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 (https://www.niaid.nih.gov/))

Funding Opportunity Title

Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Network - Coordination and Data Sharing Center (CDSC) (UG3/UH3 Clinical Trial Not Allowed)

Activity Code

UG3 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=ug3&Search.x=0&Search.y=0&Search_Type=Activity)/UH3 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=uh3&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Phased Award Cooperative Agreement

Announcement Type

New

Related Notices

NOT-OD-22-195 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-195.html) - New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html) - Implementation Details for the NIH Data Management and Sharing Policy

NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html) - Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023

NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) - 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

Notice of Funding Opportunity (NOFO) Number

RFA-AI-23-021

Companion Funding Opportunity

RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html), U19 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=U19&&Search.x=0&&Search.y=0&&Search_Type=Activity) Research Program (Cooperative Agreement)
RFA-AI-23-020 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-020.html), U19 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=U19&&Search.x=0&&Search.y=0&&Search_Type=Activity) Research Program (Cooperative Agreement)

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

This Notice of Funding Opportunity (NOFO) solicits applications to establish a Coordination and Data Sharing Center (CDSC) in support of the Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Centers. Together, the CDSC and ReVAMPP Centers will form the ReVAMPP Network. The purpose of the CDSC is to support, coordinate, and manage ongoing and planned activities within the ReVAMPP Network. The CDSC is expected to establish and maintain a collaborative ReVAMPP Network platform for data sharing and dissemination as needed to harmonize reagents, assays, animal models and exchange knowledge on structure/function-based vaccine solutions and antigen/immunogen design as well as assess the utility of vaccine technology platforms for virus families studied under the ReVAMPP Centers. The CDSC is also expected to facilitate effective communications across the ReVAMPP Centers by scheduling, and managing all meetings, tracking overall network progress and outputs, developing opportunities for collaboration among the Centers such as establishing working groups, and collating information and facilitating exchange with other NIAID/NIH programs, U.S. Government (USG) partners, and other key stakeholders, including the World Health Organization (WHO), Bill & Melinda Gates Foundation (BMGF), and Coalition for Epidemic Preparedness Innovations (CEPI) among others as appropriate.

Key Dates

Posted Date

March 16, 2023

Open Date (Earliest Submission Date)

May 08, 2023

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
June 08, 2023	Not Applicable	Not Applicable	November 2023	January 2024	March 2024

All applications are due by 5:00 PM local time of applicant organization.

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.

No late applications will be accepted for this Funding Opportunity Announcement.

Expiration Date

June 09, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts). (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)

Conformance to all requirements (both in the Application Guide and the NOFO) 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)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.

Table of Contents

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Purpose

The National Institute of Allergy and Infectious Diseases (NIAID) supports complementary research programs to understand, control and prevent viral diseases and related pandemics. As part of pandemic preparedness planning, the purpose of this Notice of Funding Opportunity (NOFO) is to solicit applications for a Coordination and Data Sharing Center (CDSC) for the Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Network. The ReVAMMP Centers, supported by separate companion NOFOs (RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html) and RFA-AI-23-020 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-020.html)), will consist of multi-project cooperative agreements that establish comprehensive, cooperative basic, and translational research Centers to carry out in-depth research on prototype members of select virus families that have the potential to emerge as pandemic pathogens. Together the CDSC and ReVAMPP Centers will form the ReVAMPP Network. This new Network will align with the goals of the American Pandemic Preparedness Plan: Transforming Our Capabilities (AP3) (https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf), which was announced in September 2021, and recognizes the need for a trans-government investment and response to combat future pandemics and NIAID's Pandemic Preparedness Plan (https://www.niaid.nih.gov/sites/default/files/pandemic-preparedness-plan.pdf).

Background

The emergence and re-emergence of infectious diseases continues to threaten the health of Americans and people worldwide. Over the past two decades, the public health community has responded to emerging infectious diseases including those caused by Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-1), the 2009 H1N1 influenza virus, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola virus, Zika virus, and most recently, SARS-CoV-2. The global pandemic caused by SARS-CoV-2 further underscored the continual threat of newly emerging and re-emerging pathogens and the critical value of basic and translational research for pandemic preparedness. Continuing to build a robust basic research portfolio and advancing translational science for other viral families with pandemic potential is essential for biomedical countermeasure preparedness. To mitigate risks associated with emerging or re-emerging pathogens, NIAID's intent for the ReVAMPP network, consisting of the CDSC and ReVAMPP Centers, is to promote focused and coordinated research needed to develop vaccines and monoclonal antibodies (mAbs) for prototype-pathogens from viral families known to infect humans (Cassetti MC, et al. JID. 2022;jic296 (https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiac296/6649664?login=true), Graham BS and Corbett KS J Clin Invest. 2020;130(7):3348–3349 (https://www.jci.org/articles/view/139601)).

The unprecedented rapid development of vaccines and mAbs for SARS-CoV-2 was enabled by decades of foundational research on related coronaviruses which allowed scientists to quickly and effectively respond once SARS-CoV-2 emerged. Likewise, in responding to pandemics over the last two decades, we have learned that the optimal strategy to prepare for the next one is to adopt a model of advanced, preparatory global coordination of scientific research and response efforts. Strategic, advanced programmatic coordination of existing and new pandemic preparedness networks will allow us to leverage and synergize valuable research findings/outputs and funding, including the discovery and development of potential shared reagents, assays, models, vaccine platforms, etc. A separate, but integrated team of administrators, communicators, and data science experts embedded within the research network will play a key role, in translating the successes of the network and will allow our investigators and our Institute to prepare in advance to rapidly share information with key stakeholders across the globe when a new pandemic/outbreak occurs.

Research Objectives and Scope

The objective of this NOFO is to establish a comprehensive CDSC to support the ReVAMPP Centers. The CDSC is expected to establish and maintain a collaborative ReVAMPP Network platform for data sharing to harmonize reagents, tools, assays, models and exchange knowledge on structure/function-based vaccine solutions and antigen/immunogen design as well as assess the utility of vaccine technology platforms for virus families studied across the ReVAMPP Network. The CDSC is also expected to facilitate effective communications across the ReVAMPP Centers by scheduling and managing all network-wide meetings, tracking overall network progress and outputs, developing opportunities for collaboration among the Centers, such as establishing working groups, and under the direction of NIAID program, collating information and facilitating exchange and dissemination with other NIAID/NIH Programs, U.S. Government (USG) partners and other key stakeholders, including the World Health Organization (WHO), Bill & Melinda Gates Foundation (BMGF), and Coalition for Epidemic Preparedness Innovations (CEPI) among others as appropriate.

The CDSC will develop new or reuse and adapt existing data sharing platforms and data templates for all types of data generated by the ReVAMPP Centers which may include building on publicly available platforms and templates within other NIAID-supported programs such as ImmPort (https://www.immport.org/home). These platforms and templates may include those related to reagents, tools, assays, models, vaccine technology platforms, immune epitope design and/or correlates of protection. The CDSC will also develop, in conjunction with NIAID and the ReVAMPP Centers' PD(s)/PI(s), a network wide ReVAMPP governance structure and provide guidance as to engagement with stakeholders within and outside the research centers.

This NOFO will utilize a bi-phasic, milestone-driven cooperative agreement award mechanism with the UG3 Phase consisting of the first 3 years, and UH3 Phase consisting of years 4 and 5. Although applicants will apply for five years of funding, near the end of year 3, grantees will submit a transition package for the UH3 Phase which will be evaluated by NIAID program staff for progress towards the development of Network data sharing platforms and facilitation of Network communication and collaboration. The administrative review will be based on successful achievement of milestones included in the application and negotiated with the recipient prior to award, overall network advancement, and the availability of funding.

CDSC Structure

Administration and Leadership Team

In consultation with the ReVAMPP Centers, the CDSC Administration and Leadership Team will be responsible for establishing a comprehensive coordination and communications plan to support the ReVAMPP Network. They will coordinate and facilitate communications across the ReVAMPP Centers and between each ReVAMPP Center and NIAID by scheduling and managing all network-wide meetings, and tracking overall network progress and outputs, and establishing opportunities for the Centers to collaborate such as the establishment of working groups. Specifically, the CDSC Administration and Leadership Team will track and coordinate sharing of reagents, tools, and assays to ReVAMPP Centers and collaborating researchers to support the development of translational products including vaccines and mAbs.

In cooperation with NIAID, the CDSC Administration and Leadership Team will provide summary information and coordinate information exchange with other NIAID Programs, USG partners and key stakeholders, including the WHO, BMGF and CEPI, among others as appropriate.

The CDSC Administration and Leadership Team will also provide oversight of the implementation of all activities that facilitate progress and completion of the overall goals of the ReVAMPP Network. The CDSC will coordinate and organize a ReVAMPP Network-wide review meeting annually in the Rockville, MD area or other NIAID approved site with the format to be determined by NIAID.

The CDSC will be required to attend an annual CDSC progress meeting to evaluate progress and effectiveness as a coordination and data center. Adherence to timelines related to ReVAMPP Network tracking, working group outputs, data platforms and template establishment will be assessed. As part of an annual review, the CDSC will be required to set up a Scientific Advisory Board (SAB) that will act as an independent, external advisory body for the PD(s)/PI(s) but will not be involved in the day-to-day activities of the CDSC. On an annual basis, the SAB will provide feedback related to effectiveness and appropriateness of programmatic duties of the CDSC as stated in the NOFO by providing a short, written summary of their findings. The SAB will include at least 3 non-conflicted external advisors with appropriate expertise. SAB membership will be established in consultation with NIAID program staff. Potential external SAB members MUST NOT be named in the application or contacted prior to completion of review activities.

The CDSC Administrative Leadership Team will assist the ReVAMPP Centers with managing quality and regulatory oversight pertaining to human subjects' research as needed.

The CDSC will also develop a ReVAMPP Network governance structure in conjunction with NIAID and the ReVAMPP Centers' PDs/PIs and provide guidance as to engagement with stakeholders within and outside the research centers.

Data Management and Analysis Team

The ReVAMPP CDSC Data Management and Analysis Team will be responsible for establishing a comprehensive data sharing center to support the ReVAMPP Centers and the overall Network.

The CDSC will foster and build upon the open-science policy by establishing and maintaining a public facing website and privately accessible (to Network members only) web portal, as well as develop an appropriate data sharing platform and templates for all types of data generated by the ReVAMPP Centers. The CDSC is expected to collaborate with other NIAID-supported data management programs, post award, to leverage existing data and metadata standards and templates. The CDSC will create a network-wide terms of confidentiality agreement to be signed by all ReVAMPP Centers for data and information shared within the ReVAMPP Network. Data will be shared confidentially within the Network to harmonize information/data related to reagents, tools, assays, animal models, vaccine technology platforms, immune epitope design and/or correlates of protection. This will allow the Network to accelerate translational research and the development of prototype vaccines and mAbs for viruses of pandemic concern. This team will serve as the hub for expertise with sharing data portal(s) as approved by NIAID. The CDSC will also work with the ReVAMPP Centers as instructed to develop efficient study designs and statistical calculations and provide support for the preliminary and final data analyses.

Applications including the following types of studies will be considered non-responsive and will not be reviewed:

- Clinical trials: Clinical research may be supported but not clinical trials, as defined by the NIH (https://grants.nih.gov/policy/clinical-trials/definition.htm (https://grants.nih.gov/policy/clinical-trials/definition.htm)).
- Applications that do not include a clear section on Milestones with Go/No-Go criteria

This NOFO solicits applications for the ReVAMPP Coordinating and Data Sharing Center (CDSC) that will oversee data coordination and sharing for the ReVAMPP Centers in the ReVAMPP Network. For ReVAMPP Center programs proposing research on virus families from Flaviviridae and Togaviridae see the companion NOFO, RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html) and on virus families from Bunyavirales, Paramyxoviridae and Picornaviridae see the companion NOFO, RFA-AI-23-020 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-020.html).

For additional information about the Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Network - Coordination and Data Sharing Center (CDSC), see "Frequently Asked Questions (FAQ)" link here: https://www.niaid.nih.gov/grants-contracts/questions-and-answers-revampp-funding-opportunities (https://www.niaid.nih.gov/grants-contracts/questions-and-answers-revampp-funding-opportunities).

Webinar Announcement

NIAID plans to hold a pre-application informational webinar for this NOFO. Details about webinar registration will be available at this same FAQ link shortly after NOFO publication. Participation in the webinar is not required to submit an application in response to this NOFO.

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 NOFO.

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. Only those application types listed here are allowed for this NOFO.

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 ~$2M in FY2023 to fund 1 award.

Award Budget

Application budgets are not expected to exceed $1.5M in direct costs per year and need to reflect the actual needs of the proposed project.

Award Project Period

The project 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 NOFO.

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)

Local 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)

Federal Government

- 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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** 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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Electron:~:text=by%22%20dates%20apply.-,2.3.9.2%20Electronic For%20applications%20submitted) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM)– (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) 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.
    - 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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active 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 their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

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 to this NOFO will not be eligible to submit to or participate in the companion ReVAMPP Centers NOFOs (RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html) and RFA-AI-23-020 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-020.html)) because of the unique, centralized role of the CDSC in ReVAMPP Network coordination and communication.

2. Cost Sharing

This NOFO 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, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). 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 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar,))

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 NOFO. 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 instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity 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:

Noton Dutta, Ph.D.
Telephone: 240-669-2857
Email: noton.dutta@nih.gov (mailto:noton.dutta@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.

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 NOFO.

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.

SF424(R&R) Senior/Key Person Profile

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

Within the biosketch, describe experience coordinating large research networks, with use of and/or coordination of databases, and experience working with large international research programs including NIH, NIAID, USG and international agencies.

R&R Budget

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

Include funds for the overall administrative effort, collaborative activities, communications, and publications.

Include funds for the PD(s)/PI(s), Project Leaders, external SAB members, additional CDSC Key Personnel (at the discretion of the PD(s)/PI(s)) to travel and attend annual mandatory CDSC progress meetings at NIAID in Years 1-4 of the project period.

Include funds to plan, coordinate, and organize logistics for the annual ReVAMPP Network-wide review meetings to be held approximately over 1-3 full days in the Rockville, MD area or other NIAID approved site. Additional funds must be included for the PD(s)/PI(s), Project Leaders, and additional CDSC Key Personnel to travel to, attend, and run these meetings, which will be held annually.

Include costs associated with submission of and depositing of all relevant data, tools, etc. into publicly accessible portal(s) approved by NIAID.

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 CDSC. Concisely describe the CDSC objectives with respect to oversight and coordination of the ReVAMPP Network and data management.

Research Strategy:

Administrative and Leadership Team Plan:

Describe the administrative and organizational structure of the CDSC 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, ReVAMPP Centers and stakeholders. Specifically address how the CDSC Administrative and Leadership Team will communicate with ReVAMPP Centers and NIAID to ensure coordination and collaboration across the ReVAMPP Network, for example, by establishing working groups. Describe plans to coordinate and facilitate collaborations with USG, international agencies and other partners including industry and private sector. Describe how unified network-wide policies around resource sharing within the Network and outside of the Network will be established in consultation with the ReVAMPP Centers.

Describe strategies for oversight and implementation of standardized approaches to ensure efficient cooperation, communication and coordination across the multiple Centers and collaborators.

Scientific Advisory Board: Describe the composition and duties of the Scientific Advisory Board (SAB), including the categories of expertise to be represented on the SAB and how the SAB will be utilized to guide CDSC activities. The description should include a discussion of how the proposed expertise of the SAB will be integrated into the operations of the Center. Describe the procedures and approaches for obtaining SAB input via teleconferences, ad hoc and annual meetings, review of written materials/data, etc. *Candidates for the SAB MUST NOT be named in the application or contacted prior to completion of review activities.*

Data Management and Analysis Team 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 ReVAMPP Centers and the overall Network.

Describe plans for development of infrastructure and capacity to manage, store, analyze, and share large, diverse datasets including the use of publicly available data-sharing platforms and templates when appropriate.

Describe the quality control procedures for the data, and how to identify and resolve issues with quality control that maintains data integrity.

Describe how the CDSC will provide support to the ReVAMPP Centers to develop efficient study designs and statistical calculation and for preliminary and final data analysis as needed.

Describe the plans for development of a public-facing website and network-only portal for sharing data.

Milestone Plan:

In a clearly labeled section titled "Project Milestones and Timelines", applicants must describe specific quantifiable, planned milestones by annum, and include annual timelines for coordinating the overall ReVAMPP Network and for tracking progress from ReVAMPP Centers, including collaborators, and stakeholders. Describe how key milestones for the Network will be established in year 1 of the grant including data sharing infrastructure and communications plan. This plan must include criteria to be met by the end of Year 3 of the award for continuation to the UH3 phase. Milestones must specify the outcome(s) for each activity. Milestone criteria should not simply be a restatement of the specific aims. Milestones should be quantifiable and include the completion of major CDSC activities, for example: development of a network-wide governance structure, a network communication plan, data sharing platforms and data templates; establishment of procedures for data management, data quality, data analyses, and dissemination for all data and data-related materials generated by the Centers; coordination and organization of network-wide meetings; establishment of an internal ReVAMPP network web portal and public facing website; and creation of a stakeholder engagement strategy for the Network. A Gantt chart or equivalent tool should be used to describe the associated timelines and identified outcomes of the CDSC.

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. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

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.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) 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.

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.html?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 (https://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. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

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 form**.** 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 NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier 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 NIAID, 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 to this NOFO: To what extent do the investigators have experience and expertise both in data and administrative management of large scientific/translational research programs? To what extent do the investigators have relevant experience working with USG and other international agencies related to coordination of efforts? How adequate are the time and effort dedicated by the investigators and other key personnel to the CDSC based on the activities proposed?

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 NOFO: To what extent does the applicant provide a clear and concise plan for how to coordinate and facilitate overall collaboration between the ReVAMPP Centers and NIAID? How well do they provide a well-reasoned plan for coordinating and facilitating collaborations with other USG and international agencies and partners including industry and the private sector? How well do the milestones support the goal of establishing a cohesive coordinated Network and plans for facilitating data sharing and dissemination?

How well do the investigators provide a well-defined plan for achieving proposed project milestones and timelines with appropriate quantifiable measures? To what extent are timelines proposed for achieving these milestones realistic and inclusive of necessary steps? How appropriate are the plans for data management and analysis including harmonization of data and development of data infrastructure?

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 NOFO: How appropriate are the plans for development of infrastructure and capacity to store, analyze, and share large, diverse datasets?

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 Animals 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

Not Applicable.

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 Resource Sharing Plan(s) (i.e., Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

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 (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

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.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this NOFO.

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 NOFO. 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 (https://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=11120).

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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

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 recipient's business official.

Recipients 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 NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

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, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159), including of note, but not limited to:

- *Federal wide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)*
- *Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)*
- *Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)*

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a condition of receiving the grant, to administer programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2Ffor-providers%2Fprovider-obligations%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63803 and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fcivil-rights%2For-individuals%2Fnondiscrimination%2Findex.html&data=05%7C01%7Ccarrie.mitchell%40nih.gov%7Ce8bc304bfdb644bb556e08dac343ad36%7C14b77578977342d58507251ca2dc2b06%

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 NOFO.

- *For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html)and https://www.lep.gov (https://www.lep.gov/).*
- *For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html (https://www.hhs.gov/civil-rights/for-individuals/disability/index.html).*
- *HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).*
- *For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/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.

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 and 2 CFR Part 200.206 "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 2 CFR Part 200, 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 recipients 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 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 recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

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

- *PD(s)/PI(s) will have the primary responsibility for coordinating activities within the overall ReVAMPP Network. Specifically, the PD(s)/PI(s) have primary responsibility as described below:*
- *The PD(s)/PI(s) will be responsible for defining the research objectives, approaches, and details of the project within the guidelines of the NOFO and retains primary responsibility for planning, directing, and executing the proposed scientific activities.*
- *The PD(s)/PI(s) will provide oversight and implementation of standardized approaches to ensure efficient cooperation, communication and coordination across the multiple Centers and collaborators.*
- *The PD(s)/PI(s) are responsible for ensuring that appropriate systems are in place to provide for biosafety and security of materials, data, facilities, and resources, including compliance with regard to Select Agent Regulations, Biosafety in Microbiology and Biomedical Laboratories (BMBL) Guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, sixth Edition; U.S. Code of Federal Regulations 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121.*

In addition, the PD(s)/PI(s) will be responsible for:

- *Organizing and chairing annual CDSC progress meetings. The annual CDSC progress meetings are anticipated to be held at a location at/near Rockville, MD or at another NIAID-approved site and will last up to 2 days.*
- *Organizing and coordinating the network wide ReVAMPP review meetings annually.*
- *Advertising the availability of the Network generated resources through outreach activities.*

Recipients 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 HHS, PHS, and NIH policies.

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

The role of the NIAID Project Scientist is to support and encourage the recipient's activities by substantial involvement as partners and facilitators in the process without assuming responsibilities that remain with the PD(s)/PI(s).

- *The NIAID Project Scientist will work closely with the PD(s)/PI(s) and other Program member scientists to facilitate collaborations and to leverage the resources available to the CDSC.*

- *The NIAID Project Scientist will monitor the progress of the CDSC, help coordinate research approaches among the CDSC and all participants of the ReVAMPP Network and contribute to the shaping of research projects or approaches as warranted. The NIAID Project Scientist will support and facilitate this process but will not direct it.*
- *Near the end of year 3 of the award, the Program Official, with assistance from the NIAID Project Scientist, will assess the progress of the CDSC through the accomplishments of the milestones and overall feasibility of program advancement. The assessment will be based on the first three annual reports, the milestones included in the application and negotiated with the recipient prior to award, any additional information that the PD/PI elects to submit, programmatic priorities, overall continuation of the ReVAMPP Network, and the availability of funding.*
- *The NIAID Project Scientist will keep the CDSC informed about other ongoing studies supported by NIAID to avoid duplication of effort and encourage sharing/collaboration in infectious diseases research.*
- *The NIAID Project Scientist will coordinate access for the CDSC to other NIAID resources, as well as assist the research efforts of the CDSC by facilitating access to fiscal and intellectual resources provided by industry, private foundations, NIH intramural scientists and other federal government agencies as appropriate.*

In addition to the NIAID Project Scientist, 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 NIAID Project Scientist and the PD/PI will hold regular program-wide discussions to facilitate the achievement of program goals.*
- *The PD(s)/PI(S) and the NIAID Project Scientist will collaborate in the establishment of the Scientific Advisory Board*
- *The NIAID Project Scientist and the PD/PI will collaborate during the course of the award to revise and/or update project milestones as appropriate.*

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 recipient. This special dispute resolution procedure does not alter the recipient'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. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients 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. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)

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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients 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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) 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: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (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: 301-637-3015

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)

Kaitlyn Morabito, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 301-204-3248
Email: Kaitlyn.dambach@nih.gov (mailto:Kaitlyn.dambach@nih.gov)

Peer Review Contact(s)

Noton Dutta, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-2857
Email: noton.dutta@nih.gov (mailto:noton.dutta@nih.gov)

Financial/Grants Management Contact(s)

Elizabeth Sihombing
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5530
Email: elizabeth.sihombing@nih.gov (mailto:elizabeth.sihombing@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 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-17-23)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

***Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).*