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/))

Funding Opportunity Title

Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) (R01 Clinical Trial Optional)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

Announcement Type

Reissue of RFA-ES-18-007 (https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-007.html)

Related Notices

- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
- NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
- **November 29, 2021** - Notice of Clarification of Award Budget Instructions for Specific Aims in RFA-ES-21-007. See Notice NOT-ES-22-004 (https://grants.nih.gov/grants/guide/notice-files/NOT-ES-22-004.html).
- **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).
- **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).
- **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html)
- **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)
- **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)

Funding Opportunity Announcement (FOA) Number

RFA-ES-21-007

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

The purpose of the ViCTER program is to use the R01 mechanism to foster and promote early-stage transdisciplinary collaborations and/or translational research efforts to address fundamental research among basic (technology and mechanism oriented), clinical (patient-oriented) and population-based researchers in the environmental health field. The newly established collaborative teams will come together in common interest to investigate potential linkages between human health and one or more environmental stressor(s). The ViCTER program is intended to support innovative high-risk, high-reward transdisciplinary/translational research projects that are more difficult to achieve in a typical R01 application. Collaboration among investigators at different institutions through a virtual consortium arrangement is encouraged.

Key Dates

Posted Date

October 06, 2021

Open Date (Earliest Submission Date)

January 01, 2022

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 01, 2022	February 01, 2022	Not Applicable	June 2022	October 2022	December 2022
February 01, 2023	February 01, 2023	Not Applicable	June 2023	October 2023	December 2023
February 01, 2024	February 01, 2024	Not Applicable	June 2024	October 2024	December 2024

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.

Expiration Date

February 02, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

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

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

Applications that do not comply with these instructions may be delayed or not accepted for review.
There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

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

   Apply Online Using ASSIST

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

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-ES-21-007) 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 National Institute of Environmental Health Sciences (NIEHS) seeks to advance understanding of how environmental agents impact human health by supporting broad research activities spanning basic research (e.g. molecular, cellular, whole animal laboratory-based studies, population-based research, etc.), to applied research (e.g. clinical trials, community-based intervention and prevention studies, etc.). As evidenced by the NIEHS portfolio of grants (http://tools.niehs.nih.gov/portfolio/ (http://tools.niehs.nih.gov/portfolio/)), the NIEHS also supports a wide range of disciplines, building upon biomedical research foundations for multiple disease endpoints and environmental agents, while also drawing from disciplines that assess the totality of exposures a human may encounter over a lifetime, including co-exposures, food/nutrition, societal factors, health disparity, severe weather, etc.

NIEHS recognizes that the vexing issues in environmental health require crosstalk between disciplines to understand root causes of disease and/or assess effectiveness of interventions. In addition, the NIEHS Strategic Plan (https://www.niehs.nih.gov/about/strategicplan/index.cfm) stresses translating science findings into knowledge that can inform real-life individual and public health outcomes. The integration and application of knowledge arising from these disparate approaches and disciplines can be achieved most effectively in transdisciplinary and translational research environments.

For purposes of this FOA, transdisciplinary research is defined as research that involves scientists from multiple disciplines working interactively on a common problem to develop novel cross-disciplinary methods, insights and research approaches that would not have occurred with a traditional uni-disciplinary investigation. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Hence, NIEHS has a special interest in promoting such integrative research efforts, which hold promise for accelerating progress toward achieving improvements in public health.

Translational research encompasses the evolution of an idea as it moves through the various phases of research with the goal of creating an impact on human health. This concept is explained in depth in the NIEHS Translational Research Framework (TRF) which describes five major translational research categories: fundamental questions, integration and synthesis, application and adjustment, practice, and impact (https://www.niehs.nih.gov/research/programs/translational/index.cfm (https://www.niehs.nih.gov/research/programs/translational/index.cfm)). At the fundamental level, the TRF defines research translation as moving between different levels of biological organization – molecular, biochemical pathway, cellular, tissue, organ, model organism, human, and population. Hence, research that addresses a fundamental environmental health question from the perspective of *in silico*, *ex vivo*, and human population would be considered translational research. As research progresses, it may be ready for application and synthesis (e.g. intervention pilot testing or other controlled testing) or even implementation and adjustment (e.g. clinical testing, intervention validation, biomarker screen validation). These examples that move fundamental science closer towards application are also considered research translation.

While some of the NIEHS-supported programs (particularly the large Centers) support translational and/or transdisciplinary research, the greater part of the NIEHS grants portfolio comprises individual research projects which tend to favor uni-disciplinary model of research. Few of these fully incorporate integrative research aims. This reflects, in part, difficulties that investigators face in pursuing interdisciplinary and collaborative research in the context of a single research project. For example, it may require extra resources to form and nurture new/novel early-stage collaborations to produce preliminary data to establish feasibility and value of the collaboration. Also, forging new ways of approaching science can be risky – despite the long-term rewards, there may be hesitance to take risks, particularly for early-stage investigators faced with establishing and advancing their careers. Lastly, investigators with complementary expertise may not be a part of one's professional network and/or could be located at different institutions, creating additional challenges for sustained engagement of interdisciplinary teams.

In 2010, NIEHS developed the Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) program to address key obstacles in conducting integrative research in the context of a single research project. This funding opportunity announcement continues the ViCTER program and invites investigators with interest and expertise in areas relevant to the field of environmental health sciences to develop and implement a translational/transdisciplinary research project. ViCTER projects are expected to foster a better understanding of the mechanism of disease/dysfunction in those areas where environmental factors are known or are suspected to influence the development or progression of disease. The initiative will allow investigators to extend existing areas of research in new directions and/or develop novel lines of inquiry through the creation of a virtual consortium that includes new perspectives, such as basic mechanistic, clinical, epidemiological, computational, engineering, behavioral/social science, health risk communication, and/or initiating approaches for intervention, prevention, and implementation. By employing translational/transdisciplinary approaches, investigators will be able to improve the potential impact of their work on public health. Furthermore, these transdisciplinary/translational research approaches also have the capacity to bring innovation to environmental health sciences. NIEHS recognizes that there is novelty in bringing together approaches from one discipline/line of inquiry and applying them to another line of inquiry. While the approaches may not always appear to be innovative independently, it is the combination of approaches together that create the innovation.

Research Objectives

The primary goal for creating this ViCTER program is to support the exchange of knowledge among individuals from a diverse set of disciplines and accelerate the translation of scientific research into meaningful improvements in human health in those areas where environmental factors are known or suspected to influence the development or progression of disease. To accomplish this goal, each newly established collaborative team is expected to initiate research in the development and application of novel approaches for understanding the etiology of environmentally-related disease and, where appropriate, explore clinical and public health implications for diagnosis, treatment and/or prevention.

Each ViCTER consortium must consist of at least three key participants (the PD/PI plus two scientists designated by the PD/PI as "co-investigators") that together represent a newly collaborative team. For the purposes of this FOA, a team is considered newly collaborative if there are no co-authored original research publications among the PD/PI and co-investigators within the last 5 years (excluding reviews, white papers, commentaries etc.). NIEHS strongly recommends but does not require that at least one co-investigator be at a different institution from the PD/PI. In addition, applicants are encouraged to assemble teams that bring diverse perspectives to the theme of the consortium, thus enhancing translational opportunities and broadening the public health impact.

A critical component of the ViCTER program, particularly in cases where team members are located at different institutions, is their virtual aspect. This allows researchers at remote locations to form a consortium to integrate their research through the development of a "virtual" center that coordinates the overall ViCTER project. The PD/PI serves as the Director of the consortium and is responsible for scheduling regular virtual (at least monthly) and in-person (at least yearly) meetings.

The PD/PI must propose a series of aims that are thematically related, foster collaboration among team members and reflect transdisciplinary/translational approaches to environmental health. The PD/PI and co-investigators should each have a substantial and meaningful role in developing and conducting the overall ViCTER project, demonstrated by each assuming primary responsibility for leading one or more of the proposed Specific Aims. The aims may include several research approaches to address a fundamental research question (i.e. moving within the TRF "fundamental questions" level), or may combine fundamental research questions with more intervention-, prevention-, and/or implementation-based approaches (i.e. moving from TRF "fundamental questions" towards "application and synthesis" and/or "implementation and adjustment"). NIEHS also particularly encourages applicants to propose research aims that are

high risk/high reward which, if successful, are likely to contribute significantly to one or more areas of environmental science and/or be the motivator of future collaborative research. In addition, ViCTER teams present a unique opportunity for cross-disciplinary training; hence, seeking opportunities to enhance and broaden skills of students is encouraged.

Applicants should prospectively plan for how scientific data generated from the proposed research project will be preserved and shared. Likewise, the team should develop a robust plan for data management and sharing to facilitate synthesis, integration, and translation of the individual aims. As applicable, applicants are highly encouraged to include an expert in data stewardship when data integration, sharing, and reuse are critical to achieving the goal of the consortium. For additional information, NIH has developed guidance for recommended elements of a Data Management and Sharing Plan (NOT-OD-21-014 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-014.html)).

Research Scope

The proposed ViCTER project must fall within the NIEHS mission. Examples of environmental exposures relevant to the mission of the NIEHS include, but are not limited to the following: industrial chemicals or manufacturing byproducts; byproducts of formal or informal resource extraction activities (e.g. mining, e-waste); metals; pesticides; herbicides; air pollutants and other inhaled toxicants (including indoor air pollutants); particulates or fibers; and fungal, bacterial or biologically derived toxins. Applications that propose laboratory-based studies using only model compounds (i.e., those without potential for human exposure) must provide a clear, reasonable and specific description as to how research on the model compound will lead to a better understanding of the mechanisms involved in response to specific environmental agents which are included in the mission responsibility of the NIEHS. In addition, several exposure scenarios are of interest to NIEHS and may serve as the basis for developing a translational/transdisciplinary ViCTER project. Such exposure scenarios include environmental health impacts of climate change on vulnerable communities; health disparities among environmental justice communities; informal electronic waste (e-Waste) or other mining operations; food-born exposures to toxicants (including metals/metalloids in baby food, drinking water contaminants, pollutants in seafood); or one-health frameworks (e.g. intersection of human, non-human, environment).

The transdisciplinary/translational ViCTER framework creates an opportunity to incorporate new approaches into environmental health studies research. Investigators who propose studies with a primary focus on NIEHS mission relevant exposures' impact on human health may include other relevant disciplines to understand the role(s) of cofactors/modifiers of the risk or protection associated with the primary exposure(s), to explore exposure processes, and/or identify patterns in data. Applicants may wish to incorporate, for example: machine learning/artificial intelligence; new approach methods (NAMs); epigenomic-epitranscriptomic crosstalk; meta-proteomics; fate, transport, and exposure modeling; integration of geospatial/satellite data streams; development and application of advanced sensor, imaging, or biomonitoring tools; infectious disease; mental health; mixed methods (qualitative and quantitative) or behavioral/social sciences; and implementation science. Applicants may also incorporate individual and structural social determinants of health (for examples, please refer to NOT-MD-21-003 (https://grants.nih.gov/grants/guide/notice-files/NOT-MD-21-003.html)) and the PhenX Social Determinants of Health toolkit (https://www.phenxtoolkit.org/collections/view/6 (https://www.phenxtoolkit.org/collections/view/6)).

Examples of collaborative research projects responsive to this ViCTER FOA include, but are not limited to, projects that seek to:

- Use recent innovative *in vitro* functional genomics tools/technologies and population-based model organisms to investigate genetic susceptibility to environmental exposures.
- Apply novel approach methods to rapidly assess health hazards of chemicals of emerging concern; incorporate toxicology or 'omics data from exposed sentinel species; integrate population-based research to assess exposures in human populations and/or identify vulnerable populations.
- Examine the mechanistic link between microbiome alterations and the gut-brain axis; relate changes in microbial metabolites or microbial activated pathways to poor health outcomes; assess mechanisms and efficacy of dietary or prebiotic interventions in protecting from chemical insult.
- Frame mechanistic research around an adverse outcome pathway model to initiate understanding impacts from chemical and nonchemical stressors; employ knowledge graphs to identify shared pathways for chemical and nonchemical stressors.
- Develop approaches (e.g. tracer methods) to determine exposure rates and/or different routes of human exposure; develop exposure metrics from scenarios such as fish consumption (e.g. mercury and polychlorinated biphenyls), soil ingestion (e.g. lead), or drinking water exposures; incorporate population-based studies to validate models/approaches.
- Develop methods/biomarkers to incorporate non-chemical stressors into statistical analyses investigating the link between environmental toxicants and adverse human health outcomes; incorporate expertise in community health intervention to translate findings for potential public health relevance.
- Community engaged, transdisciplinary projects that apply an exposome framework (e.g. exposure modeling, biomarkers of exposure, non-targeted analysis) to characterize environmental health disparities or initiate development of interventions to address environmental injustices.

The preceding examples are provided only to illustrate collaborative projects in keeping with the spirit of the ViCTER FOA. These examples fall within the broad mission areas of the NIEHS, but do not necessarily designate areas of highest priority. It is expected that applicants will develop collaborative translational/transdisciplinary approaches that blend the unique skills of specific members of the team to address a significant question in environmental health sciences.

Applicants are strongly encouraged to contact NIEHS Program staff prior to submission to determine if their project meets the interests of the NIEHS, have questions about the eligibility of their co-investigators or any other issue relevant to the ViCTER application.

NIEHS will be holding a ViCTER Funding Opportunity Webinar for potential applicants in November 2021. Please visit the ViCTER webpage for information about the webinar date and time as well as registration links:
https://www.niehs.nih.gov/research/supported/translational/victer/index.cfm
(https://www.niehs.nih.gov/research/supported/translational/victer/index.cfm).
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
Resubmission

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

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

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

Funds Available and Anticipated Number of Awards

NIEHS intends to fund an estimate of 3-4 awards, corresponding to a total of $2,750,000 for each fiscal year FY2023, FY2024 and FY2025.

Award Budget

Application budgets are limited to $475,000 direct cost per year and should reflect the actual needs of the proposed project.

Award Project Period

Applicants may request support for up to 3 years (no partial years).

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

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 Government

- 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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

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

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

Required Registrations

Applicant organizations

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

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

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

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

Eligible Individuals (Program Director/Principal Investigator)

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

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

For applications proposing multiple PDs/PIs, each PD/PI can be considered in meeting the requirement for a minimum of three members of the newly established collaborative team.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). 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 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar,)).

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

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

Letter of Intent

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

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

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

The letter of intent should be sent to:

Varsha Shukla, Ph.D.
National Institute of Environmental Health Sciences (NIEHS)
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 Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

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.

The ViCTER consortium must consist of at least three key participants, the PD/PI plus two scientists designated by the PD/PI as co-investigators. In multi-PI (MPI) applications, each MPI can be considered as one of the required three key participants on the project team. Although it is recommended that at least one of the consortium members be at a different institution than the rest of the project team, it is not required. However, since the goal is to develop new collaborations, the key consortium members must not have coauthored research publications (excluding reviews, white papers, commentaries, etc.) with one another within the last 5 years.

Other Attachments: The following "Other Attachment" shouldbe included to aid in the review of applications.

Consortium Diagram: Provide an organizational diagram to show relationship between the components of the consortium. Label aims based on NIEHS Translational Research Framework (www.niehs.nih.gov/research/programs/translational/index.cfm (https://www.niehs.nih.gov/research/programs/translational/index.cfm)) and identifying which collaborator is the lead. (Note, at least one aim should address a fundamental question (as defined in TRF as *in silico* organism, *in situ* organism, *in vitro* organism, *ex vivo* organism, *in vivo* organism, or group and population). Identify any aims that are high risk / high reward. Label roles for collaborators and other significant contributors (including administrative, data coordination, etc). Denote points of integration (including cross-training).

R&R or Modular Budget

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

Applicants can request support for a variety of activities, including but not limited to, the sharing of tissues, assays, animals, and biosamples; coordination of bioinformatics for sample analysis; coordination of analyses; cross training of students, postdoctoral fellows and technicians among labs; research dissemination and community outreach activities; and regular in-person meetings.

Allocation of Funds among Collaborative team: While the budget allocations may be predicated by need, a minimum of $75,000 direct costs should be requested to support each aim. In addition to the budget justification, include a brief statement indicating the direct and indirect costs for each aim.

Budget requests should include appropriate costs to support data management and sharing for the project, including costs associated with curating data and developing supporting documentation, costs associated with providing local data management, and fees for preserving and sharing data through established data repositories.

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

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 and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

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.

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

Specific Aims:

- State the overall transdisciplinary/translational objective of the ViCTER project and the proposed aims that will be used to meet the overall objective.
- Identify which member of the collaborative team will have primary responsibility for each aim and how each of the aims draws on unique expertise and skills of the PD/PI or co-investigator(s).
- Clearly identify any research aim(s) that are considered exploratory high risk/high reward.
- For each aim, summarize the methods to be used, the specific hypotheses to be pursued, expected outcomes and relation to the overall theme of the project.
- Describe the interdependence of the proposed collaborative aims and how each is needed to address the central problem and the potential scientific synergy to be achieved.

Research Strategy: The Research Strategy should include the following elements:

Significance:

- State and justify the complex biological problem to be solved and its relevance to environmental health sciences.
- Describe the transdisciplinary/translational nature of the ViCTER project and the range of expertise to be brought to bear on the problem. Describe the diverse perspectives brought to bear by the team and the significance of linking these disciplines.
- Identify potential outcomes of the proposed project and how the research will advance the field of environmental health science and impact human health.

Innovation:

- Describe the innovation associated with the collaborative approaches, specific methods, concepts or instrumentation proposed for the ViCTER project. Describe how the collaboration itself brings innovation to environmental health sciences through uniquely linking together approaches from one discipline/line of inquiry and applying them to another line of inquiry.
- Describe advantages of the proposed approaches over existing methods.
- Describe any potential changes in clinical or public health practice that may be spurred by the outcomes of the ViCTER project.

Approach:

- For each specific aim, describe the overall strategy, methodology, and analyses to be used.
- For any aims designated as exploratory, note the high risk/high reward nature and provide preliminary data to demonstrate the feasibility of the approaches (methodology, tools, techniques, etc.).
- For well-developed (non-exploratory) aims, provide preliminary data to support the specific hypotheses to be pursued.
- Describe the relationships and co-dependencies among the aims (e.g., sharing of data, samples).
- Discuss potential problems and alternative strategies (e.g, adjustments that will be made if one of the interdependent aims is not successful), particularly for high-risk aims.
- Note, for applications involving significant interactions with communities, please describe community engagement best practices which may include the following: description of the defined community of interest; the community's and researchers' roles (roles in design of project); benefit of the research to the community; evidence of the community's acceptance as role as a partner (e.g., letters of support from the community can be attached via Letters of Support); a management plan for maintaining transparent communications between the community and the academic partners throughout the entirety of the activity.

Investigators:

- Describe how each key participant of the proposed ViCTER team contributes unique expertise, resources, methods and/or technologies to the virtual consortium. Include past successes in transdisciplinary/translational research collaborations.
- Describe how the experiences and skills of the proposed team brings together diverse disciplines and perspectives.
- Describe the team’s expertise in data sharing and, as applicable, data stewardship.

Synergy and Structure of the ViCTER Consortium:

- Provide a succinct description of the organizational structure of the consortium including an administrative and management plan that will achieve an integrated, coordinated and interdisciplinary research consortium. Note, please see “Other Attachments” for accompanying diagram of consortium.
- Describe the roles and responsibilities of the PD/PI and designated members of the ViCTER collaborative team in the areas of leadership and oversight of the overall research efforts.
- Indicate how the consortium’s progress towards the expected scientific outcomes will be monitored and adjusted as needed.
- Describe the frequency and type (e.g., face-to-face, virtual, etc.) of meetings for all ViCTER consortium participants.
- Describe plans for cross-disciplinary training including how cross-laboratory interactions promote professional development for the individual and create synergy between the research team.
- Describe plans to synthesize research findings, integrate data from separate aims, and to translate results to public health and/or follow-on studies. Highlight how data from one aim will feed into the other aims and how the study outcomes will move the field in a new direction or stimulate new collaborations.
- Describe the strength of synergy and integration among the combined efforts of the various investigators within the overall project. Highlight how the virtual consortium would make a greater contribution to the central environmental health problem of focus than if each of the investigators conducted their projects alone.
- Describe a timeline for proposed activities including plans for synthesis of research from separate aims.

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.

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151). The Data Sharing Plan should describe the approach for how the scientific data generated from the proposed research project and any accompanying metadata will be managed, preserved, and shared, taking into account any potential restrictions or limitations. The Data Sharing Plan should address each of the following points in detail:
    - description of the scientific data to be generated and shared throughout the grant;
    - information on related tools, software, and/or code;
    - description of standards to be applied to the scientific data and associated metadata;
    - plans for data preservation;
    - description of factors affecting access, distribution, or reuse of scientific data; and
    - plans for oversight of data management and sharing.
    - Additional information on each of the elements to be addressed in the Data Sharing Plan can be found in NOT-OD-21-014 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-014.html).
    - The Data Sharing Plan should not exceed two pages in length.
- Applications that generate model organisms or genomic data must include a plan for Sharing Model Organisms and Genomic Data Sharing (GDS).

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

PHS Assignment Request Form

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

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

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

eRA Commons, and Grants.gov.

4. Submission Dates and Times

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

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov (http://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/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

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

Important reminders:

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

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

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

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by NIEHS. 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 varsha.shukla@nih.gov (mailto:varsha.shukla@nih.gov) by email at when the application has been submitted. Please include the FOA 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 the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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

The ViCTER will be reviewed as a whole with emphasis onits translational and transdisciplinary nature as well as the degree of synergy (interaction and collaborative research opportunities) that will be stimulated by the consortium.

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

Overall Impact

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?

Is the environmental health focus of the proposed virtual consortium an area where environmental factors are known or expected to influence the development or progression of disease?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Does each key participant of the proposed ViCTER team contribute unique expertise, resources, methods and/or technologies to the virtual consortium? Does the PD/PI have a track record of embracing the ideas of rigor and reproducibility and of transparency in science including data sharing and collaboration? Are the roles and responsibilities of the PD/PI and designated members adequately described, including leadership and oversight? For projects proposing research with a strong community engagement component, do the investigators have expertise in working with communities?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in

study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

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

Does the proposed virtual consortium represent a new, unique opportunity to foster translational and/or transdisciplinary research that has not been possible previously?

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/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?

For applications involving significant interactions with communities, are plans for community engagement adequate?

For applications generating model organisms or genomic data, are the Sharing Model Organisms and Genomic Data Sharing plans adequate?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

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

Are plans in place to support the regular interactions among collaborative team members, including those that may be remote?

In addition, for applications involving clinical trials

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

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

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

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

Additional Review Criteria

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.

Translational and/or Transdisciplinary Nature

Do the aims cross multiple disciplines or stimulate the bidirectional flow of information across the spectrum of in vitro, model organisms and animal models, human populations or clinically-based research to provide data useful for the prevention of, or the intervention in, human disease?

Synergy

Are there strong synergy and integration among the combined efforts of the various investigators within the overall project? Will the creation of the virtual consortium make a greater contribution to the central environmental health problem of focus than if each of the investigators conducted their projects alone? Will the outcome move the field in a new direction or stimulate new collaborations? Will data from one aim feed into the other aims? Are there adequate plans to provide cross-disciplinary training, synthesize research findings, integrate data from separate aims, and translate findings?

Study Timeline

Specific to applications involving clinical trials

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

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research

strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

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

Biohazards

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

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable.

Revisions

Not Applicable

Additional Review Considerations

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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

Not Applicable

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 Data Sharing Plan adequately describes how the scientific data and accompanying metadata will be managed and shared including information on tools, standards, and plans for data preservation/access/oversight.

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 NIEHS, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory 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 eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm).

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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

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.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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

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

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

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

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

2. Administrative and National Policy Requirements

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

- Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

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

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 (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 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

Data Management and Sharing

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

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

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)

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/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

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

Scientific/Research Contact(s)

Heather Henry, Ph.D.
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3268
Email: heather.henry@nih.gov (http://heather.henry@nih.gov)

Peer Review Contact(s)

Varsha Shukla, Ph.D.
National Institute of Environmental Health Sciences (NIEHS)
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Email: Varsha.shukla@nih.gov (mailto:Varsha.shukla@nih.gov)

Financial/Grants Management Contact(s)

Jenny Greer
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3332
Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

Section VIII. Other Information

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

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?10-08-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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