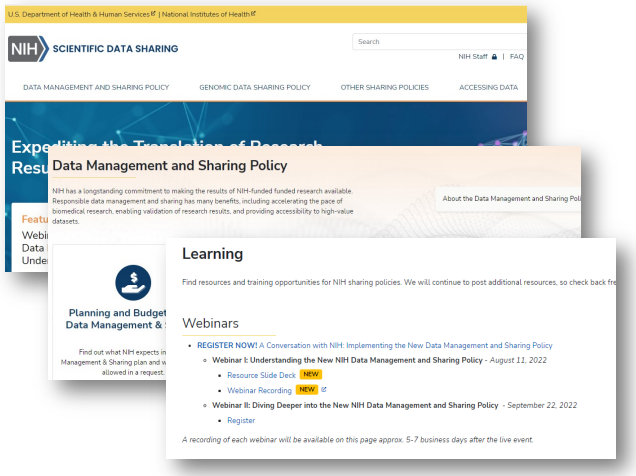
Additional NIH Data Management And Sharing Online Resources



Writing a DMS Plan

Budgeting for Data Management and & Sharing

Optional DMS Plan format page

Sample DMS Plans

DMS Policy FAQs

NIH DMS Policy Implementation Webinar Series

Federal Demonstration Partnership (FDP) NIH Data Management and Sharing Pilot

Email Box: Sharing@nih.gov

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Frequently Asked Questions

NIH FAQs – searchable resource for detailed information about:

- Application/progress report preparation, funding initiatives, policies, human subjects, sIRB, clinical trials, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc.…

http://grants.nih.gov/grants/frequent_questions.htm
https://www.era.nih.gov/faqs.htm

Grants Information: Who To Contact?

- General Application Questions:
  - E-Mail: GrantsInfo@nih.gov
- Grants.gov Customer Support:
  - E-Mail: support@grants.gov
  - Web: https://www.grants.gov/web/grants/support.html
  - Phone (U.S.): 1-800-518-4726
  - Phone (International): 1-606-545-5035
  - Hours: 24 hours a day, 7 days a week (excluding federal holidays)
- eRA Commons Helpdesk:
  - Web: https://www.era.nih.gov/need-help
  - Toll-free: 1-866-504-9552
  - Phone: 301-402-7469
  - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time (closed on federal holidays)
  - **Note:** See Dealing With System Issues if a federal system issue threatens your on-time application submission.

Grants Issues: Who To Contact?

- **CURRENT GRANT AWARDS:**
  - **Contact the Grant Management Specialist and Program Official listed in the Notice of Award.**
- Grants Policy:
  - E-Mail: GrantsPolicy@mail.nih.gov
- Grants Compliance & Oversight:
  - E-Mail: GrantsCompliance@mail.nih.gov
- Grant Systems Integration:
  - E-Mail: OPERAsystemspolicy@nih.gov
- FFR Reconciliation and Financial Closeout Support :
  - E-Mail: OPERAFFRInquiries@od.nih.gov
- Extramural Inventions and Technology Resources:
  - E-Mail: Inventions@nih.gov

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(Final)
Questions / Discussion

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Test your knowledge!

Game Time:

- Jeopardy style - correct responses in the form of a question
- Score sheets available as handouts at tables or online
- Honor system scoring
- Informal game – answer style round-robin or raised hands
- Please ask/discuss any follow-up questions about the game answers
- Prize: bragging rights and/or self-satisfaction

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National Council of University Research Administrators

SAVE THE DATE!

Join us in Honolulu, Hawaii 2024

Financial Research Administration Conference	FRA/PRA Workshop Day	Pre-Award Research Administration Conference
March 18-19	March 20	March 21-22

REGISTRATION OPENS IN NOVEMBER!