# Department of Health and Human Services

# Part 1. Overview Information

#### Participating Organization(s)

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

#### **Components of Participating Organizations**

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

#### Funding Opportunity Title

Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

#### Activity Code

<u>R21 (//grants.nih.gov/grants/funding/ac\_search\_results.htm?text\_curr=r21&Search.x=0&Search.y=0&Search\_Type=Activity)</u> Exploratory/Developmental Research Grant

#### Announcement Type

Reissue of RFA-ES-23-004 (https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-23-004.html)

#### Related Notices

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

#### Notice of Funding Opportunity (NOFO) Number

RFA-ES-23-011

#### **Companion Funding Opportunity**

None

## Number of Applications

See Section III. 3. Additional Information on Eligibility.

## Assistance Listing Number(s)

93.113, 93.143

## Funding Opportunity Purpose

This Notice of Funding Opportunity (NOFO) is intended to support novel environmental health research in which an unpredictable event or policy change provides a limited window of opportunity to collect human biological samples or environmental exposure data. The primary

RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

motivation of the NOFO is to understand the consequences of natural and human-made disasters, emerging environmental public health threats, and policy changes in the U.S. and abroad. A distinguishing feature of an appropriate study is the need for rapid review and funding, substantially shorter than the typical NIH grant review/award cycle, for the research question to be addressed and swiftly implemented.

The shortened timeframe will be achieved by more frequent application due dates and expediting peer review, council concurrence and award issuance. The entire cycle, from submission to award, is expected to be within 4-6 months.

## Key Dates

#### **Posted Date**

July 05, 2023

#### **Open Date (Earliest Submission Date)**

July 08, 2023

#### Letter of Intent Due Date(s)

30 days prior to the application due date

	Appli	<b>Review and Award Cycles</b>			
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
August 08, 2023	Not Applicable	Not Applicable	September 2023	January 2024	February 2024
October 02, 2023	Not Applicable	Not Applicable	November 2023	January 2024	April 2024
December 01, 2023	Not Applicable	Not Applicable	January 2024	May 2024	June 2024
February 01, 2024	Not Applicable	Not Applicable	March 2024	May 2024	August 2024
April 01, 2024	Not Applicable	Not Applicable	May 2024	August 2024	November 2024
June 03, 2024	Not Applicable	Not Applicable	July 2024	October 2024	December 2024
August 01, 2024	Not Applicable	Not Applicable	September 2024	January 2025	February 2025
October 01, 2024	Not Applicable	Not Applicable	November 2024	January 2025	April 2025
December 02, 2024	Not Applicable	Not Applicable	January 2025	May 2025	June 2025
February 03, 2025	Not Applicable	Not Applicable	March 2025	May 2025	August 2025

	Appli	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
April 01, 2025	Not Applicable	Not Applicable	May 2025	August 2025	November 2025
June 02, 2025	Not Applicable	Not Applicable	July 2025	October 2025	December 2025
August 01, 2025	Not Applicable	Not Applicable	September 2025	January 2026	February 2026
October 01, 2025	Not Applicable	Not Applicable	November 2025	January 2026	April 2026
December 01, 2025	Not Applicable	Not Applicable	January 2026	May 2026	June 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**

December 02, 2025

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

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

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

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

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

Apply Online Using ASSIST

- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and <u>eRA Commons</u> (<u>https://public.era.nih.gov/commons/</u>) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-ES-23-011)</u> Workspace to prepare and submit your application and <u>eRA Commons (http://public.era.nih.gov/commons/)</u> to track your application.

# Table of Contents

 Part 1. Overview Information

 Key Dates

 Part 2. Full Text of Announcement

 Section I. Notice of Funding Opportunity Description

 Section II. Award Information

 Section III. Eligibility Information

 Section IV. Application and Submission Information

 Section V. Application Review Information

 Section VI. Award Administration Information

 Section VII. Agency Contacts

 Section VIII. Other Information

# Part 2. Full Text of Announcement

## Section I. Notice of Funding Opportunity Description

This Notice of Funding Opportunity (NOFO) is intended to support research in environmental health science in which an event has or will imminently occur that provides a limited window of opportunity to collect samples and data to support the assessment of exposures and human health impact. The goal of the program is to characterize initial exposures, collect human biological samples, or collect human health and exposure data in order to provide critical information to understand exposure-health outcome relationships, with the goal of providing data that will facilitate timely action to protect public health. The program also supports the use of innovative techniques (hazard identification, sensing and mitigation technologies) that are uniquely valuable for deployment at a time of disaster to inform our understanding of the human health impacts of the disaster. Research collected during this short window of opportunity is intended to serve as the foundation for analyses of longer-term health outcomes. (Funding of these analyses would not be appropriate for this mechanism, but through the traditional application process.)

The distinguishing features of an appropriate study are 1) the unforeseen nature of the event, 2) the clear scientific value and feasibility of the study and 3) the need for rapid review and funding, substantially shorter than the typical NIH grant review/award cycle, for the scientific question to be approached and for the research design to be implemented. It should be clear that the event offers a limited opportunity to address unique and important research questions that could only be answered if the project is initiated with minimum delay. Investigators should describe their capacity to begin the project upon award.

Applications submitted to this time-sensitive NOFO will be considered only one time. Resubmission applications are not permitted.

This NOFOencourages partnerships between researchers and the affected community (e.g., community-based organizations, environmental justice groups, local health and environmental agencies, worker organizations, etc.) and the leveraging of existing cohorts as appropriate.

Applications seeking funds for the following are considered non-responsive to this announcement: 1) expansion of an existing study; 2) studies of environmental hazards or chemical agents that alone do not impact human health; 3) estimating exposure to pathogens

Examples of appropriate studies include, but are not limited to, the following:

- Assessing short-term health impacts resulting from environmental exposures following a natural or human-made disaster, using biomarkers, survey instruments, medical assessments, or other appropriate methods. Examples might include acute toxic responses or exacerbation of existing diseases. Subjects in these studies could include local residents or early responders.
- Collecting biospecimens and/or data on exposures to environmental agents immediately following a natural or human-made disaster to use in assessment of the effects of these exposures on short- or longer-term health outcomes.
- Examining the environmental health impact of rapid changes in policy or legislation that affect the environment. For example, a regulation limiting carbon emissions is to be rescinded. An application would be considered responsive in proposing to collect baseline and/or post levels of environmental and/or human biospecimens to examine the effects of changes to fine particulate matter.
- Characterization, identification of sources and quantitation of human exposure to combinations of chemicals and biological hazards through use of personal sensors or biomonitoring using targeted analysis of specific, known chemicals and/or untargeted metabolomic approaches. Applications should discuss how these data might be used in health outcome or exposure research.
- Fate and transport studies to understand the mobilization and movement of chemicals through environmental matrices for the development of models to predict individual exposures.

RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

- Characterization, source identification, and quantitation of chemical hazards in water, soil, sediment and air (both ambient and indoor air quality) using sensors, portable monitors etc., to identify contamination hotspots relevant to human exposure pathways. Use of innovative, novel detection devices practical in disaster response settings (e.g. portable, rapid, ease-of-use, low energy footprint) are highly encouraged.
- Short term studies testing effectiveness of innovative mitigation strategies in preventing exposures to hazardous substances released during disaster.

All appropriate applications responding to this NOFO will be subject to an accelerated review and award process. The entire cycle from submission to award is expected to be within 4-6 months. However, administrative requirements and other unforeseen circumstances may delay issuance dates beyond that timeline. While institutions may propose to investigate time-sensitive opportunities outside the U.S., it must be clear within the application that all the proper logistics, human subjects concerns and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement.

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

## Section II. Award Information

#### **Funding Instrument**

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

#### Application Types Allowed

New

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

#### **Clinical Trial?**

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

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

#### Funds Available and Anticipated Number of Awards

NIEHS intends to commit \$800,000 per year for fiscal years 2023, 2024, 2025, 2026 to fund 4-5 awards each year. Future year amounts will depend on annual appropriations.

#### Award Budget

The combined budget for direct costs for the 2-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

#### Award Project Period

The maximum period may not exceed 2 years.

NIH grants policies as described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11120)</u> will apply to the applications submitted and awards made from this NOFO.

## Section III. Eligibility Information

## 1. Eligible Applicants

#### **Eligible Organizations**

Higher Education Institutions

• Public/State Controlled Institutions of Higher Education

#### 7/13/23, 1:07 PM RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

• Private Institutions of Higher Education

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

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

Federal Governments

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

Other

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

#### **Foreign Institutions**

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

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

Foreign components, as <u>defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11118)</u>, **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 <u>NIH Grants Policy Statement Section 2.3.9.2</u> <u>Electronically Submitted Applications (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82423)</u> states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=82390)</u> 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.
  - <u>NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11176)</u> 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.
- <u>eRA Commons (https://grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82300)</u> Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

## Eligible Individuals (Program Director/Principal Investigator)

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

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 NOFO does not require cost sharing as defined in the <u>NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url\_redirect.htm?</u> id=11126)

## 3. Additional Information on Eligibility

## Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per <u>NIH Grants Policy Statement Section</u> 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see <u>NIH Grants Policy</u> <u>Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82423)</u>).

## 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 <u>Part 1</u> of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

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

Letter of Intent

#### RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

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 <u>Part 1. Overview Information</u>, prospective applicants are strongly advised 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
- Background information on the proposal and/or impacted community or communities
- Draft or final research aims
- Statement justifying time sensitivity/need for rapid review and funding?

The letter of intent should be sent to:

Varsha Shukla, Ph.D.

Telephone: 984-287-3288

Email: varsha.shukla@nih.gov (mailto:varsha.shukla@nih.gov)

## Page Limitations

All page limitations described in the SF424 Application Guide and the <u>Table of Page Limits</u> (<u>https://grants.nih.gov/grants/guide/url\_redirect.htm?id=61134</u>) 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 NOFO.

## SF424(R&R) Cover

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

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

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

## SF424(R&R) Other Project Information

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

## SF424(R&R) Senior/Key Person Profile

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

## **R&R or Modular Budget**

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

## **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:

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

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

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

RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

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

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

## PHS Human Subjects and Clinical Trials Information

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

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

#### Study Record: PHS Human Subjects and Clinical Trials Information

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

#### **Delayed Onset Study**

Note: <u>Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy)</u> 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 <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

## 4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url\_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11128</u>) (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 <u>eRA Commons (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11123</u>), 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 <u>NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82423)</u>.

# 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 <u>intergovernmental review.</u> (<u>https://grants.nih.gov/grants/policy/nihgps/html5/section\_10/10.10.1\_executive\_orders.htm</u>)

## 6. Funding Restrictions

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

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

## 7. Other Submission Requirements and Information

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

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

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

## Important reminders:

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

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

See more tips (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by <u>components of participating organizations</u>, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the NIEHS Referral Office by email at <u>alfonso.latoni@nih.gov (mailto:</u> <u>{alfonso.latoni@nih.govxxxx@mail.nih.gov)</u> when the application has been submitted. Please include the NOFO number and title, PD/PI name, and title of the application.

## **Post Submission Materials**

Applicants are required to follow the instructions for post-submission materials, as described in <u>the policy</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82299)

# Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the <u>NIH</u> <u>mission (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11149</u>)</u> 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**

#### RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

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?

## 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.

## Study Timeline

## **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 <u>Guidelines for the Review</u> of Human Subjects (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11175).

https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-23-011.html

RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

## 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 <u>Guidelines for the Review of Inclusion</u> in <u>Clinical Research (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11174)</u>.

## **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 <u>Worksheet for Review of the Vertebrate Animals Section (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11150)</u>.

#### **Biohazards**

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

#### Resubmissions

Not Applicable

#### Renewals

Not Applicable

#### **Revisions**

Not Applicable

#### **Additional Review Considerations**

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

## **Applications from Foreign Organizations**

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

#### Select Agent Research

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

## **Resource Sharing Plans**

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., <u>Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview</u>)) or the rationale for not sharing the resources, is reasonable.

## Authentication of Key Biological and/or Chemical Resources

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

## **Budget and Period of Support**

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

#### 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the National Institute of Environmental Health Sciences in accordance with <u>NIH peer review policy and procedures</u>

RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

(//grants.nih.gov/grants/guide/url\_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

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

<u>Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section\_2/2.4.2\_appeals\_of\_initial\_scientific\_review.htm)</u> 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 Environmental Health Sciences Council.. The following will be considered in making funding decisions:

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

#### 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the <u>eRA Commons (//grants.nih.gov/grants/guide/url\_redirect.htm?id=11123)</u>. 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 <u>NIH Grants Policy Statement Section 2.4.4 Disposition of Applications</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82416).

## Section VI. Award Administration Information

## 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the <u>NIH</u> <u>Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82418)</u>.

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

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the <u>Award Conditions and Information</u> <u>for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part\_ii\_subpart\_b.htm)</u> website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

## 2. Administrative and National Policy Requirements

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

- <u>Federal-wide Standard Terms and Conditions for Research Grants</u>
   (<u>https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_3/3.1\_federalwide\_standard\_terms\_and\_conditions\_for\_research\_grants.htm</u>)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82417)
- <u>Acknowledgment of Federal Funding</u> (<u>https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_4/4.2.1\_acknowledgement\_of\_federal\_funding.htm</u>)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect

#### RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an <u>HHS Assurance of Compliance form (HHS 690) (https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf)</u> in which the recipient agrees, as a term and condition of receiving the grant, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <u>https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html</u> (<u>https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html</u>) and <u>https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html</u>).

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

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

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <a href="https://www.hhs.gov/ocr/about-us/contact-us/index.html">https://www.hhs.gov/ocr/about-us/contact-us/index.html</a> (<a href="https://www.hhs.gov/ocr/

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

## **Cooperative Agreement Terms and Conditions of Award**

Not Applicable

## 3. Data Management and Sharing

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

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the <u>NIH Grants Policy Statement</u>

#### RFA-ES-23-011: Time-Sensitive Research Opportunities in Environmental Health Sciences (R21 Clinical Trial Not Allowed)

(<u>https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_8/8.2.3\_sharing\_research\_resources.htm#Data</u>). 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 <u>Research Performance Progress Report (RPPR)</u> (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the <u>NIH Grants Policy Statement</u> (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82419).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url\_redirect.htm?id=82420)</u>. NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

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

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

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

## **Application Submission Contacts**

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

Finding Help Online: <u>https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help)</u> (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: <u>GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov)</u> (preferred method of contact) Telephone: 301-637-3015

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

## Scientific/Research Contact(s)

Toccara Chamberlain, M.A. National Institute of Environmental Health Sciences (NIEHS) Telephone: 984-287-4482 Email: <u>toccara.chamberlain@nih.gov (mailto:toccara.chamberlain@nih.gov</u>)

## Peer Review Contact(s)

Varsha Shukla, Ph.D. National Institute of Environmental Health Sciences (NIEHS) Telephone: 984-287-3288 Email: <u>varsha.shukla@nih.gov (mailto:varsha.shukla@nih.gov)</u>

## Financial/Grants Management Contact(s)

Barbara J. Gittleman National Institute of Environmental Health Sciences (NIEHS) Telephone: 984-287-3261 <u>barbara.gittleman@nih.gov (mailto:barbara.gittleman@nih.gov)</u>

# Section VIII. Other Information

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

## Authority and Regulations

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

Awards are made under the authorization of Superfund Amendments and Reauthorization Act of 1986, Title I, Section III, and Title II, Section 209, Public Law 99- 499, as amended; Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, Section 311(a), Public Law 96-510; Public Health Service Act, Section 301, Public Law 78-410, as amended; Public Law 99-500. In addition, awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92; and under the authority in 42 CFR 65.5.

<u>Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?07-07-23)</u> <u>NIH Funding Opportunities and Notices (/grants/guide/index.html)</u>



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