European Investigator Involvement in U.S. National Institutes of Health Research: Identification of Opportunities and Grant Process

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Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD 20892

February 4, 2019 WEBINAR
European Investigator Involvement in U.S. National Institutes of Health Research: Identification of Opportunities and Grant Process

Introductions: Marta Barrionuevo

EU-US Science Cooperation: Viki Limaye

NIH Research Grant Process: Peter Jackson

TOPICS
• US National Institutes of Health: Mission / Components / Budget
• The NIH Research Support Enterprise
• NIH Support of International Research
• Research Award Types: Grants / Cooperative Agreements/ Contracts
• Identification of Funding Opportunity Announcements (FOA)
• NIH Contacts: Program, Review, Grant and Contract Officers
• Application Process
• Peer Review Process
• Post-Review Activities
• Important Issues: Human Subjects; Animal Subjects; Biohazards
• Resources
• Questions/Answers
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

NIH achieves its mission largely through awarding research grants based upon review of applications from extramural scientists.
U.S. Department of Health and Human Services

- The Secretary
  - Deputy Secretary
    - Administration for Children and Families (ACF)
    - Administration on Aging (AoA)
    - Food and Drug Administration (FDA)
    - Health Resources and Services Administration (HRSA)
      - National Institutes of Health (NIH)
    - Centers for Medicare and Medicaid Services (CMS)
      - Agency for Health Care Policy and Research (AHCPR)
    - Indian Health Services (IHS)
    - Centers for Disease Control and Prevention (CDC)
      - Agency for Toxic Substances and Disease Registry (ATSDR)
    - Substance Abuse and Mental Health Services Administration (SAMHSA)
    - Program Support Center (PSC)

National Institute of Allergy and Infectious Diseases
• Focus on Body System(s), Diseases
• Each IC has different: Missions, Priorities, Budgets, Funding Strategies, Acronyms
National Institutes of Health

NCI
6.1

NIA
3.0

NIGMS
2.8

NIMH

NIAID
5.5

NHLBI
3.4

THE NIH DATA BOOK
NIH Supports Intramural (NIH Staff/Facilities) and Extramural (Non-NIH Staff/Facility) Research

Intramural Research (on Bethesda, Maryland Campus)

- 27 Institutes & Centers; 1,500 PIs; 6,000 researchers; 27,000 staff
- NIH Clinical Center - largest research hospital
- National Library of Medicine - largest biomedical library

Approximately 80% of the NIH budget supports extramural research

Other Sites - Maryland, North Carolina, Michigan, Montana, and Arizona
Extramural Awards to National / International Institutions and People

Approximately 80% of the NIH budget is Extramural

Approximately 80,000 grant applications submitted / year

Approximately 50,000 grants awarded / year

Approximately 80% of the grants to higher education sites

Awards involve over 100 nations, 4,000 institutions, 300,000 personnel
The NIH is not an entity unto itself. The majority of research supported by the NIH is conducted at academic, industrial, governmental and private institutions across the US and the world.
NIH Supports International Research: WHY?

Special opportunities for furthering research programs through unusual talents, resources, populations, or environmental conditions not available in the U.S., or that augment existing U.S. resources.

Specific relevance to the mission and objectives of the IC

The potential for significantly advancing health sciences in the U.S.

International Research also:

- Generates Scientific Excellence
- Drives Innovation
- Create Jobs and Economic Growth
- Delivers New Global Health Technologies
- Increases Preparedness Against New Threats
- Protects Human Health

Information For Foreign Grants
About 549 Direct Foreign Grants
About 6303 Domestic Grants with Foreign Components
NIH Research: Think Globally

AS Fauci and FS Collins

“Engagement in global health protects the nation's citizens, enhances the economy, and advances U.S. interests abroad.”
NIAID Vision for Global Research

- Seek scientific opportunities and identify shared priorities
- Develop capacity through research cooperation
- Support domestic grantees to expand international collaborations and engage with investigators
- Engage partnerships among scientists and with governments, companies, and non-government organizations
2017 NIAID Support for International Research

*FY17 Total NIAID Budget 4.905B

ABOUT 10% International

*$4.749B total NIAID budget in 2016 includes $34.2M that was transferred from other NIH ICs to fund Zika response
NIAID International Funding by Region FY 2017

- Sub-Saharan Africa: 44.4%
- Americas and Caribbean: 21.4%
- Europe: 17.6%
- East Asia and Pacific: 11.6%
- Middle East and North Africa: 0.4%
- South and Central Asia: 4.6%

Total: $579.6M
119 Countries
Our Mission and Vision

Mission
The Fogarty International Center is dedicated to advancing the mission of the National Institutes of Health (NIH) by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

Learn more about global health at NIH.

Vision
The Fogarty International Center’s vision is a world in which the frontiers of health research extend across the globe and advances in science are implemented to reduce the burden of disease, promote health, and extend longevity for all people.

Learn how Fogarty’s research and research training programs support this vision.
The Fogarty International Center supports and facilitates global health research by U.S. and international investigators, builds partnerships between health research institutions in the U.S. and abroad, and trains the next generation of scientists to address global health needs.

About 6,000 scientists worldwide have received significant research training through Fogarty Programs. The program description page describes program status, eligibility, funding announcements and deadlines.

Fogarty funds more than 500 projects involving about 100 U.S. universities. The U.S. scientists collaborate with colleagues in mostly low- and middle-income countries (LMICs). Through these programs, Fogarty and its partners work to build sustainable research capacity in the developing world.

Fogarty also convenes the best scientific minds to address critical global health research problems such as polio eradication, pandemic response and strengthening research capacity in Africa.
OGR coordinates and supports collaborative international research programs focused on selected infectious diseases of substantial health importance in developing countries.

- Maintains a comprehensive knowledge base of the Institute's research programs and policies
- Coordinates with the NIH Fogarty International Center to identify relevant programs of other federal domestic agencies, bilateral research agencies and organizations, multilateral research organizations, and voluntary agencies involved in international health activities.
- Advises the NIAID director on program relationships and opportunities for collaboration.
NIAID Involvement in Europe and Multilateral Affairs

Countries
- Europe: France, Germany, Nordic Countries, Spain, Switzerland, UK
- Multilateral: EU, WHO

Disease / Research Priorities
- Antimicrobial resistance, HIV/AIDS and immunology

Major NIAID Programs
- Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)
- DAIDS Clinical Trials Global Networks
- Enhanced Collaboration Between U.S. NIH and WHO on Biomedical Research (Cooperative Agreement)
- NIH-Oxford-Cambridge Scholars Program
- NIH-Research Council of Norway Collaboration
- Trans-Atlantic Task Force on Antimicrobial Resistance
- WHO Collaborating Center for Emerging Infectious Disease Response Research and Preparedness

OGR Regional Officer: Joyelle Dominique
Joyelle.Dominique@nih.gov
Search of NIH Data System “Reporter”
Three Current R series Awards in Spain

[Image of NIH Research Portfolio Online Reporting Tools (RePORTer) search results]

- Title: UNDERSTANDING RTS S MALARIA VACCINE-INDUCED PROTECTION THROUGH INTEGRATED ANALYSIS
  - Contact PI: CARLA DORÁN
  - Organization: BARCELONA INSTITUTE FOR GLOBAL HEALTH
  - Fiscal Year: 2016
  - IC: NIAID
  - Total Cost: $619,308

- Title: TAILORED INDUCTION OF HIV-1 SPECIFIC IMMUNITY THROUGH ENGINEERED DENDRITIC CELL VACCINES
  - Contact PI: MARIO MARTíNEZ-GAYO
  - Organization: UNIVERSIDAD AUTONOMA DE MADRID
  - Fiscal Year: 2018
  - IC: NIAID
  - Total Cost: $162,000

- Title: THE FUNCTION OF RPL 5 AND RPL 11 IN INDUCTION OF P53
  - Contact PI: THOMAS GEORGE
  - Organization: FUNDACIÓN PRIVADA INT IYEST BIOMÉDICA
  - Fiscal Year: 2017
  - IC: NCI
  - Total Cost: $241,000
Specific Award Detail

![Project Information Screen](https://projectreporter.nih.gov/project_info_details.cfm?aid=9127082&icde=43076858&ddparam=8&datevalue=8&ddsub=8&acr=1&xscb=default&xcs=ASC&xpb=1)

**Project Information**

**SR01A009788-05**

**Description:** Understanding RTS, S Malaria Vaccine-Induced Protection Through Integrated Analyses

**Contact PI/Project Leader:**

- **Name:** DOBANO, CARLOTA
- **Email:** Click to view Contact PI/Project Leader email address

**Program Official Information:**

- **Name:** MO, ANNIE Y X
- **Email:** Click to view PO email address

**Organization:**

- **Name:** BARCELONA INSTITUTE FOR GLOBAL HEALTH
- **City:** BARCELONA
- **Country:** SPAIN (SP)

**Funding Information:**

- **Total Funding:** $651,308
- **Fiscal Year:** 2016
- **Award Notice Date:** 13-JUL-2016

**Administering Institutes or Centers:**

- NATIONAL INSTITUTE OF ALLERGY AND INFECTION DISEASES

**Project Funding Information for 2016:**

- **Total Funding:** $651,308
- **Direct Costs:** $547,507
- **Indirect Costs:** $43,801

**Categorical Spending by IC:**

- Click here for more information on NIH Categorical Spending
# The Current Awards in SPAIN

<table>
<thead>
<tr>
<th>Project Number:</th>
<th>Contact PI / Project Leader:</th>
<th>Title:</th>
<th>Awardee Organization:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5R01AI095789-05</td>
<td>DOBAÑO, CARLOTA</td>
<td>UNDERSTANDING RTS,S MALARIA VACCINE-INDUCED PROTECTION THROUGH INTEGRATED ANALYSIS</td>
<td>BARCELONA INSTITUTE FOR GLOBAL HEALTH</td>
</tr>
<tr>
<td>1R21AI140930-01</td>
<td>MARTIN-GAYO, ENRIQUE</td>
<td>TAILORED INDUCTION OF HIV-1 SPECIFIC IMMUNITY THROUGH ENGINEERED DENDRITIC CELL VACCINES</td>
<td>UNIVERSIDAD AUTONOMA DE MADRID</td>
</tr>
<tr>
<td>5R01CA158768-06</td>
<td>THOMAS, GEORGE</td>
<td>THE FUNCTION OF RPL5 AND RPL11 IN INDUCTION OF P53</td>
<td>FUNDACIO PRIVADA INT D'VEST BIOMEDICA</td>
</tr>
</tbody>
</table>
NEXT TOPICS

• Award Types: Grants / Cooperative Agreements/ Contracts
• Identification of Funding Opportunity Announcements (FOA)
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• Application Process
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• Post-Review Activities
• Important Issues: Human Subjects; Animal Subjects; Biohazards
• Resources

This list covers a HUGE amount of information.
I will address the topics at a high level during the WEBINAR
The Slide Appendix contains additional details
What NIH Applicants Sometime Think Will Work

SHOW ME THE MONEY!
As a US Federal Agency, NIH activities are governed by Laws, Regulations, Policies etc.

YES! There really is Grant Law!

Federal Funds cannot be dispersed unless all requirements are met. Penalties are associated with misusing Federal Funds.

NIH funds are awarded on a competitive basis.

Let’s explore how you can compete successfully.
# 1 Submit an application for a grant or contract

a. Apply for your own funding for a research project grant at any time. Use a Parent FOA for that grant mechanism (R01 Parent FOA, for example https://grants.nih.gov/grants/guide/pa-files/PA-16-160.html)

b. Or, apply as the PI to a specific FOA with set-aside funds. An example would be an RFA that supports R01s’ or a specific contract competition (RFP)
# 2 Apply Indirectly through someone who has NIAID funding

a. Collaborate as a sub-recipient an extramural awardee who is the PI of a grant.  
This approach is highly recommended for researchers with little NIH grantsmanship experience.

b. Collaborate with the Institute’s Intramural Research Program through various activities. [https://www.niaid.nih.gov/about/dir](https://www.niaid.nih.gov/about/dir) or [https://www.niaid.nih.gov/grants-contracts/collaborations](https://www.niaid.nih.gov/grants-contracts/collaborations)

Other Institutes identify their intramural collaborations.
Three Ways to Work with NIH / NIAID / Other IC

# 3 Gain access to NIAID sponsored resources (https://www.niaid.nih.gov/research/resources). NIAID offers many resources to support your research, including reagents, model organisms, and tissue samples, etc. There is a searchable list of about 100 resources.

Other Institutes also provide resources to investigators.
How Does an NIH Grant Get Funded?

Scientist Has Idea and writes application

The Institution

Submits Application

Allocates Funds

The Institute

Performs the Research

National Institutes of Health

Center for Scientific Review
Assigns to IC & IRG / Study Section

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Relevance

Advisory Councils & Board
Recommends Action

Institute Director
Makes Funding Decision
Electronic Application Process

The registration, submission and review processes take time. It may take weeks to months to register, applicants may wait a year after submission to be funded. Plan carefully. See URL below for timeline information

https://www.niaid.nih.gov/grants-contracts/timelines-applying

Institutions/ Scientists must REGISTER with the NIH before Applying

- Register with Grants.gov & eRA Commons

Find Funding Opportunity – Select the FOA*

Select Funding Opportunity (FOA) Use Grants.gov or NIH Guide

Prepare Application

Follow the Application Guide in the FOA AND all FOA Specific Instructions

Submit, Track & View

- Submit via your organizational representative
  - Track with eRA Commons

Frequently Asked Questions Applying Electronically

https://grants.nih.gov/grants/electronicReceipt/faq_full.htm
About Grants

Did you know that NIH is the largest public funder of biomedical research in the world, investing more than $32 billion a year to enhance life, and reduce illness and disability? NIH funded research has led to breakthroughs and new treatments, helping people live longer, healthier lives, and building the research foundation that drives discovery. Read on for an orientation to NIH funding, grant programs, how the grants process works, and how to apply.

Grants Process Overview

Learn the steps needed for an application to proceed from planning and submission to award and close out. Drill down on each step for guidance that can deepen your understanding of the grants process and help you improve your application.
Plan Your Application - General strategies for planning and organizing your application. This advice is relevant for all research grants but is geared toward the NIH Research Project (R01) grant type.

TOPICS
- Understand NIH
- Use RePORTER to Help Identify Where Your Research Fits
- Contact NIH Staff
- Find a Funding Opportunity Announcement
- Determine Application Submission Date
- Plan within your Institution
- Obtain Any Prior Approvals from NIH
- Get to Know the NIH Peer Review Process & Criteria
- Consider These Additional Application Elements
- Organize Your Time to Complete the Application
- Write Your Application

NIAID-specific advice for International Applications
Funding Opportunity Announcements are found at Grants.gov/FIND and in the NIH Guide for Grants and Contracts.

FOAs are publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

FOAs may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program.

FOAs have unique names and numbers. They contain all the information, instructions and forms needed for the institution and involved scientist(s), to register with the NIH, prepare and submit the application, track the peer review process, determine the outcome of review, and make appropriate next steps.

**TIP:** A FOA can change over time. Consult FOA sources often before submitting an application. Applicants are expected to follow the correct instructions and submit the proper information.

**TIP:** FOAs are complex. Study an annotated FOA at https://grants.nih.gov/grants/Annotated_FOA.pdf
Searchable, weekly publication listing FOAs and policy notices for NIH and other Agencies

List grants and contracts and Notices
Request for Applications (RFA) - grants
Program Announcements (PA) – grants
Parent Announcements – for unsolicited applications of several types
Request for Proposals (RFP)- contracts
Notices (NOT) – Information about changes to FOAs, Policies etc

NIH Award Mechanisms

- **Grants**
  - Numerous grant *mechanisms* with unique names and letter/number designations
  - R01s, R21s, R03s are Research Series awards
  - *These R awards are the most likely to be applied for by non-US applicants*
  - Compare the R awards: [https://www.niaid.nih.gov/grants-contracts/research-project-grants](https://www.niaid.nih.gov/grants-contracts/research-project-grants) - one may be best for you
  - K99’s are specialized individual awards – etc. Foreign PI allowed
  - Multi-project grants- Ps (like P01) – less likely for Non-US applicants
  - Investigator initiated applications respond to PAs.
  - Solicited applications are in RFAs

- **Cooperative agreements**
  - “U” grants, used for complex studies, most clinical trial networks
  - Substantial NIH staff involvement
  - Solicited (RFA)

- **Contracts** – Designated as N01s; FOAs for contracts are RFPs
# Types of Funding Opportunity Announcements (FOA)

<table>
<thead>
<tr>
<th>Type of FOA</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Program Announcements</strong> (PA, PAR, PAS)</td>
<td></td>
</tr>
<tr>
<td>• Highlights areas of focus; written by Program Officer</td>
<td></td>
</tr>
<tr>
<td>• Usually ongoing (3 yrs)</td>
<td></td>
</tr>
<tr>
<td>• Often use standard receipt dates</td>
<td></td>
</tr>
<tr>
<td><strong>Requests for Applications (RFA)</strong></td>
<td></td>
</tr>
<tr>
<td>• Narrowly defined scope. Written by Program Officer</td>
<td></td>
</tr>
<tr>
<td>• Usually single receipt date</td>
<td></td>
</tr>
<tr>
<td>• Set aside funds</td>
<td></td>
</tr>
<tr>
<td>• IC usually convenes review panel</td>
<td></td>
</tr>
<tr>
<td><strong>Parent Announcements</strong></td>
<td></td>
</tr>
<tr>
<td>• Type of program announcement</td>
<td></td>
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<tr>
<td>• Generally span the breadth of NIH mission</td>
<td></td>
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<tr>
<td>• By activity code (R01, R03, etc.)</td>
<td></td>
</tr>
<tr>
<td>• For “investigator initiated” or “unsolicited” research ideas</td>
<td></td>
</tr>
</tbody>
</table>

*NIH* National Institute of Allergy and Infectious Diseases
IC Funding Information- Learn what has been Funded
Use Multiple Funding Sources For Your Research
Look for New and Future Opportunities

• **NIH RePORT (Research Portfolio Online Reporting Tools)** identifies research funded by the NIH and many other sources. You can identify competitors, potential collaborators, research areas with strong or weak funding and many other parameters of funding.

• Identify NIAID funding and research priorities. Apply to the correct FOA. Each NIH institute announces its research areas. Check if your work might be of interest to more than one institute.

• **Study Funding/Financial Plans of the Different Institutes** For each Institute: a) Pay lines for different types of grants. b) Success Rates for New, Early Stage or Established investigators. Some ICs are more generous.

• **Study Institute Concepts for Potential FOAs.** All NIH institutes report new research areas as Concepts three times per year. After 1-2 years Concepts can appear as FOAs in the NIH Guide. Study different Concepts and discuss them with NIH staff named in the documents. Based on the Concepts of interest, develop ideas, a research team and preliminary data in advance of FOA publication. Since applications usually are due three months after FOA publication, this strategy provides you extra time to prepare for the FOA and to develop more competitive applications after the FOA appears.
Take Advantage of Earmarked Funds

US Congressional Earmarks - 2019

**NIH: $2 Billion increase to $39.1 Billion (+ 5.4%)**
+ $425 million for Alzheimer’s disease and related dementias
+ $100 million for the Cancer Moonshot
+ $86 million for the “All of Us” (Precision Medicine Study)

**NIAID: 4.7 % increase to $5.5 Billion**
+ $37 million for Antimicrobial Resistance
+ $40 million for Universal Flu Vaccine

NEW MONEY IN AREAS OF HIGH INTEREST
Understand Due Dates, Preparation Time and Review Cycles

For the NIH and each Institute:
Understand the grant application submission / review / award schedules before and after you apply and throughout the peer review process.

Late applications - There are only a few reasons why late applications will be accepted. However, it is not possible to guarantee in advance that a late application will be accepted.

This recent Notice explains the late application acceptance policy.
Peer Review Process
Goals of the Peer Review Process

**Fair and Objective**
- Conflicts of Interest managed
- Government extramural staff do not evaluate

**Scientifically Competent Reviewers**
- Actively engaged in relevant research

**Standardized Review Criteria**
- Significance, Approach, Innovation, Investigator, Environment

**Transparency**
- Candid advice from Review and Program staff
- Committee rosters available

**Confidentiality**
- Review assignments and committee discussions
BEFORE APPLYING, ALWAYS
Contact the NIH Staff Identified in the FOA
Do I Contact NIH Before Applying?

Yes!

Mandatory
- Application with budget $500,000 direct costs for any single year
- R13 Conference Grants

Optional
When RFA’s request a Letter of Intent

Always Recommended
When you think about applying for any grant
Peer Review Process:
SRO Responsibilities

**Pre-Meeting**
- Administrative review of the applications
- Conflicts of interest are identified
- Non-conflicted Reviewers are recruited to serve on the review panel

**Meeting**
- SROs manage the review meeting
- Non-competitive applications are identified at the meeting and then “Not Discussed”
- Discussed applications are evaluated and scored

**Post-Meeting**
- Summary Statements (SS) are prepared
- Scores are reported
Peer Review Process:
Program and Grants Management Staff Responsibilities

**Program Officer**

- Initiates and encourages interest in scientific area of importance to Institute’s mission
- Important contact for PIs before/after the review
- May attend the review meeting
- Confers with applicants after the review
- Makes decisions on awards (score; programmatic relevance; funds available)
- Manage grant and contract portfolios after award

**Grants Management Officer**

- May attend the review meeting
- Monitors administrative and fiscal aspects of the grant
- Assures compliance with Federal laws and NIH administrative policies and procedures
- Is the only NIH official authorized to obligate the NIH to funds or other terms and conditions of award
Where / How are applications reviewed?

Center for Scientific Review (CSR)
- Study Sections

- Research Project Grants (R01s)
- AREA Grants (R15s)
- Fellowships (F32s & F31s)
- SBIRs
- Shared Instrumentation Grants
- Small Grants (R03s)
- Exploratory/Developmental Grant (R21s)

Institutes
- Scientific Review Groups
- Contract Review Ctees.

- Program Project Grants (P01s)
- Center Grants (P30s)
- Training Grants (T32s)
- K Grants
- RFAs (some of which will be for R01s)
- Contracts
Criteria For Selection of Peer Reviewers

Very senior individuals- few assistant professors
Demonstrated scientific expertise
Mature judgment
Breadth of perspective
Impartiality
Adequate representation of women and minority scientists
Diversity of expertises represented
No maximum number of reviewers are assigned to an application but usually there are 3.
The NIH Welcomes
U.S. and non-U.S. Experts as Reviewers

The Center for Scientific Review has an Early Career Reviewer Program

If you do not qualify for the CSR Program, please eMail your Curriculum Vitae to the Directors of the Divisions of Extramural Activities (DEA) of the Institutes that support your science. You may be considered as a reviewer for a future review meeting. DEA Directors are identified in the staff lists of Institutes.

THE NIH IS INTERESTED IN IDENTIFYING EXPERTS ON PREVENTION RESEARCH TO BE REVIEWERS
Review criteria are in each FOA.

Applications reviewed on 5 NIH standard review criteria

Significance
Approach
Innovation
Investigator
Environment

Also FOA specific review criteria, as applicable
## Peer Review: NIH Scoring System

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

• Reviewers are vetted for conflicts, confidentiality expertise and availability and sent applications and instructions.

• Reviewers evaluate material for 3 to 4 weeks and a few days before the meeting, assigned reviewers provide initial impact score (1-9). This helps the SRO to streamline the review meeting.

• Most study sections discuss only a percentage (usually 50%) of applications assigned based on the initial scores of the assigned reviewers.

• It will typically be the case that initial scores in the better half of the scoring range (1-5) will be discussed, while those with initial scores of 7 to 9 are unlikely to be discussed.
Peer Review: Process continued

• The SRO prepares an order of review that clusters New Investigator (NI) or Early Stage Investigator (ESI) applications, and clinical applications if feasible.
• NI and ESI applications are identified for reviewers so there can be appropriate review in context of career stage.
• Expectations of preliminary data and publication records are less than for established investigators.
Peer Review: Process continued

- Scores provided by all reviewers averaged and multiplied by 10 to produce final impact/priority scores ranging from 10-90.
- These scores are percentiled against all other applications in the study section for prior 12 months.
- Percentiles are reported in whole numbers.
Study Section Meetings

- **Face-to-face meetings or Teleconference**
- **Material provided to reviewers about 4 weeks before the review meeting**
- **3 assigned reviewers per application – may be more depending on application size and scientific complexity**
- **20-30 minutes discussion per R01 application**
- **Internet Assisted Review (IAR) is another format (text based)**
The NIH Review Criteria for Evaluation of Research Applications

Five “core” criteria for most types of grant applications

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Overall Impact/Priority score for scientific/technical merit reflects: “assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five ‘criterion’. It is different from ‘Significance’

9-point scale (1 = exceptional, 9 = poor) for the five “core” review criteria and “Overall Impact”

Additional Review Criteria that Affect Final Scores

Reviewers consider the following additional items in the determination of impact/priority score, but will not give separate scores for these items:

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Resubmission Applications
- Renewal Applications (progress report)
- Biohazards

NEW GUIDANCE ON Human Subjects Research:
https://grants.nih.gov/policy/humansubjects.htm


Information on Clinical Trials and Inclusion: https://grants.nih.gov/policy/clinical-trials.htm

Policies on proposing and using animals in research: https://olaw.nih.gov/
Reviewers address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

- Budget and Period Support
- Select Agent Research
- Applications from Foreign Organizations
- Resource Sharing Plans
- Data Sharing
- Model Organism
- GWAS
Critiques (Summary Statements)

ALL discussed applications are scored and receive critiques

Discussed applications receive a resume and summary of the panel’s discussion at the meeting. Not discussed applications only receive criterion scores.

Overall Impact Paragraph
Each assigned reviewer writes a paragraph summarizing the factors that informed his/her Overall Impact score.
Review Levels

Peer Review Process

1. **First Level Review**
   - Managed by the Scientific Review Officer (SRO)
   - Applications evaluated by experts in the field

2. **Second Level Review**
   - National Advisory Council or Board
   - Assesses quality of the Peer Review
   - Concurs with or modifies Initial Review Group action
   - Reads Summary Statements
OER and CSR Review Meeting Resources

https://public.csr.nih.gov/

AFTER THE REVIEW - ACTIVITIES
If you will get an award the NIH requires several pieces of information before a Notice of Award can be prepared. Refer to the URL for this requirement.


If you will not get an award you have several options. Including sending the application to another funding source. Refer to the URL for a discussion on future directions.

https://www.niaid.nih.gov/grants-contracts/options-if-application-not-funded
Is it Possible to Provide too Much Information!?

Dr. Jackson – Can I be excused, my brain is full!
Let’s Stay in Touch!

“This is where our trails divide, Luke. You have my E-mail address, right?”

Pjackson@niaid.nih.gov
Questions??

END OF WEBINAR SLIDES
APPENDIX SLIDES

Some slides are duplicated from the WEBINAR section because they are especially important.
WRITING / GRANTSMANSHIP RESOURCES
WRITING RESOURCES

NIAID Sample applications and summary statements
https://www.niaid.nih.gov/grants-contracts/sample-applications

NIH SPECIFIC VOCABULARIES - Acronyms
http://grants.nih.gov/grants/acronym_list.htm

NIH SPECIFIC VOCABULARIES - Terms http://grants.nih.gov/grants/glossary.htm

Dictionaries
https://www.nihlibrary.nih.gov/resources/subject-guides/writing-resources
  • Dictionaries
    o Acronyms & Abbreviations
    o Medical and Scientific Dictionaries
  • Grammar and Punctuation Links
  • Open Access Links
  • Style Guides
  • Writing Training – Plain Language
Grantsmanship Resources

**NIH Data Book** – Huge volume of stats / graphs on NIH grants, contracts, awards etc

**Grants.gov - Official Site**

**NIH Guide to Grants and Contracts**

**NIH Office of Extramural Research** - [OER Home Page](https://grants.nih.gov)

**NIAID FOAs** [https://www.niaid.nih.gov/grants-contracts/opportunities](https://www.niaid.nih.gov/grants-contracts/opportunities)

**Center for Scientific Review -CSR** [https://public.csr.nih.gov/](https://public.csr.nih.gov/)

**CSR Peer Review Videos** [https://public.csr.nih.gov/NewsAndPolicy/PeerReviewVideos](https://public.csr.nih.gov/NewsAndPolicy/PeerReviewVideos)

**National Institute of Drug Abuse – Funding Opportunities for International Research**

**National Heart Lung and Blood Institute – Global Health Programs and Activities**

**You Tube** [https://www.youtube.com/user/nihgrants](https://www.youtube.com/user/nihgrants)

Global Infectious Disease Research Administration Development Award for Low-and Middle-Income Country Institutions: This NIH FOA invites applications from research institutions in low- to middle-income countries (LMIC) to provide senior administrators training in NIH grant management.

NIH Regional Seminars on Program Funding and Grants Administration: Annual training by NIH staff (2-day seminars) – Very Popular! Limited audience! Register early! Various US cities.

NIH Extramural Nexus - Advice from Director, NIH Office of Extramural Research

NIH Video Tutorial Tutorials - Videos on Grantsmanship Success

National Council of University Research Administrators: Advances research administration through development programs including international trainees.

Johns Hopkins University School of Medicine of Research Administration: Resources for research administration and clinical research management

World Intellectual Property Association: IP resources

European Association of Research Managers and Administrators: Training and mentoring resources for European scientists
These Links Work

- Understand NIH
- Use RePORTER to Help Identify Where Your Research Fits
- Contact NIH Staff
- Find a Funding Opportunity Announcement
- Determine Application Submission Date
- Plan within your Institution
- Obtain Any Prior Approvals from NIH
- Get to Know the NIH Peer Review Process & Criteria
- Consider These Additional Application Elements
- Organize Your Time to Complete the Application
- Write Your Application
RESOURCES TO IMPROVE COLLABORATIONS

Collaboration and Team Science Field Guide - cancer.gov


These Sites have Practical Advice and Tools for Setting Up Successful Collaborations While Protecting the Interests of All Involved
Important resource for all Applicants – Foreign and Domestic
More NIH- NIAID – EU - International Collaboration Material
The NIH and Foreign Investments

How NIH invests globally:

- Direct foreign grants
- Domestic grants with foreign components:
  - Formal/Direct subawards
  - **Indirect investments (Collaborations, No subawards)

Over 160 Countries
Mechanisms NIAID Uses for International Research

**Extramural**
- Awards: Direct and Indirect
- Networks
- Jointly funded programs

**Intramural**
- Collaborations
- International Centers For Excellence in Research
- Networks
- NIH Fellows and Visiting Scientists Programs

*Enhancing International Engagement and Research in Response to Outbreaks*
Principles and Strategies for NIAID International Scientific Engagement

Principles:
- Highest scientific quality
- Highest ethical standards
- Shared interest and local relevance
- Mutual benefit in partnership

Strategies:
- Local leadership and community support
- Human and lab capacity investment
- Sustained commitment
- Work with other funding organizations
NIAID - Division of AIDS: Clinical Research and Epidemiology Sites

[Map showing clinical research and epidemiology sites around the world.]

- HPTN
- HVTN
- IMPAACT
- ACTG
- MTN
- IeDEA
NIAID-Division of Microbiology and Infectious Diseases: International Research Programs

Understanding disease in its natural setting
- Tropical Medicine Research Centers (TMRC)
- International Collaborations in Infectious Disease Research (ICIDR)
- International Centers of Excellence in Malaria Research (ICEMR)
- Malaria Vaccines: Clinical Research and Trial Sites

Capacity building & sustainability
- Indo-US Vaccine Action Program (VAP)
- NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS)
- Tuberculosis Research Unit and Tuberculosis Clinical Diagnostics Research Consortium

5/2018
Challenges and Opportunities for Advancing U.S.-EU Cooperation on Global Health Research

**U.S. and EU are experiencing:**
Growing aging Populations, Rise of Infectious Diseases, Increasing Antimicrobial Resistance, Inadequate Preventive and Rapid Diagnostic Services
Continuing Health Disparities between/ within European Countries and in the U.S.

**Biomedical Research Capacities Can Vary Within and Among EU Countries**
Laboratories, Trained Researchers, Ethics Laws and Enforcement (IRB’s, Ethics Committees), Publications, Institutional Support

**Growing Number of Refugees** - some with New Diseases/ New to Europe such as Chagas that might be underdiagnosed.

**Rise in Sexually Transmitted Infections (STI’s)**

**Terrorist Incidents and the need for State-of-Art Emergency Services and Mass Gathering Medicine Policies**

**Brexit**
Current EU Funding Schemes:
- **Horizon 2020 and Framework Programs** have Statutory and Regulatory Differences Between the EU and U.S.
  - Indemnification Requirements
  - Intellectual Property Allocation

Implementing Arrangement
- Between the U.S. and the European Commission (EC) for Cooperation
- Between Researchers Funded Separately by the U.S. and the European Union’s Framework Programs on Research and Innovation, signed October 2016.
**EU-US Policies/Programs/Funding Schemes**

*Horizon Europe - European Union’s New Framework Program is Under Development, and Aims to:*

- Simplify the Grant Process
- Increase Funding Internationally
- Develop Personalized Healthcare for Vulnerable Populations (elderly, children, disabled)
- Increase Research on Infectious Diseases that Cross Borders, Through More International Cooperation,
- Digitalize Health Data/Big Data to be more accessible
- Develop Artificial Intelligence and Evolving Technologies
Collaboration with NIH/NIAID

**Infectious diseases**

- HIV/AIDS - Growing Problem in Eastern Europe
- Tuberculosis - 18 *Eastern* European High-Priority Countries for TB Control Bear 85% of TB and 99% of the multidrug-resistant TB (MDR-TB) burden
- Influenza/ Vaccine Development
- Vector-Borne Illnesses and Tickborne Infections (Crimean Congo Hemorrhagic Fever, Babesiosis)
- Immunizations - Measles Upswing in Europe; Infectious Diseases Among the Elderly; Dramatic Drop in Immunizations in Ukrainian Children
- MERS-CoV - combined European-U.S. research to prevent spread to Europe and the U.S.
**Collaboration with NIH/NIAID (continued)**

**Immunology**

European Researchers are Part of the Immune Tolerance Network, an International Consortium Co-sponsored by NIAID to Study Tolerance-Inducing Therapies for

- Autoimmune Diseases
- Asthma
- Allergic Diseases such as Peanut Allergies
- Transplant Rejection
- Primary Immunodeficiency Diseases
Other Areas of NIH / NIAID / EU Collaborations

Collaborations on Antimicrobial (AMR) Research
Collaborations on Vaccine Development (Innovative Medicines Initiative)
Collaboration on Response to Outbreaks
Personalized Medicine
Rare Diseases
Regenerative Medicine
Data Storage
Human Cell Initiative
Brain Initiative
Cancer Moonshot
Relationship of Mood Disorders and Immune Dysregulation
European Investigator Involvement in U.S. National Institutes of Health Research: Identification of Opportunities and Grant Process

NIAID R01 EU Funding FY94-FY17: Total

NIAID R01 EU Funding FY94-FY17: Total

Millions

$0$ $1$ $2$ $3$ $4$

FY94 FY95 FY96 FY97 FY98 FY99 FY00 FY01 FY02 FY03 FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 FY12 FY13 FY14 FY15 FY16 FY17
Number of NIAID EU Direct R01 Grants FY94-FY17: By Country

- UNITED KINGDOM
- SWEDEN
- SPAIN
- NETHERLANDS
- GERMANY
- FRANCE
- DENMARK

FY94 FY95 FY96 FY97 FY98 FY99 FY00 FY01 FY02 FY03 FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 FY12 FY13 FY14 FY15 FY16 FY17
Number of NIAID EU Direct R01 Grants FY94-FY17: Total

The chart shows the number of NIAID EU Direct R01 Grants from FY94 to FY17, with the highest number occurring in FY15.
ADDITIONAL ADVICE ON FOAs
Funding Opportunity Announcement (FOA)

- Publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.
- FOAs may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program.
- Funding opportunity announcements can be found at [Grants.gov/FIND](https://grants.nih.gov/grants/FIND) and in the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/).

FOAs are COMPLEX: Study an annotated version [here](https://grants.nih.gov/grants/Annotated_FOA.pdf).

FOAs can change with time; revisit them frequently.
# Types of Funding Opportunity Announcements (FOA)

<table>
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<tr>
<th>Type of FOA</th>
<th>Description</th>
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</table>
| **Program Announcements (PA, PAR, PAS)** | • Highlights areas of focus; written by Program Officer  
• Usually ongoing (3 yrs)  
• Often use standard receipt dates          |
| **Requests for Applications (RFA)**     | • Narrowly defined scope. Written by Program Officer  
• Usually single receipt date  
• Set aside funds  
• IC usually convenes review panel         |
| **Parent Announcements**                | • Type of program announcement  
• Generally span the breadth of NIH mission  
• By activity code (R01, R03, etc.)  
• For “investigator initiated” or “unsolicited” research ideas |

*NIH* National Institute of Allergy and Infectious Diseases
NOTICES

Notice (NOT)
A Notice (Guide Notice) is an official NIH announcement relating to a change in policy, procedure, form, or system. Notices also can identify changes to FOAs. Notices are posted on the NIH Guide website and users can be notified via a variety of NIH listservs.

See annotated FOA at: https://grants.nih.gov/grants/Annotated_FOA.pdf
Each FOA has the submission date(s) (also known as receipt date, due date, or application deadline) for grant applications. Dates vary depending on the activity code, specific program, or FOA.

If you cannot meet the application deadline, strongly consider delaying to the next submission date, if there are other dates.

Reviewers will be less enthusiastic if they feel an application is premature because of inadequate development and presentation.

RFAs (requests for applications) and some PARs (Program Announcements with special receipt, referral and/or review consideration) and PASs (Program Announcements with set-aside funds) have special receipt dates indicated in the FOA.
Each FOA specifies all of the review criteria and considerations that will be used in the evaluation of applications submitted for that FOA. **Read these carefully! Write to them!**

See annotated FOA at: [https://grants.nih.gov/grants/Annotated_FOA.pdf](https://grants.nih.gov/grants/Annotated_FOA.pdf)
FOA: Eligibility Check the FOA to be sure you are eligible

Principal Investigator (PI/PD)
- Education requirements
- Citizenship requirements
- Qualifications/expertise

Applicant Organization
- E.g., non-profit status
- Ability to handle federal dollars
- Capacity to conduct research
FOA: Eligibility

Section III. Eligibility Information

1. Eligible Applicants

Be sure both you and your organization are eligible before applying.

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are** allowed.

See annotated FOA at: https://grants.nih.gov/grants/Annotated_FOA.pdf
Definition of Foreign Component

Performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended.

Some activities that meet this definition include, but are not limited to:

• The involvement of human subjects or animals
• Extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities
• Any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country
Other grant activities that may be foreign components:

- Collaborations with investigators at a foreign site anticipated to result in co-authorship
- User of facilities or instrumentation at a foreign site
- Receipt of financial support or resources from a foreign entity
- Collaborations with investigators at a foreign site anticipated to result in co-authorship
- User of facilities or instrumentation at a foreign site
- Receipt of financial support or resources from a foreign entity

Foreign travel for consultation is not a foreign component.
Funding Opportunities – Grants

- NIH supports many types of grants
- Each grant type has a different number, name, function, set of requirements, format and $ limit
- Example: R series (R01, R21, R03) awards are types of “Research Project Grants” https://www.niaid.nih.gov/grants-contracts/types-funding-opportunities
- Not all ICs support the same grant types
- The NIH (and all US funding agencies) announce grants in documents called Funding Opportunity Announcements (FOAs).
- FOAs are of different types (PAR, Pas, PARs)
- Each FOA has a unique title, number and scientific focus.
- Each FOA describes the grant type and research area and includes links to the correct application forms, eligibility information, and submission instructions/requirements
- FOA details can change over time – check them often
Each NIH institute announces its research priorities. Check if your work might be of interest to more than one institute.

**NIH RePORT** *(Research Portfolio Online Reporting Tools)* identifies research funded by the NIH and other sources. You can identify competitors, potential collaborators, research areas with strong or weak funding and many other parameters of funding.

Use NIH Report to study the research supported by several funding agencies and institutions.

- Study Institute Concepts
- Study Financial Plan for the Institute
- Take advantage of recently earmarked NIH funds
US Congressional Earmarks - 2019

**NIH:** $2 Billion increase to $39.1 Billion (+ 5.4%)
- $425 million for Alzheimer’s disease and related dementias
- $100 million for the Cancer Moonshot
- $86 million for the “All of Us” (Precision Medicine Study)

**NIAID:** 4.7% increase to $5.5 Billion
- $37 million for Antimicrobial Resistance
- $40 million for Universal Flu Vaccine

Submit applications in response to a specific FOA

Use link in FOA to access specific application forms required

Read the FOA and the accompanying Form Instructions carefully (be sure to follow any Notices that have been issued in the NIH Guide)

Make sure relevant NIH Institute or Center is listed as participating organization

Check eligibility carefully! (Section III in FOA)

Check if Foreign Institutions are eligible to apply

And if collaboration with Foreign Components is allowed
APPLICATION CRITIQUES
WEAKNESSES / STRENGTHS / ADVICE
Common Weaknesses in Applications

- Insufficient preliminary data (R01, etc)
- Lack of new or original ideas
- Absence of sound scientific rationale
- Lack of testable hypothesis or no hypothesis
- Lack of letter of support
- Diffuse, superficial, or unfocused research plan
- Proposed experimental approaches are not feasible
- Lack of alternate approaches
- Inadequate power analysis
Common Weaknesses (cont’d)

- Future directions unclear
- Lack of Principal Investigator’s experience
- Lack of essential expertise in research team and/or collaborators
- Level of effort for the projects is too high or too low
- Unrealistically large amount of work (overly ambitious)
- Lack of knowledge of published relevant work (citations)
- Missing VA, HS, and Biohazards information
- Typographical errors
Common Weaknesses (cont’d)

- Lack of relationship to disease
- Methodology is not good
- Descriptive vs Hypothesis-driven
  - “Looking at” (bad) vs “testing” (good)
  - “Fishing expedition” (bad)
- No biostatistical support
- Sample size (power) calculations for animal or human studies
- Not discussing literature that is contrary to your ideas
- Not discussing strengths and limitations of your data—don’t let reviewer do it for you!
- Proposing too much for 3 or 5 years
Elements of an Outstanding Grant Application

- New or original ideas
- Pilot data (essential for R01/ less critical for Fs and Ks)
- Some FOAs call for no data if highly innovative work is the goal
- Focused, incisive research plan
- Knowledge of published relevant work
- Experience in the essential methodology
- Future directions and contingency plans
Writing Advice

- Write Specific Aims section and discuss with mentor or an NIH grantee
- Give yourself four weeks to write first draft
- Full draft to mentor one month before submission date
- Read and follow the instructions (electronic 424)
- Prepare budget with budget person
- Write for a general scientific audience
- Simple is better
- Some repetition of key material / ideas is good
• Write to the FOA requirements
• Need a simple testable hypothesis that is supported by preliminary data
• Study Sections are conservative
• No preliminary data = No award (UNLESS data is not required)
• Demonstrate medical significance
• Rationale, limitations of methods, controls, and back-up plans are critical
• Details of methods are unimportant (boring) but make sure the reviewers know you know the methods and say so
• Get collaborators and consultants- include strong letters of collaboration that summarize/define the plans specifically
• Depending on FOA instructions, a critical page in the application is a one page summary of the application
• Why is this problem significant?
• What is the exciting preliminary data?
• What are the hypothesis supported by the data?
• Avoid long (laundry) list of things (Aims) you plan to do
• 2-3 Specific Aims is sufficient
• Make Sure Applications Are Complete
• Facilitate the Peer Review process for the reviewers
• Think like a reviewer
• Write with all the review criteria in mind
• Indicate that you have addressed the review criteria when appropriate in the application
• Don’t Work In A Vacuum
• Don’t Give Up!!
• Good Data can / should convince reviewers you can do what you propose (not surprisingly)
• Show primary data for critical methods
• Use easy to read figures or tables
• **Progress Reports**- for grant renewals data is key
  • Restate Aims in a renewal (but avoid a long list)
  • Publication list MUST be very strong in a renewal.

• **SOME FOAs for EXPLORATORY, INNOVATIVE RESEARCH DO NOT REQUIRE PRELIMINARY DATA. APPLICATIONS WITHOUT DATA NEED STRONG REASONS WHY THE WORK IS SIGNIFICANT AND FEASIBLE etc**
WRITING - Methods

• Are there adequate controls?
• Are you discussing the pitfalls and alternatives?
• Avoid very specific details (volumes, components of buffers)
• Show a time line- reviewers like them. The time line if realistic, helps the application.
• Time lines often are required by the FOA.
Writing Advice Overall / Appeal Process

DO NOT GIVE UP - Initial failure is common for all NIH applicants
Learn from a failed submission and succeed - most do

- The Summary Statement is not a personal critique; don’t take negative comments personally
- Study criticism(s) and decide if repairs are possible
- Maintain a positive, appreciative tone in your responses
- Attend to each criticism and do not rush.
- If you do not agree on an issue, respectfully explain why.
- Reviewers spent time on their work and are not happy if a “fixed” application is angry, accusatory, or incomplete

“Good” amended applications tend to do well.

The NIAID REVIEW APPEAL PROCESS IS SIMILAR TO THAT IN OTHER INSTITUTES

https://www.niaid.nih.gov/research/grants-scientific-review-appeals
REGISTRATION RESOURCES FOR US and FOREIGN APPLICANTS
You must Register for e-submission

**Register on Grants.gov**
- Register with US CCR
- Obtain DUNS number
- Obtain Grants.gov credentials
- Assign an AOR to submit grants
- Non-US institution or organization may require additional registration with a North Atlantic Treaty Organization Commercial and Government Entity (NCAGE)

**Register on eRA Commons**
- Both applicant and organization must register
- One-time registration
- Enables you to receive and transmit information or application electronically
- **This process may take 4-8 weeks**
Registration Resources

Registering with Grants.gov
http://www.grants.gov/web/grants/applicants/organization-registration.html

Resources for International Applicants
Tips for International Applicants
Support Contacts for International Applicants
Questions and Answers for International Applicants
Guidance for International Applicants Blocked from Registration Websites NOT-OD-11-090.
An NIH supported webinar on Electronic Submission of Grant Applications for Foreign Institutions can be found at
http://grants.nih.gov/grants/webinar_docs/webinar_20120927.htm
FAQs Foreign Organizations
http://grants.nih.gov/grants/electronicreceipt/faq_full.htm#special
Most types of NIH grant applications are submitted electronically via Grants.Gov

eRA Commons is a web-based system for secure information exchange with applicants and applicant organizations (http://commons.era.nih.gov/)

Applicants must establish personal eRA Commons accounts to track review progress and to retrieve scores and summary statements
STAFF ROLES
NIH Staff Roles

Scientists administering the research grant process

• Program Officers
  – Provide stewardship and administer grants
  – Identifies scientific priorities
  – Provide guidance on resources for research and collaboration

• Grants Management Specialist
  – Government official for fiscal policy
  – Negotiates, approves, and processes awards for all grants

Note: NIH staff cannot influence the evaluation of an application
Scientific Review Officer (SRO)

**A Federal scientist who**

- Coordinates peer review
- Presides over a scientific review group and meeting
- Acts as an intermediary between applicants and reviewers
- Prepares summary statements for applications after review
- Ensures NIH/NIAID peer review policies are properly implemented
Roles and Responsibilities of the SRO

Checks applications for completeness, compliance and responsiveness

Identifies scientific expertise

Enlists/recruits reviewers

Develops a conflict of interest (COI) list

Selects a meeting venue/organizes the review meeting

Assigns reviewers by aligning expertise with the science in the application(s)
Selects a Chairperson to moderate discussions

Provides instructions to the reviewers

Conducts pre-review teleconference

Sets deadlines for submission of critiques and preliminary scores

Generates the summary statement

 Represents review at institute council meetings

Assures fairness during the review process
The Scientific Review Group and Reviewer Responsibilities
Scientific Review Group (SRG)

A panel of scientific experts recruited by the SRO

Experts are chosen based on their:

- Scientific expertise
- Research background
- Review experience
- Lack of conflict of interest with applications

Note:

1. A Scientific Review Group that meets for multiple review meetings is also known as a Study Section.
2. A Scientific Review Group that meets for a single review meeting is also known as a Special Emphasis Panel.
Responsibilities of the Reviewers

Disclose all conflicts of interest

Certify confidentiality

Read assigned applications thoroughly

Prepare a written evaluation (critique) that addresses all review criteria and considerations

Provide preliminary scores for each review criterion
Responsibilities of the Reviewers (cont.)

Provide preliminary overall impact score for assigned application(s)

Electronically submit critiques and scores to the eRA Commons

Participate in the discussions during the review meeting and provide final impact scores

Edit critiques as needed

Maintain confidentiality of meeting results
Peer Review Process Overview
Overview of Peer Review

Competitive process

Managed/coordinated by Scientific Review Officers

Follows NIH/NIAID policies and procedures

Follows NIH Office of Extramural Research for Peer Review policy
Overview of Peer Review (cont.)

**Two Step Process**

**Scientific Evaluation**

Scientific Review Group (SRG) evaluates the scientific and technical merit and assigns an Impact Score

**Advisory Councils at funding institutes**

Review/concur SRG results

Special consideration of applications that address high program priorities

Consider investigator appeals (rare)
The Review Meeting
The SRO is in charge
The Chairperson facilitates/moderates discussions

Opening remarks are made by Review and Program staff

Reviewers determine the applications that will not be discussed based on low preliminary scores (streamlining)

Applications with high preliminary scores are discussed and scored
Assigned reviewers (primary, secondary, tertiary) discuss strengths and weaknesses of application

Discussion of application strengths and weaknesses by the rest of the review panel (includes all scoreable items)

Final Impact Score Assigned

Additional Review Considerations
Evaluation of Applications:  
Scored Review Criteria

1. **Significance**

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
2. *Investigator(s)*

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
3. **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
4. **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
5. **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

**Note:** In Requests for Applications (RFA) or Program Announcements (PA), the criteria may be modified or contain additional elements to consider or address.
Additional Review Criteria

Not scored individually, but considered in overall score

Protection for Human Subjects

Inclusion of Women, Minorities and Children

Vertebrate Animals

Biohazards

Resubmission

May include RFA specific criteria (e.g. milestones, product development plan, etc.)
Applications from Non-U.S. Organizations- The reviewers will indicate what is special in the application that justifies the work at a foreign site.

Select Agents

Resource Sharing Plans

Budget including Duration of Support
# Scoring System

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<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
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<tr>
<td><strong>High Impact</strong></td>
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<tr>
<td></td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td><strong>Moderate Impact</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td><strong>Low Impact</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

Non-numeric Score Options:
NR = Not Recommended For Further Consideration
CF = Conflict, ND=not Discussed
## Scoring System

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

1. Conflicted reviewers leave the room.
2. All non-conflicted reviewers score applications.
3. Each application stands on its own merit; Applications are not compared with each other!
4. Reviewers evaluate the application in front of them.
5. The SRO takes notes and later writes the Resume section of the summary statement.
PI’s can access final averaged Impact scores and summary statements in eRA Commons

SRO releases Summary Statement

Program Officers make award recommendations

Awards are made to applicant institutions

Applicants can revise and resubmit one time if not awarded
Critiques (Summary Statements)

- **Summary Statements for DISCUSSED applications** have Overall and Criterion Scores and critiques.
- **Summary Statements for NOT DISCUSSED applications** have Criterion Scores and critiques.
- **Discussed applications also receive a resume and summary of the panel’s discussion** at the review meeting.
- **Overall Impact Paragraph** - Each assigned reviewer writes a paragraph summarizing the factors that informed his/her Overall Impact score.
- Applicants receive the score before the summary statement.
- Wait for the summary statement before contacting the NIH.
- The Post-review Point of Contact is the Program Officer.
- Do not contact the SRO after the review meeting.
- Read the Summary Statement carefully before contacting the Program Officer.
After the Review

• **eRA Commons**
  
  
  – Final Impact Score is available in 3 days.
  
  – Summary statement is available in 4 – 8 weeks.

• **Available to:**
  
  PD/PIs
  
  NIH officials
  
  Advisory Council members

• **NIH Program Officer = Point of Contact**
The NIH Peer Review Process

**Dual Review System for Grant Applications**

**First Level of Review:** Peer Review
- Scientific Review Group (SRG)
  *(Study Section)*

**Second Level of Review**
- NIH Institute/Center National Advisory Council
Who Makes Funding Decisions?

The Institute Director!

Factors Considered:
- Scientific Merit
- Contribution to Institute Mission
- Program Balance
- Availability of Funds
ADDITIONAL INFORMATION ON REVIEW CRITERIA
Ideas about the 5 evaluation criteria

Significance

Does the project address an important problem or a critical barrier to progress in the field?

If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Why is it important to do this study?

Project Summary/Abstract and Specific Aims critical in presenting this information

Develop/discuss potential implications but do not overstate them

Informed discussion of what is already out there

Discuss potential value of negative findings?

Assume reviewer is educatable but not necessarily knowledgeable in your field

R01-related information from http://grants.nih.gov/grants/funding/424/index.htm#inst
Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project?
If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Biographical Sketch
Training
Personal statement (not generic)
Positions and honors/awards
Selected peer-reviewed publications
Research support – another way of showing what you have done

Preliminary Studies
Approach
Is new investigator in a position (training/experience/collaborators/institutional resources) to be successful with proposed approach.
Is this person sufficiently independent from mentor?

Environment
Does description support your being an independent researcher?
Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Emphasized in review but not necessarily the be all and end all (overall impact could still be high)

Basis/need for innovation?

Logically developed/presented

Why should we believe this innovation is important or likely to succeed?

Often very small part of overall application → difficult to evaluate
Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Are potential problems, alternative strategies, and benchmarks for success presented?

If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for

1) protection of human subjects from research risks, and
2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Do not be overly ambitious (too many aims, some or all not doable)

Do not include an incompletely developed study (we will notice!)

Try to avoid having 2\textsuperscript{nd}, 3\textsuperscript{rd} aims be contingent on success of 1\textsuperscript{st}

Do not propose work that is beyond your (and possibly others') expertise

Do not ignore/undervalue the analytic plan (we will notice that too!)

Same for the human subjects section (seeming disinterest/lack of knowledge in this arena of concern)

No matter how innovative a study is, if it uses flawed methodology, its overall impact score will suffer.

Have someone else review this.
Environment

Will the scientific environment in which the work will be done contribute to the probability of success?

Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Particularly important for proposals requiring novel/extended resources

In era of limited funding, accessing institutional support, building upon existing collaborations/ cohort studies, etc likely to be viewed positively

Not having to start from scratch particularly useful with international studies

Not making use of or inadequately describing scientific environment potentially problematic
CLINICAL TRIAL APPLICATIONS
*NIH Initiatives to Enhance Clinical Trial Stewardship and Human Subjects Research

All Research Involving Human Participants

- New forms to collect human subjects information
- Use of a single Institutional Review Board (IRB) for domestic multi-site studies*
  *Foreign sites are excluded

Research that Meets the NIH Definition of a Clinical Trial

- Training in Good Clinical Practice (GCP)
- Clinical trial-specific Funding Opportunity Announcements (FOAs)
- New review criteria
- Expanded registration and results reporting in ClinicalTrials.gov
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.

- NIH Definition was clarified in October 2014
- Encompasses a wide range of types of trials, including: mechanistic, exploratory, pilot/feasibility, and behavioral
- With broader definition, many more studies are classified as clinical trials

Learn more at https://grants.nih.gov/policy/clinical-trials/definition.htm
Determining if Study is an NIH-Defined Clinical Trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm

Does your study...

1. Involve one or more human participants?

2. Prospectively assign human participant(s) to intervention(s)?

3. Intend to evaluate the effect of an intervention on human participants?

4. Have a health-related biomedical or behavioral outcome?

If “yes” to ALL of these questions, your study is considered a clinical trial.
Effective January 1, 2017 – NIH staff and NIH-funded clinical investigators who are involved in the design, conduct, oversight, or management of clinical trials are to be trained in Good Clinical Practice (GCP)

- GCP training should be refreshed every 3 years
- NIH staff and investigators should maintain documentation of GCP training
- Refer to your IC Standard Operating Procedures

GCP training options: https://nih-extramural-intranet.od.nih.gov/d/hs/gcptraining
Clinical Trial-Specific FOAs
USE THE CORRECT CLINICAL TRIAL (CT) FOA

CT Not Allowed
CT Required
CT Optional


Changes to Clinical Trial Review Criteria

https://nih-extramural-intranet.od.nih.gov/d/nih/topics/clintrials_review_criteria.html

**Scoring Review Criteria**

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance**

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications proposing clinical trials:

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or healthcare policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

**Investigator(s)**

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organizational structure appropriate for the project?

In addition, for applications proposing clinical trials:

With regard to the proposed leadership for the project, do the PD(s)/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management, and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?
INVESTIGATOR ROLES AND RESPONSIBILITIES
Understand Roles and Responsibilities at Your Institution


What is your role?

What roles do other people play?
  Authorized Organizational Representative
  Principal Investigator
  Administrator

Coordination and respect for each other’s roles is key

Understand your institutional processes and timelines for grant related activities
Grantee Institution Team

“Successful grants require close coordination between all members of the grantee team.”

Grants are awarded to institutions as represented by AORs.

PD/PIs manage and perform the science

Research Administrators support business aspects of the grant
The Grantee Institution

- Actual recipient of award
- Legally responsible for proper conduct and execution of grant
- Provides fiscal management
- Provides oversight on allocation decisions
- Assures compliance with Federal, NIH, and organization-wide requirements
Responsibilities of the Authorized Organization Representative (AOR)

Designated Representative of the grantee institution.
Accountable for appropriately utilizing Federal funds and for the performance of a project

Signs all official correspondence to NIH, including grant applications, financial reports, assurances, and certifications

Uploads application into grants.gov
Responsibilities of the Principal Investigator(s) (PIs)

Designated by the Grantee Institution

Responsible for the scientific and technical aspects of project

Directly manages the project on a day-to-day basis

Assures scientific compliance by maintaining contact with the NIH Program Officer

Coordinates with other PDs/PIs on projects with multiple Principal Investigators
Do I Contact NIH *Before* Applying?

Yes!

**Mandatory**

*Application with budget >$500,000 direct costs for any single year*

*R13 Conference Grants*

**Optional**

*When RFA’s request a Letter of Intent*

**Always Recommended**

*When you think about applying for any grant*
Responsibilities of the Research Administrator (Sponsored Project Officer)

Acts as an agent of the Principal Investigator and the Authorized Institutional Official

Gathers information needed to ensure compliance with Federal regulations, as well as organization-wide requirements

Provides essential grant-related support Cannot assume responsibilities assigned to the Authorized Organizational Official or the PI
Post-Award Issues for Investigators
Extensive List of Activities for Managing Funds and Reporting Results
