This notice has expired. For NIH, in limited situations, applications may be accepted on a case-by-case basis for a short period after expiration to accommodate NIH late or continuous submission policies. Contact the eRA Service Desk for any submission issues. Check the NIH Guide for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	Influenza Transmission Research Consortium (P01 Clinical Trial Optional)
Activity Code	P01 Research Program Projects
Announcement Type	Reissue of RFA-AI-20-008
Related Notices	• **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084. • **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. • **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189.
Funding Opportunity Number (FON)	RFA-AI-25-035
Companion Notice of Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.855
Notice of Funding Opportunity Purpose	The purpose of this notice of funding opportunity (NOFO) is to support basic research to understand the fundamental mechanisms underlying human-to-human transmission of seasonal influenza virus. The NOFO will establish an Influenza Transmission Research Consortium comprised of a network of individual Influenza Transmission Research Centers. Centers should propose collaborative, multidisciplinary teams that will investigate the dynamics and drivers of influenza transmission and develop novel resources to further the field of respiratory virus transmission.
Funding Opportunity Goal(s)	To assist public and private nonprofit institutions and individuals to establish, expand and improve biomedical research and research training in infectious diseases and related areas; to conduct developmental research, to produce and test research materials. To assist public, private and commercial institutions to conduct developmental research, to produce and test research materials, to provide research services as required by the agency for programs in infectious diseases, and controlling disease caused by infectious or parasitic agents, allergic and immunologic diseases and related areas. Projects range from studies of microbial physiology and antigenic structure to collaborative trials of experimental drugs and vaccines, mechanisms of resistance to antibiotics as well as research dealing with epidemiological observations in hospitalized patients or community populations and progress in allergic and immunologic diseases. Because of this dual focus, the program encompasses both basic research and clinical research.

Key Dates

Posted Date	September 02, 2025
Open Date (Earliest Submission Date)	October 07, 2025
Letter of Intent Due Date(s)	30 days prior to 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**
November 07, 2025	Not Applicable	Not Applicable	March 2026	May 2026	July 2026

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	November 08, 2025
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions
It is critical that applicants follow the Multi-Project (M) Instructions in the How to Apply - Application Guide, except where instructed to do otherwise (in this NOFO or in a Notice from the NIH Guide for Grants and Contracts). Conformance to all requirements (both in the How to Apply - Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply - Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Purpose

The purpose of this notice of funding opportunity (NOFO) is to establish an Influenza Transmission Research Consortium comprised of a network of individual Influenza Transmission Research Centers. Centers will conduct basic research to understand the dynamics and drivers of human-to-human transmission of seasonal influenza viruses and develop novel and/or improved resources for studying respiratory virus transmission to advance the field.

Background

The ability of influenza viruses to efficiently spread between humans directly impacts the magnitude and severity of seasonal epidemics and worldwide pandemics. Understanding how influenza transmission occurs and how to prevent transmission is critical for public health preparedness efforts. Despite decades of research, significant gaps remain in our knowledge of the transmission process including the contribution and importance of different modes of transmission (i.e. fomites, direct contact, respiratory droplets, aerosols); the relationship between symptoms, shedding, and transmission; and the impact of viral, host, and environmental factors on transmission.

In addition, it has become increasingly clear that a broader understanding of the similarities and differences between transmission of circulating respiratory viruses is required to design and implement the most efficient mitigation strategies. A recent resurgence in interest on transmission of respiratory diseases combined with improvements in technology for studying aerosolized particles make now an opportune time to support comprehensive research in this area. A better understanding of the process of influenza transmission and the factors that impact transmission will aid in the risk assessment of circulating and novel influenza viruses, and inform prevention and control measures including the design of improved influenza vaccines, which is one of NIAID's highest priorities (see "A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases").

This initiative is a renewal of RFA-AI-20-008: Multi-Disciplinary Studies to Improve Understanding of Influenza Transmission, under which programs were required to address three major research areas: develop innovative devices to sample airborne viruses, develop novel assays to assess infectivity/viability of airborne viral particles, and comprehensively evaluate viral, host, physical, and environmental factors that facilitate human-to-human transmission. While improved devices and assays for sampling aerosolized viral particles are still an area of need, this renewal expands the scope of innovation, allowing for the development of resources to aid in the study of respiratory virus transmission that are guided by each Center's focus and expertise. In addition, this renewal will support the inclusion of studies on other human seasonal respiratory viruses provided the overall focus of the Center remains on influenza.

Research Objectives and Scope

The objective of this NOFO is to establish the Influenza Transmission Research Consortium: a network of Centers conducting collaborative, multidisciplinary research that will further understanding of the factors driving human-to-human influenza transmission. Applications are sought that propose well-integrated, cross-disciplinary research teams with varied expertise that may include, but is not limited to: virology, host genetics, immunology, modeling, environmental health, physical science, engineering and behavioral science.

This initiative will support both animal and human studies of influenza transmission. Centers may use or develop/improve existing animal models, provided that the goal is to recapitulate human-to-human transmission. Applicants are encouraged, but not required, to leverage samples from ongoing human cohort studies, clinical trials and clinical studies. Although clinical trials involving nonpharmaceutical interventions may be included as an element of the proposed research, the overall research goal of the Center must not be focused on the development, testing or implementation of mitigation strategies without including mechanistic studies to understand the underlying process of viral transmission. Clinical trials of vaccines and other pharmaceuticals are not permitted. Clinical trials employing controlled human influenza virus infections will be supported. Applicants are strongly encouraged to contact one of the NIAID Scientific/Research Contacts listed in Section VII to clarify any matter related to the inclusion of a clinical trial.

Each Center should propose 2-3 Research Projects organized around a common theme investigating influenza virus transmission. Centers may also choose to include comparative studies with other human seasonal respiratory pathogens such as SARS-CoV-2, seasonal human coronaviruses, respiratory syncytial virus (RSV), rhinoviruses, human metapneumovirus and parainfluenza, as long as the primary focus of the program remains on understanding human-to-human influenza virus transmission.

Specific Areas of Research Interests
Examples of research areas of interest include, but are not limited to:

- Relative contribution of different modes of transmission (i.e., aerosols, droplets, direct contact, fomites) in different settings
- Composition of aerosols produced by infected individuals
- Host physiological, genetic and behavioral factors that impact transmission
- Relationship between symptoms, shedding, and transmission, as well as the role of asymptomatic hosts
- Role of respiratory viral coinfections in facilitating or preventing transmission
- Role of immunity in preventing transmission, including the impact of pre-existing immunity through infection and/or vaccination, the level of protection needed to interrupt transmission and the contribution of mucosal immunity to preventing transmission
- Impact of physical and environmental factors on transmission (e.g., particle size, temperature, humidity, setting, air quality, etc.)

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

- Programs that study bacterial or fungal respiratory pathogens, zoonotic viruses, or viruses that transmit through the respiratory route but do not primarily infect the respiratory tract
- Programs that focus primarily on seasonal respiratory human virus(es) other than influenza
- Clinical trials of vaccines, therapeutics or other pharmaceutical interventions
- Studies of influenza transmission at the animal-human interface
- Programs that focus on developing, testing and/or implementing preventative measures and mitigation strategies without mechanistic studies to understand the underlying process of viral transmission

Program Structure

Administrative Core
The Administrative Core, headed by the contact Program Director/Principal Investigator (PD/PI), will be responsible for managing, coordinating, and supervising the entire range of program activities, including scientific, fiscal and clinical (if applicable); monitoring research progress; and ensuring that the overall project management plan is implemented effectively and within proposed timelines.

Resource Development Core
The Program must include a Resource Development Core to develop novel tools for the scientific community for investigating influenza virus transmission. Resources developed by this Core may include, but are not limited to animal models, devices, assays, reagents, methods, metrics, computational models or software. Programs should propose development of a resource based on the specific strengths and expertise of the team. Improvements to existing resources are acceptable, but these improvements must be more than incremental. Resources developed in this Core must be widely accessible and appropriately disseminated to the broader scientific community in compliance with the NIH Research Tools Policy and/or NIH Model Organism Sharing Policy. In addition, applications must clearly describe the need for the resource(s) and how it will shift the field forward.

Research Projects
The Program must include **at least two, but no more than three** Research Projects organized around the common theme of understanding the factors that drive efficient transmission of influenza between humans and are responsive to the NOFO purpose and research objectives outlined above.

Additional Scientific Cores (Optional)
The Program may include additional Scientific Cores as relevant to the NOFO purpose and research objectives. Each Scientific Core must support at least two Research Projects.

Programmatic Meetings and Collaboration
A kick-off meeting will be held to establish the major roles and functions of the program and develop a plan for engagement across the network. Annual programmatic meetings will be held to provide progress reporting and facilitate communication and collaboration among funded Centers. Cross-Center working groups will be convened based on shared interests among Centers.

Steering Committee
Each Center will establish a Steering Committee to review progress in meeting program goals. Each Steering Committee will also make recommendations for the continuation or re-direction of the funded Research Projects and Cores to the PD(s)/PI(s) on an ongoing basis. Each Steering Committee is expected to consist of at least 3 investigators who are not current collaborators of the funded programs. Applicants should not name potential Steering Committee members in their application nor contact potential Steering Committee members prior to award, but the application should include a summary of the expertise that will be represented and how the Center will utilize the expertise of the Steering Committee.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources website for information about developing statistical methods and study designs.

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

Section II. Award Information

Funding Instrument	Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New The OER Glossary and the How to Apply - Application Guide provides details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Optional: Accepting applications that either propose or do not propose clinical trial(s). Need help determining whether you are doing a clinical trial?
Funds Available and Anticipated Number of Awards	NIAID intends to commit $8 million in FY 2026 to fund 2-3 awards.
Award Budget	Application budgets are not expected to exceed $2,500,000 direct costs per year and should reflect the actual needs of the proposed project.
Award Project Period	The total project period must be 5 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

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

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 Organizations)

Foreign Organizations/ International Collaborations

NIH will no longer issue awards (new, renewal, or non-competing continuation) to domestic or foreign entities that involve foreign subawards/subcontracts. All NIH-funded research involving foreign subawards/subcontracts must be submitted in response to a NOFO that is specifically designated for funded international collaborations. This new requirement was effective, May 1, 2025.

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or foreign components, funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

Foreign Organizations

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

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply- 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications for additional information.

- System for Award Management (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 – 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 - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support.

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 How to Apply - Application Guide.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2- Definitions of Terms.

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. 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).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this NOFO. See the administrative office for instructions if planning to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the How to Apply - Application Guide, except where instructed in this notice of funding opportunity to do otherwise and where instructions in the How to Apply - Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the How to Apply - 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:

letterofintent@csr.nih.gov

Page Limitations

All page limitations described in the How to Apply- Application Guide and the Table of Page Limits must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	6	Required	1	1
Resource Development Core	Resource Core	12	Required	1	1
Core	Core	6	Optional	0	3
Research Project	Project	12	Required	2	3

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in How to Apply- Application Guide and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required, 1
- Administrative Core: required, 1
- Resource Development Core: required,1
- Core(s): optional, maximum 3, each Core must support at least two Research Projects
- Research Projects: required, minimum 2, maximum 3

Overall Component

When preparing the application, use Component Type 'Overall'.

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions, as noted.

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

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

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Locations (Overall)

Enter primary site only.

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

Research and Related Senior/Key Person Profile (Overall)

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

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

Budget (Overall)

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

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

PHS 398 Research Plan (Overall)

Specific Aims: Describe the overall specific aims of the proposed Influenza Transmission Research Center.

Research Strategy: Provide an overview describing the key scientific aspects of the Center and how its proposed structure (e.g., Research Projects and Cores) addresses the purpose and objectives of the NOFO. The application should be comprised of interrelated Research Projects and Cores, each capable of standing on its own merit but complementary and necessary for accomplishing the proposed objectives. Address the conceptual rationale for the Center, the synergistic nature of its components and the broad strategy that will be undertaken to accomplishing the stated goals. Include a visual representation of the interactions among the components and their complementary scientific endeavors. Discuss the scientific challenges and opportunities being addressed and the benefit of a successful effort. Describe how the Center incorporates a multidisciplinary approach to its investigation of respiratory virus transmission and discuss how the overall make-up of the proposed investigation contributes to the proposed goals and objectives of the NOFO.

Clinical Trial Overview: For applications that include clinical trials spanning multiple components, provide a synopsis of the trial and explain how the research will support the program's common theme, how results and samples will be used across/within relevant Research Project(s) and/or Core(s), and how sample distribution and communication will be managed throughout the proposed program. Note: specific information must be included with the Research Project or Core which is conducting the clinical trial.

Benchmarks and Timelines: Describe quantifiable benchmarks by year as well as annual timelines for the overall research program and for tracking progress from individual Research Projects. Benchmarks should not be a restatement of the aims; rather, they should specify targets and/or outcome(s) for major research activities and be scientifically justified. Describe the associated timelines using a Gantt chart or equivalent tool.

Resource Sharing Plan:
Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply - Application Guide.

Other Plan(s):

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in How to Apply- Application Guide; any instructions provided here are in addition to the How to Apply - Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply- Application Guide must be followed.

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 How to Apply- Application Guide must be followed.

PHS Assignment Request Form (Overall)

All instructions in the How to Apply- Application Guide must be followed.

Administrative Core

When preparing your application, use Component Type 'Admin Core.'

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

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

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

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

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

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

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

List all performance sites that apply to the specific component.

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

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

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- The Administrative Core must be headed by the contact PD/PI of the application. Include details of the experience, expertise and ability of the Administrative Core Lead and key personnel to manage all aspects of the Core successfully.

Budget (Administrative Core)

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

The budget of the Administrative Core must include the following:

- *Meetings:* Funds to accommodate travel by the PD(s)/PI(s), Project Leads, Core Leads and other Key Personnel to attend the initial Kick-Off Meeting within the first 6 months of the award, and to attend the Annual Programmatic Meetings starting during the second year of award. These meetings are anticipated to be held at a location at/near Bethesda, Maryland or at another agreed-upon site following consultation with NIAID staff. Costs associated with organizing the Annual Programmatic Meeting are not allowable expenses.
- *Publications:* Funds to support publications for the research program.
- *Cross-Center Working Groups:* Funds for personnel to participate in Program-wide working groups should be requested for each year. Budgets requests may include, but are not limited to, funds for effort, travel or publications.

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

PHS 398 Research Plan (Administrative Core)

Specific Aims: Briefly describe the objectives, goals and the proposed activities and services of the Administrative Core.

Research Strategy: Describe the plans and procedures for establishing and managing the Administrative Core that provides the organizational and administrative capacity to ensure the following:

- Efficient management, coordination, and supervision of the entire range of program activities, including scientific, fiscal and clinical (if applicable); monitoring research progress; and ensuring that the overall project management plan is implemented effectively and within proposed timelines.
- Communication with the NIAID Program Officer as needed.
- Appropriate prioritization of resources to accomplish program goals.
- Collaboration and interaction among Research Projects and Cores.
- Ensuring representation for program-wide working groups and at annual meetings.

Letters of Support: If applicable, include letters of support.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply- Application Guide.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the How to Apply- Application Guide; any instructions provided here are in addition to those in the How to Apply- Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply- Application Guide must be followed.

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 How to Apply- Application Guide must be followed.

Resource Development Core

When preparing your application, use Component Type 'Resource Core.'

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Resource Development Core)

Complete only the following fields:

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

PHS 398 Cover Page Supplement (Resource Development Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Resource Development Core)

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

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

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

Project/Performance Site Location(s) (Resource Development Core)

List all performance sites that apply to the specific component.

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

Research & Related Senior/Key Person Profile (Resource Development Core)

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

Budget (Resource Development Core)

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

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

PHS 398 Research Plan (Resource Development Core)

Specific Aims: Describe the overall specific aims, the specific resource(s) to be developed and the proposed activities that will be undertaken toward development. Clearly describe how the resource(s) developed in the Core relate to the overall program's goals and how the Core's activities relate to the Research Projects and, if applicable, other Cores.

Research Strategy: Describe plans for resource development.

- Explain the scientific need and opportunity for development of the resource(s) and how the availability of this resource(s) will advance the field of respiratory virus transmission
- Describe the methods, technologies, and strategies to accomplish the specific aims.
- If proposing improvements to existing resources, explain how the improvements will be more than incremental.
- Describe any novel concepts, approaches, tools, or technologies for the proposed studies including their advantage over existing methodologies.
- Discusses the potential difficulties and limitations of the development plan as well as alternative approaches to achieve the specific aims.
- Describe the timeline to completion for development of the resource, explaining how the resource will be utilized by the Center

Letters of Support: If applicable, provide letters of support demonstrating access to key resources, samples etc. necessary for successful resource development.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply- Application Guide, with the following modification:

- Inclusion of a justification for not providing a plan for an organism that would normally require sharing is **not** acceptable for this NOFO. All applicants must include a plan for sharing Model Organisms if applicable to the proposed science.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the How to Apply- Application Guide; any instructions provided here are in addition to those in the How to Apply- Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Resource Development Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply- Application Guide must be followed.

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 How to Apply- Application Guide must be followed.

Core(s)

When preparing your application, use Component Type 'Core.'

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Core(s))

Complete only the following fields:

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

PHS 398 Cover Page Supplement (Core(s))

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Core(s))

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

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

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

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

List all performance sites that apply to the specific component.

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

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

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

Budget (Core(s))

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

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

PHS 398 Research Plan (Core(s))

Specific Aims: Briefly describe the overall specific aims, and the proposed activities and services of the Scientific Core. Clearly describe the relationship of the Core to the overall Center's goals and how the proposed activities relate to the other Research Projects and Cores.

Research Strategy: Describe how the proposed Core activities will contribute to meeting the goals and objectives of the Center and indicate the specific two or more Research Projects that it will support. Explain the rationale for the general methods and approaches proposed to accomplish the Specific Aims. Include details of the facilities, resources, and professional skills provided and explain how requests for services will be prioritized and coordinated.

Letters of Support: If applicable, provide letters of support.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the How to Apply- Application Guide.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the How to Apply- Application Guide; any instructions provided here are in addition to those in the How to Apply- Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply- Application Guide must be followed.

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 How to Apply- Application Guide must be followed.

Research Projects

When preparing your application, use Component Type 'Project.'

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Projects)

Complete only the following fields:

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

PHS 398 Cover Page Supplement (Research Projects)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Projects)

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

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

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

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

List all performance sites that apply to the specific component.

*Note: The Project

- Applicants must include a complete clinical protocol as part of the Appendix. Applicants should use the NIAID Division of Microbiology and Infectious Diseases (DMID) Protocol Templates when preparing the clinical protocol, and are urged to be succinct. Applicants are also referred to the Trans-NIAID Clinical Research Toolkit website for clinical protocol guidance and templates.
- Applications that propose a clinical trial but lack a complete clinical protocol are incomplete and will **not** be reviewed.

PHS Human Subjects and Clinical Trials Information (Research Project)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply- Application Guide must be followed, with the following additional instructions:

Section 2 - Study Population Characteristics

2.7 Study Timeline

Include the following:

- Completion of data collection time period;
- Completion of primary endpoint and secondary endpoint data analyses time period;
- Completion of final study report.
- Include a series of milestones for completion of the clinical trial and provide contingency plans should there be delays in attaining them.

This section must include:

- A timeline for the following general milestones, as applicable;
- Completion of regulatory approvals;
- Enrollment of 25%, 50%, 75% and 100% of the projected recruitment time period for all study subjects, including a plan for initial site activation and expected timing of screening/enrollment of first participant;
- Detailed protocol-specific performance milestones; these milestones will be negotiated at the time of the award, if appropriate;
- Discuss the feasibility and appropriateness of achieving and completing each milestone on-time, including alternate approaches and contingencies for dealing with potential problems and impediments.

Section 3 - Protection and Monitoring Plans

3.3 Data and Safety Monitoring Plan

The Data and Safety Monitoring (DSM)Plan must address the following areas:

- Where the monitoring will occur.
- How site(s)/center(s), and participating facilities (labs) will be monitored.
- Also address the appropriate oversight over the conduct of the trial, including at a minimum the appropriate clinical monitoring independent of the study team, safety monitoring, regulatory submissions and compliance and quality management.
- Provide a data coordination and retention plan addressing the following areas: (1) database system to be employed, (2) compliance with federal regulations, (3) security and emergency back-up, and (4) quality control of data from clinical sites and laboratories, as appropriate.

3.5 Overall Structure of the Study Team

This section must include:

- A description of committee structures needed to manage the complexity of the trial; the role of any internal or external advisory committees; the oversight, responsibilities, and coordination of any sites or Cores proposed; and the role of any subcontractors or service providers for personnel or facilities. Note: Do not name potential external advisory committee members in the application nor contact potential external advisory committee members prior to award.

Section 5 - Other Clinical Trial-related Attachments

5.1 Other Clinical Trial-related Attachments

The following additional documents, if applicable, should be included as attachments:

- Identification and qualifications of clinical trial site(s) and laboratories
- Copies of data collection forms, questionnaires, or other relevant materials
- The Investigator's Brochure or equivalent for the study products(s)
- Table of Contents of the Manual of Operations (MOPs)
- A comprehensive Laboratory Plan
- Plans and support for acquisition and administration of study agent(s)
- Documentation of co-funding of clinical trials from partners
- Documentation of any communications with regulatory authorities

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 How to Apply- Application Guide must be followed.

Foreign Organizations

Foreign (non-U.S.) organizations must follow policies described in the NIH Grants Policy Statement, and procedures for foreign institutions described throughout the How to Apply - Application Guide.

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

See Part 2. 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. 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, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, 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.

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 How to Apply- Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

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.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide. Paper applications will not be accepted.

For information on how applications will be automatically assembled for review and funding consideration after submission, refer to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

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

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply - Application Guide. 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 guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in How to Apply - Application Guide.

See more tips 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.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 and NIH Grants Policy Statement Section 4.1.35.

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program at grantdisclosures@oig.hhs.gov.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described 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 NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact - Overall

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 - Overall

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

Significance

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

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

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 appropriate is the level of commitment for the PD(s)/PI(s) to effectively manage the overall program? How appropriate is the level of commitment for the PD(s)/PI(s) of the Research Projects and/or Cores to effectively manage the individual components?
- To what extent have the PD(s)/PI(s) demonstrated strong leadership skills and capability to accomplish the proposed work and effectively manage and direct an integrated and focused research program?
- To what extent does the multidisciplinary expertise represented on the investigative team allow the Center to achieve the proposed research goals and address the NOFO purpose and objectives?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

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?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

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, 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 are the individual Research Projects and Cores integrated and synergistic to accomplish the central objectives of the program? To what extent will the integration of the individual Research Projects into a single program be more beneficial than pursuing each project independently?
- To what extent are the benchmarks and timelines well-defined, scientifically justified, and appropriate for the research proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, sex, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

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?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria – Overall, Administrative Core, Resource Development Core, Core(s), Research Projects

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

Administrative Core

- To what extent does the application clearly describe and justify the proposed Administrative Core organizational structure?
- How well do the Administrative Core objectives fit into the central focus of the Overall program?

Resource Development Core

- To what extent are the resource(s) proposed for development in the Resource Development Core and the sharing of these resources with the broader scientific community critical for moving the field forward?
- If improvements to existing resources are proposed in the Resource Development Core, to what extent is there a clearly demonstrated need for the proposed improvement? To what degree is the improvement more than incremental? To what extent will the improvement shift the field forward in a significant way?

Optional Scientific Core(s)

- How well justified is it that each Scientific Core will support at least two Research Projects and that services will be used effectively?
- To what extent is the Core connected to the central focus of the Overall program?
- Are the facilities or services provided by the Core (including procedures, techniques, and quality control) of significantly high quality and appropriate for the proposed research?

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

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.

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the American Veterinary Medicine Association (AVMA) Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

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

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations – Overall, Administrative Core, Resource Development Core, Core(s), Research Projects

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

Applications from Foreign Organizations

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

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) 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 Center for Scientific Review (CSR), in accordance with NIH peer review policies and practices, 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 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.

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 Section 2.5.1. Just-in-Time Procedures. This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 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.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons. 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.

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

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.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award and NIH Grants & Funding website, see Award Process.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that all 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.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates.

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting for additional information.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 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. 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) annually and financial statements as required in the NIH Grants Policy Statement Section 8.4.1 Reporting. To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see Post-Award Monitoring and Reporting.

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 Section 8.6 Closeout. 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 2 CFR Part 200.301.

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 (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 (preferred method of contact)
Telephone: 301-480-7075

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

Scientific/Research Contact(s)

Brooke Bozick, Ph.D.
Program Officer, Influenza and Rhinovirus Pathogen Biology and Respiratory Virus Clinical Research
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-6710
Email: brooke.bozick@mail.nih.gov

Kate Plimack Ph.D.
Program Officer, Coronavirus Pathogen Biology Research
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 301-761-6710
Email: kate.plimack@mail.nih.gov

Sonnie Kim, M.S.
Program Officer, Pneumovirus and Paramyxovirus Research
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone:240-627-3287
Email: sonnie.kim@nih.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Tamika Boyd
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-5634
Email: tamika.boyd@nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

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 2 CFR Part 200.