Partnering with International Research Organizations & the Process

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NIH Regional Seminar

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NIH and International Research

Why does NIH support international research?
NIH and International Research

Why NIH supports international research:

• Application presents *special opportunities* for furthering research programs through the use of 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 awarding IC and has the potential for significantly advancing the health sciences in the U.S.
“Because infectious diseases do not respect national boundaries and because many diseases can be studied and ultimately controlled only through integrated, global research programs, the Institute should continue its longstanding efforts to foster, support, and expand (where possible) broad-based international studies of infectious diseases....”

Task Force on Microbiology and Infectious Diseases, 1991
NIH and International Research

How NIH invests globally:

- Direct foreign awards
- Domestic awards with foreign components

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Direct Foreign Awards</th>
<th>Domestic Awards with Foreign Component</th>
</tr>
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<tbody>
<tr>
<td>2017</td>
<td>498</td>
<td>6345</td>
</tr>
<tr>
<td>2018</td>
<td>544</td>
<td>6958</td>
</tr>
<tr>
<td>2019</td>
<td>548</td>
<td>7512</td>
</tr>
<tr>
<td>2020</td>
<td>586</td>
<td>8348</td>
</tr>
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NIH and International Research

Am I eligible to apply for NIH funding?
Application: Eligibility

- Review Funding Opportunity Announcement (FOA) for Eligibility
  - Foreign Institutions may or may not be eligible
  - Foreign components may not be allowed
  - Foreign components may or may not be required
  - Foreign applicants required to submit detailed budgets
- Contact NIH program staff
Application: Eligibility

- Review Funding Opportunity Announcement (FOA) for Eligibility

Section III. Eligibility Information

1. Eligible Applicants

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.
# UNSOLICITED VERSUS SOLICITED (RFA) GRANTS

<table>
<thead>
<tr>
<th></th>
<th>Unsolicited</th>
<th>Solicited</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deadlines</strong></td>
<td>Three deadlines/cycles per year</td>
<td>A single deadline</td>
</tr>
<tr>
<td><strong>Review</strong></td>
<td>CSR reviews</td>
<td>ICs review</td>
</tr>
<tr>
<td><strong>Resubmissions</strong></td>
<td>Many resubmissions allowed</td>
<td>No revisions/resubmissions</td>
</tr>
<tr>
<td><strong>Letter of intent</strong></td>
<td>No</td>
<td>Recommended</td>
</tr>
<tr>
<td><strong>Purpose</strong></td>
<td>Researchers pursue their own research interest</td>
<td>To address a high priority or under-represented area</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>Institute sets payline</td>
<td>Set aside funds</td>
</tr>
</tbody>
</table>
FUNDING MECHANISMS

- **FUNDING MECHANISMS**
- **Research Supplement**
- **Independent**
- **Postdoc**
- **Graduate student**

**FUNDING MECHANISMS**:
- **International Research Training**
  - D43
- **International Research Scientist Development**
  - K01
  - K22
  - K99
- **Emerging Global Leaders**
  - K43
  - AREA
  - Small
  - HR/HR
- **International Research Training**
  - Multi-project
  - MERIT
  - U19
  - R01
  - R21
  - R37
Application: Eligibility

• Foreign organizations are generally not eligible to apply for these types of grants:
  • Kirschstein-NRSA institutional research training
  • Program project
  • Center
  • Resource
  • SBIR/STTR
  • Construction grants

• Note, some activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component.
Search for Funding Opportunity

https://grants.nih.gov/funding/searchguide/index.html#/
Search for Funding Opportunity

https://www.niaid.nih.gov/grants-contracts/opportunities
Section VII. Agency Contacts
We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Scientific/Research Contact(s)
Paula S. Strickland, Ph.D., MPH
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-2922
Email: pstricklan@mail.nih.gov

Peer Review Contact(s)
Louis A. Rosenthal, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5070
Email: rosenthall@niaid.nih.gov

Financial/Grants Management Contact(s)
Tseday Girma, MPA
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-747-7388
Email: Tseday.girma@nih.gov
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Are there different requirements for direct foreign applications and domestic applications with foreign component?
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.

- Activities that would meet this definition include, but are not limited to:
  - Involvement of human subjects or animals
  - Extensive foreign travel by grantee project staff for data collection, surveying, sampling, and similar activities
  - Any activity of grantee that may impact U.S. foreign policy through involvement in affairs or environment of a foreign country

- Examples of other grant-related activities that may be foreign components:
  - Collaborations with investigators at foreign site anticipated to result in co-authorship
  - Use of facilities or instrumentation at a foreign site
  - Receipt of financial support or resources from a foreign entity

Foreign travel for consultation not considered a foreign component
What is the likelihood I will get NIH funding?
Application: Success

Getting Started

https://grants.nih.gov/grants/grants_process.htm

• Choose an appropriate topic
• Write a strong proposal that addresses review criteria
• Should be important (High Impact)
• Topic must be unique
• Must align with NIH/IC Mission
  • Speak with NIH Program Staff
• Identify a funding opportunity announcement (FOA)

NIH RePORTER

- Make use of tools like RePORTER
- Applicable for US and Foreign researchers
- Search based on
  - Key terms
  - PI
  - Study Section
  - Program Officer

https://reporter.nih.gov/
Tips for Foreign Investigators

• Speak with NIH Program staff about your idea and where it may best fit

• Things review group may consider
  • Publication record
  • Previous funding (best if from NIH)
  • Justification of foreign site

Eligible does not equal competitive
Application: Review Criteria

- Each FOA specifies all review criteria and considerations that will be used in the evaluation of applications submitted for that FOA.

Section V. Application Review Information

NEW Important Update: applications for due dates

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Write your research strategy to respond to the review criteria to ensure reviewers have what they need to properly evaluate the scientific merit of your application.
BE PERSISTENT

• REMEMBER

• ~50% OF APPLICATIONS ARE “TRIAGED”

• READ YOUR CRITIQUES CAREFULLY

• CONTACT PROGRAM STAFF FOR ADVICE

• DECIDE THE BEST ROUTE FORWARD

• FIX WEAKNESSES AND RESUBMIT APPLICATION

• SUBMIT A NEW APPLICATION
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What are basic needs for submitting an application?
Foreign Institution Registrations

1. Grants.gov and NIH eRA Commons
   Must register prior to application submission

2. Data Universal Number System (DUNS)
   Changing by April 2022 (NOT-OD-21-170)

3. System for Award Management (SAM) – renewed annually

4. NATO Commercial and Government Entity (NCAGE)


6. HHS Payment Management System, required only if funded.

NOTE: PMS Registration must match SAM or funds cannot be drawn
**DUNS/UEI**

- Federal-wide transition from DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number to a new government-owned Unique Entity Identifier (UEI) **by April 2022**.

- **Implementation**
  
  - October 2021
    
    - Entities registered in eRA Commons will begin to see UEI populated in their Institutional Profile File (IPF).
      
      - No action is required by the entity.
    
    - **For applications due on or after January 25, 2022**
      
      - Applicants must have UEI at time of application submission. See NOT-OD-21-169
Foreign Institution Registration

- **EIN**
  
  - For applications, if your organization is not in the United States, enter 44-4444444.
Do I Contact NIH *Before* Applying?

- **Mandatory:**
  - Application with budget >$500,000 direct costs (excluding consortium F&A) for any budget period.
    - Does not apply to applications submitted in response to RFAs or other announcements that include specific budgetary limits.

- **Optional:**
  - When RFA’s request a Letter of Intent
  - Recommended when submitting any application
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What can I put in my budget?
Budget Considerations

• Needs to be appropriate for the science
• Foreign site salary norms
• Procurement and availability of research supplies
• Currency exchange rates
Budget Considerations

- NIH Grants Policy Statement (GPS) section 7.9.1 provides a subset of common, allowable costs. The list is not all inclusive.

- NIH GPS Section 16.6 provides unallowable costs and grant requirements for foreign grantees and foreign components.

Unallowable Costs


- Patient Care Costs are provided only in exceptional circumstances.

- Grantees are reminded that they may not invest grant funds to defray the cost of inflation.
Budget Considerations

- Consult NIH Grants Policy Statement for policies and compliance requirements
- Have SOPs
- Follow four cost principles:
  1. **Reasonableness** – The dollar amount is within the limitations that a prudent person would pay for the good or service.
  2. **Allocability** – The goods or services that can be assigned directly to the grant.
  3. **Consistency** – Routinely applied to the same category.
  4. **Conformance** – Test of allowability. Grants costs must conform to the “Allowability of costs/Activities” section of the NIH Grants Policy Statement.
F&A for Foreign Awards

• Necessary costs incurred by a recipient for a common purpose benefitting more than one cost objective, and not readily assignable to specifically award.

• Supports cost of compliance with federal requirements
  • E.g., protection of human subjects, animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct.
F&A for Foreign Awards

- 8% of modified total direct costs (MTDC)
  - exclusive of tuition and related fees
  - direct expenditures for equipment
  - subawards in excess of $25,000
Calculating F&A for Foreign Award

Total Direct Cost to Foreign Prime: $290,000
- Including Equipment Cost: $9,000
- Including 1 Subaward: $30,000 total cost

MTDC Calculation:
$290,000 (Total Direct Costs)
- $9,000 (Equipment)
- $5,000* (In Excess of Subaward Allowance)
= $276,000

F&A Calculation: $276,000 x 8% = $22,080

Total Cost calculation: $290,000 TDC + 22,080 (F&A) = $312,080
Calculating F&A for Foreign Award

Direct Cost at Foreign Prime: $260,000

Including Equipment Cost: $9,000

subaward total costs $30,000 total cost $290,000

MTDC Calculation:
$260,000 (Total Direct Costs)
- $9,000 (Equipment)
+$25,000* (In Excess of Subaward Allowance)
= $276,000

F&A Calculation: $276,000 x 8% = $22,080

Total Cost calculation: $290,000 TDC + 22,080 (F&A) = $312,080
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What are the requirements for a collaboration/subawards?
Funding Collaborations

• Traditional Subcontract/Consortium
  • U.S. Institution is responsible
  • Requires a formalized written agreement
  • Substantial scientific involvement
  • Ensure the collaborating organization(s) understand the rules and regulations
  • Determine who has the authority to sign for the organization
    • Local hierarchy in foreign organization
Funding Collaborations

- **Traditional Subcontract/Consortium**
  - Decide how and when the funds will be disbursed
    - Understand local reimbursement systems
    - Salary support for local investigators
    - Project delays = no salary support for staff
    - Check or Wire payments
    - Advance payments
  
- Establish procedures for reporting progress and use of funds
  
- U.S. awardees will flow down to foreign subrecipients applicable parts of the Uniform Guidance and monitor foreign entity progress
Overarching Considerations

- **Foreign Institutions function differently**
  - Language
  - Time Zones
  - Internet Access
  - Sponsored programs staff
  - NIH funding requirements

- **Plan for delays, differences and dialogue**

*Apply early*
NIH and International Research

What are the reporting requirements?
Project Monitoring

• Research Performance Progress Report (RPPR)

• Section E.4--What dollar amount of the award’s budget is being spent in foreign country(ies)?
  • Domestic awardees provide dollar amount obligated to first-tier subawards to foreign entities
  • Foreign awardees provide dollar amount of award excluding first-tier subawards to U.S. entities
  • Dollars should reflect Total Costs
  • For multiple foreign countries, include distribution between foreign countries
  • Foreign travel and purchases not necessary unless part of first-tier sub
Project Monitoring

• Research Performance Progress Report (RPPR)
  • Section G.9 Foreign Component—Provide information on foreign components
    • Significant scientific activity performed outside of the U.S. whether or not grant funds were expended
    • NIAID adds a Term of Award to NoA to remind Grantees that research conducted outside the United States needs to be reported
  • D.1 – Participants
    • Check “yes” and add the organization/country if the individual’s primary affiliation is foreign and working in a foreign country
Tips for Foreign Investigators

• Don’t forget about the Audit Requirements – required if expended $750,000 or more in HHS awards.
Closeout

• Documents are due within **120 calendar days** of the end of grant support:

  1. **Final Federal Financial Report (FFR) SF-425 Expenditure Data** (submitted through eRA Commons);
     • Grantees must ensure there are no discrepancies between final FFR expenditure data and Payment Management System.
     • **Obligated funds must be drawn prior to 120 days after project period end date**
     • **Reconcile award and expenditures**
       • Review carefully for restricted funds or carryovers

  2. **Final Invention Statement & Certification**;

  3. **Final RPPR (F-RPPR) and Interim-RPPR**
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What if I want to make changes?
Prior Approval

• Change in Scope

• Change of PD/PI or Institution
  • Reduction of effort by 25% or more

• Carryover of unobligated balances
  • required if NoA includes a term and condition of award

• Change or addition of a performance site within a foreign country
Prior Approval

• Transfer of a grant from foreign organization to domestic organization

• Transfer of a grant to or between foreign or international organizations
  • Requires approval of the NIH and National Advisory Council or Board.

• Contact NIH Program Officer/Grants Management Specialist for prior approvals
NIH and International Research

What else do I need to consider?
Institutional FCOI Policy

• Since November 12, 2020, NIH funded recipients are required to submit their publicly accessible Financial Conflict of Interest (FCOI) policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module).

• See NIH Grants Policy Statement Section 4.1.10 for all FCOI policies.
Key Take-Aways

• Review the Notice of Award (NoA) for funding information and to determine:
  • Streamlined Noncompeting Award Process (SNAP) vs. non-SNAP
  • Automatic carryover authority

• Federal Financial Report (FFR)
  • For non-SNAP awards - required annually
  • For SNAP awards - required at end of the competitive segment
Key Take-Aways

• Communication
  • Most foreign institutions need assistance in understanding NIH requirements

• Understand their unique policies, regulations and practices

• Be involved for the long term

• Be patient
THANK YOU!

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Information For Foreign Grants

The National Institutes of Health (NIH), part of the United States Department of Health & Human Services, is the primary U.S. Federal agency that conducts and supports medical research. To realize its mission of extending healthy life and reducing the burdens of illness and disability, NIH funds grants, cooperative agreements, and contracts that support the advancement of fundamental knowledge about the nature and behavior of living systems.

The 27 Institutes and Centers (ICs) of NIH provide leadership and financial support to researchers both inside and outside the United States. Approximately 80% of NIH funding goes to support research grants, including grants to foreign organizations. Many of the ICs have international programs/collaborations that can be linked to from their homepages.

This page provides information specifically for foreign applicants and grantees. Applications for research grant support from foreign organizations are treated as if they were applications from domestic organizations. There are a few exceptions which are highlighted on this page. This page also provides links to important information for foreign applicants as they consider and prepare applications and administer grant awards.

Important Resources

- NIH Grants Policy Statement (NIH GPS) is the policy source for terms and conditions NIH awards made to domestic and foreign organizations. It is also designed to be useful to those interested in NIH grants by providing information about NIH, its organization, its staff, and its grants process. The NIH GPS should be used extensively when applying for...
Human Subject Research

• Recipient is accountable
• Federal wide Assurance (FWA) and Institutional Review Board (IRB) rules apply to international
  • domestic sites of multi-site studies that will conduct same protocol involving non-exempt human subjects research must use a single Institutional Review Board (sIRB)
• Some countries have in-country requirements
• National ethical reviews may be required
Revised Common Rule (45 CFR 46)  
January 21, 2019, studies initiated on or after that date, ongoing studies that voluntarily transitioned to the Revised Common Rule, and studies that voluntarily implemented the three burden-reducing provisions during the delay period (7/19/18 – 1/20/19), are expected to comply with all Revised Common Rule requirements for the remainder of the study.

- New Exemption Codes “X” for applications submitted on or after 1/25/19
- Changes to IRB review criteria, IRBs are now required to review and approve the research protocol.

- Resources:
  - Protection of Human Subjects
  - NOT-OD-19-050
  - Application Guide
Human Subject Research

• NIH discontinued support of the Protecting Human Subjects Research Participants (PHRP) training.
• September 26, 2018 was the last available date for the training online

• Per policy, NIH does not endorse any specific program to fulfill requirements.
• Responsibility of fulfilling PHRP Requirements lies with the institution.
• It is up to the institution to determine what constitutes as “appropriate training.”
• FAQ section is being created for the OEP website.

• References: NOT OD-00-039, NOT OD-18-221, PHRP website
Vertebrate Animal Research

- Recipient is accountable
- Animal Welfare Assurance (AWA) required
- Foreign site must provide domestic recipient with verification of IACUC approval
- Foreign recipients provide OLAW with an Animal Welfare Assurance
  - IACUC approval is not required for direct foreign awards