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) Centers for Bunyavirales, Paramyxoviridae and Picornaviridae (U19 Clinical Trial Not Allowed)

Activity Code

U19 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=u19&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) Research Program Cooperative Agreements

Announcement Type

New

Related Notices

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-22-195 (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-22-198 (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

Funding Opportunity Announcement (FOA) Number

RFA-AI-23-020

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-23-021 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-021.html), UG3 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UG3&&Search.x=0&&Search.y=0&&Search_Type=Activity)/ UH3 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=UH3&&Search.x=0&&Search.y=0&&Search_Type=Activity) Phase 1 Exploratory/Developmental Cooperative Agreement/Exploratory/Developmental Cooperative Agreement Phase II

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) solicits applications to participate in the Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Network. The purpose of this FOA is to 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. The goal of these Centers will be to develop vaccine and monoclonal antibody strategies for prototype pathogen(s) that can be applied to closely related family members based on shared functional and structural properties. This FOA solicits for centers proposing research on virus families from Bunyavirales, Paramyxoviridae and Picornaviridae to be part of the ReVAMPP Network.

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 Multi-Project (M) 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 FOA or in a Notice from the *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 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

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, this Funding Opportunity Announcement (FOA) solicits applications to establish comprehensive, cooperative basic and translational research centers to 1) advance scientific knowledge needed to develop vaccines and monoclonal antibodies (mAbs) for prototype viral pathogens within virus families that have pandemic potential; and 2) leverage this information to develop and evaluate generalizable approaches for vaccines and mAbs for the prototype pathogens and other related family members based on shared functional and structural properties. Centers proposing research on select virus families from Bunyavirales, Paramyxoviridae and Picornaviridae are included in this FOA.

The ReVAMPP Network is comprised of ReVAMPP Centers from both this RFA (Bunyavirales, Paramyxoviridae and Picornaviridae) and its companion FOAs soliciting for ReVAMPP Centers focusing on Flaviviridae and Togaviridae (see RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html)) and the ReVAMPP Coordinating and Data Sharing Center (CDSC) (see RFA-AI-23-021 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-021.html)). ReVAMPP Centers will conduct independent research project(s) and are expected to share information and collaborate within the Network under the direction of the ReVAMPP CDSC which is responsible for establishing and maintaining a collaborative ReVAMPP Network platform for data sharing and overall collaboration among the ReVAMPP Centers.

In the event of an outbreak, the ReVAMPP Centers will be poised to leverage the expertise and resources within the network to assist in a coordinated research response. This new NIAID 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 underscores the continual threat of newly emerging and re-emerging pathogens and the critical value of basic and translational research for pandemic preparedness. 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. In recent years, considerable resources have been invested in vaccine and mAb development for coronavirus and influenza viruses to prepare for the next pandemic from these families. However, viruses from other families also propose substantial risk of causing a pandemic. Thus, 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. In addition to known threats, effective preparedness must also account for unexpected emerging disease threats. To mitigate risks associated with these yet-unknown pathogens, NIAID's intent for the ReVAMPP Network is to promote focused research needed to develop vaccines and mAbs for prototype-pathogens from viral families known to infect humans (Graham BS and Corbett KS J Clin Invest. 2020; 130(7):3348-3349 (https://www.jci.org/articles/view/139601), Cassetti MC, et al., JID. D022; jiac296). (https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiac296/6649664?login=true) As defined in this FOA, a prototype pathogen is a representative virus from which research on the virology, pathology and immunology of the prototype will generate generalizable knowledge, and in turn vaccine and mAb strategies, which can be applied to other members of the viral family. As the prototype pathogen approach proposes, viruses are organized into families based upon shared functional and structural similarities and thus candidate vaccine strategies developed against a prototype pathogen may similarly work against other members in the same family. Through targeted basic and applied research on these prototype pathogens, a solid foundation of knowledge will enable a rapid response when a previously unknown (or known but understudied) pathogen emerges or spreads from any of the known high-risk viral families. This anticipatory approach will increase the knowledge base needed for preparedness and enable rapid development and translation of candidate vaccines and mAbs into clinical trials and large-scale production.

Research Objectives and Scope

The objective of this FOA is to establish multidisciplinary research Centers to be part of the highly collaborative ReVAMPP Network focused on in-depth basic and translational research on prototype members of certain virus families that have the potential to emerge as pandemic pathogens, namely Paramyxoviridae, Picornaviridae and Bunyavirales including Arenaviridae, Hantaviridae, Nairoviridae, Phenuiviridae, and Peribunyaviridae. The major goal of these Centers will be to develop vaccine strategies for prototype pathogens that can be applied to other closely related family members based on shared functional and structural properties. Additionally, these Centers may perform basic research to expand foundational knowledge of virology, pathology, and immunology, or perform early development activities for mAbs for prototype viruses. Towards these goals, each Center will encompass a multi-project multidisciplinary research program that employs innovative virology, structural biology, and immunology to identify strategies for vaccine design. Each Center will collaborate across the ReVAMPP Network through the sharing of data, reagents, protocols, and animal models to facilitate advancement toward pandemic preparedness for all virus families.

Priority Viral Families for Pandemic Preparedness

A prototype pathogen is a representative virus from which research on the virology, pathology and immunology of the prototype will generate generalizable knowledge, and in turn vaccine and mAb strategies, which can be applied to other members of the virus family. For this FOA, each ReVAMPP Center will support a multi-project research program directed towards enabling basic and translational research and development of vaccines, and optionally early development of mAbs, against prototype viruses from one or more of the following selected virus families of pandemic potential, and Centers are encouraged to work on more than one virus family (listed alphabetically, all of equivalent priority):

- Bunyavirales
  - Arenaviridae (e.g., Lassa virus, Junin virus)
  - Hantaviridae (e.g., Andes virus, Sin Nombre virus, Hantaan orthohantavirus virus)
  - Nairoviridae (e.g., Crimean-Congo Hemorrhagic Fever virus (CCHF), Hazara virus)
  - Phenuiviridae (e.g., Rift Valley Fever virus, Severe Fever with thrombocytopenia syndrome virus, Punta Toro virus)
  - Peribunyaviridae (e.g., LaCrosse virus (LAC), Cache Valley virus)
- Paramyxoviridae (e.g., Menangle virus, HPIV1, HPIV3, Canine Distemper virus, Cedar virus)
- Picornaviridae (e.g., Enterovirus A71, Enterovirus D68, Echovirus B29, Rhinovirus C)

Centers are encouraged to include research projects focused on multiple virus families and may include a single prototype or multiple prototypes from a family. The investigators will determine which virus should serve as a prototype for a given family, but prototype selection must be justified. Considerations may include, but are not limited to, how well the prototype reflects properties shared by other members of the family, whether a single prototype is sufficient or whether multiple prototypes are needed to address differences amongst family members, the ease of working with the prototype virus, and whether vaccines against the prototype would have potential value for current public health needs.

These selected priority virus families of pandemic potential were identified by NIAID based on the ability to infect humans, the potential to cause a pandemic, and the current resources invested. The Coronaviridae and Orthomyxovirdae virus families were not included in this list as vaccine development and preparedness research for these families is supported through other mechanisms such as NOT-AI-21-002: Emergency Awards: Notice of Special Interest (NOSI) on Pan-Coronavirus Vaccine Development Program Projects (https://grants.nih.gov/grants/guide/notice-files/NOT-AI-21-002.html) and NIAID Centers of Excellence for Influenza Research and Surveillance (https://www.niaidceirs.org/), among others. In November 2021, NIAID convened a workshop titled NIAID Workshop on Pandemic Preparedness: The Prototype Pathogen Approach to Accelerate Medical Countermeasures - Vaccines and Monoclonal Antibodies where experts summarized current knowledge of the basic and translational research landscape, described research and intervention gaps, and proposed suitable prototype pathogens for further study and medical countermeasure development (Graham BS and Corbett KS J Clin Invest. 2020; 130(7):3348-3349 (https://www.jci.org/articles/view/139601), Cassetti MC, et al. JID. 2022;jiac296. (https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiac296/6649664)) This workshop highlighted the critical need to continue to expand basic research efforts and advance translational science for nine of the selected virus families. NIAID's intent for the ReVAMPP Network is to promote focused and coordinated research needed for the development of vaccines, and optionally early development of mAbs, for prototype-pathogens from virus families known to infect humans.

Research Areas

This FOA will support basic research such as virology studies to better understand cell tropism and receptor/entry requirements and to determine replication mechanisms, pathogenesis, and capacity for antigenic diversity. It will also support structural biology research to define the atomic-level details of surface proteins likely to be antigenic/immunologic targets. It will support research to assess the immune response in humans to natural infections and existing vaccines as well as determine correlates of immune protection, establish robust animal models, and develop reagents and new immunological assays.

This FOA will also support early and Investigational New Drug Application (IND)-enabling translational research for vaccines. Translational activities may include antigen/immunogen design and evaluation, screening technology platforms or adjuvants for immunogenicity and efficacy in animal models, development of assays and reagents, identification of correlates or surrogate markers of protection, lead optimization, stability, and manufacturability testing, and/or early process development. Once lead vaccine

candidates/strategies have been identified, the same generalizable approach will be applied to other viruses within in the same family to validate the overall strategy for the virus family. Given the need to respond rapidly to emerging threats, the vaccine strategies should incorporate technologies that are amendable to antigen interchange and rapid manufacturing such as plug and play platforms.

The development of prototype vaccine strategies and structure-function characterization of the immune response to infection and vaccination is likely to result in the identification of mAbs with therapeutic potential. Thus, this FOA will support functional characterization of candidate mAbs and early translational activities for mAb development for prototype viruses. These activities may include discovery, *in vitro* characterization including epitope identification, neutralization potency, effector function analysis and structural studies, mAb optimization, determination of mechanism of action, *in vivo* evaluation including efficacy, dose titration, and route of administration studies in animal models, and candidate down-selection. If early mAb development is included, following the identification of lead mAb candidates for the prototype virus, it should be determined if antibodies with similar epitopes and/or properties are effective against other viruses within the same family.

Milestones

This FOA will utilize a bi-phasic, milestone-driven cooperative agreement award mechanism with Phase I consisting of the first 3 years, and Phase II 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 which will be evaluated by NIAID program staff for progress of research towards development of a generalizable vaccine strategy for the proposed viral family(ies), and if applicable early mAb development, and contribution to the ReVAMPP Network through data sharing and collaboration. The administrative review for funding of years 4 and 5 will be based on successful achievement of milestones included in the application and negotiated with the recipient prior to award, overall feasibility of program advancement,compliance with the ReVAMPP Network data sharing and CDSC requests, evidence of collaboration with other ReVAMPP Centers, programmatic priorities, and the availability of funding.

Industry Partnership

Each ReVAMPP Center is expected to have an established, or have plans to establish when appropriate, collaboration with an industry partner which will provide access to vaccine expertise in manufacturing, clinical development, and regulatory pathways. For Centers proposing IND-enabling translational research, an industry partnership is required. For the purpose of this FOA, "industry" is defined as a large or small, domestic, or foreign, pharmaceutical, biotechnology, or bioengineering company, or a related non-profit entity. The establishment of these public-private-partnerships is expected to extend the reach of the Center's comprehensive translational efforts, helping to ensure a focused, critical path through early-phase clinical trials for the most promising candidates. Centers will be encouraged to create partnerships/in-licensing opportunities and intellectual property strategies in compliance with NIH Intellectual Property Policy (https://grants.nih.gov/policy/intell-property.htm) to support advancing promising vaccine, and if applicable mAb, candidates into the clinic and to allow for hand-off to industry for advanced development. Centers are encouraged to develop and use intellectual property strategies that promote accessibility, similar to efforts from the World Health Organization (WHO), NIAID, and Bill & Melinda Gates Foundation (BMGF) to make COVID-19 vaccine and mAbs technologies accessible for the developing world (COVID-19 technology access pool (https://www.who.int/initiatives/covid-19-technology-access-pool)).

NIAID Resources

Each ReVAMPP Center is expected to provide lead candidates for comparative studies using NIAID's preclinical services or other gap filling mechanisms. It is anticipated that after award NIAID's comprehensive suite of preclinical services (Resources for Researchers | NIH: National Institute of Allergy and Infectious Diseases (https://www.niaid.nih.gov/research/resources)), NIAID's Division of Allergy, Immunology, and Transplantation (DAIT) programs (Adjuvant Discovery Program (https://www.niaid.nih.gov/research/adjuvant-discovery-program), B cell and T cell Epitope Discovery program, etc.) and repositories could be leveraged as needed to support ReVAMPP objectives including reagent storage/development, assay and animal model harmonization and evaluation, and development of lead vaccine and mAb candidates developed under this Network. NIAID program officials will connect ReVAMPP investigators to these services.

ReVAMPP Network interactions

Collaboration and data sharing among ReVAMPP Centers and with external partners is key to successful achievement of the ReVAMPP network goals. Therefore, each ReVAMPP Center must adopt FAIR data principles (https://www.go-fair.org/fair-principles/) as per the NIH Data Management Sharing Plan (DMSP (https://sharing.nih.gov/data-management-and-sharing-policy)) and manage and rapidly share data within the Network of ReVAMPP Centers under the direction of the ReVAMPP CDSC. This data will be shared confidentially within the Network to harmonize reagents, assays, and animal models and exchange knowledge on structure/function-based vaccine solutions and antigen/immunogen designs as well as assess the utility of vaccine technology platforms for virus families. To assist in the administration and management of information exchange, a separate ReVAMPP CDSC will be directing these efforts for the Network. The ReVAMPP CDSC will facilitate collaboration within and outside the Network, and each ReVAMPP Center will be expected to comply in accordance with network-wide timelines. As such, the CDSC will develop network-wide data sharing platforms and templates for all types of data generated by the ReVAMPP Centers. This may include information/data 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 the Centers, a network wide ReVAMPP governance structure, provide guidance as to engagement with stakeholders within and outside the research centers, and collate information and facilitate exchange with other NIAID Programs, U.S. Government partners and other key stakeholders, including the WHO, BMGF, and Coalition for Epidemic Preparedness Innovations (CEPI), among others as appropriate.

ReVAMPP Center Structure

Each Center in the ReVAMPP Network will be organized around a multidisciplinary research program with interrelated projects focused on the prototype member(s) of virus families that have the potential to emerge as pandemic pathogens to inform a strategy for development of vaccines for the prototype pathogen and other closely related family members based on shared functional and structural properties, with the objective of translating research results to product development. Each Center is expected to include the following components:

Administrative Core

An Administrative Core will manage, coordinate, and supervise all Center activities under the direction of the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s). The Administrative Core will also ensure seamless communication across the projects through regular meetings of Center participants and the ReVAMPP network as directed by the ReVAMPP CDSC. In addition, the Administrative Core will coordinate detailed communication of Center efforts and progress with NIAID program staff, including organizing annual ReVAMPP Center progress meetings with NIAID, and participating and assisting with ReVAMPP Network meetings as necessary virtually and/or at NIAID. The Administrative Core will also be responsible for leading coordination and collaboration efforts with the CDSC and other Centers within the Network and ensuring the Center program complies with requests from the CDSC and NIAID program staff.

Scientific Advisory Board

Each Center will include 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 Center. The SAB will facilitate Go/No-Go decision making and recommend new research directions as appropriate. The SAB will participate in annual ReVAMPP Center progress meetings at NIAID to review Center activities and evaluate progress, adherence to milestones and timelines, and the continued relevance of each Research Project, including those within industry partnerships, to the overall Center objective(s). If requested by the PD(s)/PI(s) and NIAID Project Scientist, the SAB will provide a summary written evaluation of the group's activities and recommendations following the annual ReVAMPP Center progress meeting. The SAB will include at least 5 non-conflicted external advisors. Centers must have at least 2 of the external advisors who have demonstrated and relevant industry-level 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.*

Data Management Core

A Data Management Core will be responsible for housing data generated by the Center and managing the transfer of data within the Center and to the ReVAMPP Network as directed by the ReVAMPP CDSC, including the upload of data to the ReVAMPP Network data sharing platforms. The Data Management Core will also be responsible for collating and collecting information from the Center as requested by the ReVAMPP CDSC or NIAID program staff in accordance with network-wide timelines, and ensuring the Center complies with network data sharing policies.

Scientific Cores

A Center may include up to three Scientific Cores to support resources and/or facilities that are essential for the activities of two or more Research Projects, but inclusion of Scientific Cores is not required. Scientific Cores are intended to only serve the needs of Center project researchers and they may not conduct research independent of the Research Projects. In lieu of a Scientific Core, use of existing institutional core facilities may be included in specific Research Projects.

Research Projects

Each Center must include at least 2 and no more than 5 interdependent Research Projects focused on prototype members of the priority virus families of pandemic potential listed above. At least one Research Project must focus on development of vaccines, and other Research Projects may focus on additional vaccine development, early mAb development or foundational research in virology, immunology, pathology, and structural biology necessary for such development. Each Research Project must clearly and directly contribute to the Center's approach and objective(s). The Center PD(s)/PI(s) will monitor all Research Projects and actively promote efforts that foster integration, collaboration, and synergy across the program. Research Project Leaders may be affiliated with either an academic organization or industry.

Research Projects are expected to incorporate state-of-the-art technology and approaches and may include consortium arrangements for required activities. Applicants are encouraged to carefully consider the scope and range of research proposed and develop a Center that is coherent overall and consistent with available resources and personnel.

Example ReVAMPP Centers:

Center programs and objectives may range from research and development of single or multiple prototype vaccines targeting one or more of the priority virus families, and activities may range from early basic research aimed at gaining the foundational knowledge needed to design a generalizable vaccine strategy, to mAb discovery and characterization to late-stage preclinical vaccine development with industry participation. Examples of hypothetical ReVAMPP Centers follow:

Example 1:

Center for Countermeasure Discovery for Bunyaviruses

Administrative Core

Data Management Core

Scientific Core: Virology, Reagents, and Assays

Scientific Core: Structural Biology of Viral Proteins, Vaccines, and Monoclonal Antibodies

Research Project 1: Viral receptor discovery and characterization for Nairoviruses and Peribunyaviruses

Research Project 2: Characterization of the human immune response and antibody discovery

Research Project 3: Antigen design and immunogenicity evaluation of Nairovirus vaccines

Research Project 4: Animal model development and determination of CCHF and LAC pathogenesis

Research Project 5: Antigen design and immunogenicity evaluation of Peribunyavirus vaccines

Example 2:

Paramyxovirus and Arenavirus Vaccine and Monoclonal Antibody Development Center

Administrative Core

Data Management Core

Scientific Core: Animal model development and candidate vaccine and monoclonal antibody evaluation

Research Project 1: Antigen design and immunogenicity testing of Paramyxovirus vaccine candidates

Research Project 2: Antigen design and immunogenicity testing of Arenavirus vaccine candidates

Research Project 3: Determination of correlates of protection for different vaccine platforms

Research Project 4: Preclinical evaluation of monoclonal antibodies targeting paramyxoviruses and arenaviruses

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)).
- Centers proposing only monoclonal antibody discovery and development without vaccine development.
- Projects proposing toxicology studies or GMP manufacturing for vaccines.
- Projects proposing later-stage development of monoclonal antibodies including process development, tissue cross-reactivity studies, toxicology studies, or GMP manufacturing.
- Centers proposing research on Coronaviridae, Orthomyxoviridae or other virus families not listed under *Priority Viral Families for Pandemic Preparedness*.
- Centers proposing research on Flaviviridae or Togaviridae families which are covered in the companion RFA-AI-22-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-22-019.html)
- Applications that do not include a clear section on Milestones with Go/No-Go criteria for the Overall Program and each individual project.

This FOA supports research on virus families from Bunyavirales, Paramyxoviridae and Picornaviridae. For ReVAMPP Center programs proposing research on virus families from Flaviviridae and Togaviridae see the companion FOA, RFA-AI-23-019 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html). The ReVAMPP Coordinating and Data Sharing Center (CDSC) will oversee data coordination and sharing for the ReVAMPP Centers in the ReVAMPP Network (companion FOA, RFA-AI-23-021 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-021.html)).

For additional information about the Research and Development of Vaccines and Monoclonal Antibodies for Pandemic Preparedness (ReVAMPP) Centers), see the "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 FOA. Details about webinar registration will be available at this same FAQ link shortly after FOA publication. Participation in the webinar is not required to submit an application in response to this FOA.
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. Only those application types listed here are allowed for this FOA.

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 ~$70-85M in FY2024 to fund 5-6 awards. Funding in subsequent years is subject to the availability of funds.

Award Budget

Application budgets are not expected to exceed $10M direct costs/year 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)

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 Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

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.

- 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://era.nih.gov/) - 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 his/her 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 listed as a PD(s)/PI(s) for this FOA will not be eligible to be listed as PD(s)/PI(s) on applications submitted to the companion FOA (RFA-AI-23-019) (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-019.html) ReVAMPP Centers for Flaviviridae and Togaviridae but can participate as collaborators on subcomponents of those Centers. Applicants to this FOA will not be eligible to submit to or participate in the companion ReVAMPP CDSC FOA (RFA-AI-23-021 (https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-021.html)) due to the centralized role of the CDSC in the Network coordination and communication.

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, 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 or an institutional system-to-system solution. A button to apply using ASSIST is 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 Multi-Project (M) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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:

Frank De Silva, Ph.D.
Telephone: 240-669-5023
Email: fdesilva@niaid.nih.gov (mailto:fdesilva@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.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	12	Required	1	1
Data Management Core	Data Management Core	6	Required	1	1
Core	Core	6	Optional	0	3
Project	Project	12	Required	2	5

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing a multi-component application.

The application should consist of the following components:

Overall: required

Administrative Core: required

Data Management Core: required

Scientific Cores: optional, maximum 3, each Scientific Core must support at least two Research Projects

Projects: required, minimum 2, maximum 5

Overall Component

When preparing your application, use Component Type Overall .

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

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Facilities & Other Resources

Describe any unique features in the environment and/or resources that make this a strong research program.

In the " Facilities & Other Resources" attachment include a clearly marked section titled BSL3/4 facilities detailing availability of adequate access to BSL3/4 biocontainment facilities to support the proposed Center program, if applicable. Applicants must identify all Research Projects within the application that will require BSL3/4 containment facilities and provide a description of facilities including that are available currently or planned at either the applicant institution or though consortium institutions. A table format may be used to list each activity that requires BSL3/4 access and the likely facilities to be used. All information on BSL3/4 facilities should be contained in the Overall and not within individual Research Projects.

If institutional core facilities will be utilized, in a clearly marked section titled "Institutional Core Facilities" describe how institutional core facilities will be used to support the Research Projects.

Project/Performance Site Locations (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims: List in priority order, the broad, long-range objectives, and goals of the proposed Center. Concisely describe the Center objectives.

Research Strategy: This narrative section summarizes the overall research plan for the multi-project application. The multi-project application should be viewed as a confederation of interrelated research projects, each capable of standing on its own scientific merit, but complementary to one another. This is an important section for it provides the group of investigators an opportunity to give conceptual wholeness to the overall program by giving a statement of the general problem area and by laying out a broad strategy for attacking the problems.

Applicants should clearly define the Center program and its significance regarding the scientific approach in terms of discovery and development of vaccines, and if applicable early development of mAbs, against prototype viruses from families with high pandemic potential. Discuss the rationale behind the overall approach and prototype selected for research and development including the public health need and benefit of a successful effort, and the range of activities being pursued. For the prototype selection justification, considerations may include, but are not limited to, how well the prototype reflects properties shared by other members of the family, whether a single prototype is sufficient or whether multiple prototypes are needed to address differences amongst family members, the ease of working with the prototype virus, and whether vaccines against the prototype would have potential value for current public health needs. Include a discussion of the current state of foundational knowledge and maturity of product development for the proposed virus families, and how this Center program will advance vaccine development, and if applicable, early development of mAbs, and enhance the ability to respond rapidly to an emerging virus from the prototype virus's family. Additionally, each application must detail how each Research Project and Core contributes to the Center program, objectives, and project interdependence. Applications should outline expected synergies provided by the proposed Center structure and any other special features that make this application strong or unique.

Milestone Plan: In a clearly labeled section titled Program Milestones and Timelines , applicants should describe specific quantifiable milestones for the overall program, including detailed quantitative and qualitative criteria for Go/No-Go decisions by annum and include annual timelines for the overall research program and for tracking progress from individual research projects and Cores. This plan must include Go/No-Go criteria to be met by the end of Year 3 of the award for continuation to Phase II. Milestones must specify the outcome(s) for each activity. Milestones should be quantifiable and scientifically justified, and include major milestones from the individual research projects and Cores. Include any milestones that are integrated from independent research projects or Cores. 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 Center.

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

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.
- Investigators must develop data structures that are FAIR (FAIR Principles - GO FAIR (go-fair.org) (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.go-fair.org%2Ffair-principles%2F&data=05%7C01%7Cchelsea.boyd%40nih.gov%7C8247f78a75c04c5ea99208db1b643066%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C638133 This will produce data sets that are harmonized and facilitate progressive data sharing models. Applications must provide a well-thought-out plan for how data will be shared using the FAIR principles.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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 (Overall)

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

Administrative Core

When preparing your application, use Component Type Admin Core.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the Are Human Subjects Involved? and 'Is the Project Exempt from Federal regulations? questions.

Vertebrate Animals: Answer only the Are Vertebrate Animals Used? question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of Other with Category of Project Lead and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

- The Core Lead must commit at least 0.6 person months effort per year to these responsibilities.
- Include funds for the overall administrative effort, collaborative activities, communications, and publications.
- Include costs related to Regulatory expertise as defined effort or periodic consultation.
- Include funds for the PD(s)/PI(s), Project Leaders, additional Center Key Personnel and postdocs/researchers/students (at the discretion of the PD(s)/PI(s)), to travel and attend annual ReVAMPP Network-wide review meetings to be held over an approximately 1-3 full days in the Rockville, MD area or other NIAID-approved site for data presentation, progress evaluation and related activities.
- Include funds for the PD(s)/PI(s), Project Leaders, external SAB members, and additional Center Key Personnel (at the discretion of the PD/PI) to travel and attend annual mandatory ReVAMPP Center progress meetings at NIAID in Years 1-4 of the project period.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: List in priority order, the broad, long-range objectives, and goals of the proposed Core. In addition, state the Core's relationship to the Center's program and how it relates to the individual Research Projects or other Cores in the application.

Research Strategy: The Administrative Core must include a Management Plan that identifies and discusses: The Administrative Core organizational structure, the roles of Administrative Core personnel, the facilitation of communications throughout the Center, including with industry partners and how a strong collaborative environment will be established within the Center. The plan should specifically address continual evaluation of research and development progress, communications, group meetings and teleconferences, the identification and proposed resolution of problems and engagement of the NIAID staff as appropriate. A description of how consortia (subcontracts) will be managed should be provided and should include how communications such as periodic meetings and conference calls will be organized, managed, and documented. The plan should also detail how Center and research-related travel will be managed.

Describe how the Center will coordinate communication and collaborations with the CDSC, NIAID Staff, and other Centers within the Network. Describe how the Administrative Core will ensure the Center program complies in a timely manner with requests from the CDSC and NIAID program staff.

Each Administrative Core must include the following:

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 Center 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. The SAB must include at least two members with relevant industry-level experience and procedures for identification and selection of the SAB should be included. *Candidates for the SAB MUST NOT be named in the application or contacted prior to completion of review activities.*

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.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **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#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.

Data Management Core

When preparing your application, use Component Type Data Management Core.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Data Management Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Data Management Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Data Management Core)

Human Subjects: Answer only the Are Human Subjects Involved? and 'Is the Project Exempt from Federal regulations? questions.

Vertebrate Animals: Answer only the Are Vertebrate Animals Used? question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Data Management Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Data Management Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of Other with Category of Core Lead and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Data Management Core)

Budget forms appropriate for the specific component will be included in the application package.

The Core Leader should commit to the Core at least 1.2 person months of effort.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Data Management Core)

Specific Aims: List in priority order, the broad, long-range objectives, and goals of the proposed Core. In addition, state the Core's relationship to the Center program and how it relates to the individual Research Projects or other Cores in the application.

Research Strategy: Describe the organizational structure and role of the Data Management Core in the overall Center research activities and include a Strategy for Management of Data Activities Plan that describes 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 Center to the ReVAMPP CDSC. 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 Data Management Core will ensure compliance with the ReVAMPP network-wide data sharing.

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.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Data Management Core)

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

Scientific Core

When preparing your application, use Component Type Core.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Scientific Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Scientific Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Scientific Core)

Human Subjects: Answer only the Are Human Subjects Involved? and 'Is the Project Exempt from Federal regulations? questions.

Vertebrate Animals: Answer only the Are Vertebrate Animals Used? question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Scientific Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Scientific Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of Other with Category of Core Lead and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Scientific Core)

Budget forms appropriate for the specific component will be included in the application package.

The Core Leader should commit to the Core at least 1.2 person months of effort.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Scientific Core)

Specific Aims: List in priority order, the broad, long-range objectives, and goals of the proposed Core. In addition, state the Core's relationship to the Center program and how it relates to the individual Research Projects or other Cores in the application.

Research Strategy: Describe and justify the role of the Core in the overall Center research activities, describe how the proposed Core activities will contribute to meeting the Center's goals and objectives, specify how a proposed scientific Core provides a unique service that cannot be obtained through institutional or commercial means, and explain the rationale for selection of the general methods and approaches proposed to accomplish the specific aims. Describe the facilities or services that will be provided by the Core including procedures, techniques, and quality control to ensure high quality outputs. In addition, this section should indicate the relevance of the Core to the primary objectives of the application. Provide details of the services or resources provided by the optional Cores to at least two Research Projects and clarify how the optional Cores are not duplicative of other services or facilities. Additionally, plans for staffing, managing, and prioritizing use of the Cores must be provided, as well as plans for determining fees to users if charging fees is necessary.

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.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Scientific Core)

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

Research Project

When preparing your application, use Component Type Project.

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

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. If required, the Data Management and Sharing (DMS) Plan must be provided in the Overall component.

SF424 (R&R) Cover (Research Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Project)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Project)

Human Subjects: Answer only the Are Human Subjects Involved? and 'Is the Project Exempt from Federal regulations? questions.

Vertebrate Animals: Answer only the Are Vertebrate Animals Used? question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Project)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of Other with Category of Project Lead and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Project)

Budget forms appropriate for the specific component will be included in the application package.

Each project leader must commit at least 1.2 person months effort to their project per year.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Project)

Specific Aims: List, in priority order, the broad long-range objectives and goals of the proposed project. Concisely describe the research activities to be performed. In addition, concisely state the individual Research Project's relationship to the Center program and how it relates to other projects or cores.

Research Strategy: Use this section to describe how the proposed research will contribute to meeting the Center objectives and explain the rationale for selecting the methods to accomplish the specific aims, and the biological significance of the research.

At least one Research Project must focus on development of vaccines, and other Research Projects may focus on additional vaccine development, early mAb development or foundational research in virology, immunology, pathology, and structural biology necessary for such development.

Describe the research design, conceptual procedures, and analyses to be used to accomplish the specific aims of the project. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, techniques, methodologies, tools, or technologies for the proposed studies that will fundamentally advance how vaccines, and if applicable mAbs, will be developed. Discuss whether traditional approaches will be used in a new, novel way and how reliable, validated methods that mitigate risk will be balanced with innovative new approaches to expand foundational knowledge and advance product development. Describe plans for how the vaccine strategies and other research findings from the prototype virus research will be applied broadly to other viruses within the family to assess the breadth of the approach within and outside of the virus family to validate the generalizability of the approach. Discuss how the vaccine technologies or platforms used can be rapidly adapted for response to known or novel emerging viruses within the same family. If proposing early mAb development, describe plans for the assessment of whether antibodies with similar epitopes and/or properties of identified lead mAb candidates for the prototype virus are effective against other viruses within the same family. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

Milestone Plan: In a clearly labeled section titled Project Milestones and Timelines" include a clear delineation of goals with measurable milestones, including detailed quantitative and qualitative criteria for Go/No-Go decision-making, and a timeline for the attainment of each goal and milestone and should be reflected in the Milestone Plan for the overall Program. This plan must include Go/No-Go criteria to be met by the end of Year 3 of the award for continuation to Phase II. 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, for example, identification of protective epitopes, animal model development, vaccine or mAb candidate down-selection, identification of correlates of protection, validation of vaccine or mAb strategies for other family members, and analysis, sharing and publication 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 Center.

Industry Expertise and Regulatory Considerations: For projects proposing early vaccine development, describe how industry partners will be identified and incorporated into the proposed project including a timeline for inclusion. For projects proposing IND-enabling later stage vaccine development, NIAID requires Centers to include active participation of an industry partner to ensure access to vaccine technology platforms, expertise in manufacturing, clinical development, and regulatory pathways. Applicants should describe the role of this partner in the proposed project and/or team to facilitate discovery, candidate evaluation and/or product development. For the purpose of this FOA, "industry" is defined as a large or small, domestic or foreign, pharmaceutical, biotechnology, bioengineering, or chemical company, or a related non-profit entity.

Additionally, each Center is expected to consider anticipated regulatory barriers for the targeted vaccine technology, particularly for new technology platforms for which there are no precedents for FDA approval. Describe anticipated regulatory barriers and propose research and/or strategies to resolve or overcome these barriers. For a project where multiple and/or complementary expertise is required, discuss plans for coordination among investigators and other collaborators including industry partners and the process to overcome obstacles to achieve the Center aims.

Letter of Support: For projects proposing later stage vaccine development where an industry partner is required, provide a Letter of Support from the Industry partner(s). For projects without later stage vaccine development, a Letter of Support from Industry partners may be included. Provide any additional letters of support that are specific to this project.

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.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Research Project)

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

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 described throughout the SF424 (R&R) Application Guide.

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) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//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.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (//grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

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) and component Project Leads 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.

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

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).

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 - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Program 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 Program proposed).

Scored Review Criteria - Overall

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

Significance

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

Specific to this FOA:

How well does the application describe a single clearly defined and scientifically justified program that supports the development of vaccine strategies for prototype pathogens that can be applied to other family members? Understanding that the different virus families have different levels of existing foundational knowledge and different states of maturity for product development, how appropriate is the research to increase knowledge to advance vaccine, and if applicable mAb, development for the proposed virus family? If successful, how likely will the proposed Center program enhance the ability to rapidly respond to an emerging known or currently unknown virus from the prototype virus's family?

How well does the Center as a whole leverage scientific gains and synergy by combining the component projects into a multi-project program beyond the gains achievable if each project were pursued independently? To what extent is the program cohesive and do the Research Projects and Cores relate to a common objective demonstrating cohesion, multidisciplinary interactions, and coordination? How well are the scientific cores justified relative to the Overall?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA:

To what extent is there an appropriate balance between investigators with expertise studying the virus families and investigators with product development experience? To what extent is there appropriate and adequate representation of investigators with the necessary vaccine discovery and development experience and expertise? For projects involving IND-enabling later stage activities, how appropriate are industry partnerships proposed to support this effort? For early development projects, how appropriate is the plan and timeline for identification and incorporation of industry partnership to facilitate rapid transition of vaccines into clinical development? How sufficiently are the academic and industry partners coordinated to facilitate discovery, candidate evaluation and/or product development? How adequate is the level of commitment of the PD(s)/PI(s) and key personnel to manage the overall Program?

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?

Specific to this FOA:

To what extent is there an effective balance between reliable, validated methods that mitigate risk with innovative, new approaches that could expand the field? How well have the investigators used traditional approaches in new, novel ways? To what extent are there techniques, methodologies, concepts, or processes which fundamentally advance how vaccines, and if applicable mAbs, are developed?

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:

How well is the selection of the prototype(s) justified, and likely to generate generalizable knowledge that can be applied to develop vaccines for related viruses? To what extent do the investigators propose a well-reasoned plan to evaluate their vaccine approach broadly to other viruses within a given family to validate the generalizability of the approach? If proposing early mAb development, to what extent do the investigators propose a well-reasoned plan to validate the generalizability of the approach by assessing whether mAbs with similar epitopes and/or properties of lead candidate mAbs against the prototype virus are effective against other viruses within a given family?

To what extent does the approach use technologies and platforms that could be rapidly adapted for response to known or novel emerging viruses within the same family? How appropriate is the proposed project given the current level of knowledge and vaccine development landscape for the virus family? For programs that include IND-enabling translational research, how well does the approach take into consideration the anticipated regulatory process and any anticipated regulatory barriers and resolutions?

How well are the overall Timelines and proposed Milestones defined with quantifiable measures and criteria that are appropriate for enabling clear Go/No-Go decisions and assessing the success of the overall program? How well do the overall milestones support the goal of advancing generalizable vaccine, and if applicable, mAb solutions? How realistic are the timelines proposed for achieving these overall milestones?

How well do the individual projects contribute, either directly or through generation of essential resources or foundational knowledge, to the identification of generalizable vaccine, and if applicable mAb, approaches for a given virus family? How well are the Research Project milestones defined with quantifiable measures and appropriate for enabling clear Go/No-Go decisions and assessing the success of the individual Research Projects? How well do the investigators provide a clear plan for achieving defined Research Project milestones and timelines? To what extent are the timelines proposed for achieving these Research Project milestones realistic or inclusive of necessary steps?

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: To what extent do the investigators have access to facilities with the appropriate biocontainment and capacity and resources for the proposed research?

Additional Review Criteria - Overall, Administrative Core, Data Management Core, Scientific Core, and Research Projects

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.

Administrative Core

How appropriate is the administrative and organizational structure and adequate to achieve the goals of the proposed program? How appropriate is the Management Plan for fiscal accountability and communication within the program? How appropriate are the plans for coordination and the establishment of a strong collaborative environment for the program? How adequate are the plans for communication among the Centers and with the CDSC to facilitate collaborative activities? How appropriate is the plan for collaboration with industry partners clear given the state of the program? How sufficient is the time and effort committed by the PD/PI and Key Personnel to adequately manage the Program? To what extent do the investigators provide a well-thought-out plan for coordination, communication, and collaborations with the CDSC, NIAID Staff, and other Centers within the Network? How well have the applicants developed a plan for ensuring timely communication and collaboration with the CDSC, NIAID Staff, and other Centers within the Network?

Data Management Core

How appropriate and adequate is the organizational structure to achieve the goals of the proposed program? How appropriate is the Strategy for Management of Data Activities Plan for the type of data generated by the research program? How sufficient are the described data management activities sufficient? To what extent do the investigators provide a well-thought-out plan for network-wide sharing of the data generated by the Center?

Scientific Core

How sufficiently is the Core justified? To what extent does it support at least two Research Projects? How well is the core connected to the central focus of the overall program? To what extent are the facilities or services provided by the core (including procedures, techniques, and quality control) high quality and well-justified? How effectively will the services be used? To what extent are the core leader and key personnel well qualified and is there an adequate commitment of time?

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 - Overall, Administrative Core, Data Management Core, Scientific Core, and Research Projects

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 Resource Sharing Plan(s) (e.g., 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. 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 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=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.6. 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 (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: Grantee 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) (https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf) in which the recipient agrees, as a term and condition of receiving the grant, to administer their 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. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. 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)andhttps://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 the Projects and Cores within the overall Program. 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 projects within the guidelines of the FOA and retains primary responsibility for the planning, directing, and executing the proposed scientific activities
- The PD(s)/PI(s) will monitor all Research Projects and actively promote efforts that foster integration, collaboration, and synergy across the projects.

- The PD(s)/PI(s) will be responsible for ensuring timely compliance with ReVAMPP Network policies for template usage, data sharing, and collaboration.
- 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 ReVAMPP Center Progress meeting activities. The annual ReVAMPP Center 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.
- Advertising the availability of the Program 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 PDs/PIs.

- 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 ReVAMPP Network.
- The NIAID Project Scientist will monitor the progress of the Center, help coordinate research approaches among all Centers funded through the FOA 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, Program Staff will assess the progress towards development of generalizable approaches for vaccine, and if applicable early development of mAbs, for virus families of pandemic concern through the accomplishment 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, evidence of collaboration with other ReVAMPP Centers, compliance with the ReVAMPP Network data sharing and CDSC requests, programmatic priorities, and the availability of funding.
- The NIAID Project Scientist will keep the ReVAMPP Centers 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 recipients to other NIAID resources, as well as assist the research efforts of the Program 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(s)/PI(s) 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). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

Recipients will be required to adhere to the FAIR Principles (FAIR Principles - GO FAIR (go-fair.org) (https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.go-fair.org%2Ffair-principles%2F&data=05%7C01%7Cchelsea.boyd%40nih.gov%7C8247f78a75c04c5ea99208db1b643066%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C638133889348
for data management and sharing.

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 FOAs 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 the threshold. 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 75.113and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, 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 75and 2 CFR Part 200 Award Term and Condition 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)

Frank De Silva, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5023
Email: fdesilva@niaid.nih.gov (mailto:fdesilva@niaid.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.

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