International Researchers: Where to Start

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Division of International Training and Research

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NIH Mission

NIH . . . Turning Discovery Into Health®

Seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
“Time and again it has been demonstrated that the goal of better health has the capacity to demolish geographic and political boundaries and to enter the hearts and minds of men, women, and children in the four corners of the earth. ...And there is widespread belief that the nations of the world can and must share their knowledge and other resources so that people everywhere may have the blessing of better health, and through health, may move forward to new levels of peaceful productivity.”

~ John E. Fogarty, 1958
The NIH and International Research

Reasons 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.
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)

- In FY 2015, the NIH awarded 526 direct foreign grants and 6128 domestic grants with foreign components.
- In FY 2016, the NIH awarded 549 direct foreign grants and 6303 domestic grants with foreign components.
Definition of Foreign Component

The 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:

- 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

Examples of other grant-related activities that may be foreign components are:

- 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 considered a foreign component.
Session Objectives

Upon completion of this session, attendees will gain knowledge of:

• NIH extramural funding opportunities available to international investigators;
• How to determine eligibility for NIH funding opportunities;
• Policies and procedures unique to foreign awards; and
• Resources available to international investigators.
Agenda

1. Pre-Award issues for international investigators
2. Post-Award issues for international investigators
3. Funding opportunities for international investigators
NIH Application Process

Find funding opportunity, download the instructions and **READ CAREFULLY**

Prepare the application (a lot of team work!) & Make sure required registrations are in place (DUNS, SAM, NCAGE, eRA Commons, Grants.gov)

Submit to Grants.gov:

1. Check submission status in eRA Commons
2. Review the application image for **errors**.

Mission Complete!
NIH advertises availability of grant support through Funding Opportunity Announcements (FOAs)

- Search for FOAs at: [Grants.gov/FIND](https://grants.gov/FIND) and in the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/).
- Submit applications in response to a specific FOA
- Use link in FOA to access specific application forms required

Read the FOA carefully and read the 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)
  - whether *Foreign Institutions* are eligible to apply
  - whether collaboration with *Foreign Components* are allowed

See annotated FOA at: [https://grants.nih.gov/grants/Annotated_FOA.pdf](https://grants.nih.gov/grants/Annotated_FOA.pdf)
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
FOA: Eligibility

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: Review Criteria

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!

See annotated FOA at: https://grants.nih.gov/grants/Annotated_FOA.pdf
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Who: Grant Proposal Team

- Investigators (US and/or foreign responsible for the program plan/research)
- Program managers (US and/or foreign responsible for logistics, supplemental proposal components)
- Finance managers (responsible for mechanisms for moving project funds to the site)
- Sponsored Programs Office (responsible for budget review and uploading application into Grants.gov)
Who: Information from Foreign Investigators

- NIH Biosketch
- NIH Other Support
- Foreign site salary base & FTE

START EARLY with good communication, inclusion, feedback.
What: Proposal Stage Considerations

- Foreign performance site information - NIH approved
- Resources Section – description of facilities and infrastructure
- Foreign institution’s organizational chart
- Local FWA and OLAW/IACUC in place
Where: Support from a Foreign Institution

- Letters of support (subcontract dollar amounts)
- MOU or collaborative agreement (commitment from Gov orgs: MOH; non-Gov orgs: NGOs; academic institutions: deans, local grants management office leaders, co-PIs)
- Community advisory board

Good communication, inclusion, feedback
Budget considerations

- Foreign site salary norms
- Procurement and availability of research supplies
- Currency exchange rates
- F&A = 8% for foreign institutions (parent or subcontracts)
- Housing, transport, visas, immunization, travel insurance
- Face-to-face team meetings
- Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols
- If subawards are involved, prime grantee is responsible for subawardee compliance and for safeguarding U.S. funds
NIH Application Process

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Prepare the application (a lot of team work!)

&

Make sure required registrations are in place (DUNS, SAM, NCAGE, eRA Commons, Grants.gov)

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Mission Complete!
GET REGISTERED!

Start early: Registration is a multistep process that can take 8 weeks or more!

All registrations must be complete in order to submit application

Applicant Organizations

• Dun and Bradstreet Universal Numbering System (DUNS) number
• System for Award Management (SAM) active registration (requires annual renewal)
• Foreign organizations must obtain an NCAGE in order to register in SAM.
• eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration.
• Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

*PI and Signing Official (SO) need separate accounts in eRA Commons because each has different privileges.*
Registration Requirements

GET REGISTERED!

Start early: Registration is a multistep process that can take 8 weeks or more!

All registrations must be complete in order to submit application

Program Directors/Principal Investigators (PD(s)/PI(s))
• eRA Commons account (can take up to 2 weeks)

NEW! For Career Development Award (K) applications, primary mentors must have eRA Commons account (NOT-OD-16-082)
Registration Resources

Registering with Grants.gov


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

FAQs Foreign Organizations
- http://grants.nih.gov/grants/electronicreceipt/faq_full.htm#special
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Mission Complete!
Applying for Grants at Grants.gov:

Step 1: Search for and identify a grant opportunity in the NIH Guide for Grants and Contracts or on Grants.gov.

Step 2: Download the grant application package.

Step 3: Complete the application. Be sure to save a copy of the application locally on your computer.

Step 4: The Authorized Organizational Representative (AOR) submits the application to Grants.gov either directly or through a Service Provider. All required registrations must be completed prior to submission.

Step 5: Grants.gov performs basic form validation and virus check on submitted application.
Electronic Submission: How it Works

Step 6: Track the status of the submitted application package at Grants.gov until you are notified via email that NIH has received it.

Step 7: eRA software performs NIH business rule validation on submitted application.

Step 8: NIH notifies Authorized Organization Representative (AOR)/Signing Official (SO) and the Principal Investigator (PI) by email to check the eRA Commons for results of NIH validations check.

Step 9: AOR/SO and PI find out if the grant application passed or failed the rule check. If it failed: all errors must be corrected and the entire corrected application must be submitted to Grants.gov.
Electronic Submission: How it Works

Step 10: AOR/SO and PI will have two weekdays after application assembly to review the application in the eRA Commons.

Step 11: The AOR has the authority to “Reject” the assembled application if it does not correctly reflect the submission, due to a Grants.gov or eRA Commons system issue (e.g., garbled or missing parts) or to address warnings.

PIs must work through the AOR/SO to “Reject” the application.

If no rejection occurs within 2 weekdays of application availability in eRA Commons, the submission process is complete and the application automatically moves forward to Receipt and Referral.

Step 12: Applicants can track the progress of their application in eRA Commons.

Applications are accepted by Grants.gov by 5:00pm local time of the applicant organization on the submission date.

Only the AOR is allowed to submit.
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Mission Complete!
The peer review of applications from foreign institutions is the same as that for applications from U.S. institutions.

In addition, the following are assessed as part of the review process and award decisions for applications from foreign institutions:

- 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.
Peer Review

First Level of Review
Scientific Review Group
(Study Section)

Second Level of Review
NIH Institute/Center Council

NIH Center for Scientific Review
http://www.csr.nih.gov
Additional Clarification or documentation as needed, as each application is unique.

- Updated Other Support
- Federal-Wide Assurance (FWA)
- Updated Human Subjects’ Institutional Review Board (IRB) Approval—it is renewed annually
- Human Subjects’ Training Education Certification - completed by anyone involved in the design or conduct of NIH-funded HS research.
- Animal Assurance Number
- Updated Institutional Animal Care and Use Committee (IACUC) approval date—good for 3 yrs.
Who at NIH Can Answer Your Questions?

Before You Submit Your Application
• A Program Officer at an NIH Institute or Center
• Scientific Review Officer

After You Submit
• Your Scientific Review Officer

After Your Review
• Your Assigned Program Officer
1. Pre-Award issues for international investigators

2. Post-Award issues for international investigators

3. Funding Opportunities for international investigators
Getting Started

• Set up team communication
  ▪ Regular Skype calls
  ▪ Regular team face-to-face meetings

• Define roles and responsibilities
  ▪ Procedures for directing and monitoring activities
  ▪ Procedures for payment and approval of expenditures
  ▪ Policies to be followed, such as travel reimbursement and salaries and fringe benefits
Prime grantees are responsible for subaward compliance

• Human subjects
  ▪ Foreign sites must have a Federal Wide Assurance.
  ▪ Foreign sites must have IRB approval annually.
  ▪ Foreign sites are subject to the education requirements.

• Animal subjects
  ▪ Foreign sites must have an Animal Welfare Assurance.
  ▪ Foreign sites are not required to have IACUC approval.
  ▪ Foreign sites are encouraged to follow same standards.
Human subjects/Vertebrate animals

REQUIRED:
1 local/in-country IRB: National Health Sciences Research Committee in Lilongwe, Malawi
1 U.S. Based IRB: UNC-CH IRB in Chapel Hill

Simultaneous submission process:
• Start with sub-award site first: learn the local IRB meeting schedule; expect months of waiting, months b/w submission, feedback and approval. Find a connection on the board in country, if possible.
• Primary institution second
• Funds for human subjects/ IACUC related activities are restricted until IRB approval
Project Implementation

• Project tracking – expenditures

• Compliance issues:
  ▪ ethics certifications
  ▪ IRB approval letters
  ▪ conflicts of interest

• Sub-awardee reporting

*Document, document, document!*
Notice of Award (NoA)

• Projects are programmatically approved for entire project period
• Projects are funded in 12-month increments (budget periods)

• Notice of Award
  ▪ Approved project period and budget period dates
  ▪ Amount of funds authorized
  ▪ Anticipated future-year commitments
  ▪ Applicable terms and conditions
  ▪ Any restriction on the use of funds

Read your NoA carefully! Especially any restrictions
Progress Reporting
Research Performance Progress Report (RPPR)

- Describe progress, study results, the significance of the findings, and any significant changes
- Provide additional information to NIH upon request

> Each report should be a self-contained document

- The RPPR is REQUIRED for all non-competing progress reports submitted on or after October 17, 2014 (NOT-OD-14-092)

New information to be provided by grantees with the RPPR includes:
- Foreign component information
- Dollars spent in foreign country(ies) [via first-tier subawards]
- Organizational affiliation of personnel at foreign sites

Progress Reporting
Research Performance Progress Report (RPPR)

What slows down the award process?

- Lack of, or slow, response to inquiries
- Delays sending essential information (IRB, IACUC approvals, other support, etc.)
- Information sent without identification (e.g., grant number)
- Lack of institutional signatures/concurrence
- Budgets with inadequate justification
- Other Support for an individual that adds up to more than 100% or more than 12 person months per year
- Missing information for key personnel
- Calculations of F&A that do not make sense
- Lack of population data for clinical grants
In general, the NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes.

- Some changes may be made at grantee’s discretion.
- Some changes require NIH prior written approval.

Degrees of discretion permitted vary by type of grant, grantee, and coverage by special initiative.
Actions likely to be considered a change in scope include, but are not limited to:

- Change in the specific aims
- Change in research from one disease area to another
- Change from the approved use of research subjects
- Substitution of one animal model for another
- A clinical hold by the FDA
- Application of a new technology
- Transferring the performance of substantive programmatic work to a new foreign component
- Change in key personnel
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval
Post-Award
Administrative Requirements

Process to Request Prior Approval

1. Prepare a letter from the PI and signed by the institutional business official.
   Include:
   • Reason for the change
   • Impact on the project activities
   • Impact on the project timing
   • Impact on the budget
   • Supporting documentation
   • Biosketches and other support if applicable

2. Send letter to the Grants and Program staff at NIH.

Enact change **only** if written approval is received from the NIH
Managing subawards

- Agreement must be in writing and periodically updated.
- Communication channels must be clear and consistent.
- **Prime grantee is responsible for subawardee compliance and for safeguarding U.S. funds.**
- Arrangements must be consistent with your institutional policy and procedures.
Closeout of an award is the process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the grantee and NIH.

**Grantees must submit the following closeout reports:**

- Final Federal Financial Report (except for Fellowships)
- Final Progress Report (except for Fellowships for which the Termination Notice will continue to serve as the Final Progress Report)
- Final Invention Statement and Certification (except for Training grants, Fellowships, and certain other programs—e.g., activity codes C06, R13, R25, S10)

All applicable closeout reports are due no later than 120 days after the project end date.

Failure to submit timely and accurate final reports may affect future funding to the organization and/or awards with the same PD/PI.
Resources

• eRA Commons: https://commons.era.nih.gov/commons/
• Electronic Research Administration: http://era.nih.gov/
• Applying Electronically: http://grants.nih.gov/grants/ElectronicReceipt/
• FAQs for Foreign Organizations: http://grants.nih.gov/grants/electronicreceipt/faq_full.htm#special
• NIH About Grants: http://grants.nih.gov/grants/oer.htm
• SF424 (R&R) Application Instructions: https://grants.nih.gov/grants/how-to-apply-application-guide.htm
• Research Portfolio Online Reporting Tools (RePORT): https://report.nih.gov/
Agenda

1. Pre-Award issues for international investigators
2. Post-Award issues for international investigators
3. Funding Opportunities for international investigators
African medical education program enters next phase

Fogarty is working with its partners to plan how to build on the success of the Medical Education Partnership Initiative (MEPI) and continue to strengthen and expand capacity building in sub-Saharan Africa.
The Fogarty International Center at NIH offers a variety of funding opportunities to support the field of global health research. Fogarty also offers a variety of resources for those seeking global health research funding across NIH, and from other organizations.

- Fogarty Funding Opportunities
- Funding News Email Updates
- Trans-NIH Programs and Collaborations
- Other NIH Funding Opportunities
- Non-NIH Funding Opportunities
  - Predoctoral/Graduate
  - Postdoctoral
  - Faculty
  - Health Professionals
  - Institutions
  - Travel
- Funding Strategy
- Foreign Grant Information

Subscribe to Fogarty's Global Health Matters newsletter, and weekly funding news for global health researchers.

> SUBSCRIBE
Foreign Grant Information

https://www.fic.nih.gov/Grants/Pages/Foreign.aspx

The Fogarty International Center at NIH serves as a bridge between NIH and the greater global health community. Fogarty supports basic, clinical and applied research and training for U.S. and foreign investigators working in the developing world. Learn more about Fogarty’s role in global health.

Find information and resources specifically for foreign NIH grant applicants and institutions.

- Guidance for International Applicants Blocked from Registration Websites (NOT-OD-11-090), released June 16, 2011
- E-submission information for international applicants
  - Transcript and Recorded Webinar: Electronic Submission of Grant Applications Webinar for Foreign Institutions from NIH Office of Extramural Research, recorded September 27, 2012
  - NIH E-submission Tips for International Applicants [PDF, <1M]
- Foreign Grants Information from the NIH Office of Extramural Research (OER) - Details on elements of the grants process specific to foreign applicants/grantees, including general information, process information and policies.
- Fogarty Grantee Frequently Asked Questions (FAQs) - A general list of answers to the most frequently asked questions by foreign grant applicants and grantees, including many questions applicable to foreign institutions.
- Cost Considerations for Foreign Grantees - Highlights from the NIH Policy Statement on allowable costs for foreign grants.
- NIH Grants Policy on Foreign and International Institutions - Excerpts from the NIH Grants Policy Statement pertaining to awards directly to foreign institutions, international organizations, domestic grants with foreign components, and the allowance of F&A costs for foreign and international organizations.
Building a robust global health workforce

Developing leaders in the field requires:
1) well-trained individuals
2) protected time to conduct research in LMICs
3) strong mentorship from U.S. investigators with experience working in LMIC settings AND from LMIC investigators
Fogarty Career Development Programs

Fogarty offers two mentored global health research career development programs

**K01**

*Since 1999 – K01 for U.S. investigators*

International Research Scientist Development Award (IRSDA; K01; PAR-17-002)

**K43**

*New program – K43 for Low- and Middle-Income Country (LMIC) investigators*

Emerging Global Leader Award (K43; PAR-17-001)
## Fogarty Programs

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Fogarty Funding Opportunities - Dates and Deadlines
http://www.fic.nih.gov/Funding/Pages/Fogarty-Funding-Opps.aspx
Questions?