

# Department of Health and Human Services

## Part 1. Overview Information

### Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

### Components of Participating Organizations

National Institute of Allergy and Infectious Diseases ([NIAID \(https://www.niaid.nih.gov/\)](https://www.niaid.nih.gov/))

### Funding Opportunity Title

Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19) (R21 Clinical Trial Not Allowed)

### Activity Code

[R21 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r21&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r21&Search.x=0&Search.y=0&Search_Type=Activity)  
Exploratory/Developmental Research Grant

### Announcement Type

New

### Related Notices

None

### Funding Opportunity Announcement (FOA) Number

PAR-20-177

### Companion Funding Opportunity

[PAR-20-178 \(https://grants.nih.gov/grants/guide/pa-files/PAR-20-178.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-20-178.html), [R01 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant,

### Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

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

93.855

## Funding Opportunity Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to provide an expedited funding mechanism for research on Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19). NIAID is issuing this FOA in response to the declared public health emergency issued by the Secretary, HHS, for 2019 Novel Coronavirus (COVID-19).

## Key Dates

### Posted Date

April 30, 2020

### Open Date (Earliest Submission Date)

April 30, 2020

### Letter of Intent Due Date(s)

Not Applicable

### Application Due Date(s)

Applications will be accepted on a rolling basis, beginning on 04/30/2020.

All applications are due by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on the listed date(s).

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

### AIDS Application Due Date(s)

Not Applicable

### Scientific Merit Review

Applications will be handled on an expedited review and award basis to meet the goals of this program.

### Advisory Council Review

Not Applicable

### Earliest Start Date

Applications will be handled on an expedited review and award basis to meet the goals of this program.

### Expiration Date

April 30, 2021

### Due Dates for E.O. 12372

Not Applicable

## Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), except where instructed to do otherwise (in this FOA or in a Notice

from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/\)](https://grants.nih.gov/grants/guide/)).

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

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

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 \(http://public.era.nih.gov/commons/\)](#) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-20-177\)](https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-20-177) 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. Funding Opportunity Description

#### Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to provide an expedited funding mechanism for research on Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and/or Coronavirus Disease 2019 (COVID-19). NIAID is issuing this FOA in response to the declared public health emergency issued by the Secretary, HHS, for 2019 Novel Coronavirus (COVID-19).

#### Background

SARS-CoV-2 is a novel coronavirus that has recently been identified as the causative agent of COVID-19, a respiratory disease that exhibits a wide range of clinical outcomes from mild disease to severe viral pneumonia and Acute Respiratory Distress Syndrome (ARDS). SARS-CoV-2 is able to spread efficiently from person-to-person and cases have been detected in most countries. On March 11, the SARS-CoV-2 outbreak was classified as a [pandemic by the WHO \(https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020\)](https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020). Transmission characteristics and the associated morbidity and mortality, viral

pathogenesis, host immunity, natural history, and host range are currently poorly understood. Research is an important component of the public health emergency response before, during and after the emergency. Given this, there is an urgent public health need to better understand SARS-CoV-2/COVID-19, particularly to improve understanding of fundamental virology, immunology, and the development of animal models, reagents, and medical countermeasures and to share findings quickly and broadly.

## Research Objectives and Scope

Areas of high priority include, but are not limited to, the following:

- Studies to understand critical aspects of viral infection, replication and pathogenesis including:
  - Understanding host compartments of viral replication and duration of shedding;
  - Predictors of disease severity and outcome including viral and host determinants of infection, replication, and recovery;
  - Pathophysiology of disease and clinical prognosis associated with viral loads and immune-based biomarkers;
  - Identification of molecular markers of pathogenesis;
  - Studies on the emergence and evolution of SARS-CoV-2, including the identification of factors that affect viral host-range and virulence and changes to the virus that occur over time in circulation;
- Studies to understand critical aspects of viral transmission including:
  - Studies to comprehensively evaluate viral, host, physical, and environmental factors that facilitate efficient human-to-human SARS-CoV2 transmission utilizing novel and/or improved devices, assays, study designs and/or animal models;
  - Modes and duration of person-to-person transmission;
  - Role of different age groups in transmission dynamics;
  - Potential impact on transmission dynamics from host biology/behavior or environmental factors in superspreading events;
  - Importance of asymptomatic transmission;
  - Development of novel assays for assessing infectivity and viability of viral particles collected from the air;
- Identification and characterization of the onset and duration of immunity in healthy and at-risk populations, including:
  - Innate, cellular and humoral immune responses to SARS-CoV-2 infection and/or candidate vaccines;
  - Protective or pathogenic B cell or T cell epitopes from individuals exposed to SARS-CoV-2, including identification of immune epitopes that cross-react with other human coronaviruses;
  - Host immune receptor repertoire studies related to understanding protective immunity or disease pathogenesis;
  - Computational modeling of the immune response to infection and/or vaccination
  - Screening of potential adjuvants or immune modulators that improve vaccine efficacy, provide prophylactic protection, or limit/prevent severe disease;
  - Mechanisms of immune-mediated pathology or host factors that might predispose to, or prevent, severe infection;
- Virologic and serologic surveillance studies and natural history studies to understand the origin of the virus including the animal host reservoir, potential intermediate hosts, factors leading to spill over events, evidence of continued spill over events and studies at the human-animal interface;
  - Identifying capacity for SARS-CoV-2 and other coronaviruses to infect potential intermediate hosts;
  - Identify diversity of coronaviruses in bats and other wildlife;
  - Improve detection and diagnostic technologies for use in animal surveillance;
- Studies to assess and characterize the natural history and long-term consequences of SARS-CoV-2 infection in various human populations including at risk populations;
- Development or improvement of clinical diagnostic tests for SARS-CoV-2 to increase the sensitivity, specificity and ability to provide rapid results;
- Development and testing of SARS-CoV-2 therapeutic candidates, in relevant *in vitro*, *ex vivo* or animal models, including:
  - Discovery of drug targets or novel drug candidates specific for SARS-CoV-2;
  - Host-directed therapies;
  - Broad-spectrum therapeutics against multiple coronavirus strains;
  - Examination of SARS-CoV-2 antiviral activity of existing or candidate therapeutics initially developed for other indications;
  - Combination therapies;
- Development of SARS-CoV-2-specific or broadly protective coronavirus vaccine candidates including:
  - Novel antigen design strategies;
  - Novel platforms or delivery approaches,
  - Addition of adjuvants;
- Studies to inform the development of vaccination strategies for at-risk populations including use of age-specific adjuvants or novel

- antigen formulations/dosing,
- Development of assays and animal models to;
  - Evaluate the potential of enhanced disease after vaccination for SARS-CoV-2;
- Assess animal models for SARS-CoV-2 and how the models compare to human infection including animal models that represent at risk populations (elderly, immunocompromised, very young, pregnant models);
- Development of animal models for transmission experiments;
- Development of organoid culture models and/or *ex vivo* explant models;
- Computational modeling studies to identify and evaluate interventions to protect at-risk populations and for making public health policy decisions for control and mitigation measures;
- Study interactions and impact between SARS-CoV-2 and other respiratory pathogens including influenza (e.g., co-infections, interference);
- Comparative studies of SARS-CoV-2 to other coronaviruses including SARS-CoV-1 and MERS;
- Data science approaches to develop algorithms, models, and informatics solutions such as:
  - clinical prediction of COVID-19 disease outcomes based on multiple data streams including EHRs, mobile technologies, and other large data sets
  - enabling remote monitoring and precision interventions based on individual risk
  - strategies for establishing federated collections of SARS-CoV-2/COVID-19 clinical and experimental data and associated metadata with the ability to develop synthetic cohorts within and across studies.

This program is designed to provide expedited funding for research projects focusing on obtaining time-sensitive data in light of this public health emergency (e.g., the research questions cannot be efficiently addressed in another context and the nature of the event and/or impacted populations are well suited for the proposed study). Hence it is critical to enhance data-sharing and access and to have NIAID-funded data be findable, accessible, interoperable, and reusable ([FAIR \(https://www.nature.com/articles/sdata201618\)](https://www.nature.com/articles/sdata201618)). **All NIAID-funded researchers are expected to share research data to enhance the rigor and reproducibility of research results and secondary use per the NIAID Data Sharing Guideline** at <https://www.niaid.nih.gov/research/data-sharing-and-release-guidelines> (<https://www.niaid.nih.gov/research/data-sharing-and-release-guidelines>), as appropriate and consistent with achieving the goals of the program

Potential applicants are strongly encouraged to contact Scientific/Research staff before submitting an application to this FOA to determine whether or not the proposed work is within the intended scope of this program, whether requested expedite funding is likely to be available, and whether the idea should be considered for initial submission as a fully developed application. Inquiries not meeting the expedite guidelines will be guided to other grant mechanisms and to program contacts to discuss alternatives.

PAR-20-177 uses the R21 mechanism, PAR-20-178 uses the R01 grant mechanism. The R21 activity code is intended to encourage new exploratory and developmental research projects that lack preliminary data. For example, such projects could assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research. Studies also may include the unique and innovative use of an existing methodology to explore a new scientific area. These studies may involve considerable success risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, reagents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.

Applications for R21 awards should describe projects distinct from those supported through the traditional R01 activity code. For example, long-term projects, or projects designed to increase knowledge in a well-established scientific area, will not be considered for R21 awards. Applications submitted to this FOA should be exploratory and novel. These studies should break new ground or extend previous discoveries toward new directions or applications.

See [Section VIII. Other Information](#) for award authorities and regulations.

## Section II. Award Information

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### Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

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### Application Types Allowed

New

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

## Clinical Trial?

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

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

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## Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

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## Award Budget

The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

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## Award Project Period

The total project period may not exceed 2 years.

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

# Section III. Eligibility Information

## 1. Eligible Applicants

### Eligible Organizations

#### Higher Education Institutions

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

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

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

#### Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Governments

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

- U.S. Territory or Possession

#### Other

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

### Foreign Institutions

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

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

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

### Required Registrations

#### Applicant organizations

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

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. In the case of Emergency awards, if the applicant is unable to comply with the requirement to complete and maintain SAM registration at the time of application submission, contact the agency immediately.
  - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

### Eligible Individuals (Program Director/Principal Investigator)

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

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

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).  
([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

### 3. Additional Information on Eligibility

#### Number of Applications

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

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

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

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

### 2. Content and Form of Application Submission

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

#### 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=11133](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133)) must be followed.

#### Instructions for Application Submission

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

#### SF424(R&R) Cover

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

#### SF424(R&R) Project/Performance Site Locations

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

#### SF424(R&R) Other Project Information

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

#### 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.

#### 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:

**Research Strategy:** Describe how the proposed studies will advance understanding of SARS-CoV-2 and/or COVID-19 virology, pathophysiology, or the development of medical countermeasures. If the proposed research relies on clinical samples (e.g. patient samples, isolates, etc.), describe how the investigators will have timely access to the samples in sufficient quantities to achieve the aims of the proposed research.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan. It is expected that awardees will rapidly disseminate data, results, and analyses to the broader scientific community, using existing public repositories whenever possible, as a foundation for further study.

## **Appendix:**

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

## **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 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11137\)](https://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 \(https://grants.nih.gov/grants/guide/url\\_redirect.html?id=82380\)](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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH’s electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late

Application Submission.

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

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

## 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

## 6. Funding Restrictions

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

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

Pre-award costs may be incurred from January 20, 2020 through the public health emergency period and prior to the date of the federal award.

## 7. Other Submission Requirements and Information

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

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

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

### Important reminders:

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

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

See [more tips](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146](https://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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

## Post Submission Materials

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

# Section V. Application Review Information

## 1. Criteria

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

For this particular announcement, note the following:

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

## **Overall Impact**

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

## **Scored Review Criteria**

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

### **Significance**

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

### **Investigator(s)**

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

### **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 FOA:**

Do the investigators have immediate access to the resources (e.g. patient samples, isolates, etc.) at sufficient quantities to achieve the aims of the proposed research?

## **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?

## **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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

### **Inclusion of Women, Minorities, and Individuals Across the Lifespan**

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

### **Vertebrate Animals**

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

### **Biohazards**

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

### **Resubmissions**

Not Applicable

### **Renewals**

Not Applicable

### **Revisions**

Not Applicable

## **Additional Review Considerations**

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

### **Applications from Foreign Organizations**

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

### **Select Agent Research**

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

### **Resource Sharing Plans**

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

Data Sharing Plan: If the proposed research will generate unique resources or data that may impact the public health response or medical countermeasure development, does the resource sharing plan adequately address the rapid dissemination of data, results, and analyses to the broader scientific community, using existing public repositories whenever possible, as a foundation for further study?

### **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 NIAID,, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#)

[\(file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#\\_1\\_.\\_Criteria\).](file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1_._Criteria).)

Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. 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.
- Applications that include plans to rapidly make data available to the research community.

## **3. Anticipated Announcement and Award Dates**

## Section VI. Award Administration Information

### 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

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

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

**Institutional Review Board or Independent Ethics Committee Approval:** Grantee institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. 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 <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/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 further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please 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>).

<https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf> (<https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>). 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>).

- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please 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 "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**

Not Applicable

## **3. Reporting**

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) (<https://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161). ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161))

NIAID plans to make awards using funds provided in the emergency supplemental appropriations for COVID-19 and coronavirus research: "The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020" and "The Coronavirus Aid, Relief, and Economic Security (CARES) Act". Funds awarded using appropriations provided by the "The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020" and "The Coronavirus Aid, Relief, and Economic Security (CARES) Act" will be issued in unique subaccounts in the HHS Payment Management System, and will require separate financial reporting from any other funds awarded.

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

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

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

or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

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

### Application Submission Contacts

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

Finding Help Online: <http://grants.nih.gov/support/> ([//grants.nih.gov/support/](http://grants.nih.gov/support/))(preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>)(preferred method of contact)

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov) (<mailto:support@grants.gov>).

### Scientific/Research Contact(s)

Diane Post, Ph.D.

Division of Microbiology and Infectious Diseases

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-627-3348

Email: [postd@niaid.nih.gov](mailto:postd@niaid.nih.gov) (<mailto:postd@niaid.nih.gov>).

Kentner Singleton, Ph.D.

Division of Allergy, Immunology, and Transplantation

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-5499

Email: [NIAID.DAIT.SARS2.PAR@nih.gov](mailto:NIAID.DAIT.SARS2.PAR@nih.gov) (<mailto:NIAID.DAIT.SARS2.PAR@nih.gov>).

### Peer Review Contact(s)

Gregory Jarosik, Ph.D.

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-5080

Email: [gjarosik@niaid.nih.gov](mailto:gjarosik@niaid.nih.gov) (<mailto:gjarosik@niaid.nih.gov>).

### Financial/Grants Management Contact(s)

Vandhana Khurana

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-2966

Email: [khuranav@niaid.nih.gov](mailto:khuranav@niaid.nih.gov) (<mailto:khuranav@niaid.nih.gov>).

Donna R. Sullivan

National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-669-2979

Email: [Donna.Sullivan@nih.gov](mailto:Donna.Sullivan@nih.gov) (<mailto:Donna.Sullivan@nih.gov>).

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11163) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11163](http://grants.nih.gov/grants/guide/uri_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](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11164)

([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11164](http://grants.nih.gov/grants/guide/uri_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](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120)).

### Authority and Regulations

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?05-01-20\)](/grants/guide/WeeklyIndex.cfm?05-01-20)  
[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)



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