Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of Allergy and Infectious Diseases (NIAID (http://www.niaid.nih.gov))

Funding Opportunity Title

Emerging Infectious Diseases Research Centers (U01 Clinical Trial Not Allowed)

Activity Code

U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

- **April 04, 2019** - Notice of Budget Change in RFA-AI-19-028. See Notice NOT-AI-19-056 (/grants/guide/notice-files/NOT-AI-19-056.html).

Funding Opportunity Announcement (FOA) Number

RFA-AI-19-028

Companion Funding Opportunity

RFA-AI-19-029 (https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-19-029.html), U01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project – Cooperative Agreements

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.855

Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to establish a coordinated network of Emerging Infectious Disease Research Centers (EIDRCs) in regions around the globe where emerging and re-emerging infectious disease outbreaks are likely to occur. Multidisciplinary teams of investigators will conduct pathogen/host surveillance, study pathogen transmission, pathogenesis and immunologic responses in the host, and will develop reagents and diagnostic assays for improved detection for important emerging pathogens and their vectors.

Key Dates

Posted Date

March 5, 2019

Open Date (Earliest Submission Date)

May 28, 2019

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

June 28, 2019, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on this date.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

November 2019

Advisory Council Review

(http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) January 2020

Earliest Start Date

March 2020

Expiration Date

June 29, 2019

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to establish a coordinated network of Emerging Infectious Disease Research Centers (EIDRCs) in regions around the globe where emerging and re-emerging infectious disease outbreaks are likely to occur. Multidisciplinary teams of investigators will conduct pathogen/host surveillance, study pathogen transmission, including evaluating zoonotic hosts and reservoirs, study pathogenesis and immunologic responses in the host, and will develop reagents and diagnostic assays for improved detection for important emerging pathogens and their vectors. These EIDRC will conduct research project(s) and will collaborate under the direction of a separate EIDRC Coordinating Center (EIDRC CC, RFA-AI-19-029 (https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-19-029.html)), to develop and formulate strategies for detecting, controlling and preventing emergence or re-emergence of infectious diseases. Rapid translation of these findings to development of reagents, diagnostic tools, etc. that will be provided to downstream partners to advance therapeutic and preventive interventions is key.

Background

A core component of the NIAID mission in the 2017 Strategic Plan is to “develop flexible domestic and international capacity to efficiently undertake research required in response to newly emerging threats wherever they occur.” Clearly, recent infectious pathogens with significant potential to threaten the United States are emerging /re-emerging with increasing frequency. Most of these naturally occurring outbreaks have been caused by RNA viral pathogens characterized by zoonotic reservoirs and/or arthropod vectors propagating transmission to humans. These outbreaks

have revealed gaps in the research infrastructure that impact the ability to respond rapidly and effectively to these emerging pathogens; obtaining contemporary knowledge of the pathophysiology and natural history, accurate detection/diagnosis of the infections, and development of critical research and product development reagents, were challenges during previous outbreaks.

This FOA and its companion (https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-19-029.html), will serve as important components of the broader NIAID strategy for pandemic preparedness by establishing infrastructure and scientific expertise in geographical regions of the world that are prone to emerging and re-emerging infectious diseases. These Centers will draw on skills from teams of multidisciplinary scientists, including infectious disease clinicians, epidemiologists, virologists, clinical microbiologists, veterinarians, and entomologists, to conduct field studies of endemic diseases that have the greatest potential of becoming pandemic threats, such as zoonotic and vector-borne viruses, develop reagents for the broader research community and have the flexibility and ability to re-direct work among the EIDRC in the event of an outbreak to mount a rapid and effective research response.

Research Objectives and Scope

The Emerging Infectious Diseases Program comprised of the EIDRC CC and the EIDRCs, is designed to improve our knowledge of emerging and re-emerging infectious diseases, complement and leverage existing NIAID international research efforts when possible, and allow NIAID to develop the flexibility and capacity to respond rapidly and effectively to outbreaks where they occur. The program as a whole is designed to improve our knowledge of the natural history, incidence, and prevalence of emerging/re-emerging infectious diseases. In many instances, re-emerging pathogens circulate at low levels for several years before breaking out and causing major public health problems, in other cases new pathogens emerge rapidly.

Research activities at the centers may include pathogen discovery; surveillance in humans, animal reservoirs, and vectors as it relates to assessment of prevalence and molecular epidemiology of specific pathogens in their geographic regions; evaluation of factors related to transmission, emergence and adaptation to new hosts; natural history of infection and contemporary clinical disease in humans as well as immunologic responses to the infection; development of reagents, new diagnostic methods for improved detection of infectious agents, and development of appropriate animal models, if/when necessary. Clinical cohorts with symptoms of acute infections may be used to define the pathophysiology and clinical outcomes of the infection and disease, describe the spectrum of disease presentation and severity, elucidate factors associated with disease transmission and progression, evaluate important immune responses to the emerging pathogen, determine clinical and molecular diagnostic criteria, and provide the basis for sample collection.

Importantly, the centers will provide reagents, tools and assays to NIAID and partners to support the development of translational products and will readily share information, data, samples, diagnostics, reagents and tools across the network in the event of an outbreak. In that regard, the centers will provide a clear plan for accomplishing effective coordination and collaboration with the entire network and the EIDRC CC.

The EIDRCs will complement and leverage existing NIAID international research efforts- such as the Centers of Excellence for Influenza Research and Surveillance (CEIRS), International Centers of Excellence for Malaria Research (ICEMR), Tropical Medicine Research Centers (TMRC), and Centers for AIDS Research (CFAR)- and/or other US Government or internationally funded research infrastructure as needed to conduct proposed research and exhibit the flexibility to expand capacity in response to outbreaks in their geographic area, as directed by NIAID and the EIDRC CC. Each EIDRC will have the flexibility to study any emerging pathogen (viral, bacterial or eukaryotic), however, the initial focus will be on infectious pathogens that are most likely to emerge/remerge including, but not limited to: Flaviviruses, Filoviruses, Alphaviruses, Coronaviruses, Bunyaviruses, and Enteroviruses that are not already studied by other NIAID funded networks (e.g. HIV, influenza, malaria) and for which countermeasures are not developed or are sub-optimal.

Each EIDRC will have relevant scientific expertise and experience working in one or more geographic areas located within the tropical or subtropical regions of the world (Tropics: latitude between 23.5o -Tropic of Cancer and Capricorn-Subtropics: between tropic and temperate zones (35-66.5o N and S of the equator) with the goal to

establish multiple sites in targeted areas of the globe such as South and Central America, West/Central Africa and Southeast Asia. In an effort to train the next generation of investigators, develop expertise in emerging infectious disease research and expand regional capacity in these countries, the centers will be required to conduct a pilot project research program, that will be coordinated, including the awarding of projects, by the EIDRC CC.

EIDRC Structure

Administration and Leadership Team

The Administration and Leadership Team, led by the Program Director(s)/Principal Investigator(s), will be responsible for organizing, coordinating, and providing oversight for the implementation of activities that facilitate progress and completion of the research project(s) and conduct of pilot research projects, if awarded. This team will provide administrative oversight, coordination and facilitated communications with other EIDRCs and interact directly with the EIDRC CC and NIAID.

Data Management and Analysis Team

The Data Management and Analysis Team will be responsible for implementing standard procedures provided by the EIDRC CC for the collection, oversight and inventory of data and biological samples, including; harmonization, quality control, and uniformity of data collection processes, troubleshooting data system problems and developing solutions. Team members will also work with the Administration and Leadership Team, to develop efficient study designs and statistical calculations and provide support for the preliminary and final data analyses for the study. This team will serve as the hub for expertise with sharing data portal(s) as approved by NIAID. This team is responsible for directly depositing all relevant data, samples, reagents, tools, etc. as outlined to the EIDRC CC

Clinical Research Support Team

The Clinical Research Support Team will be responsible for coordinating the functions at all enrollment sites to recruit, enroll, and collect data and biological samples from participants. This Team will ensure adherence to NIH and EIDRC CC guidelines on research and data quality and all local and other regulatory oversight pertaining to all human subjects' research. This team will serve as the process and procedure hub for the interaction among the clinical sites and other functional work areas.

External Advisory Committee (EAC)

One External Advisory Committee, comprised of experts in the field outside of the EIDRCs and EIDRC CC, will be established after award to review progress for the Emerging Infectious Diseases Program (EIDRCs and EIDRC CC) and to share recommendations for the program with NIAID as part of the annual programmatic meeting. **Note that applicants should not name or contact potential EAC members in their application.**

Annual Programmatic Meetings

Each EIDRC will attend a combined kick-off meeting and annual program meetings under the leadership of the EIDRC CC to articulate and establish the major roles and functions of the program and to facilitate collaborations, provide progress reporting, seek new research directions and ideas, and update NIAID on issues of need. These meetings will be attended by the PD(s)/PI(s), Key personnel, NIAID staff, and the EAC membership and will be held in the Washington DC area.

Applications proposing any of the following topic areas will be considered nonresponsive and will not be reviewed:

- Applications that focus on pathogens that are not on the NIAID list of Emerging diseases (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens)). Research focus should be emerging/remerging viruses, but if studying coinfected population with a pathogen not on the Emerging Diseases list, application should include a strong justification and rationale for inclusion.

- Pathogens already studied by other NIAID funded networks, such as influenza, tuberculosis, malaria and antibiotic resistant bacteria. Please contact the Scientific/Research Contact if further clarification is needed.
- HIV, SIV or AIDS studies.
- Genome-wide association studies (GWAS).
- Behavioral research.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIAID intends to commit $6M in FY 2020 to fund 2-4 awards.

Award Budget

Applications budget are limited to up to $850,000 per year in direct costs and need to reflect the actual needs of the proposed project.

Award Project Period

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

NIH grants policies as described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)* will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

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. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

Applicants for the EIDRC CC (RFA-AI-19-029 (https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-19-029.html)) may also apply to this FOA.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)*

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Section IV. Application and Submission Information

1. 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. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent 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

The letter of intent should be sent to:

Eleazar Cohen, Ph.D.
Telephone: 240-669-5081
Email:ecohen@niaid.nih.gov (mailto:ecohen@niaid.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed, with the following additional instructions.

For this specific FOA, the Research Strategy is limited to 30 pages.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed. With the following additional instructions:

Facilities and Other Resources:

In a separate section entitled "Information Technology Access" include a brief description of the features of the institutional environment that are relevant to the effective implementation of the proposed unified collaborations across Teams and functions. Describe in general available IT resources associated with the enrollment and field sites with respect to access to computers, source and status of reliable, secure internet connections, and other communications.

In a separate section entitled "Biological Sample Storage and Access", describe the facilities available to store, manage and retrieve biological specimens for use by the PD(s)/PI(s) and key personnel.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed. With the following additional instructions:

- Within the Biosketch under Personal Statement, describe the leadership approach and experience of the PD(s)/PI(s) with respect to developing and executing multi-disciplinary research program(s) of a similar size and nature.
- Within the Biosketch under Personal Statement, all Key Personnel should demonstrate strong administrative, technical, and management expertise in areas critical to the success of the application, including experience working productively in team collaborative environments. Demonstrate how specific expertise supports the multi-disciplinary approach to guarantee a successful, integrated effort towards the goals of the research project.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed. With the following additional instructions:

In Year 01, include funds in the budget for the PD(s)/PI(s), collaborators, key personnel to travel and attend a kickoff meeting to be held shortly after the award over 1 full day in the Bethesda, MD area. Beginning in Year 02 include funds in the budget for an annual program meeting to be held over two full days in the Bethesda, MD area. Do not include costs associated with organizing and holding the kickoff or annual program meetings.

Include costs associated with submission of data into publicly accessible portal(s) approved by NIAID. Also include costs associated with biological sample collection, processing, shipping, and storage as well as costs for depositing data, reagents and tools to the EIDRC CC.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Specific Aims: List in priority order, the broad, long-range objectives and goals of the proposed research including surveillance, transmission, pathogenesis and immunologic responses in the host, and reagent and diagnostic assay

development for improved detection for important emerging pathogens and their vectors and indicate how these goals will be accomplished. Concisely describe the hypothesis or hypotheses to be tested with an initial emphasis on RNA viruses and plans for incorporation of other pathogens and emerging infectious diseases. Indicate how the work proposed dovetails to address the overall goals and objectives of the research.

Research Strategy:

In a clearly labeled section entitled “Administrative Plan”:

- Describe the administrative and organizational structure of the EIDCRC Administrative and Leadership Team. Include the unique features of the organizational structure that serve to facilitate accomplishment of the long-range goals and objectives.
- Describe how communications will be planned, implemented, and provided to collaborators, teams, or sites. In addition, describe plans to achieve synergy and interaction within the EIDRC to ensure efficient cooperation, communication and coordination.
- Specifically address how the EIDRC Team will communicate with other EIDRCs, the EIDRC CC and NIAID and how the EIDRC will implement plans and guidance from the EIDRC CC to ensure coordination and collaboration across the Emerging Infectious Disease Program as a whole. Describe how the study site will provide information, if any, back to the local health authorities and the study subjects as needed. Note any adjustments or changes needed for rapid and flexible responses to outbreaks in emerging infectious diseases.
- Describe the overall management approach, including how resources will be managed, organized and prioritized, including pilot research projects.
- Highlight how the proposed staffing plan incorporates scientific and administrative expertise to fulfill the goal to develop the flexibility and capacity to respond rapidly and effectively to outbreaks in emerging infectious diseases in an international setting.

In a clearly labeled section entitled "Data Management Plan”:

- Describe internal and external data acquisition strategies to achieve harmonization of systems and procedures for data management, data quality, data analyses, and dissemination for all data and data-related materials generated by the research study with the EIDRC CC.
- Within the plan, indicate the extent to which dedicated systems or procedures will be utilized to harmonize the acquisition, curation, management, inventory and storage of data and samples. Describe how training for the data and sample collection, in terms of the use of electronic data capture systems, will be provided to all staff including those at enrollment sites.
- Describe the quality control procedures for the data and biological specimens, and how to identify and resolve issues with quality control that maintains integrity of data and specimens.

In a clearly labeled section entitled "Clinical Management Plan":

- Describe plans, processes, and procedures for the following activities: clinical site selection including feasibility, capacity, and capabilities, and study development, conduct, and oversight.
- Describe strategies for oversight and implementation of standardized approaches in the recruitment and clinical characterization of adequate numbers of relevant patient populations to ensure the prompt screening, enrollment, retention and completion of studies. Describe novel approaches and solutions to study enrollment. including the clinical meta-data that will be captured and describe how the staff at each enrollment/collection site will be trained and comply with the quality standards for data and sample collection and compliance with the standardized procedures. Provide a general description of the methods for establishing clinical cohorts and how cohorts may be leveraged for new emerging pathogens.
- Provide general approaches to identification of the types of clinical cohorts needed to fulfill the goals of the EIDRC. Discuss types of clinical cohorts and clinical assessments that will be utilized to study natural history and pathophysiology of disease, including characteristics of the cohort, site for recruitment, types of samples collected and how they can be used for disease surveillance or provide the basis for discovery of novel

pathogens, along with a detailed description on how samples can be utilized for immunologic studies, pathogenesis and reagent and diagnostic assay development.
- Describe methods that might be applied to either elucidate a zoonotic source or a vector of transmission.
- Describe capacity for and approaches to clinical, immunologic and biologic data and specimen collection, and how these data and specimens will address and accomplish the overall goals and objectives of the research study.
- Provide plans for the potential addition of new sites and expanding scientific areas of research when needed for an accelerated response to an outbreak or newly emerging infectious disease.

In a clearly labeled section within the Research Strategy entitled "Statistical Analysis Plan":

- Describe the overall plan for statistical analysis of preliminary research data, including observational cohort data.
- Describe the overall staffing plan for biostatistical support and systems available for following functions: 1) preliminary data analyses, 2) estimates of power and sample size, 3) research study design and protocol development.
- Describe the quality control and security procedures for the data and biological specimens, and how to identify and resolve issues with quality control that maintains integrity of data and specimens.
- Describe any unique or innovative approaches to statistical analysis that may be utilized.

In a clearly labeled section entitled “Project Milestones and Timelines”:

- Describe specific quantifiable milestones by annum and include annual timelines for the overall research study and for tracking progress from individual sites, collaborators, and Teams. Milestones must specify the outcome(s) for each activity. Milestones should be quantifiable and scientifically justified, and include the completion of major research study activities, including, for example, protocol development, case report forms, scheduled clinical visits, obtaining clearances study completion, and analysis of final data. Milestone criteria should not simply be a restatement of the specific aims. Using a Gantt chart or equivalent tool, describe the associated timelines and identified outcomes for the research study.

Note: if the proposed research includes a clinical study, specific information for that study will be entered using the PHS Human Subjects and Clinical Trials Information and should not be duplicated in the Research Strategy.

Letters of Support: Include any letter necessary to demonstrate the support of consortium/site participants.

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, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan that details the rapid sharing, release and access of datasets, analysis tools, computational models, reagents, and other resources, which are generated by the Center to the broader scientific community in adherence to the requirements and timelines described in the NIAID Data and Reagents Sharing and Release Guidelines (https://www.niaid.nih.gov/research/data-sharing-and-release-guidelines) and the NIH Genomic Data Sharing (GDS) Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html).
- NIAID encourages the use of NIH supported open access Data Sharing Repositories as a first choice and a list of them can be found at https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html. (https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html) Provide a timeline for the planned acceptance, quality check, transfer and upload of data of all types.
- All investigators funded under this FOA will be expected to share their data through a portal(s) approved by NIAID as well as any collected biological samples, including clinical and animal research specimens. Therefore, the Resource Sharing plan should include a summary of how the applicant will manage data submission and interactions with the chosen portal(s), as well as sharing of biological samples with the scientific community.
- All Investigators are expected to be aware of and abide by all applicable NIH guidance for sharing of research resources and data, consistent with existing laws, regulations, and policies.

- All investigators should provide a plan for how to accomplish sharing of critical diagnostic reagents and tools when necessary, to NIAID, NIAID supported repositories, the other EIDRCs, the CC, and the broader research community.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or 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.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

Section 3 - Protection and Monitoring Plans

3.1 Protection of Human Subjects

3.1.1 Risks to Human Subjects

3.1.1.b Study Procedures, Materials and Potential Risks

Additional Instructions

For applications proposing to use samples from ongoing or completed clinical research, provide a timeline for the request, transportation and receipt of the biological samples, and the timeline associated with the preparation and use of the biological samples.

For all research projects provide information on:

- Describe the type(s) of biosamples to be used
- Describe the handling and processing of biosamples at the collection site (collection, processing, storage, transportation and quality control measures to ensure sample integrity)
- List the research laboratory(ies) to be used and describe the selection rationale and qualifications
- Describe the laboratory methodology(ies) to be used for each proposed assay/test and provide evidence of assay feasibility

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137)*, and procedures for foreign institutions.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. 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.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143)*.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-

submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** 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. See Section III of this FOA for information on registration requirements.

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. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

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

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

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

Scored Review Criteria

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?

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 for this FOA: Is the level of commitment of the PD(s)/PI(s) and key personnel adequate to manage the overall project? Do the investigators/collaborators have a previous history of translational research efforts?

Do the investigators have relevant scientific expertise and experience working in one or more geographic areas located within the tropical or subtropical regions of the world (Tropics: latitude between 23.5o -Tropic of Cancer and Capricorn- Subtropics: between tropic and temperate zones (35-66.5o N and S of the equator)? Does the team have a multidisciplinary expertise that could successfully be applied to characterizing the clinical features and transmission cycle of a newly emerging infectious disease?

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?

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? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

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: Do the investigators provide a clear plan for how to add new sites and/or expand scientific areas of research when needed for an accelerated response to an outbreak? Has the investigator described the establishment of a clinical cohort (or cohorts) that is likely to improve our understanding of the natural history of an emerging pathogen? Is the rationale for eligibility for inclusion in the cohort sound? Are the recruitment and retention plans and study timelines reasonable?

Do the targeted pathogen(s)/disease(s) address the FOA's intent to focus on the most relevant emerging pathogens? Are the contributions of each individual activity proposed within the research design well integrated with the aims of the project? Are the coordination and synergy within the project adequate to ensure the achievement of its central objectives?

Are the proposed host systems adequate, well-documented and characterized? If using animal models, are the models relevant and appropriate to investigate emerging ID infections?

Are the proposed technologies well justified, critical and relevant to the project aims?

Do the investigators provide a clear plan for achieving defined project milestones and timelines?

Are the described data management activities sufficient?

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?

Specific to this FOA: Do the investigators plan to complement and leverage existing NIAID international research efforts- such as the Centers of Excellence for Influenza Research and Surveillance (CEIRS), International Centers of Excellence for Malaria Research (ICEMR), Tropical Medicine Research Centers (TMRC), and Centers for AIDS Research (CFAR) and/or other US and internationally funded existing infrastructure as needed to conduct proposed research?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the 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) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions
Not Applicable

Renewals
Not Applicable

Revisions
Not Applicable

Additional Review Considerations
As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations
Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research
Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans
Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153). Do the investigators provide a clear and concise plan for sharing of information, data, and biological samples, and the development and sharing of critical research reagents and tools when necessary, according to specified timelines to NIAID supported repositories, the other EIDRCs, the CC, and the broader research community?

Authentication of Key Biological and/or Chemical Resources:
For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process
Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Allergy and Infectious Diseases, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

- Will receive a written critique.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156)*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157)*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120)* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157)* and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research

projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html); and https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html (https://www.hhs.gov/civil-rights/for-individuals/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to 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. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Serving as the administration oversight for the proposed research, including overseeing, managing, and coordinating the overall Centers/proposed research.
- Sharing data collected under this award through a NIAID approved portal(s), as well as sharing any collected biological samples with the scientific community, as appropriate and consistent with achieving the goals of the program.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.
- Rapidly responding to outbreaks as directed by NIAID and the EIDRC CC. Examples include but are not limited to; providing information, samples, data, reagents, etc. to another Center, the Coordination Center and/or other collaborators, in addition to planning and/or performing critical experiments to advance the development of new diagnostic tools and reagents.
- Publishing research results, presenting at professional meetings, developing quality diagnostic capability and managing pilot projects.
- Demonstrating collaborative effort within the larger EIDRC network, including the other EIDRCs, the CC and NIAID

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Coordinate NIAID staff assistance, including participation in periodic on-site monitoring with respect to compliance with Federal regulations, quality control, accuracy of data recording, sample accrual, enrollment, etc.
- Facilitate collaborations with and access to other NIAID-supported research resources and services.
- Serve as liaison/facilitator between the awardee and the EIDRC CC, related to database and biological sample storage (approved by NIAID).
- Assist in establishing an External Advisory Committee (EAC).
- The NIH Project Scientist will review and assist in developing the operating guidelines and consistent policies for dealing with situations that require coordinated action.
- The NIH Project Scientist will periodically review the data generated under this award.
- Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

- The PD(s)/PI(s) and NIH Project Scientist will review the entirety of program milestones annually and update them based on recommendations from the EAC.
- The NIH Project Scientist and the PD(s)/PI(s) will coordinate the overall Center objectives and progress at the annual workshop to facilitate the achievement of program goals.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171)* for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Jean Patterson, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-292-4830
Email: jean.patterson@nih.gov (mailto:jean.patterson@nih.gov)

Peer Review Contact(s)

Eleazar Cohen, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5081
Email: ecohen@niaid.nih.gov (mailto:ecohen@niaid.nih.gov)

Financial/Grants Management Contact(s)

Bora Mpinja
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-5434
Email address: bora.mpinja@nih.gov (mailto:bora.mpinja@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-08-19)
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