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

Computational Models of Influenza 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

- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html).
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).

Notice of Funding Opportunity (NOFO) Number

RFA-AI-23-056

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855

Funding Opportunity Purpose

This Notice of Funding Opportunity (NOFO) invites applications for the Computational Models of Influenza Immunity (CMII) Cooperative Agreement Program. The program will employ computational modeling and immunologic studies to advance our understanding of the requirements for improving anti-influenza immunity, including inducing broad immune protection and enhancing immune durability. This program will help inform design of universal or improved seasonal flu vaccines. Projects may lead to a better understanding of how pre-existing immunity and repeat exposures (natural infection and/or vaccines) shape an individual's immune "landscape." Predictive

modeling of adjuvants/vaccine formulations and experimental validation supported by this program should lead to enhanced host immune responses and universal or improved seasonal influenza vaccine efficacy.

Key Dates

Posted Date

September 13, 2023

Open Date (Earliest Submission Date)

December 26, 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 - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 26, 2024	Not Applicable	Not Applicable	July 2024	October 2024	December 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.

Expiration Date

January 27, 2024

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 How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in 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.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=RFA-AI-23-056) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support the development of computational models and immunologic studies that will advance our understanding of the requirements for improving anti-influenza immunity, including inducing broad immune protection, and enhancing immune durability that will inform design of universal or improved seasonal flu vaccines. Projects are expected to lead to a better understanding of how pre-existing immunity and repeat exposures (natural infection and/or vaccines) shape an individual's immune "landscape." Predictive modeling of adjuvants/vaccine formulations and experimental validation supported through this program also can enhance host immune responses and provide foundational information for further development of universal and improved seasonal influenza vaccines.

Background

The goal of this program is to develop computational models of influenza immunity that will accelerate development of novel or improved seasonal or universal influenza vaccines by advancing our understanding of the mechanisms/pathways needed to induce and sustain anti-influenza immunity, including broad immune protection and enhanced durability. Seasonal influenza epidemics, caused by influenza A and B viruses, result in 3–5 million severe cases and 300,000–500,000 deaths globally each year. The burden of influenza can vary widely between seasons, in part due to characteristics of the circulating viruses, the existing immunity in the population, and the effectiveness of seasonal influenza vaccines against the circulating virus strains.

The generation of broad protective immunity to natural influenza infection or vaccination requires a coordinated, carefully regulated series of events involving a variety of cell types. Computational modeling methods can 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.

NIAID is implementing the NIAID Universal Influenza Vaccine Strategic Plan (https://pubmed.ncbi.nlm.nih.gov/29506129/) through a variety of programs. Many NIAID-supported research studies involve the analysis of responses to influenza infection and vaccination in cohort studies or the testing of novel influenza vaccine candidates in clinical trials. Detailed analysis of the findings from these studies, especially using computational tools well-suited to complex and large data sets, has the potential to reveal new correlates of immune protection, or other predictive markers of response to both universal and seasonal influenza vaccines.

This initiative combines computational approaches and experimental techniques, with a wealth of existing data and clinical samples to create an opportunity for significant progress in developing and validating computational models of immunity to both influenza infection and vaccination. Such models and biologic insights will support further development of universal or improved seasonal influenza vaccines.

Research Objectives and Scope

This NOFO focuses on informing the development and refinement of seasonal and universal influenza vaccines by addressing outstanding questions in influenza immunity through immunological studies and computational modeling. For this NOFO, 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. Immunologic experimentation proposed in the application must be used to develop and/or refine and validate the computational models being produced. Integration of existing and/or publicly available molecular, genetic, cellular, patient and/or population-level data sets are encouraged. Applications are sought that propose well-integrated, cross-disciplinary research teams with strong computational, immunologic, and virology expertise.

Responsive research applications under this NOFO must focus on improving our understanding of the requirements for induction and maintenance of protective anti-influenza immunity, including induction of broad, durable immune protection, with the ultimate goal of informing design of universal or improved seasonal influenza vaccines. The computational models may be data-driven, macromolecular, or hypothesis-based mechanistically-driven and may be generalizable to multiple types of immune perturbations (e.g., infection, vaccination, pre-existing immunity, etc.). Projects must focus on human studies. Immunologic analyses using appropriate animal models are also permitted, where the animal studies will complement the human immunology studies and enhance computational model development/refinement. 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.

This initiative will support iterative computational and immunologic research on topics such as, but not limited to:

- Identification of the host immune parameters of response/non-response to existing or novel seasonal influenza vaccine formulations and/or candidate universal influenza vaccines.
- Elucidation of required immunologic parameters, beyond neutralization antibodies to viral hemagglutinin, that lead to protective immunity and can serve as correlates of protection to foster development of effective seasonal or universal influenza vaccines.
- Determination of how pre-existing immunity and repeat exposures (natural infection and/or vaccines) shape an individual's immune "landscape" and affect vaccine efficacy.
- Examination of the role of adjuvants/vaccine formulations in improving host responses and long-lived immunity, including in healthy individuals across the lifespan (infants, children, adults, and older adults), and immunocompromised populations.

In addition to computational models, applicants may propose the development and/or refinement of bioinformatic (data analysis) tools, but only as necessary for completion of the proposed studies, not as the focus of the application. Data-mining software that retrieves data from databases may be incorporated into proposals but should not be the focus of the application.

The Computational Models of Influenza Immunity (CMII) Program applicants will be encouraged to work together and with other NIAID-supported programs to facilitate validation and integration of the computational models being generated by this program. Recipients are encouraged to incorporate common meta-data standards and tools, to facilitate the use of computational models of influenza immunity by the broader research community (e.g., biological ontologies, SBML extensions, annotation standards for computational models of influenza immunity).

Applications that propose studies in any of the following areas will be considered non-responsive and will not be reviewed:

- Applications that are not focused on outcomes to influenza vaccination and/or infection.
- Applications based exclusively on infection or vaccination studies in animals.
- Clinical trials (any phase), although the use of clinical samples and/or data from independently funded studies is allowed and encouraged.
- Applications focused exclusively on virulence factors and/or pathology without consideration of immunological processes affecting the outcome of influenza infection or vaccination.
- Epidemiological and forecast modeling.
- Applications that focus on development of computational models of influenza immunity in the absence of immunological experimentation to refine or validate the models.
- In vitro studies using only human cell lines, although human cell lines may be used in conjunction with primary human cells.
- HIV/AIDS and related 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).

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments,

improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust. NIH encourages applicants to include a diverse group of scientists in their research programs, including individuals from underrepresented backgrounds (see NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html), Notice of NIH's Interest in Diversity and NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html), Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities).
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIAID intends to commit $8 million dollars in FY 2025 to fund six to eight (6-8) awards.

Award Budget

Application budgets are not expected to exceed $750,000 direct costs per year but must 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 NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)

- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- 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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) – (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) 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.

Inclusion of investigators with experience in computational modeling, immunology, influenza virology, data management and data sharing policies is encouraged.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.htm?id=82415). 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 NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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

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

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

The letter of intent should be sent to:

Kristin McNally, Ph.D. (She/Her)
Telephone: 406-375-9641
Email: mcnallyk@niaid.nih.gov (mailto:mcnallyk@niaid.nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed, with the following additional instructions:

For this specific NOFO , 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 NOFO.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

Budget funds to travel to Rockville, MD for: (a) kickoff meeting with NIH and other recipients shortly after awards are made, and (b) for an annual program progress meeting with the NIH and other recipients thereafter. For each of these meetings anticipate a 1.5 - 2-day meeting with a 2-3-night stay for the contact PI and up to four key personnel.

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.

Describe immunological experiments that will advance understanding of the immune mechanisms needed to induce and maintain broad protective influenza immunity and serve as correlates of protection to foster development of effective seasonal or universal influenza vaccines.

Discuss how the study will provide valuable computational models of influenza immunity and facilitate discovery of new knowledge on human immune responses to influenza infection, vaccination, and provide foundational knowledge for improvements to seasonal or universal influenza vaccine development.

Research Strategy: Describe the goals of the proposed program. Summarize the special features in the research and intellectual environment, such as the community of scientists, that make this application strong or unique.

Describe a research project, focusing on the development, refinement, and validation of computational models of influenza immunity, and on the generation of, and/or leverage of pre-existing, immunological data to support the computational model development, refinement, and validation.Discuss data collection and analysis methods in terms of quantitation, controls, development or refinement, and validation of the computational models of influenza immunity.

Describe the immunologic studies that will elucidate host immune responses that generate long-lived influenza immunity to natural influenza infection or vaccination.

Describe the source(s), and availability of human subject materials that will be available for immunological experimental assessment.

Describe how bioinformatics tools will used for data mining and data interrogation and will lead to enhanced development, refinement, and validation of the computational models of influenza immunity developed in this application.

If novel bioinformatic tool development is proposed, describe how the development of these tools are necessary for completion of the proposed studies and computational modeling effort.

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).

Discuss how FAIR (Findable, Accessible, Interoperable, and Reusable) data principles will be incorporated as part of the research strategy.

Describe annual milestones for the five-year program with a more detailed description for year one where program goals can be more rationally designed.

Letters of Support: Provide any institutional letters of support specific to the research program. Include support letters from clinical trial or repository 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.

Other Plan(s): Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

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

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
- Investigators are encouraged to use NIH-supported scientific data repositories, particularly those sponsored by NIAID (https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data (https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data)), such as ImmPort (http://ImmPort) (www.immport.org (http://www.immport.org)), or other public portals approved by NIH/NIAID.

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

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

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

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

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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

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

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

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.
Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by the National Institute of Allergy and Infectious Diseases, 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

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?

Specific to this NOFO

To what degree will the results of this study provide valuable computational models of influenza immunity and facilitate discovery of important new knowledge on human immune responses to influenza 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?

Specific to this NOFO

How adequate is the level of commitment and availability of the investigators to manage the overall program? How appropriate is the level of 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?

Specific to this NOFO

- To what degree is there adequate focus on developing computational models of immune responses to influenza infection or vaccination to advance understanding of the immune mechanisms needed to induce and maintain broad protective influenza immunity?
- To what extent are FAIR data principles incorporated in the research strategy?
- If applicable, how appropriately justified is the development or refinement of bioinformatics tools for data mining or data interpretation included in the application as project goals? To what degree are bioinformatics tools included for activities necessary for completion of the proposed studies and computational modeling effort?
- How appropriate are the data collection and analysis methods in terms of quantitation, controls, and development or refinement and validation of the computational models of influenza immunity?
- To what extent will the immunological experiments proposed provide the required data for the computational modeling studies in the project?
- How appropriate and adequate are the human subject samples to meet the study goals? To what extent is the timing of sample collection appropriate for the stated goals?

Environment

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

Specific to this NOFO

To what extent is there sufficient infrastructure to support the data management 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).

Study Timeline

Inclusion of Women, Minorities, and Individuals Across the Lifespan

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

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

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 policies and practices (//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 NOFO.

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

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

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//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 Section 2.4.4 Disposition of Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=82416).

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=82418).

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159), including of note, but not limited to:

- Federal-wide Standard Terms and Conditions for Research Grants (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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82417)
- 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 NOFO.

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

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships."

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 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 NIH as defined below.

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

- Management of the overall research project, research staff, and collaborators involved in the project.
- Ensuring successful completion of milestones within the time frame negotiated with NIAID.
- Draft the initial and annual milestones for the project.

- Negotiating access to any datasets or resources proposed for use to conduct 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.
- 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 NIAID Project Scientist will or may:

- Provide guidance for design and coordination of research activities and efforts.
- Coordinate NIAID staff assistance, to include participation in periodic on-site monitoring with respect to compliance with Federal regulations, quality control, accuracy of data recording, sample accrual, etc.
- Review and approve annual milestones and work with the principal investigator(s) on a corrective plan if those milestones are not met.
- Direct collaborations with, and access to, other NIAID-supported research resources and services, may facilitate negotiations with companies interested in participating in clinical studies with CMII investigators.
- Advise on project management and technical performance.
- NIAID staff will use data generated under this Cooperative Agreement in the preparation of internal reports on program progress.
- 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. The NIAID Program Officer will 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 CMII data sharing, computational model-sharing, or other resource-sharing plans.

Areas of Joint Responsibility include:

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

- Review schedules for submission of CMII-generated data and data analyses from each CMII project to an appropriate database or repository for public access.
- Review schedules for submission of CMII-generated computational models and bioinformatics tools from each CMII project to public repositories for public dissemination.
- Define procedures for the publication and/or oral presentation of results or data collected.
- Promote compliance of CMII projects with the CMII policies and schedules for data and other resource-sharing.
- Participate in quarterly progress meetings and annual programmatic/technical meetings to facilitate the achievement of program goals.
- Negotiate redirection of the research within the original scope of the application, as needed and in a timely fashion.
- Negotiate milestones prior to award, and review on an annual basis.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between recipients and NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened: 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 HHS regulation 45 CFR Part 16.

3. Data Management and Sharing

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

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

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82419).

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=82420). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over the threshold. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 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 75 and 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)

Timothy A. Gondré-Lewis, Ph.D. (He/Him)
Division of Allergy, Immunology, and Transplantation
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-627-3566
Email: CMII@niaid.nih.gov (mailto:CMII@niaid.nih.gov)

Michelle Arnold, Ph.D. (She/Her)
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)
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Email: CMII@niaid.nih.gov (mailto:CMII@niaid.nih.gov)

Brooke Bozick, Ph.D. (She/Her)
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-6710
Email: CMII@niaid.nih.gov (mailto:CMII@niaid.nih.gov)

Peer Review Contact(s)

Kristin McNally, Ph.D. (She/Her)
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 406-375-9641
Email: mcnallyk@niaid.nih.gov (mailto:mcnallyk@niaid.nih.gov)

Financial/Grants Management Contact(s)

Katherine Matheson (She/Her)
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301- 594-4218
Email: katherine.matheson@nih.gov (mailto:katherine.matheson@nih.gov)

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?09-15-23)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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