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

Computational Models of Immunity (U01 Clinical Trial Not Allowed)

Activity Code

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

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-AI-19-011

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

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

93.855

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) solicits applications developing computational models of immunity that advance understanding of the mechanisms required to induce and/or maintain protective immunity to infectious pathogens, other than HIV, and/or vaccines against such pathogens. The main goal of this FOA is to advance development and application of computational models of immunity that are refined through iterative immunological

experimentation to validate and improve the utility and robustness of the computational models. Another goal of this FOA is to make the computational models and data developed under this initiative readily available to the broader research community for further refinement or direct use in biological experimentation. This program will also support workshops and symposia to foster the use of computational models of immunity by the broader research community.

Key Dates

Posted Date

January 30, 2019

Open Date (Earliest Submission Date)

May 10, 2019

Letter of Intent Due Date(s)

May 10, 2019

Application Due Date(s)

June 10, 2019, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on this date.

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

November 2019

Advisory Council Review

January 2020

Earliest Start Date

March 2020

Expiration Date

June 11, 2019

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000),except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications to develop computational models of immunity to infectious diseases other than HIV/AIDS. Applications are sought to develop, refine, and validate computational models of immune responses: (1) during or following infection, and/or (2) before and after vaccination against an infectious disease through an iterative approach involving computational studies and immunological experimentation. Investigators are encouraged to develop widely generalizable models or those that focus on immunity to infectious diseases other than HIV/AIDS.

This FOA seeks to advance our understanding of the complex immune mechanisms triggered by infection and/or vaccination through the development and application of computational models of immunity, coupled with immunological experimentation to validate and improve the utility and robustness of the computational models. Another goal is to share the computational models and data developed under this initiative, via appropriate public repositories, with the broader research community for further validation and refinement, as well as to encourage direct use of the immunological data and computational models for development of novel/improved vaccines and therapeutics to prevent and treat infectious diseases. The program will also support workshops and symposia to foster the use of computational models of immunity by the broader research community.

Background

The generation of protective immunity to natural infections or vaccines requires a coordinated, carefully regulated series of events involving a variety of cell types within different tissues and organs. Computational modeling methods hold great promise to deepen our understanding of this dynamic system, as they have already provided novel insights

into various aspects of immune system function, including: antibody production and maturation/somatic mutation; T cell activation; T cell development and differentiation; generation and maintenance of immunological memory; and host:pathogen interactions. Computational modeling approaches often utilize data generated from standard immunological assays as the basis for schematic representations of the immune system or integrate knowledge of different immune components to predict the effects of various perturbations on immune function. Advances in high through-put technologies and systems biology approaches also offer a wealth of multidimensional immunological data for computational modeling. In addition to providing novel insights of basic immune system function, computational models may also be developed to identify key variables and their importance in human immune responses to natural infection or experimental vaccines *in silico*, either through comparison of results from *in vivo* and *in vitro* animal studies with *in vitro* studies using human cells, or direct calculations from *in vitro* human studies coupled with analysis of *in vivo* human data from related infections or vaccines. Such studies would accelerate the development of vaccines and immune-based therapeutics for infectious diseases and could be especially useful for vaccines against emerging/re-emerging infections and for infectious diseases for which vaccine development has been difficult, including where vaccine efficacy or induction of durable immunity have been sub-optimal.

In 2005, NIAID established a computational modeling of immunity program entitled, Modeling of Immunity for Biodefense (MIB). This long-standing program has supported the development of novel or improved computational models to analyze and predict human immune responses to infection, vaccination, or immune-based therapeutics to protect against NIAID Category A, B and C Priority Pathogens (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens). The most recent MIB awardees have provided computational models for analysis of adaptive immune response to influenza vaccination and infection; structure-based design of antibodies and vaccines; and insights into the dynamics and evolution of immune responses to influenza viruses. In addition, much of the biological data used to develop the computational models from current and previous MIB awardees have been made available through the ImmPort database (http://www.immport.org/immport-open/public/home/home), an NIAID-supported public resource providing immunological datasets and data analysis tools to the broader research community. The computational models and datasets developed under the MIB projects could serve as a foundation for further advances in computational immunology.

The broader field of computational biology has contributed significantly to our understanding of basic physiological mechanisms and is also being applied to clinical diagnoses and/or therapeutic interventions. Specifically, computational modeling of HIV viral replication dynamics has uncovered the major mechanism of anti-retroviral drug resistance and suggested possible treatments for long-term prevention of drug resistance and elimination of viral reservoirs in infected individuals. Computational modeling also enabled investigators to postulate and test that lack of boosting with anti HA antibodies may be due to epitope masking as opposed to alternative models. Furthermore, MIB investigators have made improvements in predicting anti-influenza antibody antigen interactions with an iterative approach of computational refinements and traditional experiments with binding and functional assays. These contributions may well allow for a more universal and effective approach to an influenza vaccine in the future.

A long-term goal of this program is to develop computational immune models that will accelerate development of novel/improved therapeutics and vaccines. Such efforts may ultimately require higher order modeling and/or the integration of computational models of specific immune parameters into larger models of immune function. Several hurdles currently exist regarding model sharing and integration, including inaccessibility of the computational models due to inadequate annotation methods or lack of standards for model sharing. In addition, gaps in knowledge of critical immune parameters and availability of quantitative immunological data inhibit model building. Efforts to refine standards for sharing computational models of immunity and to support quantitative immunological studies will help advance the field of computational immunology and hasten the development of improved vaccines and therapeutics against infectious diseases.

Research Objectives

The goal of this program is to support the development and/or refinement and validation of computational models of immunity to infection or vaccination, through an iterative process that includes direct biological experimentation coupled with model development, refinement and validation. For this FOA, computational modeling is defined as the use of mathematical approaches and/or computer simulations to represent or describe biological phenomenon, with

the goal of advancing understanding of the biological processes being modeled. The computational models developed under this program may target one or multiple scales of immune function, from molecular to whole organism responses. In addition, the computational models may be data-driven or hypothesis-based mechanistically-driven and may be generalizable to multiple types of immune perturbations (*e.g.*, different types of infections, vaccines, environmental factors etc.). Immunologic experimentation proposed in the application must be used to develop/refine and validate the computational models being produced.

To promote public access to the computational models and data generated through the CMI program, all CMI Principal Investigators (PIs) funded under this initiative will be expected to share their computational models through a publicly accessible repository such as BioModels (http://www.ebi.ac.uk/biomodels/) and their data through ImmPort (http://www.immport.org/immport-open/public/home/home) or other public portals designated by NIAID, consistent with achieving the goals of the program.

This program is milestone-based and includes the flexibility to quickly redirect or replace research projects during the funding period. Milestones will be negotiated with NIAID staff prior to award and reviewed on an annual basis.

Specific Areas of Research Interest

Immunological areas of interest for computational model development, refinement and validation include, but are not limited to those listed below:

- Dynamics of innate immune responses to pathogenic infections, immune-based therapeutics, or vaccination, including adjuvant functionality, such as:

- elucidation of signaling pathways and regulatory networks of Toll-Like Receptors (TLR's), RIG-I like Receptors (RLRs), Nod-Like Receptors (NLRs), and other pathogen recognition molecules that play a role in protective immunity;
- examination of mechanisms for expression and activation of anti-microbial peptides and other host anti-microbial molecules; and/or
- comprehension of the mechanisms by which innate immunity orchestrates or cooperates with adaptive immune responses to provide protection against infections or in response to vaccination.

- Elucidation of adaptive immune pathways leading to protective immunity to infection or vaccination, including such events as:

- mechanisms of T cell activation, effector function, and memory in response to infection, vaccination, or therapeutic interventions;
- mechanisms of B cell activation including: plasma cell differentiation, antibody production and class switching, and generation of memory;
- effects of antigen processing and presentation events, such as antigen presenting cell (APC) maturation, differentiation, and function during infection with pathogenic organisms, or following vaccination or immunotherapeutic interventions against these pathogens on the induction and maintenance of protective immunity; and/or
- interplay of mucosal and systemic immune responses on the development, progression and longevity of a protective immune response to infection or vaccination.

- Elucidation of homeostatic mechanisms controlling induction and maintenance of protective immunity, while limiting immune-mediated pathology.
- Determination of the mechanisms governing protective immune receptor:antigen interactions, which can inform discovery or development of novel antigens, therapeutics or vaccines against infectious pathogens.
- Determination of the mechanisms regulating the effects of age, sex, microbiome, or immune status on host immunity to natural infection or vaccinations, such as seasonal or universal influenza vaccines.

In addition to original experiments, investigators are encouraged to utilize freely and publicly available datasets and computational modeling frameworks for building/refining computational models to address the immunological questions proposed in their projects.

Although clinical trials will not be supported under this initiative, studies may include the use of biological samples/data from planned, ongoing or completed independently-funded clinical trials.

NOTE: At least one of the aims of the combined immunology and computational research project must focus on human studies. Immunologic analyses using appropriate animal models also are permitted, where the animal studies will complement the human immunology studies and enhance computational model development/refinement.

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

- Clinical trials (Phases I - III), although the use of clinical samples and data obtained from independently funded clinical trials is allowed
- HIV/AIDS and related studies
- *In vitro* studies using only human cell lines, although human cell lines may be used in conjunction with primary human cells
- Animal studies in the absence of studies on human immunity
- Projects that focus on development of computational models of immunity in the absence of immunological experimentation to refine or validate the models
- Projects that focus on development/refinement of computational models to elucidate mechanisms of pathogen infection (including vector biology), replication, and/or dissemination either within a host or at the population level
- Epidemiological studies
- Applications that do not include at least one scientist with expertise in immunology and/or computational modeling as Program Director/Principal Investigator (PD/PI)

Organizational Structure

Each CMI application must propose a project that incorporates human immunological studies, within the specified scientific areas of interest, and proposes computational methods and modeling platforms that will allow ready integration with other models, and that are comprehensively annotated.

Each awardee will be required to develop/execute activities that encourage the use of computational modeling by the immunology community. Such activities may include workshops or scientific symposia to create opportunities to encourage the use of computational modeling of immunity.

The CMI Program awardees will work together to facilitate validation and integration of the models being generated, and to build centralized resources, such as common meta-data standards and tools, to facilitate the use of computational models of immunity by the broader research community (*e.g.*, biological ontologies, SBML extensions, annotation standards for computational models of immunity).

Steering Committee

A CMI Steering Committee will be established in collaboration with NIAID Program Officers to serve as the governing board of this collaborative research program.

External Advisory Board

After award of the grants, the NIAID will establish an External Advisory Board (EAB) by evaluating and prioritizing the scientific progress of the individual awardees and the overall CMI Program. EAB members will be selected by NIAID and investigators should NOT contact any individuals for the purpose of serving on this EAB, nor should they identify any such individuals in their applications.
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

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

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials
Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIAID intends to commit $4.0 million in FY 2020 to fund 3 - 4 awards.

Award Budget

Application budgets are limited to $750,000 direct costs per 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 project period is 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

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

Other

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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration , but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

The application must include at least one scientist with primary expertise in immunology and/or computational modeling as Principal Investigator or multiple Principal Investigators (MPI) for the entire program.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

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

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

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

Letter of Intent

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

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

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Geetanjali Bansal, Ph.D.

Telephone: 240-669-5073

Email: geetanjali.bansal@nih.gov (mailto:geetanjali.bansal@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
For this specific FOA, the Research Strategy section is limited to 30 pages.

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Facilities & Other Resources: Provide information regarding infrastructure available to support the data management and data sharing activities.

SF424(R&R) Senior/Key Person Profile

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

Include biosketches for key personnel, including at least one scientist with expertise in immunology and/or computational modeling as Principal Investigator (PI). Provide evidence that the key personnel have prior experience in computational modelling and/or immunology, as well as data management and sharing.

R&R or Modular Budget

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

- Budget funds to travel to Rockville, MD for: (a) kickoff meeting with NIH and other awardees shortly after awards are made, and (b) for an annual program progress meeting with the NIH and other awardees thereafter. For each of these meetings anticipate a 1-day meeting with a 2-night stay for the PI and up to three key personnel.
- Budget funds to support the organization and administration of workshops (2-3 days) and scientific symposia (1-2 days) to encourage the use of computational modeling by the broader immunology community. Assume the execution of one workshop and one symposium over the entire project funding period.
- Budget funds for key personnel to travel to 3 workshops (2-3 days each) and 3 scientific symposia (1-2 days each). Assume these will be held at CMI domestic locations.

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:
Specific Aims: Describe the immunological hypothesis or hypotheses to be tested and how the proposed computational models will facilitate testing of these hypotheses. Discuss how the study will provide valuable computational models of immunity and facilitate discovery of new knowledge on human immune status and responses to infection or vaccination.

Research Strategy: Describe the goals of the proposed program. Summarize the special features in the environment that make this application strong or unique.

Describe a research project, focusing on the development, refinement and validation of widely generalizable computational models of immunity, and on the generation of immunological data to support the computational model development, refinement and validation. Any development/refinement of bioinformatics tools proposed in the application should constitute a relatively minor effort within the project and be necessary for completion of the proposed studies. Discuss data collection and analysis methods in terms of quantitation, controls, and development/refinement/validation of the computational models of immunity. Describe annual milestones with a more detailed description for year one.

For samples provided by independently-funded clinical trials provide a description of the plans to implement and monitor Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), as appropriate.

Provide a plan for tracking community usage of the computational models developed under this program and for development and maintenance of a program-specific website (if one is proposed).

Describe the work to be completed to support organization and execution of one workshop and one scientific symposium over the life of the award focused on computational modeling of immunity. Include proposed workshop and symposia topics, advertising methods, and selection criteria for student travel awardees.

Letters of Support: Provide any institutional letters of support specific to the research program.

Include support letters from clinical trial sponsors, confirming access to clinical samples (where applicable).

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.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Include a plan to make CMI-supported data, computational models and other resources publicly accessible. These resources are expected to be implemented in a timely manner through ImmPort, BioModels or other appropriate public repositories, as determined by NIAID. Include a description of the data management and quality control systems and procedures to be used, including the transmission, storage, confidentiality, and retrieval of study data for data transfer.

Appendix:

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

Include the following (Required, if applicable):

- Synopsis of the protocol(s) used in any independently-funded clinical trial(s) from which samples/data will be obtained.
- Copies of the informed consent form(s) or draft informed consent form(s) for any proposed additional independent studies or independently-funded clinical trials.

PHS Human Subjects and Clinical Trials Information

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Section 2 - Study Population Characteristics

2.7 Study Timeline

If applicable, timelines should address the time needed to acquire samples from independently funded clinical research or clinical trials.

Section 3 - Protection and Monitoring Plans

3.1 Protection of Human Subjects

Human Subjects Involvement, Characteristics, and Design. For studies involving the use of identifiable human biospecimens collected from independently-funded clinical research or clinical trials, include both historical and current study information that is clearly distinguishable within the information requested in the study record forms.

Delayed Onset Study
Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11137), and procedures for foreign institutions 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.html?id=82380) , the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

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

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.
Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

What is the likelihood that the results of the study will provide valuable computational models of immunity and facilitate discovery of important new knowledge on human immune status and responses to infection or vaccination?

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?

Do the key personnel have sufficient prior experience in computational modeling and/or immunology ? Is the level of commitment and availability of the investigators adequate to manage the overall program? Is there sufficient effort and expertise dedicated to both data management and data sharing policies?

Innovation

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

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project ? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Is there a predominant focus on developing widely generalizable computational models of immune responses to infection or vaccination? If development/refinement of bioinformatics tools is included in the application, are these activities necessary for completion of the proposed studies and do they constitute only a relatively minor effort within the project? Will data collection and analysis methods be appropriate in terms of quantitation, controls, and development/refinement/validation of the computational models of immunity?

Will the immunological experiments proposed provide the required data for the computational modeling component(s) of the project? Are the human subject samples to be analyzed well characterized and appropriate for the study goals, available in sufficient numbers, and Is the timing of sample collection appropriate for the stated goals?

Are the plans for the organization and execution of the workshops and symposia adequate and appropriate, including proposed workshop and symposia topics, advertising methods, and selection criteria for student travel awardees?

If applicable, are the protocols, consent forms and draft consent forms complete , and is the information contained within those documents sufficient to determine the appropriateness of the samples to be used in the research proposed?

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?

Is there sufficient infrastructure to support the data management and data sharing activities?

Additional Review Criteria

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.
Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council.

The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.
Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).
A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).
Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a

Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

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

Cooperative Agreement Terms and Conditions of Award

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

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

The PI(s) will have primary responsibility for:

- Accepting close coordination, cooperation, and participation of NIAID Program staff in the scientific aspects of the project.
- Ensuring successful completion of the data- and model-sharing and other resource-sharing milestones within the time frame negotiated with NIAID after award.
- Negotiating access to any background datasets or resources proposed for use to conduct the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain any rights needed by the PI to perform the project. The PI must negotiate access to datasets or resources in a manner that will enable their use and redistribution, including incorporated data, consistent with the terms of this award.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.

NIH staff have substantial programmatic involvement that is above and beyond the normal

stewardship role in awards, as described below:

Two NIH Project Scientists will have substantial programmatic involvement as described below:

- Provide guidance for design and coordination of research activities and efforts
- Coordinate NIAID staff assistance, including participation in periodic on-site monitoring with respect to compliance with Federal regulations, quality control, accuracy of data recording, sample accrual, etc.
- NIAID program staff may negotiate modifications of sharing plans with awardees.
- Ensure that all CMI investigators conform to the CMI data-sharing, computational model-sharing, and other resource-sharing policies as appropriate
- Determine funding levels annually based on scientific progress (*e.g.*, meeting the mutually agreed upon milestones between NIAID and awardee) and/or compliance with the CMI data sharing, computational model-sharing, or other resource-sharing plans
- Facilitate collaborations with, and access to, other NIAID-supported research resources and services
- Facilitate negotiations with companies interested in participating in clinical studies with CMI investigators
- Advise in project management and technical performance
- Serve as liaison/facilitator among awardees and with the ImmPort database
- Have confidential access to data generated under this Cooperative Agreement, for use in the preparation of internal reports on the activities of the awardees
- Provide guidance on plans for incorporation of new technologies or other resources.
- Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

Both the PD(s)/PI(s) and the NIAID Project Scientist(s) will:

- Facilitate interactions with the ImmPort staff
- Review schedules for submission of MIB-generated data and data analyses from each CMI project to the ImmPort database for public dissemination
- Review schedules for submission of CMI-generated computational models and bioinformatics tools from each CMI project to public repositories (*e.g.*, BioModels) for public dissemination
- Promote compliance of CMI projects with the CMI policies and schedules for data and other resource-sharing
- Define procedures for the publication and/or oral presentation of results or data collected
- The final scheduling of workshops and symposia across the CMI Program will be determined in conjunction with NIAID staff and the CMI Steering Committee after award.
- Have the flexibility to quickly negotiate redirection of the research within the original scope of the application.
- Negotiate milestones prior to award, and review on an annual basis.
- After award of the grants, the NIAID will establish an External Advisory Board (EAB) to advise NIAID by reviewing, evaluating, and prioritizing the scientific progress of the individual awardees and the program.

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 CMI chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

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

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

Scientific/Research Contact(s)

Joseph J. Breen, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-292-4123
Email: jbreen@niaid.nih.gov (mailto:jbreen@niaid.nih.gov)

Timothy A. Gondré-Lewis, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-627-3566
Email: tglewis@niaid.nih.gov (mailto:tglewis@niaid.nih.gov)

Peer Review Contact(s)

Geetanjali Bansal, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5073
Email: geetanjali.bansal@nih.gov (mailto:geetanjali.bansal@nih.gov)

Financial/Grants Management Contact(s)

Mariama Diallo
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-7851
Email: Mariama.diallo@nih.gov (mailto:Mariama.diallo@nih.gov)

Section VIII. Other Information

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

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?02-01-19)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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