

Fogarty International Center

Global Environmental and Occupational Health Program

Pre-Application Webinar

Thursday, April 29, 2021

8:30-10:00am EDT



Fogarty International Center

RFA-TW-21-001 and RFA-TW-21-002

GEOHealth Pre-Application Webinar Participants



Program

Christine Jessup, PhD, GEOHealth Program Director, Fogarty International Center

Curt DellaValle, PhD, MPH, National Cancer Institute

Damali Martin, PhD, MPH, National Institute on Aging

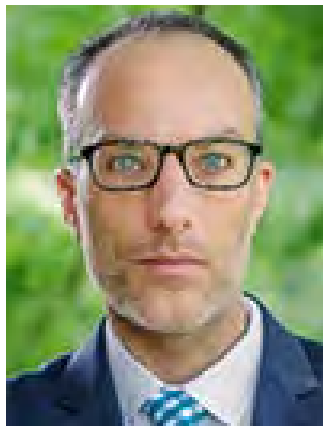
John Phillips, PhD, National Institute on Aging

Michael Humble, PhD, National Institute of Environmental Health Sciences

Regine Douthard, MD, MPH, Office for Research on Women's Health

Grants

Mollie Shea, Grants Management Officer, Fogarty International Center



Webinar Overview



- **Purpose and Goals of GEOHealth Hubs**
- **GEOHealth Hub Structure and Function**
- **Eligibility Criteria**
- **Scientific Review**
- **Grants Management Matters**
- **Question & Answer Session**

A recording of this webinar will be made available within two weeks on Fogarty's GEOHealth Program Page at <https://www.fic.nih.gov/Programs/Pages/environmental-occupational.aspx>

Submit questions during the webinar by completing the **Live Feedback Form**

GEOHealth Program - Objectives



- 1) To support the development of institutions in the Low- or Middle-Income Countries (LMICs) that will serve as regional hubs for collaborative
 - research
 - data management
 - training
 - curriculum and outreach material development
 - policy supportaround high priority local, national, and regional environmental and occupational health threats.

- 2) To form an international network of GEOHealth Hubs, a platform for coordinated environmental and occupational health research and research training activities.

Overall Goals of the GEOHealth Hubs



- Conduct innovative **multidisciplinary and interdisciplinary research** around high priority local, national, and regional environmental and occupational health threats in LMICs.
- Provide **leadership** in environmental and occupational health research and in **training a new generation** of environmental and occupational health experts in LMICs.
- Strengthen environmental and occupational health-related **research collaborations**.
- Create relevant advanced **educational curricula and outreach material**.
- Support the research and training needed to identify and design **mitigation strategies** for the adverse consequences of environmental exposures and **inform relevant policy** development in LMICs.
- Become attractive for further investments in these LMIC institutions.

GEOHealth Hub – Scientific Area and Approach



Bring together multiple disciplines to advance the pace of scientific discovery initially in one focal environmental or occupational health area that represents a priority threat in the LMIC(s).

Scientific Areas

Outdoor and indoor air quality
Electronic waste
Extractive industries
Food safety
Water quality
Toxic waste
Climate change health science
Agricultural health
Occupational health
Informal work
Disaster response

Scientific Approach

Epidemiology
Surveillance
Biostatistics
Genetics
Clinical research
Environmental science
Industrial hygiene
Workplace risk assessment
Systems science
Toxicology
Behavioral science
Social science
Exposure assessment
Biomarkers
Hazardous waste assessment
Implementation science
Community-based research
Cost-benefit analyses

Health Problems *In the context of environmental exposures*

Cancers
Developmental disorders
Neurological disorders
Mental disorders
Heart disease
Respiratory disease
Trauma and injury
Obesity
Immune function
Type 2 diabetes
Infectious diseases
Aging-related diseases (Alzheimer's Disease and Alzheimer's Disease Related Dementias, etc.)

**Examples. Others may be proposed. The selected area, approach and health problem should address a priority need and build on demonstrated capacity.*

Studies addressing the interactions between exposure factors are strongly encouraged.

GEOHealth – NIH Funding Partners



Fogarty International Center (FIC)

National Cancer Institute (NCI)

National Institute on Aging (NIA)*

National Institute of Environmental Health Sciences (NIEHS)

Office of Research on Women's Health (ORWH)*

*New partners in GEOHealth program

Partner Interests

Fogarty International Center (FIC)



Advancing science for global health

- 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
- **Training the next generation** of scientists to address global health needs
- FIC supports a diversity of research and research training grants that advance **basic to implementation science** with a focus on Low- and Middle-Income Countries (LMICs)

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.

Scientific Contact: Dr. Christine Jessup, christine.Jessup@nih.gov

Partner Interests

National Cancer Institute (NCI)



Research and research training for cancer control and prevention

- Assessment of **carcinogenic effects of environmental or occupational exposures**
- **Molecular epidemiologic** methods to understand carcinogenesis with respect to exposures in the environment or occupational settings
- Integration of environmental or occupational components in **local and regional LMIC cancer registries**
- **Translation** of environmental and occupational health discoveries into **policy and practice** designed to prevent and control cancer

Partner Interests

National Institute on Aging (NIA)



Expanding GEOHealth to the science of Aging, Alzheimer's Disease and related dementias

- Integrating environmental or occupational risk factors into cohort studies in high-exposure areas
- Studies that elucidate the sequence of events that lead to AD and ADRDs resulting from exposure to environment and/or occupational factors
- How differences in where people live and work relate to health and cognitive outcomes, especially via changes in access to educational or work opportunities
- Consequences of occupational and workplace policies on health outcomes at older ages;
- Vulnerable or under-researched LMIC populations, including women, children, and older adults

These and other NIA interest areas are detailed in the funding announcements.

Scientific Contacts:

Dr. Damali Martin, Division of Neuroscience, martinda@mail.nih.gov

Dr. John Phillips, Division of Behavioral and Social Research, john.phillips@nih.gov

Partner Interests

National Institute of Environmental Health Sciences (NIEHS)



The mission the NIEHS is to discover how the environment affects people in order to promote healthier lives.

- How exposures to toxic environmental insults alter biologic processes, are linked to disease initiation, progression or morbidity
- Activities that lead to the development of prevention and intervention strategies to reduce environmentally induced diseases.
- Research examining health consequences due to the interplay between environmental exposures and cofactors such as infectious agents or social factors that contribute to environmental health disparities.

Examples of exposures, topics, and disease outcomes are detailed in the funding announcements.

Scientific Contact: Dr. Michael Humble, humble@niehs.nih.gov

Partner Interests

Office of Research on Women's Health (ORWH)



Advancing science for the health of women

- Research that considers the **influence of sex and gender on health and disease**, and the total health of women across the full spectrum of research
- Innovative and multidisciplinary research to understand **sex and gender differences in global environmental health**
- Building a **diverse research workforce** in the field of global environmental and occupational health
- Interdisciplinary approaches and partnerships to support research that examines ways to integrate **evidence-based practices, interventions, and policies** into practice settings to improve the health of women

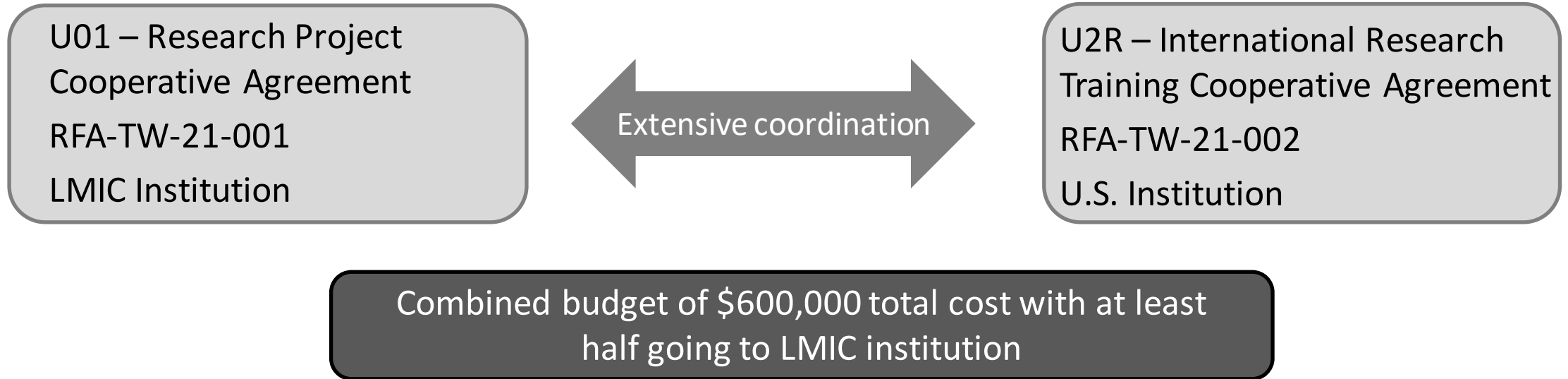
For more information on ORWH and The Trans-NIH Strategic Plan for Women's Health Research covering FY 2019 – 2023, please visit ORWH website (<https://www.nih.gov/women/strategicplan>).

Scientific Contact: Dr. Regine Douthard, douthardr@mail.nih.gov

Collaborative U01/U2R – Linked Applications, Linked Awards



GEOHealth Hub - A multidisciplinary group of researchers and their institutions based in a LMIC, who, with their collaborators, focus on a core set of common research and training topics that address environmental and/or occupational health priorities in that country and/or the region.



Cooperative Agreement (U series) – support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.



GEOHealth Hubs – Research

U01 (RFA-TW-21-001)

**Hubs of Interdisciplinary Research and Training in Global
Environmental and Occupational Health (GEOHealth) – Research
(Collaborative U01 Clinical Trial Optional)**

Submit questions during the webinar by completing the **Live Feedback Form**

Funding Opportunity Objectives

- Conduct **innovative multidisciplinary and interdisciplinary research** around high priority local, national, and regional environmental and occupational health threats in LMICs.
- Stimulate innovation in the development and implementation of technologies and other locally relevant **solutions to address environmental and occupational health problems.**
- Catalyze interaction between researchers, policymakers and program implementers to promote uptake of evidence into global environmental and occupational health **policy and practice.**
- Advance research on **prevention and control** of communicable and noncommunicable diseases and disabilities related to environmental and occupational exposures.
- Build and strengthen **partnerships** to advance global environmental and occupational health research and research capacity.

Eligibility

- The following Low- and Middle-Income Country (LMIC)* organizations/institutions are eligible to apply:
 - Higher Education Institutions
 - Nonprofits Other Than Institutions of Higher Education
- *As defined by the [World Bank](#), including “low-income,” “lower-middle-income,” and “upper-middle-income” countries. See Notice of Change in Country Eligibility for Fogarty International Training Grants ([NOT-TW-12-011](#)) and [Country Eligibility](#) for additional restrictions. U.S. and other High-Income Country (HIC) institutions are not eligible. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.
- LMIC institutions must **demonstrate collaborations** with U.S. partner institutions
 - Applicants are encouraged to involve **multiple U.S. and LMIC partner entities**. Inclusion of many partners requires strong justification.
 - **One application per institution** in response to this FOA. That institution can participate in one additional GEOHealth Hub through an application submitted by another institution.
 - **Paired applications required.** Applications received without an eligible linked application in response to [RFA-TW-21-002](#) will be considered incomplete and will not be reviewed.
 - New and renewal applications are eligible.

Key Research Features

Innovative multidisciplinary public health-relevant research project that

- focuses on an environmental or occupational health topic,
- is based on a documented **needs and opportunities assessment** that addresses the policy environment in the LMIC,
- involves appropriate **governmental, subnational, private sector, and regulatory decision makers** in order to maximize uptake of evidence in policy and practice,
- **informs and is supported by the research training activities** under the linked research training application [RFA-TW-21-002](#), and
- includes a plan to **disseminate research results** to serve scientific and policy communities beyond the participating investigators and institutions.

One main research project. *May propose pilot research in up to two aligned areas.*

Unique Application Instructions

- Letters of Intent invited (due 30 days before application deadline)
- Multiple PI is required
- Linked application titles (see FOA instructions)
- External Advisory Committee attachment (see FOA for requirements)
- Research strategy
 - Significance – A “needs assessment”, complement other activities at LMIC institution.
 - Innovation - How the linked U01 and U2R applications provide an innovative and integrated model for addressing environmental and occupational health needs in the LMIC(s).
 - Approach – propose one main research project; may propose pilot research in up to two additional areas
 - Coordination – identical in the linked applications
 - Plan for Partnership – identical in the linked applications
- Data Sharing Plan is required
- Progress Report for Renewal Applications
- Institutional Letters must address institutional commitment to harassment and discrimination

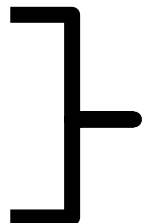


U01 Review Criteria – as noted in Section V of the FOA

5 Scored Review Criteria

Each Scored from 1 to 9

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



Overall Impact

Scored from 1 to 9 (1=highest impact;
9 = lowest impact)

Assessment of the likelihood for the project to
*exert a sustained, powerful influence on the
research field(s) involved*

Each criterion includes **FOA specific review questions**, such as (see more in FOA):

Does the proposed research project contain explicit strategies to strengthen capacity through the linked U2R research training application and does the proposed collaboration lead to sustainable enhancement of the LMIC institution's research capacity and contribute to overall institutional excellence?

Do the PDs/PIs, collaborators and other researchers demonstrate a willingness to engage in research and capacity building activities across the network of funded GEOHealth Hubs?

Do letters of support from officials in LMIC government entities and/or non-governmental organizations (NGOs) show evidence for collaborative relationships that will enable research findings to inform environmental and occupational health policy formulation and public health practice?

Additional Scorable Review Criteria to assess Overall Impact

- Coordination and integration of linked GEOHealth applications
- Protections of human subjects
- Inclusion plans of sex/gender, race/ethnicity, and age of human subjects across the lifespan
- Appropriate use of vertebrate animals
- Management of biohazards
- For renewals, progress

Additional Considerations that do not affect Overall Impact

- Resource sharing plans
- Select Agent Research
- Authentication of Key Biological /Chemical Resources
- Foreign Organizations
- Select Agents
- Budget

GEOHealth Hubs – Research Training U2R (RFA-TW-21-002)

**Hubs of Interdisciplinary Research and Training in Global Environmental
and Occupational Health (GEOHealth) – Research Training
(Collaborative U2R Clinical Trial Optional)**

Submit questions during the webinar by completing the **Live Feedback Form**

GEOHealth Hubs – Research Training (U2R) RFA-TW-21-002

Funding Opportunity Objectives



- Develop environmental and occupational health **research training and career development programs** for LMIC scientists and health research professionals -- in support of and informed by the linked GEOHealth research award.
- Facilitate the **transition of trainees to positions of responsibility, authority, and influence** in their home countries, regionally and internationally.
- Strengthen the capacity to conduct **independent and sustainable environmental and occupational health research** at LMIC institutions.
- Build **in-depth scientific expertise** in environmental and occupational health and **enhance complementary skills**.
- Develop and strengthen regional **collaborations**, including partnerships among governmental and non-governmental organizations, research institutions, and health service groups.

Eligibility

- The following U.S. institutions are eligible to apply (Foreign Institutions and Non-Domestic Components of US Organizations are NOT eligible):
 - Higher Education Institutions
 - Nonprofits Other than Institutions of Higher Education
- U.S. institution must **demonstrate collaborations** with eligible LMIC* partner institutions
 - *As defined by the [World Bank](#), including “low-income,” “lower-middle-income,” and “upper-middle-income” countries. See Notice of Change in Country Eligibility for Fogarty International Training Grants ([NOT-TW-12-011](#)) and [Country Eligibility](#) for additional restrictions.
- Applicants are encouraged to involve **multiple U.S. and LMIC partner entities**. Inclusion of many partners requires strong justification.
- **One application per institution** in response to this FOA. That institution can participate in one additional GEOHealth Hub through an application submitted by another institution.
- **Paired applications required**. Applications received without an eligible linked application in response to [RFA-TW-21-001](#) will be considered incomplete and will not be reviewed.
- New and renewal applications are eligible.

Trainees

- Only individuals who are **citizens of eligible LMICs** may receive training.
- Training must be targeted toward individuals from LMICs **who will pursue responsible academic and/or public health-oriented research positions** in environmental and occupational health in their home countries.
- Research **training may be offered to a wide range of scientists**, including laboratory scientists, social scientists, clinicians and other health professionals, as well as technical and administrative staff in order to meet the needs for research capacity gaps at the LMIC institution.
- Attention should be given to recruiting and retaining LMIC trainees from **groups underrepresented** in environmental and occupational health in the partnering country.
- All medium- and long-term trainees (more than 1 month) are required to **pursue their research training full time**, normally defined as 40 hours per week.
- *Applications that propose research training exclusively at the U.S. institution are not responsive.*
- *Applications that propose exclusively short-term training experiences of less than one month are not responsive.*

Unique Application Instructions

- **Letters of Intent** invited (due 30 days before application deadline)
- PHS 398 Research Training Program Plan Form is comprised of the following sections:
 - Training Program
 - Faculty, Trainees, and Training Record
 - Other Training Program Sections

Applicants will include information on Background, Program Administration, Program Faculty, Proposed Training, Training Program Evaluation, Trainee Candidates, and more.

- **Multiple PI** is required
- Linked **application titles** (see FOA instructions)
- Administrative Oversight Committee (AOC; in Program Plan)
- External Advisory Committee (EAC) attachment (see FOA instructions)
- Training Tables – use **International Training Tables**
- **Progress Report for Renewal Applications**
- Institutional Letters must address **institutional commitment to harassment and discrimination**



Review Process

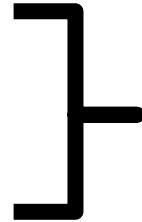
U2R Review Criteria – as noted in Section V of the FOA

** Unique review categories **

5 Scored Review Criteria

Each Scored from 1 to 9

- Training Program/Environment
- Training Program PD(s)/PI(s)
- Preceptors/Mentors
- Trainees
- Training Record



Overall Impact

Scored from 1 to 9 (1=highest impact;
9 = lowest impact)

Assessment of the likelihood that the proposed training program will prepare individuals for successful, productive, research careers and thereby exert a sustained, powerful influence on the research field(s) involved

Each criterion includes **FOA specific review questions**, such as (see more in FOA):

Does the proposed program contain explicit strategies to strengthen capacity through the linked U01 Research application and does the proposed collaboration lead to sustainable enhancement of the LMIC institution's research capacity and contribute to overall institutional excellence?

Are the mentors currently engaged in research relevant to the LMIC environmental and occupational health priorities?

Additional Scorable Review Criteria to assess Overall Impact

- Coordination and integration of linked GEOHealth applications
- Protections of human subjects
- Inclusion plans of sex/gender, race/ethnicity, and age of human subjects across the lifespan
- Appropriate use of vertebrate animals
- Management of biohazards
- For renewals, progress

Additional Considerations that do not affect Overall Impact

- Training in Responsible Conduct of Research
- Select Agent Research
- Select Agents
- Budget

Other features of Linked GEOHealth Hub RFAs

Submit questions during the webinar by completing the **Live Feedback Form**

Clinical Trial Optional



- [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 a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavior outcomes.
- You are strongly encouraged to review [NIH policy on clinical trials](#) and [case studies for reference](#).
- Four questions determine if your proposed research study is a clinical trial:
 - Does the study involve human participants?
 - Are the participants prospectively assigned to an intervention?
 - Is the study designed to evaluate the effect of the intervention on the participants?
 - Is the effect being evaluated a health-related biomedical or behavioral outcome?

What are Cooperative Agreements?



Support mechanism used when there will be **substantial Federal scientific or programmatic involvement**: after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

NIH Role: support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities.

Awardee Role: The dominant role and prime responsibility resides with the awardees for the project as a whole.

GEOHealth Awards will include NIH scientific officers involved as **Project Collaborators** who

- Provide advisory input on the design, implementation and analysis of research and research training activities
- Serve as a point of contact for scientific and technical issues.
- Participate in scheduled meetings to discuss program coordination and/or progress
- Facilitate collaboration with other NIH- and U.S. Government-supported researchers and research resources
- Serve as a resource and advisor for major transitional changes during the award
- Assist in avoiding unwarranted duplication of effort with other NIH efforts.
- Make recommendations for continued support

See Cooperative Agreement Terms and Conditions in RFAs (Section VI.2)

Management of GEOHealth Hubs



Administrative Oversight Committee (AOC)

Role: Overall management, communication, coordination, oversight, evaluation and supervision of the pair of linked research training (U2R) and research (U01) awards

Composition: PDs/PIs of one pair of linked GEOHealth U01 and U2R awards

External Advisory Committee

Role: Provide ongoing assessment of the progress of the research and research training, discuss future research and training goals, aims and ideas

Composition: Experts and relevant professionals not involved in GEOHealth Hub awards; at least 50% LMIC membership; expertise in relevant research, research training, and research translation to policy and practice

Steering Committee

Role: Main governing board of the network of GEOHealth Hubs

Composition: PDs/PIs of all GEOHealth awards and the U.S. Government Project Collaborators

Network Scientific Advisory Group (NSAG)

Role: Review progress and provide scientific advice for the GEOHealth Hubs, including intersecting and joint activities

Composition: NIH program staff

Selection and Funding Considerations



- Scientific and technical merit
- Availability of funds
- Relevance of the proposed project to program priorities
- Relevance of the proposed project to the FOAs and funding partner priorities
- Scientific content for program balance
- Geographic balance
- Extent of coordination between and integration of linked applications, potential impact of the linked proposed training program on the proposed research, and scientific quality of the linked application
- Potential to contribute other NIH- and U.S. government-supported research initiatives in the participating LMICs
- Potential for coordination with other major environmental and occupational health initiatives in LMICs

Key Dates



Letters of Intent (optional): June 8, 2021

Open Date (Earliest Submission Date): June 8, 2021

Applications Due: July 8, 2021 ***by 5:00 pm local time of the applicant institution***

Scientific Merit Review: October 2021

Advisory Council Review: January 2022

Earliest Start: March 2022

Start Early! Submit Early! To allow time to correct any unexpected errors or submission issues

GEOHealth Program Grants Management

Mollie Shea

FIC Grants Management Officer

Thursday, April 29, 2021

Submit questions during the webinar by completing the **Live Feedback Form**

- Policy Updates
- GEOHealth RFA Information
- Pre-Application Information

Submit questions during the webinar by completing the **Live Feedback Form**

Policy Updates

Biographical Sketch and Other Support Format Page



- Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021
- In an effort to support strong collaboration between Federal research agencies, NIH has updated its application forms and instructions to support the need for applicants and recipients to provide full transparency and disclosure of all research activities, foreign and domestic.
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html>

Consideration of Sex as a Biological Variable in NIH-funded Research



NOT-OD-15-102

<https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html>

This notice focuses on NIH's expectation that scientists will account for the possible role of sex as a biological variable in vertebrate animal and human studies. NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. Investigators are strongly encouraged to discuss these issues with NIH program staff prior to submission of applications. Further information regarding NIH expectations for the consideration of sex as a biological variable is provided at the following website:

http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf

FORMS-F Grant Application Forms & Instructions



NOT-OD-20-077

This notice reminds the NIH and AHRQ applicant and recipient community that applicants must use FORMS-F application packages for due dates on or after May 25, 2020

Additional Updates:

- ❖ FORMS-F Grant Application Instructions are now posted on the [How to Apply - Application Guide](#) page. All significant changes to form instructions are listed at: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.120-significant-changes.htm>.
- ❖ FORMS-F application packages are currently being posted to active Funding Opportunity Announcements (FOAs).
- ❖ All [Parent Announcements](#) will be reissued for due dates on or after May 25, 2020. Consequently, FORMS-F application packages will not be added to the existing [Parent Announcements](#) with FORMS-E application packages.

Key FORMS-F Changes to the PHS Human Subjects and Clinical Trials Information Form:

As of June 13, all applicants and recipients submitting post-submission updates in the Human Subjects System (HSS) will use the FORMS-F PHS Human Subjects and Clinical Trials Information Form for the submission.

For a full list of significant FORMS-F changes, see

<https://grants.nih.gov/grants/electronicreceipt/files/high-level-form-change-summary-FORMS-F.pdf>.

NIH Implementation of Anti-Harassment Policy

- Employees, trainees, patients and other supported by NIH funding can report sexual harassment to NIH via GranteeHarassment@od.nih.gov
- NIH Office of Extramural Research will contact institution to verify issues & take appropriate actions.
- If institution is noncompliant, NIH can take actions: change senior personnel or suspend or terminate grant.
- More information at:
 - <https://www.nih.gov/anti-sexual-harassment>
 - <https://grants.nih.gov/grants/policy/harassment.htm>

NIH Implementation of Anti-Harassment Policy

Funding Announcements

Additional instructions for **Institutional Letters of Support** to address commitment to protections

Awards

Under Terms & Conditions of Award in Notice of Award NIH requires institutions to:

- Provide harassment-free environment
- Maintain professional codes of conduct
- Ensure staff awareness
- Provide process to report sexual harassment
- Provide safety & protection from retaliation
- Investigate of allegations & take appropriate sanctions
- Notify NIH of actions that change status of senior/key personnel on an NIH award.

GEOHealth RFA Information

GEOHealth RFAs



RFA-TW-21-001 <https://grants.nih.gov/grants/guide/rfa-files/RFA-TW-21-001.html>

Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health (GEOHealth) – Research (Collaborative U01 Clinical Trial Optional)

RFA-TW-21-002 <https://grants.nih.gov/grants/guide/rfa-files/RFA-TW-21-002.html>

Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health (GEOHealth) – Research Training (Collaborative U2R Clinical Trial Optional)

GEOHealth Application Budgets



RFA TW21-001 – U01 Research Budget

- The application budget should be developed in close coordination with the linked U2R research training application ([RFA-TW-21-002](#)) because the combined budget for both linked applications cannot exceed \$600,000 in total costs per year (including 8% F&A), and at least 50% of the combined budget must be in the LMIC's U01 application.

RFA TW21-002 – U2R Research Budget

- Anticipated budget total costs may not exceed \$300,000 per year. The U2R application budget should be developed in close coordination with the linked U01 research application ([RFA-TW-21-001](#)) because the combined budget for both linked U01 and U2R applications cannot exceed \$600,000 in total costs per year (including 8% F&A) and at least 50% of the combined budget must be in the LMIC's U01 application.

ELIGIBILITY BOTH FOR INSTITUTIONS AND PRINCIPAL INVESTIGATORS (PIs)



- Check the FOA
- Institutions: Governments & Federal Institutions, Academic Institutions, Other Non-Profit orgs and Hospitals.
- PIs – Educational requirements, Citizenship requirements and Qualifications/expertise – See FOA Section III: Eligibility Information

Pre-Application Information

NIH APPLICATION PROCESS AND REGISTRATION



- Start **EARLY**
- 4 weeks prior to the application due date is recommended.
- Read your FOA, download the instructions
- Submit through ASSIST, and/or Grants.gov
- Organizations must submit applications to [Grants.gov](https://www.grants.gov) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems.
- Applicants must (then) complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

NIH APPLICATION PROCESS AND REGISTRATION (cont.)



- All Institutions must be registered with DUN & Bradstreet, have a Data Universal Numbering System (DUNS) number and have an active Systems Award Management (SAM) account.
- PIs must be registered in the ERA Commons with a commons ID#. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.
- PI and Signing Official (SO) need separate accounts in eRA Commons because each has different privileges.
- The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM).

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

1. Register with [NATO Support Agency \(NSPA\)](#)
2. If you wish to do business with the U.S. you must:
 - a. Register with [Dun & Bradstreet \(D&B\)](#).
 - b. Register with [System for Award Management \(SAM\)](#).
 - c. Review [Business Identification Number Cross-reference System \(BINCS\)](#):
a search engine (help with SAM registration) for foreign and domestic manufacturers, suppliers and potential contractors supporting the Federal supply chain.

Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements



Notice Number: NOT-OD-19-098

- The purpose of this Guide Notice is to alert NIH recipients of the Federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) to a new Government-owned unique entity identifier (UEI). Effective December 2020, the system for Award Management (SAM) will become the central repository for the new SAM Managed Identifier (SAMMI) that will be incorporated into an institution's SAM registration.
- The assignment of the SAMMI will be incorporated into the SAM registration process, eliminating the need for applicants to seek external identifiers in order to register.
- The transition from DUNS to SAMMI is ongoing, and GSA will provide details to agencies related to the full implementation by December 2020. NIH will provide updates and guidance to recipients on changes to policies and procedures as additional information becomes available.

SYSTEM AWARD MANAGEMENT (SAM)



- Your organization must be registered in SAM and your SAM credentials must be active at time of grant submission and time of grant award. A yearly renewal process is required to keep your credentials active. SAM uses the term "entity" to refer to your organization.
- **Purpose of SAM**
- SAM is a system required by the federal government to collect information on organizations applying for grants and contracts.
- [https://www.sam.gov/SAM/transcript/Quick Guide for International Entity Registration.pdf](https://www.sam.gov/SAM/transcript/Quick_Guide_for_International_Entity_Registration.pdf)

APPLICATION TIPS FOR FOREIGN ORGANIZATIONS



- **START EARLY**
- Your organization representatives are responsible for ensuring the various organization registrations needed to apply for grant funding are in place and active. NIH recommends starting the organization registration process **six weeks** prior to your deadline to allow plenty of time to address unforeseen issues along the way.
- https://grants.nih.gov/grants/ElectronicReceipt/files/Tips_for_International_Appllicants.pdf

F&A for Grants to Foreign and International Organizations



F&A for Foreign and International Organizations: NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8% of modified total direct costs, exclusive of equipment, tuition and related fees, and subawards in excess of \$25,000. These funds are paid to support the costs of compliance with federal requirements. This applies to direct foreign awards and foreign subawards.

Resources for Potential Applicants



Fogarty International Center Grant Resources (includes section “For Applicants” and “Grants FAQs”)

<https://www.fic.nih.gov/Grants/Pages/default.aspx>

Resources for INTERNATIONAL Applicants

- **NIH Application Tips for International Applicants**
[https://grants.nih.gov/grants/electronicreceipt/files/Tips for International Applicants.pdf](https://grants.nih.gov/grants/electronicreceipt/files/Tips%20for%20International%20Applicants.pdf)
- **Electronic Submission: Quick Contact Support for International Applicants**
https://grants.nih.gov/grants/ElectronicReceipt/files/international_support.pdf
- **Common Questions & Answers for International Applicants**
https://grants.nih.gov/grants/ElectronicReceipt/files/international_qa.pdf
- [Grants.gov - Organization Registration](#)
- **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** http://grants.nih.gov/grants/webinar_docs/webinar_20120927.htm.

Peer Review Resources

- **NIH Peer Review Videos:** <https://public.csr.nih.gov/NewsAndPolicy/PeerReviewVideos>
- **Insider’s Guide to Peer Review for Applicants:** <http://www.csr.nih.gov/applicantresources/insider>

Resources for Potential Applicants



Application Instructions: Follow the SF424 Application Guide and instructions in each FOA. Start required registrations early. <https://grants.nih.gov/grants/how-to-apply-application-guide.html>

General NIH Application Questions

E-Mail: GrantsInfo@nih.gov

Phone: 301-435-0714

eRA Commons Help Desk

Web: <http://era.nih.gov/help/>

Telephone: +1-301-402-7469 or +1-866-504-9552 (Toll Free)

Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

<http://grants.nih.gov/support/index.html> commons@od.nih.gov

Grants.gov Customer Support

Telephone: +1-800-518-4726

<https://grants-portal.psc.gov/ContactUs.aspx>

E-mail: support@grants.gov

Resources for Potential Applicants



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

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Thank You!

Presentation will be posted and FAQ page will be updated within 2 weeks at:

<https://www.fic.nih.gov/Programs/Pages/environmental-occupational.aspx>

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