Fogarty International Center

M314: Managing National Institutes of Health (NIH) Awards with Foreign Components

SRA International Annual Meeting – October 2017

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&

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FIC, NIH Grants Office
Presentation Topics

• Overview of FIC @ 50th Anniversary

• Pre-Award & Post-Award – Highlights

• Policy Change – Highlights

• Case studies
Fogarty at 50 - Congressman John E. Fogarty, a powerful & outspoken advocate for NIH & medical research

During his tenure as chair of the Appropriations Subcommittee for health funding, NIH budget grew substantially

**NIH budget:**
1949: $37 M
1967: $1 B
The Fogarty International Center Mission: 
Advancing Science for global health

- Address global health challenges through innovative & collaborative programs for research & training
- Support & advance the NIH mission through global partnerships
- Cultivate the next generation of global health scientists

“...a man who, for more than a quarter of a century, worked tirelessly for a healthy America, in a healthier world.”

-Tribute by Congressman Laird

Cong. Melvin Laird (R-WI) with Cong. Fogarty in 1967
The Fogarty International Center Mission:
Advancing Science for global health

Over the decades, Fogarty’s programs have made significant contributions by filling the pipeline of global health leaders, extending the frontiers of science and accelerating discovery. Above all, Fogarty invests in people—the most important resource in global health research—who serve on the front lines of the fight against diseases that threaten populations in the U.S. and around the world. Fogarty provides a bridge between NIH and the greater global health community by facilitating exchanges among investigators, providing training opportunities and supporting promising research initiatives in developing countries. Over the last five decades, Fogarty programs have provided significant research training for about 6,000 scientists worldwide.
Building sustainable global health research capacity at home & abroad

- Thousands of scientists worldwide have received significant research training
- Support for ~500 research & training projects, involving collaborations with at least 100 academic institutions
- Multidisciplinary programs focus on:
  - Infectious diseases
  - Chronic conditions
  - Informatics, bioethics
  - Implementation science
  - Brain disorders & mental health
  - Biodiversity & natural products discovery
  - Tobacco cessation research
  - Climate change & environmental health
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
## Active Fogarty Extramural Grant Programs

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His wisdom inspires our work today

“I should like to see a plan to bring into being at Bethesda a great international center for research in biology and medicine, dedicated to international cooperation in the interests of the health of mankind.”
Pre and Post Award
Pre-Award

- Funding Opportunity Announcement (FOA)
- Registration Requirements
- System for Award Management (SAM), FAQ’s
Funding Opportunity Announcement (FOA)

- 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 – **START EARLY**
Registration Requirements

- Applicant organizations must complete one-time only registration.
- Principal Investigators do not need to register with Grants.gov
- Good for electronic submission to all Federal agencies

Detailed instructions at: http://grants.gov/applicants/get_registered.jsp

- Grants.gov registration requires institutions to: Obtain a Data Universal Numbering System (DUNS) number
- SAM (* New organizations should allow extra time for this step)

Registration not required to find funding opportunity or download application package, only to submit completed application
Registration Requirements: eRA Commons

• Applicant institutions must complete one-time only registration.
  ▪ Principal Investigators (PIs) must work through their institutions to register. The PI must hold a PI account and be affiliated with the applicant organization.
  ▪ PIs currently registered only for Internet Assisted Review (IAR) must work through their institutions for full eRA Commons registration.

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

• See http://era.nih.gov/ElectronicReceipt/preparing.htm for additional information
Foreign Inst. interested in conducting business with the United States (U.S.) Federal Government must complete the following:

**How to Obtain A Commercial and Government Entity (CAGE)/North Atlantic Treaty Organization (NATO) CAGE (NCAGE) Code:**

**Companies located outside the U.S.:** [http://www.dlis.dla.mil/Forms/Form_AC135.asp](http://www.dlis.dla.mil/Forms/Form_AC135.asp)

1. Register with [NATO Support Agency (NSPA)](http://www.dlis.dla.mil/Forms/Form_AC135.asp)
2. If you wish to do business with the U.S. you must:
   a. Register with [Dun & Bradstreet (D&B)](http://www.dunandbradstreet.com/).
   b. Register with [System for Award Management (SAM)](http://www.sam.gov).

**Companies located in the U.S.:**

1. Register with [Dun & Bradstreet (D&B)](http://www.dunandbradstreet.com/).
2. Register with [System for Award Management (SAM)](http://www.sam.gov).

**Note:** Approximately 4-5 business days after your SAM application is approved, NCAGE/CAGE Codes will be assigned and delivered by e-mail.


U.S. territories (Guam, Puerto Rico, Virgin Islands, American Samoa and Northern Mariana Islands, etc.) will be assigned by the U.S and must register in SAM.
SAM.gov FAQs for Foreign Organizations

- **I am an international registrant and cannot access the SAM website. Why and what do I do?**
  A technical or security issue may be preventing you from accessing the SAM website. Please visit this Federal Service Desk FAQ for guidance on how to proceed: [https://www.fsd.gov/app/answers/list](https://www.fsd.gov/app/answers/list).

- **I am an international registrant and cannot access the NATO CAGE Code website. Why and what do I do?**
  In certain circumstances, specific locations may be blocked for technical or security reasons. If you cannot access the website, please visit this Federal Service Desk FAQ for guidance on how to proceed: [https://www.fsd.gov/app/answers/detail/a_id/564/kw/international](https://www.fsd.gov/app/answers/detail/a_id/564/kw/international).

- **I am an applicant who lives outside the U.S. and am unable to access the System for Award Management (SAM) site. What should I do?**
  A few countries may have trouble accessing the SAM website. The applicant should send an email to [security@bpn.gov](mailto:security@bpn.gov) and copy the NIH Electronic Submission mailbox at [NIHElectronicSubmit@mail.nih.gov](mailto:NIHElectronicSubmit@mail.nih.gov).

- **Are International Organizations required to hold a DUNS and register in Grants.gov?**
  Yes.

- **Can I register my organization in Commons in my native language?**
  We can accept any foreign names that use the English alphabet. Unfortunately our systems cannot accept special characters.

- **Are there any tips to assist foreign organizations while registering in eRA Commons?**
  Keep these handy pointers in mind while registering in eRA Commons. Applicant organizations:

  - Must have a DUNS number before registering in the eRA Commons. This DUNS number must match the DUNS number provided at the SAM registration with Grants.gov.
  - Must have a valid e-mail and should ensure that any filters on their email do not interfere with NIH email. Must also keep in mind that the sooner they reply to emails, the faster NIH can complete their registration.
FAQs Foreign Organizations

- Some of the data fields in the 424 (R&R) do not really apply to foreign organizations. How will this be handled?
  For some of the data, special instructions are included in the Application Guide for foreign organizations.

- Are International organizations required to obtain an EIN number as part of the grant submission process?
  NIH does not require international organizations to obtain an EIN number for application submission. International organizations may use 44-4444444 for the Employer Identification field in the SF424 (R&R) Cover Component of the application package. [See NIH eSubmission Tips for International Applicants (PDF - 343 KB)].

- How do I know if a foreign organization is eligible to apply?
  Each funding opportunity has a section for Eligibility. In that section there will be a clear statement about whether foreign institutions are eligible to apply.

- Which budget form should I use if I am a foreign organization?
  Foreign institutions must use the Research and Related Budget form.

- On the SF424 (RR) application the field for "state" appears to be required. What do I do?
  Make sure you select your country first. If you select a country other than the US or Canada, the state field will become optional. Inclusion of Providence is required for Canada.

- How does the system handle phone numbers in different formats?
  The phone number field on the SF424 (RR) application has a 25 character limit, but no specific format requirements.

- What should I include in the Congressional District field?
  Foreign institutions should use 00-000 for the Congressional District.
NIH eSubmission Tips for International Applicants (cont.)

**Prepare Application**

- Follow instructions in the application guide and within the FOA. **Instructions in the FOA overrule those found in the application guide.**
- Foreign applicant organizations must use the R&R **detailed budget form (NOT-OD-06-096). Updated: September 2013**
- R&R Other Project Information component – a.) Section 6 activities outside the U.S. must be completed. b.) Add an attachment titled “Foreign Justification” under Other Attachments, Item 12.
- Include the PD/PI eRA Commons Username in the “Credential, e.g. agency login” field of the R&R Senior/Key Person Profile component. NIH requires it for application processing.
- If a effort level greater than zero, include effort in either calendar months or a combination of academic and summer months for all Senior/Key Persons listed in the budget.
Application Submission - Updates

**NOT-OD-17-062**

- Applicants must choose the appropriate application package for their due date when presented with both FORMS-D and FORMS-E application packages on the same FOA.
- For a transition period, both FORMS-D and FORMS-E application packages will be active.

**USE FORMS-D Application package for:**

- Applications submitted with due dates on or before January 24, 2018 or--
- If your application due date(s) are on/or BEFORE 1/24/18 or subject to NIH Late Policy or NIH Continuous Submission policy for 1/7/18 AIDS policy.
Application Submission – Updates (cont.)

• **NOT-OD-17-119 – FORMS-E required**
  
  **IMPORTANT** – You must use updated grant forms and instructions (FORMS-E) for due dates on or after January 25, 2018 to be eligible for funding consideration – includes new Human Subject and Clinical Trial Information Form.

• On or After 1/25/18 including: All application types (New, Resubmission, Renewal, Revision) Applications submitted early for intended dues dates on or after January 25, 2018
Application Submission - Updates (cont.)

NOT-OD-16-129

• Most Appendix Materials are “now” eliminated for NIH Applications due dates on or after 1/25/2017.

Allowable appendix materials
Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017, the only allowable appendix materials are:

• For applications proposing clinical trials (unless the FOA provides other instructions for these materials):
  • Clinical trial protocols; Investigator's brochure from Investigational New Drug (IND), as appropriate
Application Submission - Appendix Materials (cont.)

- For all applications (allowable appendix materials):
  - Blank informed consent/assent forms
  - Blank surveys, questionnaires, data collection instruments

- FOA-specified items.
  - If appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.
Consequences for submitting disallowed appendix materials

Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

• Reference NOT-OD-17-035 Reminder for New Appendix Policy
Post Award
Research Performance Progress Report (RPPR)
Three Types of RPPR’s Annual, Final, Interim

- **Annual RPPR** – Use to describe a grant’s scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.

- **Final RPPR** – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.
Interim RPPR – Use when submitting a renewal (Type 2) application. If the Type 2 is not funded, the Interim RPPR will serve as the Final RPPR for the project. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.
Annual RPPR Reporting

- Reference NOT-OD-15-014 –
- No new policies to report, format same:
- B – Accomplishments;
- C – Publications;
- D – Participants, Trainee Tables required to be reported here, training data table formats must be used for RPPRs for applications submitted for due dates on or after May 25, 2016. Applicants may create tables for their applications and RPPRs either by using fillable tables in MS Word or via the xTRACT system;
- E – Impact;
- G – Special Reporting Requirements, i.e., Special NoA terms, Mentor’s report, Human subjects, animal research, etc.;
- H - Budget
RPPR - ANNUAL PROGRESS REPORTING

• RPPR Sections especially relevant for Foreign components:
  ▪ C.1 Publications
  ▪ D.1 Participants
  ▪ E.4 Dollars spent in foreign countries
  ▪ G.8 Project/Performance Sites
  ▪ G.9 Foreign Components

• http://grants.nih.gov/grants/rppr/index.htm
• https://era.nih.gov/modules_user-guides_documentation.cfm
RPPR Section C.1 Publications

• Until further notice, manuscripts written in scripts other than Latin (e.g. Russian, Japanese) cannot be processed by the NIHMS. These manuscripts are not required to be posted on the PubMed Central and do not require evidence of compliance on applications, proposals, or reports. The NIHMS continues to process manuscripts written in Latin (Roman) script that contain characters and fonts used in standard mathematical notation.

• [https://publicaccess.nih.gov/policy.htm](https://publicaccess.nih.gov/policy.htm)
“Is the individual’s primary affiliation with a foreign organization?”

- Check **No** if the individual’s primary affiliation is with a foreign organization but the individual is working on this award solely while in the U.S.
- If **Yes**, provide the name of the organization and country.
RPPR Section E.4 Dollars Spent in Foreign Countries

- “What dollar amount of the award’s budget is being spent in foreign country(ies)?”
  - For domestic awardees provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period. For foreign awardees provide the dollar amount of the award, excluding all first-tier subawards to U.S. entities, for this reporting period. Dollars provided should reflect total costs.
  - If more than one foreign country identify the distribution between the foreign countries.
  - Report only cumulative first-tier subawards dollars by country. Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.
RPPR Section G.8 Project/Performance Sites

- All performance sites should be clearly indicated in this section of the RPPR.
- **NOTE:** NIH prior approval is required before adding or changing a foreign component under a grant.
RPPR Section G.9 Foreign Component

• All Foreign Components must be reported in this section of the RPPR including a description of each foreign component.

• Definition: *Foreign component* is defined as significant scientific activity that was performed outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds were expended.

• **NOTE:** NIH prior approval is required before adding or changing a foreign component under a grant.
Final RPPR (FRPPR)

- Effective January 1, 2017 the FRPPR replaced the Final Progress Report (FPR). NIH will no longer accept FPR’s.
- FRPPR due 120 days from the period of performance end date of the competitive segment
- Generally the format will be the same as the annual RPPR – However recipients will be required to report on I-Project Outcomes.
- NOT-OD-17-022
This section will be made publically available, thus allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

- NIH FRPPR Format –
  - A-Cover;
  - Page-B. Accomplishments;
  - C-Products;
  - D-Participants;
  - E- Impact – SBIR/STTR only;
  - F-Changes;
  - G-Special Reporting Requirements;
  - H-Budget
  - I - Project Outcomes
Interim-RPPR (I-RPPR)

- Effective February 2017, NIH will require that organizations submit an “Interim-RPPR” while their renewal application (Type 2) is under consideration.
  - In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.
  - If the Type 2 is not funded, NIH will treat the Interim-RPPR as the institution’s Final-RPPR.

Like the Final-RPPR, recipients will be required to adhere to the new requirement to report on Project outcomes in the Interim-RPPR.
I-RPPR Format

- A. Cover Page
- B. Accomplishments
- C. Products
- D. Participants
- E. Impact – SBIR/STTR only
- F. Changes
- G. Special Reporting Requirements
- H. Budget
- I. Project Outcomes
New ERA Commons Prior Approval Module for a No Cost Extension

• Prior Approval Request for No Cost Extension (NCE)
  Signing Officials (SOs) will be able to request an NCE electronically through eRA Commons via Prior Approval.

  ▪ When is a grant eligible for a NCE through Prior Approval?
    • When an NCE under expanded authority has already been used and the grant is within 90 days of the project end date.
    • When the grantee is not under expanded authority and the grant is within 90 days of the project end date.
    • When the project end date has expired and has not been closed or has not entered unilateral closeout, whichever comes first.
Signs Officals (SOs) can initiate the request for a Change of Program Director/Principal Investigator (PD/PI) electronically through eRA Commons via Prior Approval.

- The following conditions must be met for a grant to be eligible for a Change of PD/PI Request:
  - The grant is awarded, and the Project Period End Date has not passed.
  - The grant is not a Fellowship or Career.
  - The details for the request require some basic information:
    - Who is being replaced, removed or added to the grant?
    - What will their level of effort be?
    - What is the effective start date for the requested changes?

- Additionally, some files will need to be uploaded as an attachment to the request.
  - Biosketch for any new PD/PI
  - Other Support for any new PD/PI
SAM.gov Entity Registration

• Institution SAM.gov registration must be renewed annually.
• NIH policy: The expiration date cannot be within 30 days of the budget start date. (e.g.- A grant with a 12/1 start date cannot have a SAM.gov entity expiration date before 12/31)
• Your institution must be authorized for display in SAM’s Public Search.
  ▪ In SAM, Entity Data section “Information Opt Out” make sure you have NOT selected the following “I DO NOT authorize my entity information to be displayed in SAM’s Public Search.”

IF YOUR SAM.gov REGISTRATION IS NOT COMPLIANT WE CANNOT ISSUE ANY FUNDS
OTHER IMPORTANT REMINDERS
Cost Considerations affecting Foreign grants: Allowable Costs (NIH GPS Ch. 7 and 16)

• Allowable:
  ▪ Generally the same costs allowable for domestic grants.
  ▪ Items normally covered under full F&A.*
  ▪ Supplements/Additional funds for fluctuations in currency exchange.*
  ▪ Customs and Import Duties (e.g.- Consular fees (visa costs*), customs surtaxes, value-added taxes and other related charges).

  Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (NIH GPS 7.9.1)

• This list is not all-inclusive or exhaustive.
• DOCUMENT INSTITUTIONAL POLICIES!
Cost Considerations: Customs and Import Duties (NIH GPS 7.9.1)

- **Value Added Tax (VAT)** - Now allowable
  - Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards.
  - Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC.
  - For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.

- **Visa Costs** - Allowable as recruiting cost
  - Allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. It is the responsibility of the institution to monitor the status of the individual's visa and ensure they have sufficient time to fulfill the obligations of the research they are being paid for on the grant. However, if the person is already an employee and the cost in question is a visa renewal then this isn't a recruiting cost so the cost would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable.
Cost Considerations: Fluctuations in Currency Exchange Rates. (NIH GPS 16.5)

- Cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding, as determined by the awarding IC.
- Prior approval of exchange rate fluctuations is required only when the charge results in the need of additional Federal funding, or the increased costs result in the need to significantly reduce the scope of the project.
- The non-Federal entity is required to make reviews of local currency gains to determine the need for additional federal funding before the expiration date of the Federal award. Subsequent adjustments for currency increases may be allowable only when the non-Federal entity provides the awarding IC with adequate source documentation from a commonly used source in effect at the time the expense was made, and to the extent that sufficient Federal funds are available.
Cost Considerations affecting Foreign grants: Unallowable Costs (NIH GPS Ch. 7 and 16)

- Unallowable:
  - Full F&A for foreign institutions
  - Patient Care costs- (Allowable in exceptional circumstances)
  - Major Alterations and Renovations >$500,000
  - Honoraria for speakers*
  - Meals and refreshments*

- This list is not all-inclusive or exhaustive.
- DOCUMENT INSTITUTIONAL POLICIES!
Policy Updates
Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality (CoC)

Notice Number: NOT-OD-17-109

- NIH is updating its policy for issuing Certificates of Confidentiality (Certificates) for NIH-funded and conducted research

- Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this Policy is deemed to be issued a Certificate through this Policy and is therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act.
Policy Supporting the Next Generation Researchers Initiative

Notice Number: NOT-OD-17-101

This notice announces a new policy implementing special funding consideration for early and mid-career (early established) investigators.

Early Stage Investigator (ESI)

- A Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found here. ESIs are encouraged to enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons profile to ensure their correct identification.

- ESI applications with meritorious scores will be prioritized for funding.

Early Established Investigator (EEI)

- Principal Investigator (PD/PI) who is within 10 years of receiving their first substantial, independent competing NIH R01 equivalent research award as an ESI. EEIs may be prioritized for funding of meritorious research applications if they are either:

1. losing or are at risk for losing all NIH research support if they are not funded by competing awards this year, OR

2. supported by only one active award.
NIH Single IRB & Exceptions Process (sIRB)

Notice Number: NOT-OD-17-120

• The NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research becomes effective for applications with due dates of January 25, 2018 and after

• NIH funded multi-site domestic studies involving non-exempt human subjects research are expected to use a sIRB
  - Conducting the same protocol
  - All Human Subjects, not just Clinical trials
  - All new and recompeting applications

Policy does not apply:
  - Foreign sites
  - Career development awards (K), Institutional training (T) and Fellowship awards (F)

  - Single IRB of record does not have to be the IRB of the parent award. It is the best IRB for the study.

  - The sIRB will be expected to carry out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46.
Notice Number: NOT-OD-17-083

- On January 23, 2017, President Trump signed the Presidential Memorandum reinstating the 2001 Presidential Memorandum on the "Mexico City Policy," and directing the Secretary of State to implement a plan to extend the Mexico City Policy to "global health assistance furnished by all departments or agencies."

- Under this expanded policy, "global health assistance" includes funding for international health programs, such as those for HIV/AIDS, maternal and child health, malaria, global health security, and family planning and reproductive health.

- Protecting Life in Global Health Assistance does not reduce the amount of global health assistance the U.S. Government makes available, and funding previously obligated will not be affected as a result of this policy. The United States remains deeply committed to supporting health programs around the world.

- Effective the date of publication, the National Institutes of Health (NIH) will implement the requirements of Protecting Life in Global Health Assistance through terms and conditions of award for all applicable new PEPFAR grants and cooperative agreements and to existing awards when amended to add new funding.

- Applies to:
  - All grant awards supported by President’s Emergency Plan for AIDS Relief (PEPFAR) funds
    - Including new grants, non-competing continuations, competitive renewals, and supplemental awards
  - Foreign NGOs (e.g., foreign private universities) directly supported by, or that are subrecipients of, US NGOs

- Does NOT apply to:
  - US NGOs
  - Foreign governmental organizations (e.g., foreign public universities, multilateral organizations)
  - Sub-recipients of awards made to US governmental institutions, such as public universities

The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials

This notice informs the community of the implementation of new and more rigorous review criteria for evaluating clinical trial applications for research projects (grants and cooperative agreements) submitted to due dates on or after January 25, 2018.

The following questions are in addition to the existing research review questions.

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**
- **Study Timeline**
Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research

Notice Number: NOT-OD-16-109 provides sIRB’s costing guidance

- **Primary activities**
  - Activities associated with conducting the ethical review of the proposed research protocol and the review of the template informed consent document describing the study.
  - These routine activities are usually included in the F&A rates

- **Secondary activities**
  - Activities associated with the review of site-specific considerations (unlike circumstances) for all of the participating sites.
  - Project-specific activities “above and beyond” IRB review of human subjects research

- In general, **primary activities** should be charged as **indirect costs** if those activities are included in an organization’s Federally-approved indirect cost rate agreement. **Secondary activities** may be charged as **direct costs**, with appropriate budget justification.

- The institution that is incurring sIRB costs should include the sIRB costs on their budget page. Other sites that are not serving as the sIRB should not have any IRB cost included in the budgets.
Case studies
Stellenbosch University South Africa regarding refreshment cost

Stellenbosch University South Africa have a general question relating to claiming food on NIH awards. According to 2CFR200.435 ENTERTAINMENT it states:

- **Cost of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the Federal awarding agency.**

- So if meetings or workshops are held which has a programmatic purpose, will snacks/food for the attendees at the meeting be considered an allowable expense?
An award is currently issued with a delayed onset restriction for human subjects. The grantee recently wrote to the IC requesting written approval to issue stipends to human subjects as compensation for their participation in the study.

• The following is found in the Year 2 eSNAP RPPR:
  • **Human Subjects**: Yes
  • **Research Exempt**: No
  • **Has the Involvement of Human Subjects changed since previous submission?** No
University of Science is the prime grantee that involves two foreign institutions in Vietnam and they also serve as MPIs. They need clarification regarding the Vietnam Academy of Science and Technology (VAST) institution listed in the grant application and notice of award.

The VAST principal investigator is also the Deputy Director at the Institute of Marine Biochemistry (IMBC) which is part of VAST but which is not listed in the grant application. The VAST PI wish to register in sam.gov under IMBC's DUNS rather than VAST’s.

University of Science would like to know if VAST are able to do this being they are a foreign institution and the grant has already established that VAST is the institution on record.

In sum, they would prefer the grant funds allocated to IMBC rather than VAST.
Non U.S. High Income Country (HIC) investigators are not eligible as PD/PIs on some PAR’s

Request for clarification regarding eligibility criteria that at least one UMIC and at least one LMIC must be involved regarding the R21 research grant.

May a UK Institution be involved? Can the UK Institution lead, as long as there is an UMIC and LIC partner?


From the guidelines: “At least one institution in the U.S. OR an UMIC, and at least one institution in a LMIC must be involved as partners in the grant application (UMIC institutions are eligible to partner either with U.S. institutions or directly with other LMIC institutions).”
Case study on fixed price subcontract

Firm Fixed Price (FFP) subcontracts/ subawards – are they allowed?

• U01 grantee has entered into a cost reimbursement subcontract agreement for application submission. During the 03 year, the grantee wants to change the arrangement with the approved subcontract to an FFP, is this allowed, can they do it?

• What information is required?

• What prior approvals, if any are required?
Case study on a K01

Dr. S. is the primary mentor for Dr. Lee on his current K01 award from Fogarty. Dr. S. wants to highlight the following points about the CDC grant opportunity for Dr. Lee

1) PI role- Dr. Lee was chosen as the grant PI at the time of resubmission based on his international reputation in Humanitarian Response. He was responsible for addressing concerns and the grant was awarded and evaluated with him as PI.

2) Independent research opportunities with CDC grant-The CDC grant will provide significant opportunities for secondary data analysis and improving our approach to humanitarian response. This field has not had the opportunity until very recently to collect these key data in order to inform how we respond to these emergencies. Dr. S suspects this will provide Dr. Lee with many opportunities to both publish and generate preliminary data for future NIH grant applications.

3) Continued Career Development in the next year- Dr. S is devoted to providing ongoing mentorship to Dr. Lee in the last months of his K award. Dr. S views the CDC award as a perfect opportunity to provide ongoing mentorship in support of Dr. Lee’s first role as a major grant PI.

4) Dr. Lee clarify, that he was not the original PI on this grant when it was submitted to CDC last fall in response to the RFA. However, the original PI had to step down soon after the grant was submitted, and Dr. Lee was asked by International Medical Corps (IMC) to join as the PI of the grant prior to the resubmission this summer. In this role, Dr. Lee led the project team at IMC in extensively revising the grant application and responding to the reviewer comments on the original submission prior to resubmitting the grant application.

5) Dr. Lee’s preference would be to reduce the effort on the K01 award for the remaining 9 months of the award to 50%, allowing him to commit 25% effort to this new grant.
NIH requires that specific criteria be met in order to allow effort reduction on a K01 in the last two years.

Per NOT-OD-08-065:

• To be eligible for salary support from peer-reviewed research awards from any Federal agency:
  • The K award recipient must be one of the named PIs on a competing NIH research grant application (R01, R03, R15, R21, R34, or equivalent application from another Federal agency) or a sub-project director on a competing multi-component research or center grant or cooperative agreement application (P01, P50, U01, etc. or an equivalent application from another Federal agency).

• The K award must be active when the competing research grant application is submitted.

• The K award must be in its final two years before the reduction in effort to 6 person-months (50% full-time professional effort) is permitted.
Case study on a K01 (cont.)

- As an awardee of this FOA, CDC does recognize Dr. Lee as the named PI for IMC.

- The Aims described in Dr. Lee’s message do not appear to involve research. This is a non-research grant.

- Dr. Lee unfortunately, could not squeeze the CDC grant into his remaining 25% non-K effort, as he has other research and clinical obligations occupying that percent effort. As such, he decided to relinquish his K award at this time.
Case study on submitting appendices

• We had issues with people submitting appendices even when a NOT-OD-16-129 was published that there were very limited types of appendices that would be acceptable.

• Three applications were rejected by CSR for non-compliance with the guidelines and restrictions on appendices. I don’t think the PO believed that the applicants were using the appendices to get around page limits (I believe this is one of the original intent of the policy) but CSR would not make exceptions or remove parts of appendices that were non-compliant.

• Four of our seasoned D43 applicants were withdrawn from consideration for that reason and lost a whole year!
You are asked by a PI to stop at an office supply store on your way to work and pick up a few items (pens, envelopes and paperclips). The PI also asked you to get some donuts for a lab meeting that morning. When you arrive at work, the PI tells you that all of the items should be charged to the grant.

Your Departmental Administrator tells you that these purchases must come from Departmental funds. Why?
• If the office supplies are not specifically allocable to the grant, they are considered general office supplies and should not be charged as a direct cost to the grant account.

• Entertainment costs, such as food, are unallowable.
Meals are allowable on a research grant when:

1. they are provided to subjects or patients under study provided that such charges are not duplicated in participant’s per diem or subsistence allowances, if any; and

2. such costs are specifically approved as part of the project activity in the NoA.
• Meals may be an allowable cost, on a research grant, when:
  o The primary purpose is the dissemination of technical information, and
  o Necessary and reasonable for successful performance under the award

• An institution is expected to have a written and enforced policy in place that addresses the following:
  o Ensures consistent charging of meal costs
  o Defines what constitutes a meeting for the dissemination of technical information
  o Specifies when meals are allowable for such meetings
  o Establishes limitations and other controls on this cost
REMEMBER:
Recurring business meetings, such as staff meetings, are generally not considered meetings to disseminate technical information.
Dr. Admins from the University of Education submits a research grant application that seeks salaries of administrative and clerical staff, two laptops and a smartphone.

Are these types of costs generally appropriate for an “R01” grant application?
Salaries of administrative and clerical staff:

- Direct charging of these costs should normally be treated as indirect (F&A) costs.
- NIH GPS 8.1.1.5 provides that direct charging of these costs may be appropriate only if all of the following conditions are met:
  1. Administrative or clerical services are integral to a project or activity
  2. Individuals involved can be specifically identified with the project or activity
  3. Such costs are explicitly included in the budget, and
  4. The costs are not also recovered as indirect costs

- Such charges must also meet the criteria for allowable costs as described in NIH GPS 7.2.
Salaries of administrative and clerical staff:

NIH’s implementation of Uniform Regulation

- NIH prior approval is *not* required to rebudget funds for salaries of administrative and clerical staff if conditions provided in NIH GPS 8.1.1.5 are met.

- NIH prior approval *required* when:
  - additional funds are requested for such a position or
  - the incurrence of such costs constitutes a change in scope

- For Modular grants, these costs must be included in the Personnel Justification. Provide:
  - the person’s name, percent effort and role.
  - justification documenting how they will meet all four requirements in NIH GPS 8.1.1.5
A project leader on an NIH-funded program project grant (a P01 award) submitted a research (R01) grant application to NIH. The R01 application is selected for funding. Because the individual plans to spend 12 person months (100% effort) on the R01 project, the individual withdraws from the currently-funded P01 project.

1. Does the recipient institution need to obtain NIH prior approval for a change in status of a Project Leader on a P01 award?

2. What if the P01 PD/PI wants to withdraw from the project? Is NIH prior approval required?
Recipients are required to notify the NIH Grants Management Officer in writing if the PD/PI or Senior/Key personnel specifically named in the NoA will either:

- withdraw from the project entirely,
- be absent from the project during any continuous period of 3 months or more, or
- reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award.

NIH must approve any alternate arrangement proposed by the recipient, including any replacement of the PD/PI or Senior/Key personnel named in the NoA.
The requirement to obtain NIH prior approval for a change in status pertains only to the PD/PI and those Senior/Key personnel NIH named in the NoA regardless of whether the applicant organization designates others as key personnel for its own purposes.

NIH prior approval is also required when there is a change:

- From multiple PD/PIs to a single PD/PI
- From a single PD/PI to multiple PD/PIs
- In the number or makeup of the PD/PIs on a multiple PD/PI award
HELPFUL RESOURCES
Please let us know if you have any other questions!

• Mollie Shea
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  - 301-451-6830

• Satabdi Raychowdhury
  - Satabdi.Raychowdhury@nih.gov
  - 301-496-9750
References and Links

GENERAL: NIH, FIC, AND FOREIGN GRANTS:

- **NIH Office of Extramural Research (OER) webpage:** https://grants.nih.gov/grants/oer.htm
- NIH OER Information for Foreign Applicants and Grantees: http://grants.nih.gov/grants/foreign/
- eRA Commons User Guides: http://era.nih.gov/commons/user_guide.cfm
- FIC and Foreign Funding Opportunities: http://www.fic.nih.gov/Funding/Pages/default.aspx
- Fogarty Funding New Emails: https://public.govdelivery.com/accounts/USNIHFIC/subscriber/new
- FIC Foreign Grant Information: http://www.fic.nih.gov/Grants/Pages/Foreign.aspx

RPPR:


PUBLIC ACCESS:

- Non-English Guides to PubMed: http://nnlm.gov/training/resources/intlpubmedlinks.html
PAYMENT MANAGEMENT SYSTEM:

- Use available resources:
  - Foreign and U.S. colleagues with experience
  - Self-help web portal: http://www.psc.gov/one-dhhs
  - Program Support Center:
  - Paperwork and account questions:
    - US Institutions refer to your PMS accountant
    - Foreign Institutions refer to Raynette.Robinson@psc.hhs.gov; (301) 492-4938
  - Helpdesk:
    - Email: PMSSupport@psc.gov
    - Phone: (877) 614-5533
    - Hours: Monday – Friday 7 a.m. to 9 p.m. Eastern Time
Points of Contact

- **General NIH Application Questions:**
  - E-Mail: GrantsInfo@nih.gov
  - Phone: 301-435-0714

- **Grants.gov Customer Support:**
  - E-Mail: support@grants.gov
  - Webpage: http://grants.gov/
  - Phone: 800-518-4726

- **eRA Commons Helpdesk:**
  - Web: http://era.nih.gov/help/
  - Toll-free: 1-866-504-9552
  - Phone: 301-402-7469
  - Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time
Points of Contact

• NIH Division of Grants Policy:
  - E-Mail: GrantsPolicy@mail.nih.gov
  - Phone: 301-435-0949

• NIH Division of Grants Compliance and Oversight:
  - E-Mail: GrantsCompliance@mail.nih.gov
  - Phone: 301-435-0949

• SAM.gov HelpDesk- The Federal Service Desk:
  - Webpage/Electronic Helpdesk Ticket: https://fsd.gov/fsd-gov/home.do
  - U.S. Calls: 866-606-8220
  - International Calls: 334-206-7828
  - DSN: 866-606-8220
  - Hours: Monday – Friday 8 a.m. to 8 p.m. Eastern Time
NIH OER LISTSERVS

- NIH Guide for Grants and Contracts:
  - Official publication for NIH Grant Policies, Guidelines & Funding Opportunities

- Office for Human Research Protections (OHRP):

- Office of Laboratory Animal Welfare (OLAW):
  - [http://grants.nih.gov/grants/olaw/references/list.htm](http://grants.nih.gov/grants/olaw/references/list.htm)

- eSubmission:
  - Separate listservs available for scientists and administrators
Thank you! Any questions?