Grant Writing for Success Preparing a NIH Grant Application

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Division of Extramural Activities

National Institute of Allergy and Infectious Diseases (NIAID)

National Institutes of Health (NIH)

Objective

Upon completion of this session, participants will be able to:

- list significant steps involved from application to award;
- explain the fundamentals of writing a clear and concise research grant application; and
- describe the differences in writing a career development (K) grant application compared to research grant opportunities.

Where to Look For Funding Opportunity Announcements (FOA)

Start with Grants.gov web Page

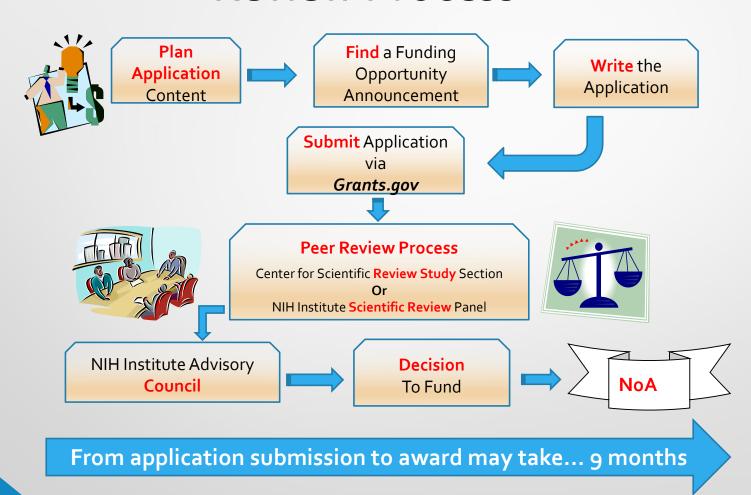
Narrow your search – go to NIH Guide for Grants and Contracts

Specific area of research - read the NIH Institutes and Centers research missions

Information to consider *before* you submit a NIH grant application...



NIH Grant Application and Review Process



NIH Institutes and Centers



- Become familiar with:
- NIH organizational structure
 - 27 institutes and centers (IC)
 - Research mission of each IC
 - Types of people and organizations eligible to apply
 - Grant programs offered
- Determine if you need prior approval from your organization and/or NIH to apply
- Communicate with your organization's designated Authorized Organizational Representative (AOR) or Signing Official (SO)

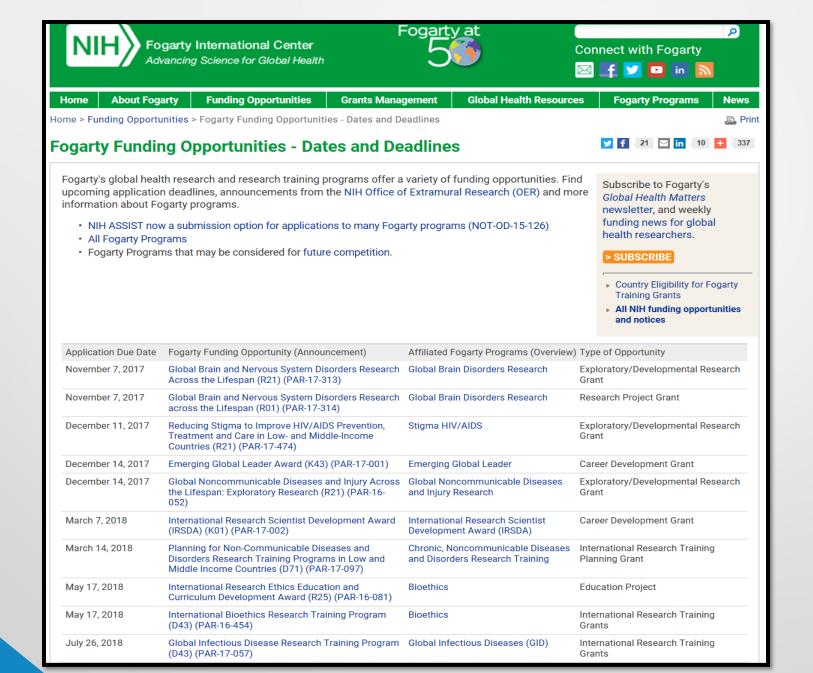
National Institutes of Health

Office of the Director National Institute National Institute National Institute National Institute **National Cancer National Institute** of Arthritis and of Child Health on Alcohol Abuse of Allergy and on Aging Musculoskeletal Institute and Human and Alcoholism Infectious Diseases and Skin Diseases Development National Institute on National Institute National Institute National Institute of Dental and Deafness and Other of Diabetes and National Institute National Eve of Environmental Craniofacial Digestive and on Drug Abuse Communication Institute **Health Sciences** Research Disorders Kidney Diseases National Institute **National Institute** National Heart, National Human **National Institute** of Neurological National Institute Genome Research of General Lung, and Blood Disorders and of Mental Health of Nursing Research **Medical Sciences** Institute Institute Stroke National Center **National Center** National Center on National Institute **Fogarty** for Complementary **National Library** for Advancing Minority Health of Biomedical International and Alternative **Translational** of Medicine Imaging and and Health Center Medicine Sciences Disparities Bioengineering Center Center NIH for Information for Scientific **Clinical Center** Technology Review

Fogarty International Center (FIC)

Research grants:

- Researcher training
- Fund research capacity building programs in low- and middleincome countries
- Fund research projects in a variety of areas such as infectious diseases, chronic conditions, population health, informatics, genetics, and clinical, operational and health services
- Collaborative programs partner with other NIH Institutes/Centers/Offices to support non-U.S. research

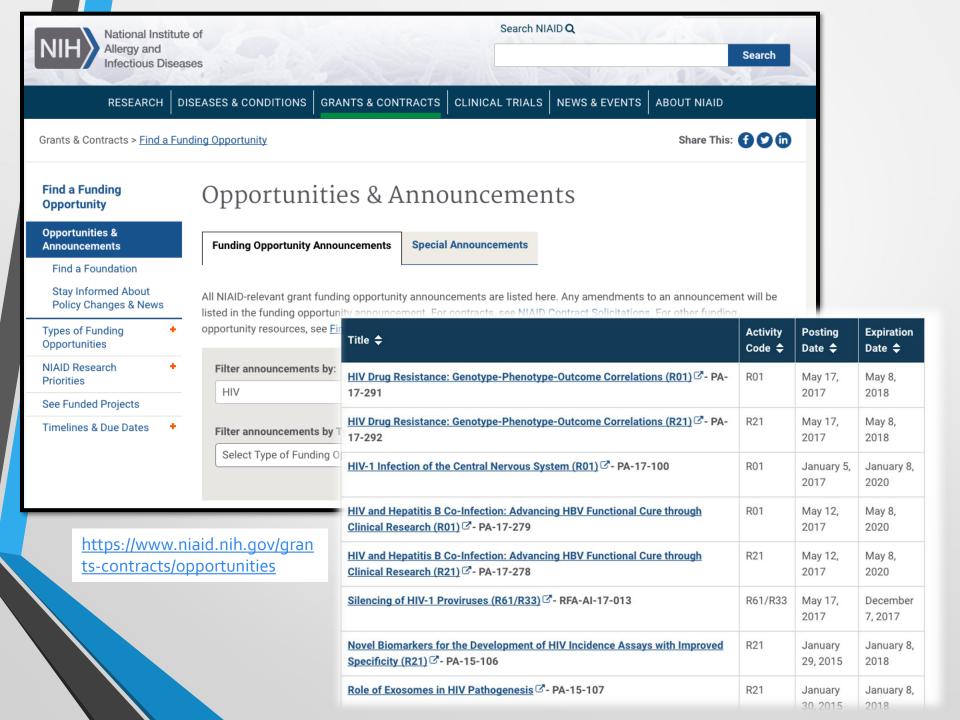


National Institute of Allergy and Infectious Diseases (NIAID)



- Supports and conducts global research
- Funds a wide range of international biomedical research in infectious, immunologic, and allergic diseases and conditions.
- Trains and collaborates with scientists from around the world
- Supports projects in more than 100 countries.
- Global research covers a broad spectrum of diseases and conditions including
 - HIV/AIDS, malaria, influenza, tuberculosis, diabetes, asthma, and many others.

https://www.niaid.nih.gov/



NIH Award Mechanisms

Grants

- Investigator initiated
- Program Announcement (PA)
- Request for Applications (RFA)

Cooperative agreements

- Substantial NIH staff involvement
- Solicited RFA

Contracts

 Solicited – Request for Proposals (RFP), Broad Agency Agreement (BAA), other contract mechanisms

Types of Research Grants

Small Grant Program (Ro3)

- Limited funding for a short period of time to supports various types of projects, including: pilot or feasibility studies, collection of preliminary data
- Direct costs generally up to \$50,000 per year
- Limited to two years of funding

Exploratory/Developmental Research Grant Award (R21)

- New, exploratory & developmental projects, supports early stages of project
- Limited to up to two years of funding
- Budget for direct costs for the two year project period up to \$275,000.
- No preliminary data is generally required

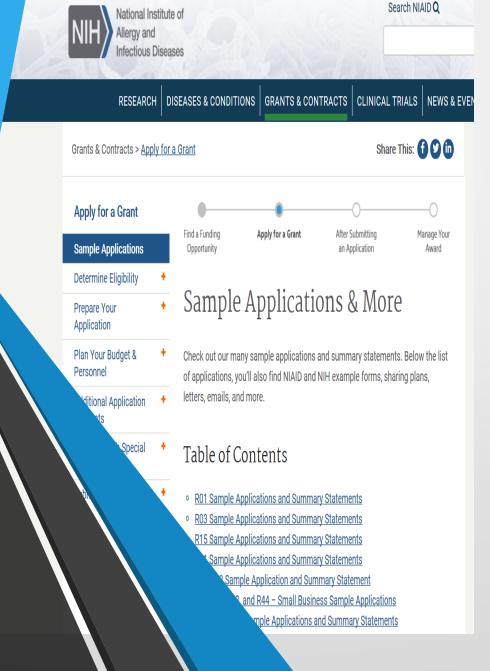
Research Project Grant (Ro1)

- Used to support a discrete, specified research project
- NIH most commonly used grant program
- Budget costs appropriate for the project, typically <\$500K/year
- Generally awarded for 3-5 years

Research Project Cooperative Agreement (Uo1)

- Supports discrete, specified projects to be performed by investigator(s) in an area representing specific interests and competencies
- Substantial NIAID program staff involvement
- No specific dollar limit amount and years specified in FOA

View sample applications from former applicants



Identify Collaborative Research and Research Administration Opportunities

- Examples:
- Develop and implement collaborative research projects conducted with current NIH awardees.
- Identify opportunities for scientist exchanges between early stage scientists and experts in your field or related field of research.
- Conduct workshops or symposia to bring together scientists, and expert researchers, and clinicians performing related research.
- Network with research administrators who are managing NIH awards

Specific Aims and Research Strategy

Specific Aims:

 Think about and develop language that clearly describes the research project aims and indicate which partner of the collaboration will be responsible for accomplishing each of the aims.

Research Strategy:

- Ensure there is sufficient information in the grant application to allow evaluation of the proposed research
- Provide clear plans and goals of the research especially the roles and responsibilities of all participating partners
- Engage research administrator to develop a well developed, and appropriately budgeted, financial management plan

Clinical Trial (CT) or Non-CT

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."

Beginning for Due Dates on or after January 25, 2018

Applicants proposing clinical trials - must apply to a FOA that allows CTs. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-114.html

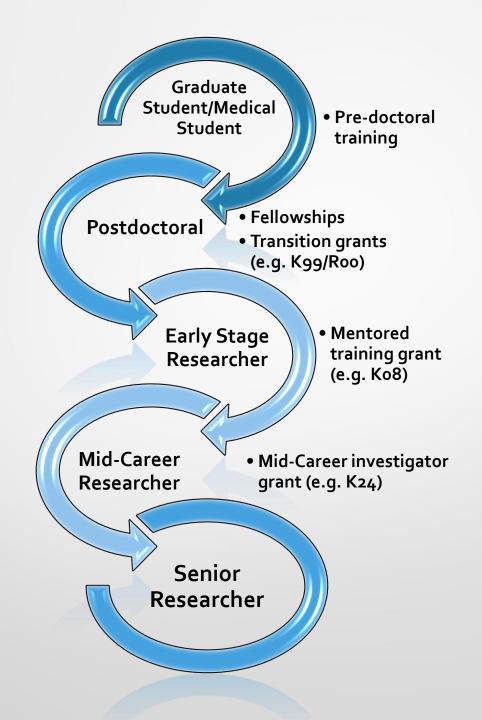
Applications submitted through a non-CT FOA will be <u>returned</u> without review.

New NIH "FORMS-E" Grant Application Instructions

- New Forms and Instructions for application due dates on or after January 25, 2018.
 - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-119.html
 - Video Tour
 https://www.youtube.com/watch?v=nzgNWFhYOG8&list=PLOEUw
 SnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1
- Includes new PHS Human Subjects and Clinical Trials Information form, and other policy information.

Career Development Applications (K)

ABOUT GRANTS FORMS & DEADLINES GRANTS POLICY NEWS & EVENTS ABOUT OF ER HOME Division of Biomedical Research Workforce National Institutes of Health SEARCH Research Training and Career Development Contact Us About DBRW Career Path Programs Institute/Program Matrix Undergraduate Postdoctoral/Residency Early Career Established Investigator Graduate/Doctorate Career Path RTCD Home > Career Path NIH programs help to prepare the skilled, creative and diverse biomedical research workforce of tomorrow Predoctoral Training/ Early Research Career Undergraduate and Postdoctoral Investigator Postbaccalaureate **Clinical Doctorate** Training/Clinical Development and Development Education Residency Mentoring



Career

Stage

FOA- Career Development Example

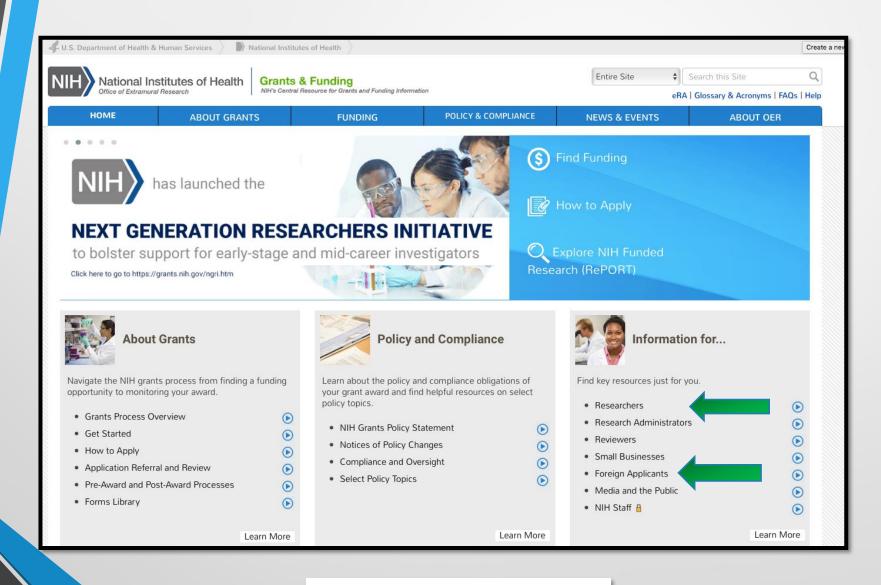
Funding Opportunity Title	Mentored Clinical Scientist Research Career Development Award
	(Parent K08)
Activity Code	K08 Clinical Investigator Award (CIA)
Announcement Type	Reissue of PA-14-046
Related Notices	 May 10, 2017 - New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018. See NOT-OD-17-062. March 17, 2017 - NCI will support training in Patient-Oriented Research through K08 Awards and increase K08 Salary and Research Support. See Notice NOT-CA-17-042.
	 September 13, 2016 - NHLBI Policy Concerning Mentored Career Development (K08 and K23) Awards. See Notice NOT-HL-16-443. June 2, 2016 - Notice to Extend the Expiration Date for PA-16-191. See Notice NOT-OD-16-098.
Funding Opportunity Announcement (FOA) Number	PA-16-191
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.847; 93.242; 93.856; 93.855; 93.846; 93.213; 93.113; 93.398 93.279; 93.839; 93.838; 93.837; 93.859; 93.867; 93.273; 93.121; 93.286; 93.866; 93.173; 93.853 93.865; 93.172;
Funding Opportunity Purpose	The primary purpose of the NIH Mentored Clinical Scientist Research Career Development Awards (K08) program is prepare qualified individuals for careers that have a significant impact on the health-related research needs of the Nation. This program represents the continuation of a long-standing NIH program that provides support and "protect time" to individuals with a clinical doctoral degree for an intensive, supervised research career development experier in the fields of biomedical and behavioral research, including translational research. Individuals with a clinical doctoral degree interested in pursuing a career in patient-oriented research should refer to the NIH Mentored Patient-Oriented Research Career Development Award (Parent K23).
	Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetar information: <u>Table of IC-Specific Information</u> , <u>Requirements and Staff Contacts</u> .

Writing a K Application?

- Career Development Award
 - Ks for clinicians at different career stages
 - Also K99/Roo transition award
- Check <u>eligibility</u> requirements for you and your mentor(s)
- Review criteria
 - Candidate
 - Mentor(s), Co-mentor(s) mentoring team
 - Career development plan/career goals and objectives
 - Research Plan
 - Environment and Institutional Commitment

Where to find help throughout the process...





http://grants.nih.gov/grants/oer.htm

Funding Opportunity Announcement (FOA)

Read the FOA Sections Carefully and Completely

- Identify FOA of interest and check application due date
- Read Eligibility Section to ensure non-U.S. entities are eligible to apply

Non-U.S. research partners, questions to consider:

- Does the application/proposal
 - Present special opportunities for furthering research programs?
 - Describe use of unusual talent, resources, populations, or environmental conditions?
 - Propose research not readily available in the United States or that augments existing U.S. resources as well as your local population?

FOA For Research Award Key Points - Example

Open Date (Earliest Submission Date) May 22, 2018

<u>Letter of Intent</u> Due Date(s) 30 days before the application due date

Application Due Date(s)

July 27, 2018, October 14, 2018, February 17, 2019, October 14, 2019 by 5:00 PM local

time of applicant organization

Applicants are encouraged to apply early to allow adequate time to make any

corrections to errors found in the application during the submission process by the

due date.

AIDS Application Due Date(s) Applicable or Not Applicable

Scientific Merit Review Nov 2018, Feb 2019, July 2019, Nov 2019, Feb 2020

Advisory Council Review Jan 2019, May 2019, Oct 2019, Jan 2020, May 2020

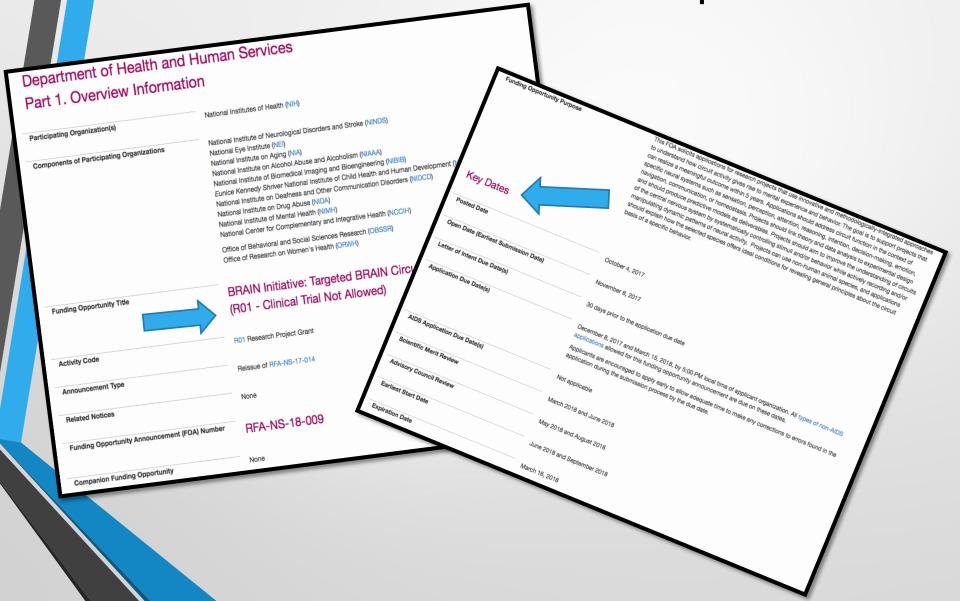
Earliest Start Date April 2019, July 2019, Dec 2019, April 2020, July 2020

FOA Expiration Date October 15, 2019

- Eligible Organizations (Section III) check eligibility
- Foreign Institutions: Non-domestic (non-U.S.) Entities (Foreign Institutions) <u>are</u> eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations <u>are</u> eligible to apply

FOA: RFA Example



Example Program Announcement (PA): FOA Research Administration Development

PAR-15-131 Global Infectious Disease Research Admin Development Award for LMIC Institutions (G11)

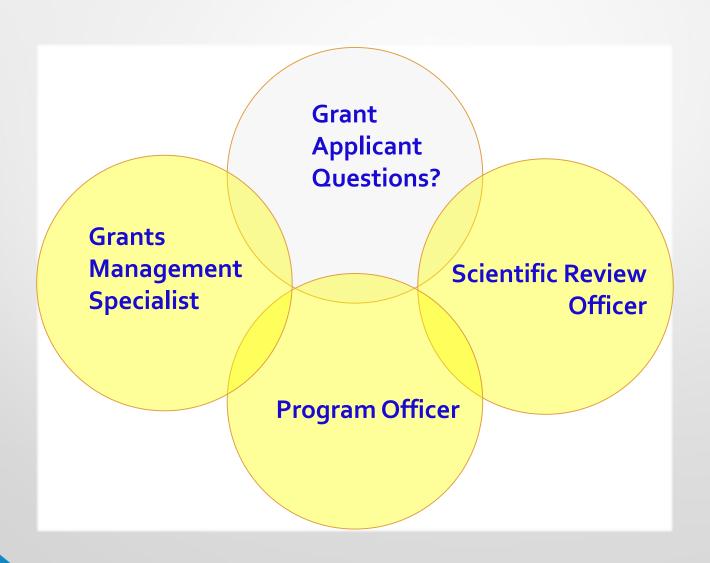
Purpose:

- Provide senior administrators from LMICs with advanced training in the management of NIH grants – improve in-country oversight & compliance
- Train-the-Trainer: to generate long-term training programs for grants management staff from within the local institution

Eligible Applicants:

- Located in a LMIC as defined by the World Bank
- Currently receiving funds from NIAID, directly or as a sub-awardee
- Received less than \$2.2 million in total NIH grant or cooperative agreement support over the last 5 years (NOT-Al-16-029)

NIH Extramural Research Team



Scientific Review Officer (SRO):

- Peer review process official
- Each Grant Application Study Section is led by a SRO.
- The SRO is an extramural staff scientist and Designated Federal Official (DFO) responsible for ensuring that each application receives an objective and fair initial peer review and that all applicable laws, regulations, and policies are followed.



Credit: NIH, CSR

Scientific Program Officer (PO)*

- Scientist and administrator
- Manages scientific research portfolio
- Identifies research opportunities and needs
- Sets priorities and stimulates interest in specific scientific areas
- Communicates research program priorities
- Can provide advice before and after peer review meetings

^{*}Also called a Program Director (PD), Contracting Officer Representative (COR)

Grants Management Specialist (GS)

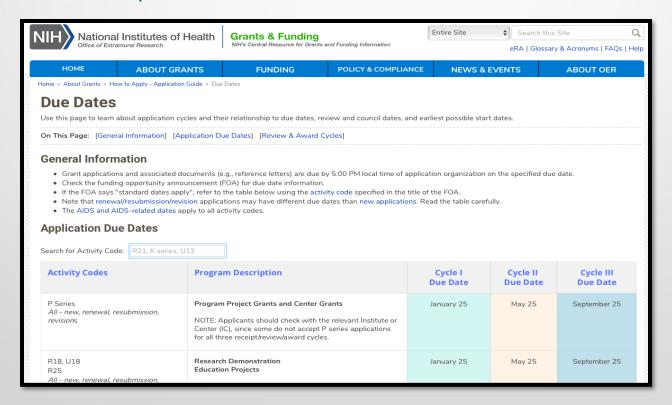
- Provides NIH grants policy guidance to awardees and applicants
- Interprets grants policies as they relate to the grant award process
- Negotiates and issues all grant awards
- Handles all matters relating to the notice of grant award, including funding levels and terms and conditions
- Oversees and resolves budget and administrative grant issues

Applying for Grants: e-Submission



Adhere to Application **Due Dates**

<u>Submit by Due Date</u>: Check the FOA – Recommend: submit several days early <u>Latest Submission Time</u>: Due **by 5:00 PM local time** of the applicant organization on the specified due date.



NEXT...Peer Review



Peer Review: Evaluation Criteria

- Criteria described below are considered in Evaluating the Application
 - Five Individually Scored Review Criterion
 - significance
 - investigator(s)
 - innovation
 - approach
 - environment
 - Reviewers consider each criterion score in formulating an overall impact/priority score for the application
 - Resubmission— applicable to applications that have been through ONE round of peer review. Respond to comments from the previous review

Peer Review: Evaluation Criteria...cont.

- Also includes initiative specific review criteria, when applicable
- Additional review criteria (HS, Animals, Biohazards, resubmission, renewal)
- Additional review considerations:
 - Applications from Foreign Organizations
 - Select Agents
 - Resource Sharing Plans
 - Budget and Period of Support
- Reviewers evaluate and score each application

Peer Review: NIH Scoring System

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

After Initial Peer Review ...

- Application receives an overall impact/priority score
- Summary statement is written provides a summary of the reviewers discussion and recommendations
- Information is also available to NIAID staff
- Priority score and summary statement are available to the applicant in the NIH eRA Commons system



Second Level of Review

- After the Initial Peer Review is complete
- The Second level of Review is done by the Institutes' Advisory Council/Board members



To Fund or Not To Fund?

- Funding decisions
 - Details documented in each institute's procedures.
- Review products used in funding decisions
 - Impact score and percentile
 - Summary statement
 - Criterion scores
- Program factors in funding decisions
 - Relevance to institute's mission and priorities
 - Council recommendations
 - Early-stage PI status
 - Other Institute specific factors
- Institute final funding decisions based on advice from staff and the Advisory Council/Board
- Successful applicants receive a Notice of Award from the funding institute's grants management officer

Resources For Researchers

Some NIH institutes offer resources that can help facilitate preclinical and/or clinical research

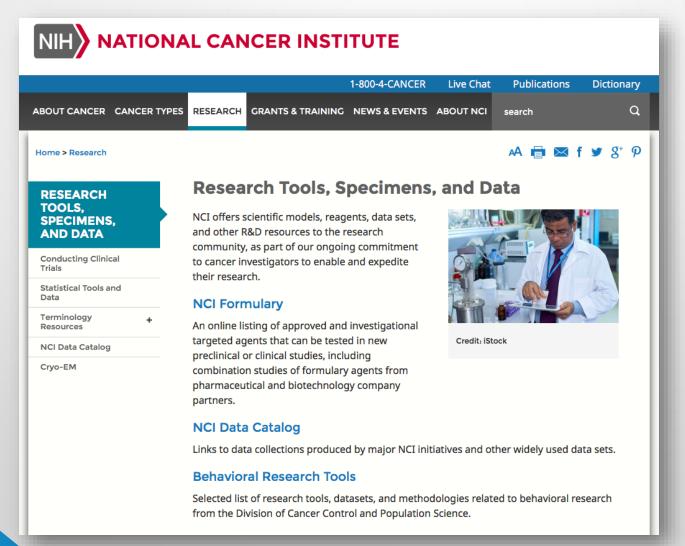
NIAID Resources for Researchers

- Helps translation of basic research into safe and effective drugs, vaccines, and diagnostics
- Requests can come from an investigator in academia, a not-forprofit organization, industry, or government in the United States or worldwide
- Requesters do not have to be NIAID/NIH awardees

Tools, Datasets & Services

- Bioinformatics
- Biological Materials
- Translational Research
- <u>Technology Transfer & Intellectual Property</u>
- Partnering With NIAID
- HIV/AIDS Research Resources
- Allergy, Immunology, Transplantation Research Resources
- Microbiology and Infectious Diseases Resources
- •Research Rules & Policies

National Cancer Institute Research Resources





Research Portfolio Online Reporting Tools (RePORT)

- Free database of funded projects, investigators, publications, and patents.
- Use to identify research areas that are highly supported or underrepresented
- Useful for identifying potential collaborators in your area of science.

- Use to identify awards by location
- Helpful for identifying research not readily available in the U.S.
- Provides frequently requested and customized funding reports
- Includes RePORT tutorials

https://report.nih.gov/index.aspx

"Matchmaker"

 The <u>NIH RePORTER</u> database includes a "Matchmaker" tab. If you enter your specific aims or project summary you will find similar projects that have been funded by the NIH, which institutes funded those projects, which study sections reviewed them, and potential collaborators funded in your subject or geographic area to ask for advice.

sciences, or social sciences. Go to Search for Opportunities .

Go to Opportunities of to see what's available and Application System of to set up an account.

proposalCENTRAL ☑ -e-grantmaking website shared by government, non-profit, and private grantmaking organizations.

Websites



Research Funding Opportunities

- U.S. Department of Health and Human Services http://www.hhs.gov/grants/
- Grants.gov (grants)
- http://www.grants.gov/
- FedBizOps (contracts)
- https://www.fbo.gov/
- Grants and Funding:
 - https://grants.nih.gov/grants/oer.htm See the "Information for..."section
 - administrators and researchers find this site very useful.
- How to Apply Application Guide
 - https://grants.nih.gov/grants/how-to-apply-application-guide.html

- Subscribe to NIH Guide LISTSERV:
 - Official publication for Grant Policies, Guidelines and Funding Opportunities
 - http://grants.nih.gov/grants/guide/listserv.htm
- NIAID Funding information:
- Funding News https://www.niaid.nih.gov/grants-contracts/funding-news
- Opportunities & Announcements
- Sample Applications https://www.niaid.nih.gov/grants-contracts/sample-applications
- NIAID Grants Policy and Management Training for Foreign Investigators
- https://www.niaid.nih.gov/grants-contracts/foreign-grantsmanagement



Much Success in Your Research!

Questions?