Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	## International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	• **August 5, 2022** - Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189. • **August 8, 2022** - New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023. See Notice NOT-OD-22-195. • **August 31, 2022** - Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198. • **October 26, 2022** - Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available. See Notice NOT-OD-23-012.
Funding Opportunity Announcement (FOA) Number	RFA-AI-23-023

https://grants.nih.gov/grants/how-to-apply-application-guide.html

RFA-AI-23-023 - Background

- The NIAID has a long-standing interest in, and commitment to, global health and international research.
- Topics of interest for this program cover **a broad range of infectious diseases** research topics, including, but not limited to:
  - ➤ TB
  - ➤ Malaria
  - ➤ HIV/AIDS
  - ➤ Parasitic diseases
  - ➤ Vectors and vector-borne diseases
  - ➤ Drug resistance (antimicrobial and/or insecticide)
  - ➤ Zoonoses with public health consequences
  - ➤ Other emerging and re-emerging infectious diseases that are of public health significance.

- Development of basic, immunological, microbiological, biostatistical, bioinformatics, genomics, epidemiological, data management, and clinical research capacity is encouraged.

Purposes

- The purpose of this FOA is to support applications for high-priority, regionally relevant infectious diseases research by **international investigators in resource-constrained countries.**

- **Applicant organizations** must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, **lower-middle-income economies**, and upper-middle-income economies by World Bank Classification.

- The intent of the grant is **to foster, stimulate and/or expand basic, translational, and applied research that will advance scientific discovery and engage local sci**entists in areas of infectious diseases research.

- Research should reflect **the highest possible scientific rigor and focus on infectious diseases**, including HIV/AIDS, of interest to the local and/or **regional public health needs and priorities, and important from a global health perspective.**

Purposes

- These grants will serve **to build independent research capacity by providing direct funding to investigators** who do not currently have NIH-funded grant or contract awards for research projects. The intent of these activities is to advance the development of local scientific expertise.

Submission date July 02 – August 02, 2023 (due by 5:00 PM local time of applicant organization)**.**

Letter of intent 30 days prior to the application due date.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Research Objectives and Scope

- Studies may be proposed on any aspect of infectious disease research (except clinical trials), including but not limited to:

  ➢ Basic biological studies of pathogens and vectors;

  ➢ The epidemiology, natural history, pathogenesis, immunopathogenesis of infectious diseases;

  ➢ Epidemiologic studies to define the incidence, clinical presentations, and outcomes of diseases;

  ➢ Identification of resistance mechanisms and patterns;

  ➢ Characterization of susceptible cohorts for a particular pathogen;

  ➢ Pilot and feasibility studies in preparation for larger studies;

  ➢ Studies focused on the effects of climate change on the incidence, prevalence and severity of infectious diseases.

Research Objectives and Scope

- Note: HIV/AIDS studies must address NIAID priorities as described https://www.niaid.nih.gov/about/division-aids-overview. With the ultimate goal of creating an "AIDS-Free Generation," the division develops and supports the infrastructure and biomedical research needed to:
  - ➢ Halt the spread of HIV through the development of **an effective vaccine and biomedical prevention strategies** that are safe and desirable;
  - ➢ Develop **novel approaches for the treatment and cure** of HIV infection;
  - ➢ **Treat and/or prevent HIV co-infections and co-morbidities** of greatest significance;
  - ➢ Partner with scientific and community stakeholders to **efficiently implement effective interventions**.
- The four scientific programs include the:
  - ➢ **Basic Sciences Program**, which includes the Pathogenesis and Basic Research Branch, Targeted Interventions Branch, and the **Epidemiology Branch**;
  - ➢ **Therapeutics Research Program**, which includes the HIV Research Branch, Drug Development and Clinical Sciences Branch, TB Clinical Research Branch, and the Complications and Co-infections Research Branch;
  - ➢ **Vaccine Research Program**, which includes the Preclinical Research and Development Branch, Vaccine Translational Research Branch, and the Vaccine Clinical Research Branch; and
  - ➢ **Prevention Sciences Program**, which includes the Preclinical Microbicide and Prevention Research Branch, Clinical Microbicide Research Branch, Clinical Prevention Research Branch, and the Maternal, Adolescent, and Pediatric Research Branch

Research Objectives and Scope

- **Collaborative projects** involving investigators and institutions from **international sites and the U.S. are encouraged; however, a U.S. partner is not required.**

- Collaborative projects involving institutions in -low and -lower-middle economy countries are particularly encouraged. **Applicants are encouraged to establish multi-institutional collaborations and to include activities that involve the transfer of technologies and research methods, sharing of core resources including the administration of research grant programs, and expansion of linkages** to other sites via attendance at national and international meetings and other methods of communication.

- NIH supports several international research programs on infectious diseases, including HIV/AIDS. This International Research in Infectious Diseases (IRID) Program is intended to complement these programs by expanding the breadth of research supported at international sites and by providing support to new researchers. This may include sites where NIH or NIAID already has significant investment in research and/or infrastructure. However, previous NIH funding is not a requirement.

Award Information

- **Award Budget**

Application budgets should not **exceed $125,000 (1,834,193,750.00 IDR) in direct costs per year** and should reflect the actual needs of the project.

- **Award Project Period**

The scope of the proposed project should determine the project period. **The maximum project period is 5 years.**

Eligibility Information

Eligibility Applicants

- Eligible Organizations: non-domestic (non-U.S.) Entities (Foreign Institutions).
- Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies) by World Bank Classification at the time of application submission.

Required Registrations

- Applicant organizations must complete and maintain the following registrations as described in **the SF 424 (R&R) Application Guide** to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted.

Eligibility Information

- **Registration can take 6 weeks or more**, so applicants should begin the registration process as soon as possible.
  - ➢ **System for Award Management (SAM)**– Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - ➢ **NATO Commercial and Government Entity (NCAGE) Code** – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - ➢ **Unique Entity Identifier (UEI)**- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
  - ➢ **eRA Commons** - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at **least one Signing Official (SO)** and at least one **Program Director/Principal Investigator (PD/PI) account** in order to submit an application.
  - ➢ **Grants.gov** – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Eligibility Information

Program Directors/Principal Investigators (PD(s)/PI(s))

- **All PD(s)/PI(s) must have an eRA Commons account**. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. **Obtaining an eRA Commons account can take up to 2 weeks**.

Required Registrations

- Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted.

Application and Submission Information

Requesting an Application Package

The application forms package specific to this opportunity must be accessed through **ASSIST, Grants.gov Workspace or an institutional system-to-system solution**.

Content and Form of Application Submission

- Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted.

- Prospective applicants are asked to submit **a letter of intent** (to Soheyla Saadi, Ph.D. T: 240-669-5178. Email: saadisoh@nih.gov) that includes the following information:
  - ➢ Descriptive title of proposed activity
  - ➢ Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  - ➢ Names of other key personnel
  - ➢ Participating institution(s)
  - ➢ Number and title of this funding opportunity

Application and Submission Information

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions: No more than 20% of the budget (direct costs) in any year may be subcontracted to an institution in a high-income economy country (World Bank Classification). All subcontracts combined to such high-income economy countries should account for no more than 20% of the budget (direct costs). Subcontracts to eligible foreign institutions are not subject to this cap.

Research Strategy

- Provide **evidence that the scientific question(s) addressed are important** to the country/region in which the research will be conducted and important from a global health perspective.
- Explain **how the proposed research team will increase scientific capacity** related to the proposed subject area.
- If proposed, outline plans for **collaboration and explain how the proposed research and collaborative research team are likely to advance** the development of local scientific expertise or increase collaborative research capacity at the foreign site.

Application and Submission Information

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R& R) Application Guide.

Other Plan(s)

- Note: Effective for due dates on or after January 25, 2023, **the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages**.
- All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions: All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix

- **Only limited Appendix materials are allowed.**
- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

Application and Submission Information

PHS Human Subjects and Clinical Trials Information

- When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) **follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide**, with the following additional instructions:
  - ➢ If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or Delayed Onset Study record.

Submission Dates and Times

- Organizations **must submit applications to Grants.gov** (the online portal to find and apply for grants across all Federal agencies).
- 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 and Grants.gov systems check the application against many of the application instructions upon submission.

Application and Submission Information

Submission Dates and Times

- Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. **Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.**

- Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

- Upon receipt, applications will be evaluated for **completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by NIAID, NIH**. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Application Review Information

Scored Review Criteria

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

- **Significance**

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

  Specific to this FOA: Does the application adequately demonstrate that the scientific question is of interest to the region in which the research will be conducted and important from a global health perspective?

Application Review Information

- **Investigator(s)**
  Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
  Specific to this FOA: Is the research team, as proposed, likely to increase scientific capacity in the county/region related to the proposed subject area?

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

Application Review Information

- **Approach**
  - ➢ Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

  Specific to this FOA: If proposed, are plans for collaboration sufficiently developed? Is there likelihood that proposed collaborations will advance the development of local scientific expertise or increase collaborative research capacity at the local site?

- **Environment**

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