

NIH Fundamentals

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AGENDA

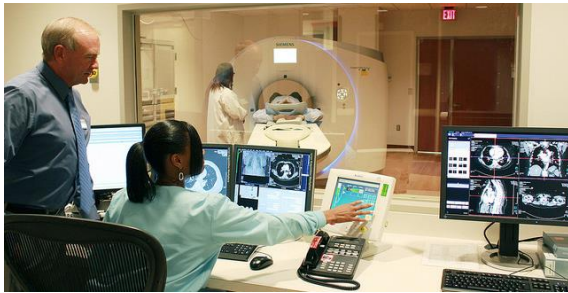
- NIH overview
- Developing and submitting applications
- The peer-review process
- Post-Award administration
- Resources

THE NATIONAL INSTITUTES OF HEALTH

The Nation's Steward of Medical & Behavioral Research



“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.”

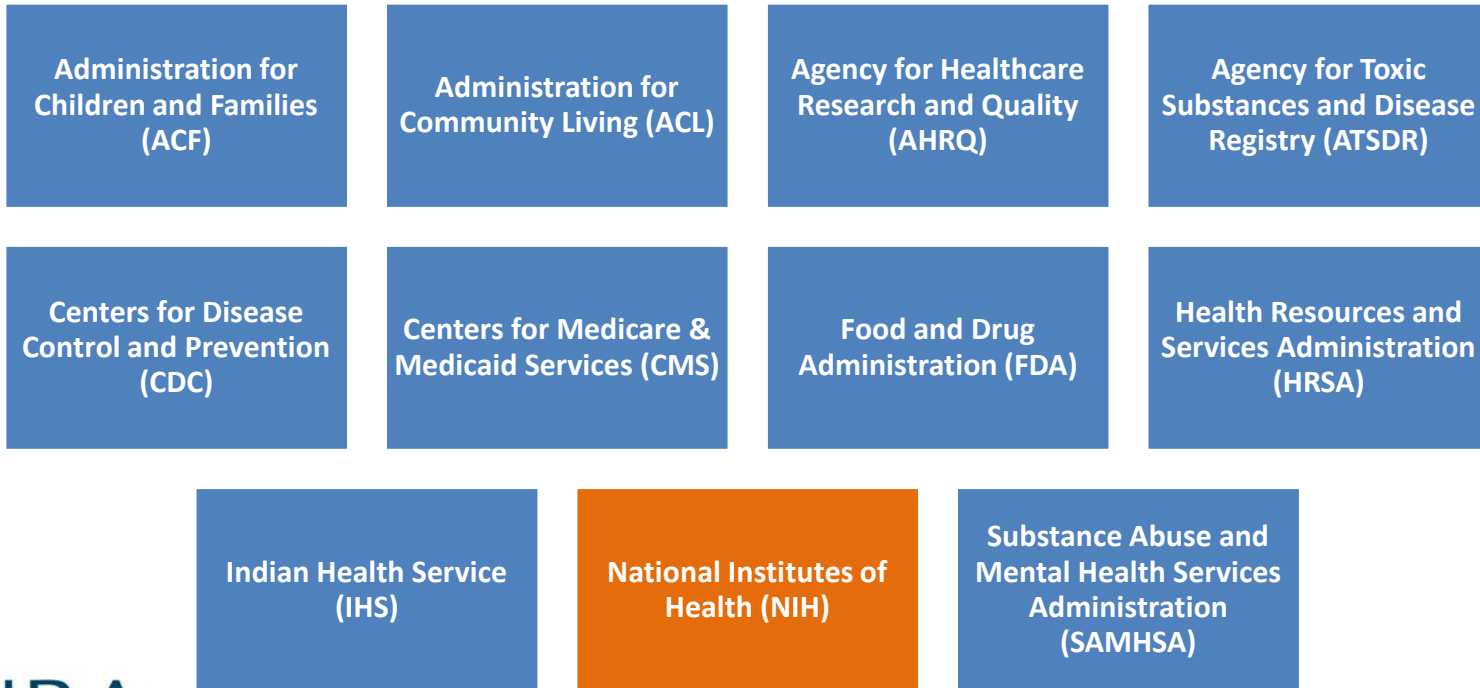


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HHS ORGANIZATION

- HHS has 11 Operating Divisions, including NIH



NIH BY THE NUMBERS – FY18

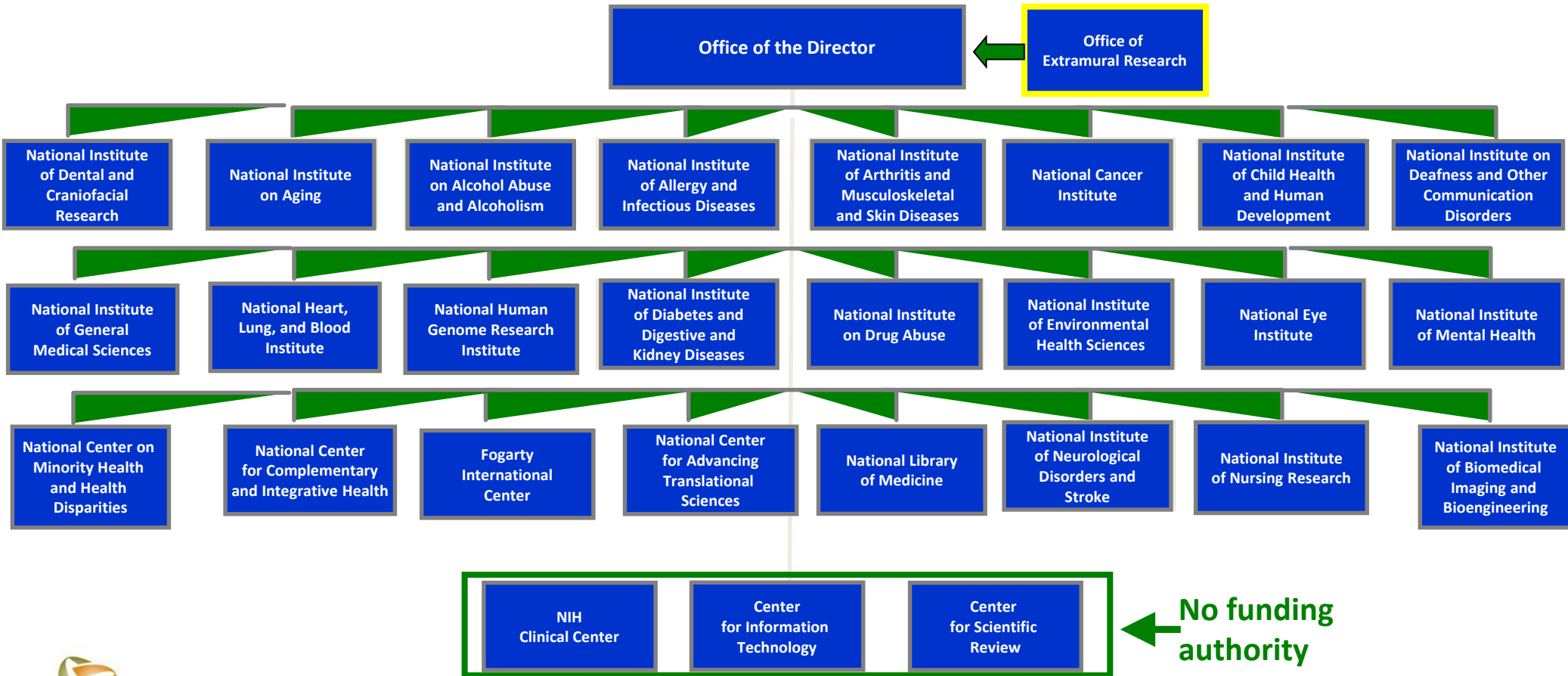
- Budget: \$36.4 Billion
- Issued 52,643 grant awards, totaling \$27.1 billion
- Reviewed 73,608 grant applications
 - Success rate 22.7%
- Awards made to over 2,600 recipient institutions

NIH DATA SOURCES

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



NATIONAL INSTITUTES OF HEALTH



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 research, based on their mission and priorities, budget, and funding strategy
- In FY2017 NIH awarded 44,389 Research Grants, 3,380 Cooperative Agreements and 1,981 Research and Development Contracts



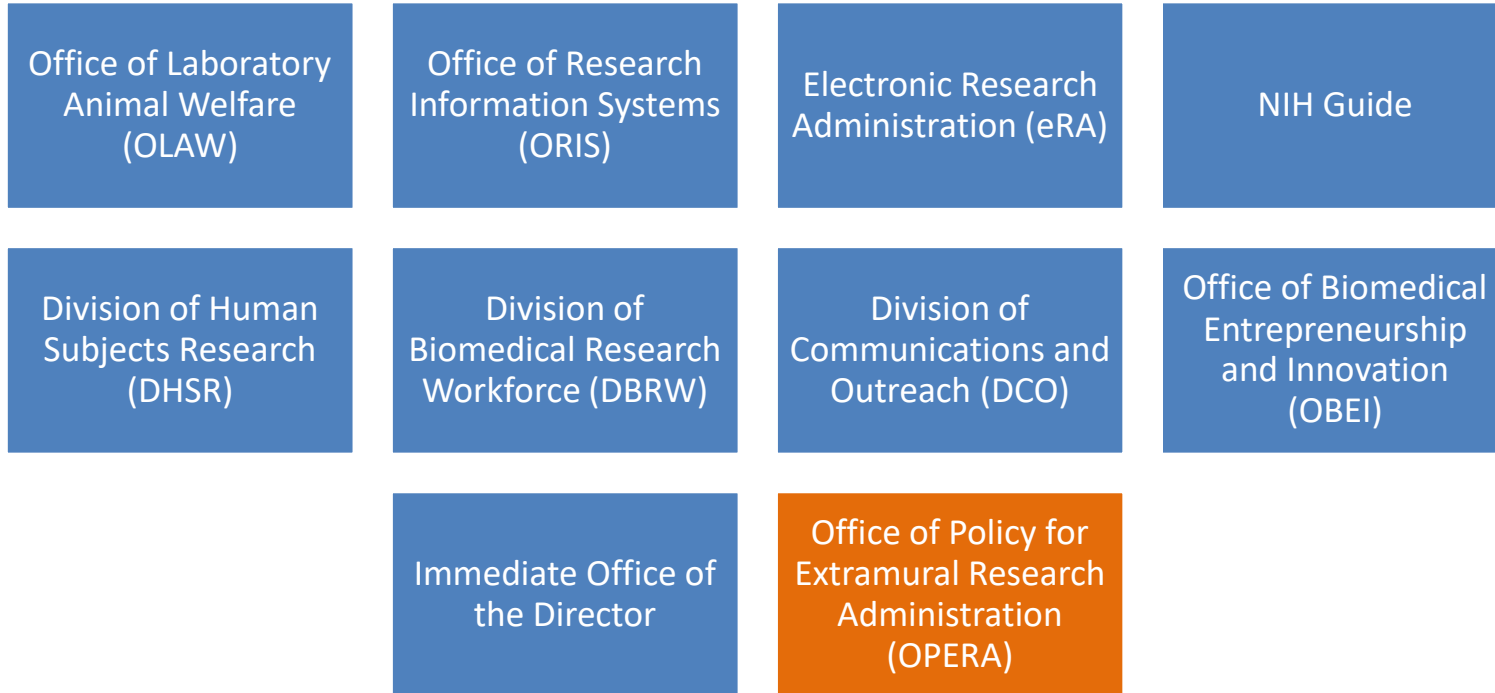
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OER MISSION

To provide the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio.

OER ORGANIZATION



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OPERA PARTNERS

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

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

CATEGORIES OF ACTIVITIES FUNDED WITH GRANTS

- Research Projects
- Small Business Innovation Research
- Training & Fellowships
- Construction
- Shared Instrumentation
- Center Grants
- Conference Support
- Clinical Trials

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 programmatic involvement in the project
- The funding opportunity announcement (FOA) will outline the responsibilities of both the NIH staff and the recipient, as well as joint responsibilities and obligations

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



INSTRUMENT TYPE - OTHER TRANSACTION

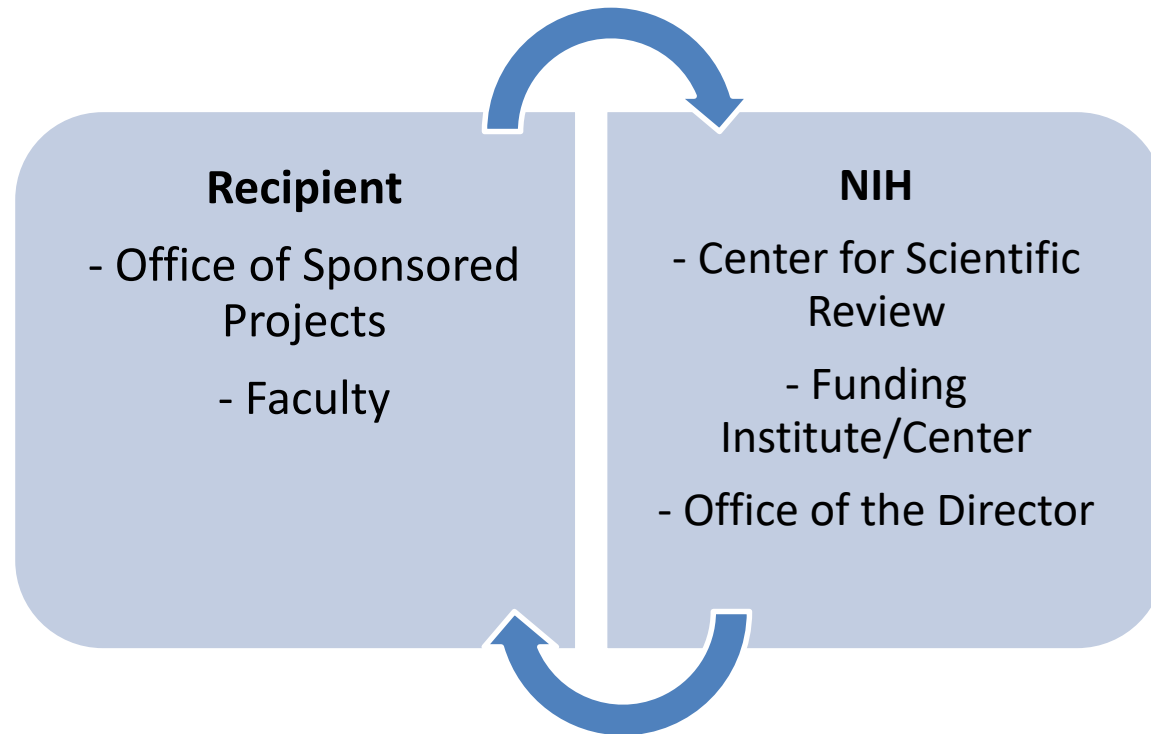
- Not a grant, not a cooperative agreement, not a contract
- Requires Congressional authorizing language, budget
- Used when NIH needs greater flexibility to identify and engage nontraditional research partners, or to engage traditional partners in new ways
- Negotiate terms and conditions that will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



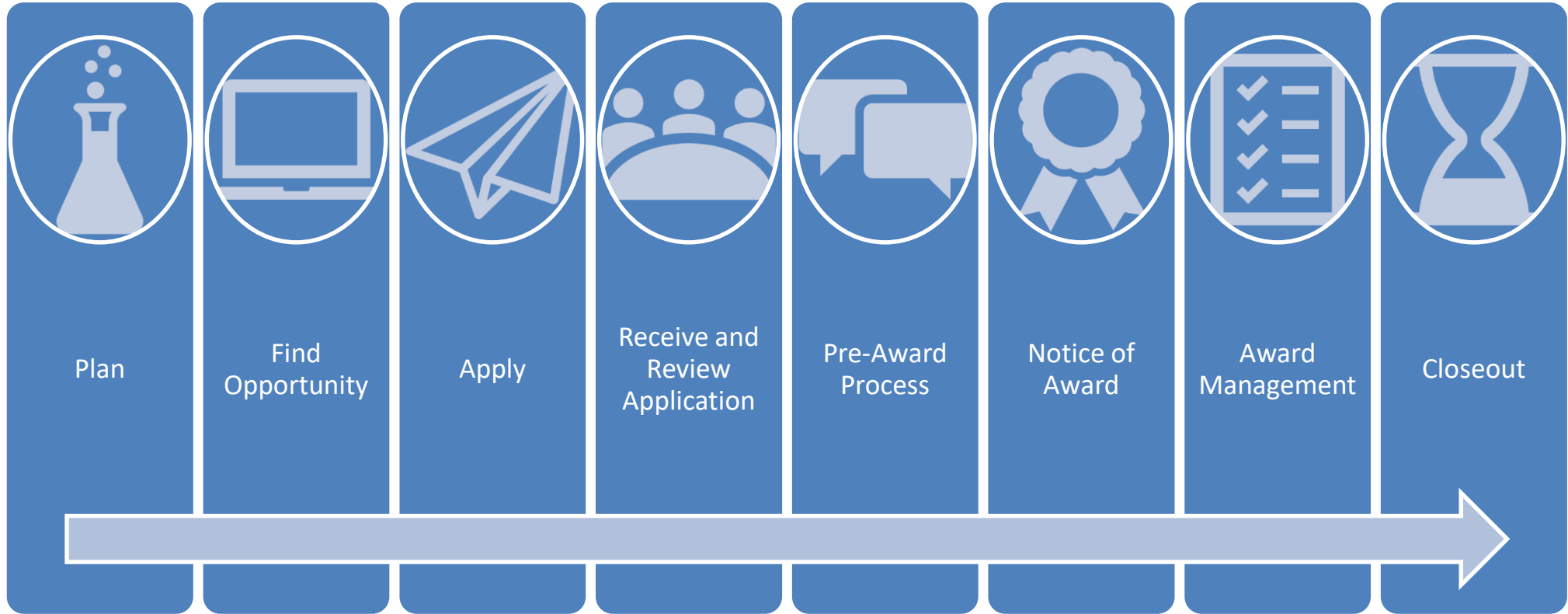
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NIH'S BIRDS EYE VIEW - PARTNERS IN THE GRANTS PROCESS



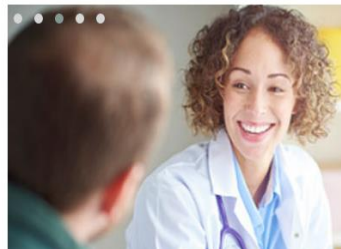
THE NIH GRANTS LIFECYCLE



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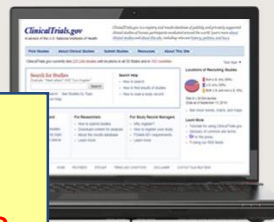
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BEGINNING OF THE LIFE CYCLE



New Policies and Reforms for Clinical Trials

[read more >](#)



Find Funding



How to Apply



Explore NIH Funded Research (RePORT)

GRANTS.nih.gov – your home base for info on NIH grant opportunities, policies, processes



About Grants

Navigate the NIH grants process from finding a funding opportunity to monitoring your award.

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



Policy and Compliance

Learn about the policy and compliance obligations of your grant award and find helpful resources on select policy topics.

- [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](#)
- [NIH Staff](#)



DEVELOPMENT OF AN APPLICATION

- All applications submitted to NIH must be in response to a Funding Opportunity Announcement (FOA)
- FOAs are published in the NIH Guide for Grants and Contracts
- Types of FOAs
 - Program Announcements (PA)
 - Notices of Special Interest (NOSI) 
 - Program Announcements with Review Criteria (PAR)
 - Requests for Applications (RFA)

PROGRAM ANNOUNCEMENTS

- 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
- There are Parent Program Announcements for many grant mechanisms to allow applicants to submit unsolicited applications.



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NOTICES OF SPECIAL INTEREST

- Developed to streamline the FOA process
- Highlight areas of scientific interest
- Direct applicants to submit applications in response to NIH Program Announcements
- Notice number must be listed on application as instructed in the Notice

PROGRAM ANNOUNCEMENT WITH SPECIAL REVIEW CRITERIA

- Similar to general PAs; however these announcements contain special review criteria
- Can be reviewed by an individual IC's review branch or by the Center for Scientific Review (CSR)
- Do not have any special set-aside for funds – have to compete for general funding with all other grants submitted for a given year



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REQUEST FOR APPLICATIONS

- 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



CLINICAL TRIAL FOAS

- All applications involving one or more clinical trials must be submitted through a FOA specifically designed for clinical trials
- FOAs specify the allowability of clinical trials in the FOA 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



NIH ELIGIBLE 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 FOA!

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 and new investigator status
- Profile data used in other electronic processes (e.g., Summary Statements, eNotifications)
 - Degrees
 - Position Titles
 - Adresses – e-mail and postal

APPLICATION SUBMISSION

SUBMISSION OF AN APPLICATION

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

The screenshot shows the NIH Grants & Funding website. The header includes the NIH logo, "National Institutes of Health Office of Extramural Research", and "Grants & Funding NIH's Central Resource for Grants and Funding Information". There is a search bar and navigation links like "eRA", "NIH Staff", "Glossary & Acronyms", "FAQs", and "Help". A navigation bar has tabs for "HOME", "ABOUT GRANTS", "FUNDING", "POLICY & COMPLIANCE", "NEWS & EVENTS", and "ABOUT OER". The main heading is "NIH Guide to Grants and Contracts". Below it, text states: "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!**".

On the left, there are filters for "Organizations" and "Activity Code". The "Organizations" filter includes "Issuing Only" and "All" (checked), with sub-options for AHRQ, CDC, CSR, DHHS, FDA, FIC, HRSA, and NASA. The "Activity Code" filter includes "All" (checked).

The search results section shows "Active FOAs and Notices" with a search bar and "Search" button. It indicates "Displaying: 1 to 25 of 12548 results" and "Results Per Page" set to 25. There are buttons for "Export to", "Share Search", and "Save your Search".

Title	FOA Number	Organization	Release Date	Expiration Date	Activity Code
Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities (R43/R44 - Clinical Trial Optional)	RFA-MD-19-001	NIMHD	Jan 18, 2019	Apr 2, 2019	R43/R44
Development of New Technologies and Bioengineering Solutions for the Advancement of Cell Replacement Therapies for Type 1 Diabetes (R43/R44)	RFA-DK-18-023	NIDDK	Jan 18, 2019	Mar 22, 2019	R43/R44

SUBMISSION OF AN APPLICATION

- Prepare an application using the SF 424 and its instructions

The screenshot shows the NIH Grants & Funding website. At the top, there is the NIH logo and the text 'National Institutes of Health Office of Extramural Research'. To the right, there is a search bar and a dropdown menu for 'Entire Site'. Below the search bar, there are links for 'eRA', 'NIH Staff', 'Glossary & Acronyms', 'FAQs', and 'Help'. The main navigation bar includes 'HOME', 'ABOUT GRANTS', 'FUNDING', 'POLICY & COMPLIANCE', 'NEWS & EVENTS', and 'ABOUT OER'. The page title is 'How to Apply - Application Guide'. Below the title, there is a paragraph explaining that the application instructions found on this page should be used 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. The page is divided into three main sections: 'Prepare to Apply', 'Write Application', and 'Submit'. Each section contains a list of sub-topics. There is also a 'How to Access Grant Application Forms' section and a 'Related Resources' section.

NIH National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site Search this Site

eRA | NIH Staff | Glossary & Acronyms | FAQs | Help

HOME ABOUT GRANTS FUNDING POLICY & COMPLIANCE NEWS & EVENTS ABOUT OER

Home » About Grants » How to Apply - Application Guide

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
 - Understand Funding Opportunities
 - Types of Applications
 - Submission Options
 - Obtain Software
- Write Application**
 - Write Your Application
 - Develop Your Budget
 - Format Attachments
 - Rules for Text Fields
 - Page Limits
 - Data Tables
 - Reference Letters
 - Biosketches
- Submit**
 - Submit, Track, and View
 - How We Check for Completeness
 - Changed/Corrected Applications

HOW TO APPLY
Video Tutorials
WATCH NOW

How to Access Grant Application Forms

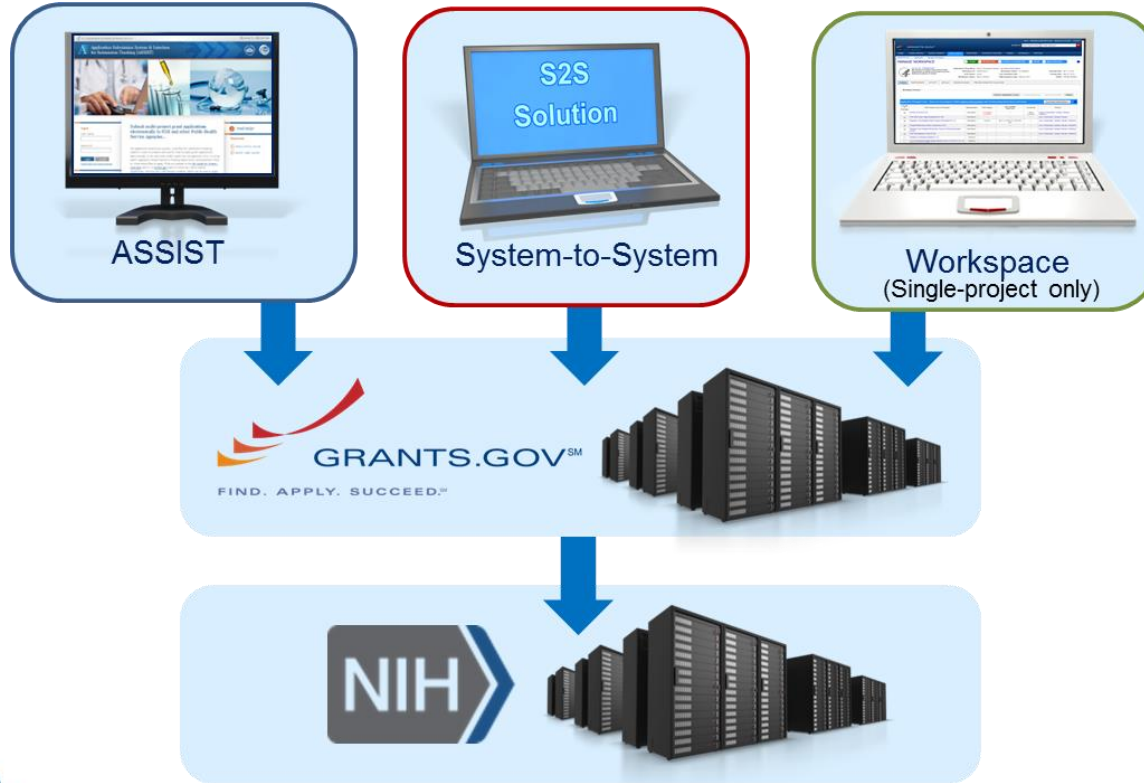
Related Resources



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
- Many activity codes use standard due dates
- These due date cycles allow NIH to distribute the receipt of applications throughout the fiscal year
- Always check the FOA to confirm the due date
- <https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm>

APPLICATION SUBMISSION OPTIONS





ASSIST

- Managed by NIH
- Multi-user access
- Leverages eRA Commons accounts
- Pre-population from eRA Commons profiles
- Pre-submission validations
- Pre-submission preview in agency format
- Track application status in a single system
- Copy application data to another opportunity or to a different package for the same opportunity



Grants.gov Workspace

- Managed by Grants.gov
- Multi-user access
- Requires additional user registrations
- No pre-population from existing profiles
- Pre-submission validations
- Pre-submission preview in agency format
- Must track application in multiple systems
- Reuse forms; copy application data
- Supports 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



APPLICATION REVIEW

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
- Conducts peer review for about 75% of NIH applications

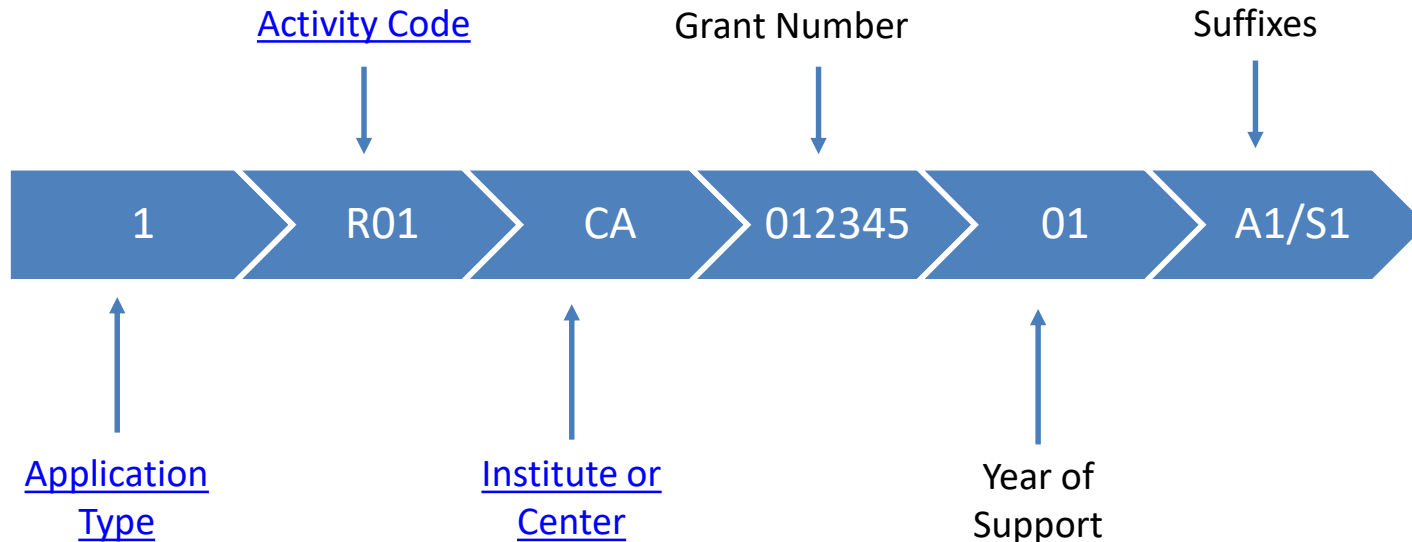
RECEIPT AND REFERRAL

- 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 completeness
 - Determines area of research and which specific IC to assign it to
 - 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



THE NIH GRANT NUMBER

DRR assigns each application a grant number



WHAT IS PEER REVIEW?

- Peer review is our opportunity to maximize competition to the greatest extent possible and review all applications for scientific merit.
- Two-step process
 - Peer review
 - Council review



INITIAL REVIEW

- Can occur at CSR or at the funding IC
- Focus of discussion on major strengths and weaknesses relative to review criteria
- Reviewers score all applications for which they are present and not in conflict
- Final scores are recorded
- Non-scored items discussed only after final score



INITIAL REVIEW

- Evaluations and the assigned score 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

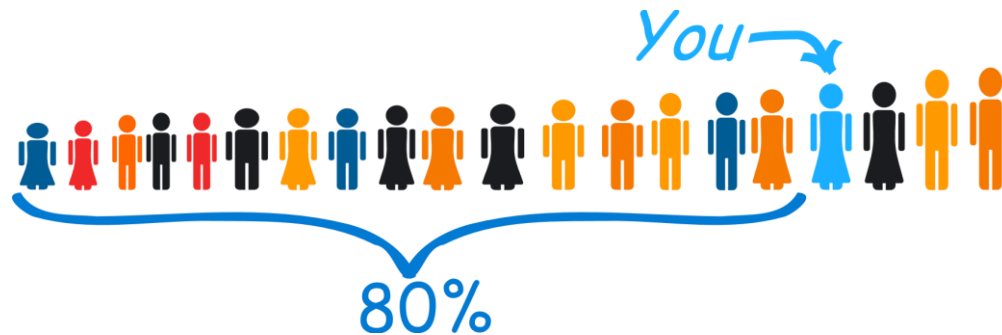


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INITIAL REVIEW

- 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.



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.

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

SECOND LEVEL OF REVIEW

- Only applications that have been favorably recommended by an initial review group with concurrence with the Advisory Board can be funded.
- Once the scores of the applications are known, a ranking list is prepared of similar kinds of applications that have been recommended for approval.
- In general, a fundable range is set and applications are paid in order to that level
- ICs post funding strategies online
<https://grants.nih.gov/policy/nih-funding-strategies.htm>



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PRE-AWARD PROCESS

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.

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.

Comprised of:

- Other Support
- IACUC approval
- IRB approval

Requirements:

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

OTHER SUPPORT

Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individuals' research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards.

- IC scientific program and grants management staff will review this 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.

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



NON-COMPETING AWARDS (TYPE 5) RPPR REVIEW

- Changes

- Scope
- Effort
- Personnel
- Performance Sites
- Use of Human or Animal Subjects
- Other Support
- Significant Budget Changes
- Leadership Plan (MPI)
- Publications - Compliance with Public Access Policy
- Review Foreign Involvement (existing and new)
- Invention Reporting
- Follow-up on Restrictions and Special Terms



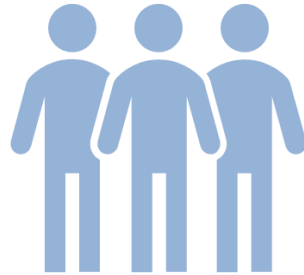
NOTICE OF AWARD (NOA)

- 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

THE AWARD HAS BEEN MADE WHAT'S NEXT?



ROLES AND RESPONSIBILITIES



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.

NIH STAFF

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.

CHIEF GRANTS MANAGEMENT OFFICER

- Principal grants officer in the funding IC
- Provides leadership to the organizational component responsible for the management of an IC's grant portfolio.
- Appoints and provides oversight to GMOs
- At NIH, each awarding component has a CGMO.



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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.

GRANTS MANAGEMENT SPECIALIST

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

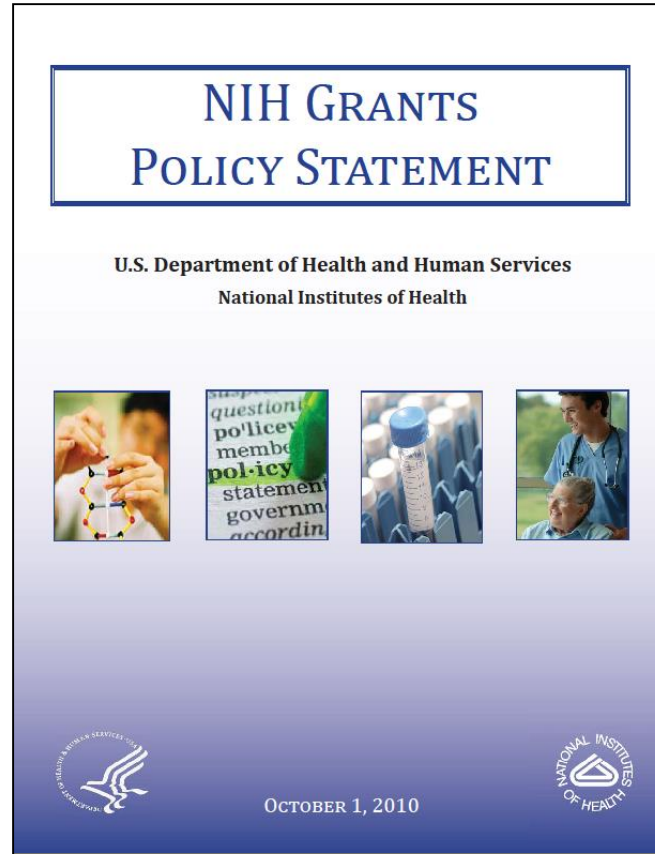
- Assures compliance with laws and NIH/HHS policies and procedures
- Analyzes grant applications and budgets
- Provides technical assistance, interprets NIH policies and Institute procedures
- Awards grant funds
- Reviews and responds to grantee prior approval and rebudgeting requests

MANAGING YOUR AWARD

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

NIH GRANTS POLICY STATEMENT!

Annual Updates
Generally Posted each
October



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NIH GRANTS POLICY STATEMENT (GPS)

- Provides, in a single document, policy requirements that serve as terms & conditions of NIH grant awards
- **Part I:** General Information—glossary, definitions, roles & responsibilities, application/review process, information sources
- **Part IIA:** Generally applicable terms & conditions

NIH GPS

- **Part IIB:** Separate sections on specific terms
 - Multiple PD/PI
 - Construction Grants
 - Kirschstein-NRSA (Fs & Ts)
 - Career Awards (Ks)
 - Modular Applications & Awards
 - Conference Grants
 - Consortium Agreements
 - Foreign Institutions
 - Federal Grantees
 - For-Profit Organizations
 - Patient Care Costs
- **Part III:** Provides points of Contact information
- **Authors:** Coordinated by OPERA, input from NIH staff & grantees
- **Target Audience:** NIH Staff & Grantees

EXPANDED AUTHORITIES

NIH is committed to reducing administrative burden for NIH grantees.

Under expanded authorities, the grantee institution has the authority to take certain actions on grants without agency prior approval.

EXPANDED AUTHORITIES

- 1st 12-month No-Cost Extension of a project period
- 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

Written approval by an HHS authorized official (e.g. the IC GMO) evidencing prior consent before a recipient undertakes certain activities or incurs specific costs.

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

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

PRIOR APPROVAL

Actions Likely to Indicate a Change in Scope

- Change in aims
- Shift in research emphasis
- 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)
- Application of new technology

PRIOR APPROVAL

Of particular note:

- Significant reduction in the level of effort of key personnel requires NIH prior approval
 - Significant is defined as a 25% or more reduction in effort
 - PI is **always** defined as key personnel
 - Other key personnel would need to be specifically named in the terms of the notice of grant award

PRIOR APPROVAL

All requests for NIH approval must be:

- Submitted in writing 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 GMO, not the PO or any other NIH official, are valid.



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A RULE OF THUMB



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

- Office for Sponsored Research
- NIH Grants Policy Statement
- NIH grants management official



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Annual Reporting Requirements

- Research Performance Progress Report (RPPR)
- Federal Financial Report (FFR)/Federal Cash Transaction Report (FCTR)
- Public Access
- FCOI

RPPR

- Research Performance Progress Report (RPPR)
 - Annual Progress Reports
 - Due 45 (SNAP) to 60 (non-SNAP) days prior to the anniversary date
 - Submit via eRA commons
- In 2018, NIH launched the Human Subjects System (HSS), which is used to report on human subject and clinical trial activities

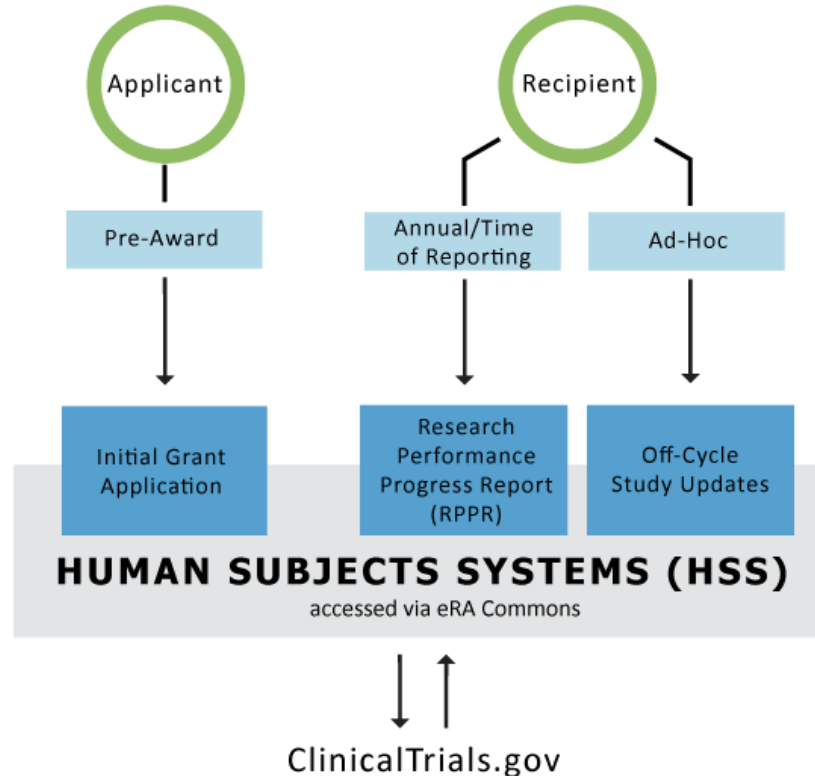


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HUMAN SUBJECTS SYSTEM

UPDATING STUDY INFORMATION WITH HSS



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.



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FEDERAL CASH TRANSACTION REPORT (FCTR)

- FCTR is a portion of the SF-425
- Submitted quarterly in PMS (due 3- days following calendar quarter end)
- Reports the disbursements on a grant by grant basis
- Must reconcile with the expenditure FFRs submitted to NIH

PUBLIC ACCESS

- Since 2008, compliance with the [NIH public access policy](#) has been a statutory requirement and a term and condition of all grant awards and cooperative agreements.
- The 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

Public



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PUBLIC ACCESS

- Proposals and Reports must include citations for all applicable papers that are authored by the Principal Investigator (PI) or arose from the PI's NIH funds.
- Investigators will need to use [My NCBI](#) to enter papers onto progress reports. Papers can be associated electronically using the RPPR
- Additional Information on the NIH Public Access policy and requirements, including the Submission Methods can be found at the NIH Public Access site: <http://publicaccess.nih.gov/index.htm>

FINANCIAL CONFLICT OF INTEREST

- 42 CFR Part 50, Subpart F, Objectivity of Research, applies to:
 - Prime Recipients
 - Subrecipients
 - Domestic and Foreign
 - Each investigator who is planning to participate in, or is participating in, such research
 - ***Does not apply to Phase 1 SBIR/STTR awards***

FINANCIAL CONFLICT OF INTEREST

Requirements:

- Investigator must disclose All SFIs related to Investigators' institutional responsibilities
- Institution is responsible for determining whether SFIs are financial conflicts of interest (FCOI)
- When an FCOI is identified, submit an FCOI Report to NIH Prior to Expenditure of funds or within 60 days of any subsequently identified FCOI

FCOI REPORTING

- Initial Report
 - Grant Number and PI
 - Name of the entity with which the Investigator has a FCOI
 - Value of the financial interest
 - Nature of FCOI, and description of how FCOI relates to PHS-funded research
 - Basis for the Institution's determination of a conflict
 - Key elements of the Institution's management plan
- Annual FCOI Report (Due at the same time as RPPR)
 - Status of FCOI (i.e., still being managed or no longer exists)
 - Changes to management plan, if applicable

COMPLIANCE REQUIREMENTS (THE NOT SO SMALL PRINT)



COMPLIANCE THROUGH THE LIFE CYCLE

- *Preparing the application:* Respond fully to all requirements in the FOA
- *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

COMMON CONTRIBUTORS TO NONCOMPLIANCE

- Insufficient knowledge of grant compliance requirements
- 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)

GRANTS CLOSEOUT

- Three required closeout documents
 - Final Federal Financial Report
 - Final Invention Statement (this is not required for Fs, Ts, CO6, R13, R25, S10)
 - Final Research Performance Progress Report (FRPPR)
 - If a competing continuation 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

GRANTS 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 ([NOT-OD-18-107](#)). This is a serious action and depending on the financial status, could put the recipient in a debt status.
 - At 270 days delinquent awards are automatically closed at NIH*



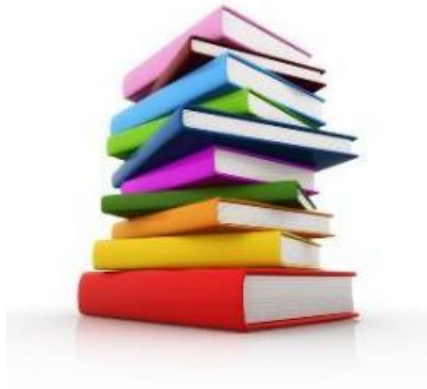
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GRANTS CLOSEOUT – THE BIG PICTURE

- In 2016, the Grants Oversight and New Efficiency Act (GONE Act) was passed. Requires reporting to Congress on grants that have not closed.
 - NIH GONE Act report: As of 9/30/18, 3,217 accounts remain open. Over \$32 million in grant funds sitting in PMS.
- eRA captures NIH closeout reports, but financial information in PMS must reconcile for financial closeout
- Recipients are responsible for reconciling PMS data with NIH FFRs

HELPFUL NIH RESOURCES



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RPPR RESOURCES

- RPPR Webpage: <http://grants.nih.gov/grants/rppr/>
- Includes links to:
 - RPPR Guide
 - RPPR Guide Notices
 - Frequently Asked Questions
 - Training
 - Contacts

Policy & Compliance

[NIH Grants Policy Statement](#)

[Notices of Policy Changes](#)

[Compliance & Oversight](#)

Select Policy Topics

[Animal Welfare](#)

[Application Submission Policies](#)

Clinical Trial Requirements

[Clinical Trial Definition](#)

[Why the Changes](#)

[Good Clinical Practice](#)

[Specific Funding Opportunities](#)

[Clinical Trial-Specific Review Criteria](#)

[New Form](#)

[Single IRB Policy](#)

[Protocol Template](#)

[Registration and Reporting](#)

[NIH Funding Strategies](#)

[Human Subjects Research](#)

[Intellectual Property Policy](#)

[Lobbying Guidance for Grantee Activities](#)

[Early Stage and Early Established Investigator](#)

Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

NIH Definition of a Clinical Trial

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

Your human subjects study may meet the NIH definition of a clinical trial.

FIND OUT HERE



On This Page:

- [Why Changes to Clinical Trial Policies?](#)
- [Good Clinical Practice Training](#)
- [Clinical Trial-specific Funding Opportunities](#)
- [Clinical Trial-Specific Review Criteria](#)
- [New Human Subject and Clinical Trial Information Form](#)
- [Single IRB Policy for Multi-site Research](#)
- [Clinical Trials Protocol Template](#)
- [Clinictrials.gov Registration and Reporting](#)



Related Resources

[FAQs](#)

[Training Resources](#)

[Important Terms](#)

[Research Involving Human Subjects](#)

[Resource on Research Methods](#)

[ClinRegs: international clinical trials regulations](#)

[Clinictrials.gov](#)

[For NIH Staff](#)

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

FREQUENTLY ASKED QUESTIONS

FAQs –searchable websites for:

- 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

SUMMARY OF HELPFUL NIH WEB PAGES

- Office of Extramural Research (OER) Web Page: <http://grants.nih.gov/grants/oer.htm>
- NIH Grants Policy Statement (Rev. 10/18): <http://grants.nih.gov/grants/policy/nihgps/>
- NIH Extramural Nexus – newsletter for the extramural community:
<http://nexus.od.nih.gov/all/nexus-by-date/>
- Grant Application Basics: http://grants.nih.gov/grants/grant_basics.htm
- eRA Training: Video Tutorials http://era.nih.gov/era_training/era_videos.cfm

SUMMARY OF HELPFUL NIH WEB PAGES

- How to Apply - Application Guide:
- <http://grants.nih.gov/grants/how-to-apply-application-guide.htm>
- Annotated SF424 (R&R) Application Forms (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>

Self Help Resources page:

<http://grants.nih.gov/support/index.html>



SUMMARY OF HELPFUL NIH WEB PAGES

- eRA Commons Web pages: <http://era.nih.gov/>
- eRA Commons User Guides: http://era.nih.gov/commons/user_guide.cfm
- Intellectual Property Policy: <http://grants.nih.gov/grants/intell-property.htm>
- Research Portfolio Online Reporting Tools (RePORT): <http://report.nih.gov>
- RePORT Expenditures & Results (RePORTER): <http://projectreporter.nih.gov/reporter.cfm>

[HTTPS://GRANTS.NIH.GOV/GRANTS/OER.HTM](https://grants.nih.gov/grants/oer.htm)

U.S. Department of Health & Human Services | National Institutes of Health

NIH National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site | Search this Site


eRA | Glossary & Acronyms | FAQs | Help

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

Open Mike

- Citations Per Dollar as a Measure of Productivity
- Building a Better Biomarker Glossary
- Innovating to Make it Easier for You to Find the NIH Grants Information You Need

Open Mike



- Find Funding
- How to Apply
- Explore NIH Funded Research (RePORT)

About Grants

Navigate the NIH grants process from finding a funding opportunity to monitoring your award.

- Grants Basics
- Grants Process Overview
- How to Apply
- Pre-Award Process
- Post Award Monitoring and Reporting
- Forms Library

Policy and Compliance

Learn about the policy and compliance obligations of your grant award and find helpful resources on select policy topics.

- 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



NIH OER LISTSERVS

- NIH Guide for Grants and Contracts:
Official publication for NIH Grant Policies, Guidelines & Funding Opportunities
<http://grants.nih.gov/grants/guide/listserv.htm>
- Office for Human Research Protections (OHRP):
<http://www.hhs.gov/ohrp>
- Office of Laboratory Animal Welfare (OLAW):
<http://grants.nih.gov/grants/olaw/references/list.htm>
- eSubmission:
Separate listservs available for scientists and administrators
<http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm>



GRANTS INFORMATION: WHO TO CONTACT?

- General Application Questions:
 - E-Mail: GrantsInfo@nih.gov
 - Phone: 301-945-7573
- Grants.gov Customer Support:
 - E-Mail: support@grants.gov
 - Webpage: <http://grants.gov/>
 - Phone: 1-800-518-4726
- eRA Commons Helpdesk:
 - Web: <https://grants.nih.gov/support/index.html>
 - Toll-free: 1-866-504-9552
 - Phone: 301-402-7469
 - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

GRANTS POLICY: WHO TO CONTACT?

- Division of Grants Policy:
 - E-Mail: GrantsPolicy@mail.nih.gov
 - Phone: 301-435-0949
- Division of Grants Compliance & Oversight:
 - E-Mail: GrantsCompliance@mail.nih.gov
 - Phone: 301-435-0949
- Division of Extramural Inventions and Technology Resources:
 - E-Mail: Inventions@nih.gov
 - Phone: 301-435-1986