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 on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

Funding Opportunity Title

Research to Action: Assessing and Addressing Community Exposures to Environmental Contaminants (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-20-002 (https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-20-002.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

Funding Opportunity Announcement (FOA) Number

PAR-22-210

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.113, 93.307

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) encourages multidisciplinary projects to investigate the potential health risks of environmental exposures of concern to a community and to develop and implement an environmental public health action plan based on research findings. Projects supported under this program will employ community-engaged research methods to conduct research and to translate research findings into public health action. This announcement reflects NIEHS' and NIMHD's commitment to environmental health disparities and environmental justice research. This FOA also advances efforts to nurture and sustain trust and bi-directional communication between academic researchers and affected communities. The Research to Action program is part of the National Institute of Environmental Health Sciences (NIEHS) "Partnerships for Environmental Public Health" (PEPH) network (https://www.niehs.nih.gov/research/supported/translational/peph/index.cfm (https://www.niehs.nih.gov/research/supported/translational/peph/index.cfm)).

Key Dates

Posted Date

July 15, 2022

Open Date (Earliest Submission Date)

September 05, 2022

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 05, 2022 *	November 05, 2022 *	Not Applicable	March 2023	May 2023	July 2023
February 05, 2023 *	March 05, 2023 *	Not Applicable	July 2023	October 2023	December 2023
June 05, 2023 *	July 05, 2023 *	Not Applicable	November 2023	January 2024	April 2024
October 05, 2023 *	November 05, 2023 *	Not Applicable	March 2024	May 2024	July 2024
February 05, 2024 *	March 05, 2024 *	Not Applicable	July 2024	October 2024	December 2024
June 05, 2024 *	July 05, 2024 *	Not Applicable	November 2024	January 2025	April 2025
October 05, 2024 *	November 05, 2024 *	Not Applicable	March 2025	May 2025	July 2025
February 05, 2025 *	March 05, 2025 *	Not Applicable	July 2025	October 2025	December 2025
June 05, 2025 *	July 05, 2025 *	Not Applicable	November 2025	January 2026	April 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

September 08, 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 SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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/url_redirect.htm?id=11164)).

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=PAR-22-210) 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

Background

The National Institute of Environmental Health Sciences (NIEHS) has supported and advanced community-university programs and partnerships to better understand environmental health disparities and respond to environmental justice concerns of affected community groups and natural and technological disasters. Since 2009, the NIEHS has invited applications for the Research to Action program to support collaborative projects focused on community-identified environmental health issues. A description of currently funded grants under the Research to Action program can be found at: https://www.niehs.nih.gov/research/supported/translational/rta/index.cfm

(https://www.niehs.nih.gov/research/supported/translational/rta/index.cfm). This program is a key component of the Partnerships for Environmental Public Health (PEPH) network. The PEPH encompasses a variety of research, communication, and training/educational activities to identify, prevent, reduce, or eliminate environmental exposures that are associated with adverse health outcomes in affected communities. Further, Research to Action is a central program to the Institute's commitment to Executive Orders 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) and 14008 (Tackling the Climate Crisis at Home and Abroad (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/)) and in implementing recommendations outlined in the U.S. Department of Health and Human Service's strategic plan to address Environmental Justice. Finally, Research to Action is building upon a long history of shared interests between the NIEHS and the National Institute on Minority Health and Health Disparities (NIMHD) to understand and reduce or eliminate environmental health disparities.

Protecting the public from environmental health risks requires the translation of hypothesis-driven, etiologic research characterizing environmental exposures and exposure-health relationships into action to prevent, reduce or eliminate exposure(s), and disease. To meet the needs of affected communities, authentic community participation in all aspects of the research process is essential. Developing trusted and equitable community-university partnerships in environmental public health research helps ensure that:

- Communities identify and define problems and risks related to environmental exposures and stressors that are of greatest importance to them.
- Communities receive the scientific and financial support necessary to conduct rigorous research in partnership with academic researchers that will accurately characterize the distributions and sources of environmental exposures and exposure-health relationships (if any) in their community and empower all involved to take action to reduce potential health risks.
- Communities co-develop training/education, communication, remediation, prevention and interventions with academic researchers and other project partners to reduce or eliminate such exposures and to improve health outcomes.
- Training/education, communication, remediation, prevention and interventions are equitably implemented and provided in accessible, culturally appropriate formats and developed at a literacy level and in language(s) appropriate for members of that community.

Community Engaged Research (CEnR) is a continuum that reflects the level of involvement of community members, or representatives of specific subpopulations, in the research process. The continuum ranges from community consent and outreach to shared leadership of community members in the research design and implementation of the project. Community-based participatory research (CBPR) is one recognized approach in the CEnR spectrum.

For this FOA, we encourage CEnR approaches that include the full participation of community members in the identification of exposures of concern to that community, suitable cohorts and the specific needs of subpopulations; the co-development of the research questions and research design; the translation and dissemination of study results; the co-development and implementation of an environmental action plan; and the co-development of methods for evaluating the success of the project.

Recognizing that communities are not monolithic, CEnR approaches should entail the involvement of sufficient numbers of individuals and community-based organizations to adequately represent all segments of their community. Involving larger numbers of community members can ensure that projects more effectively reflect the diversity of community values, create an inclusive environment for all affected project partners, nurture collaboration, build community capacity to sustain interventions and implementation plans, and increase health and environmental health literacy among those involved.

CEnR approaches are essential when addressing environmental justice (EJ) issues, social determinants of health (SDOH), and structural/systemic barriers. EJ is a social movement to remedy the unequal burden of exposure and disease borne by groups that have been socioeconomically disadvantaged (see the NIH definition (https://www.nimhd.nih.gov/about/overview/#:~:text=NIMHD%20has%20been%20a%20leader,in%20relation%20to%20health%20disparities.) for populations that experience health disparities) (https://www.britannica.com/topic/environmental-justice (https://www.britannica.com/topic/environmental-justice)). SDOH are "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (https://health.gov/healthypeople/priority-areas/social-determinants-health (https://health.gov/healthypeople/priority-areas/social-determinants-health)). These conditions such as housing quality, air pollution, and water contamination play important roles in the health of these sub-populations and across generations. Furthermore, structural or systemic barriers such as historical redlining has been shown to lead to increased environmental exposures and disease burden among people who are economically least able to cope with such stressors. Active participation of community members in the formulation of environmental health research questions, and in the conduct and translation of research findings, can better identify the role SDOH can play in the lived experience of community residents, increase the use of and appreciation for local knowledge in research, help community members better understand the associated health risks, and empower residents to make informed decisions or to initiate local activities to prevent ongoing chronic and/or cumulative exposures that disproportionately affect them.

For this FOA, "community" refers to populations and groups affected by, or with a shared interest in, environmental exposures and related health outcomes. Communities may include NIH defined populations that experience health disparities as well as geography, exposure(s), age, occupation, religion, disability, illness, or other health condition. The term "community-based organization" (CBO) is broadly defined. The CBO may be a formally recognized organization, such as a non-profit organization that serves the needs of EJ communities or populations facing environmental health disparities, and may also be an established community group or network with a common interest in a particular

environmental health concern and that includes representatives of the community. As noted above, the involvement of more than one CBO may be necessary to represent the interests and concerns of all members of the community (for example, the distinct needs of different age groups or diseases, the cultural constraints related to a particular ethnic or religious sub-population.)

Objectives and Scope

This FOA strengthens and advances NIEHS' commitment to community-engaged research projects that respond to the identified needs of community groups and make research actionable. The FOA will also expand the scope and reach of projects supported through the Research to Action program (https://www.niehs.nih.gov/research/supported/translational/rta/cfg/index.cfm (https://www.niehs.nih.gov/research/supported/translational/rta/cfg/index.cfm)). The main objectives of this program remain the same as prior solicitations: 1) promote community engagement in environmental health research, 2) support multi-disciplinary research to collect and characterize information about environmental health concerns of significance to a community, and 3) stimulate research translation and dissemination to community members, public health professionals and/or policymakers to inform an action that will ultimately promote the reduction of exposure(s) and reduce the health impact from environmental stressors. To meet these stated objectives, applicants must propose CEnR projects that incorporate all three elements: community engagement, research, and public health action. A fourth optional element is evaluation. These elements are discussed in detail below.

Given the advanced scope of the NIH R01 mechanism used for this FOA, it is anticipated the community-research partnerships will already be established and that applicants will be able to demonstrate evidence of successful past collaboration such as, but not limited to, preliminary data from previous research in the community.

Element #1: Community-Engagement

All projects must demonstrate an authentic community-university partnership. Research teams must include:

- Health researcher(s) with a background in environmental health research.
- Community partner(s). This could include member(s) of affected communities and/or representatives of CBOs (as defined above).

Optional partners could include:

- Health care and public health professional(s).
- Housing, education, social service and/or state or local government officials
- Social science, implementation science and health/risk communication researcher(s).
- Decision maker(s) from a local or state public health departments and laboratories.
- Regional or national organizations whose mission is to address environmental risks to health.

The proposed projects should focus on environmental agents or diseases that have been identified by the community as potential or existing public health issues. Furthermore, the proposed team should appropriately draw upon the unique strengths that each brings to the partnership and demonstrate equitable contributions throughout the proposed project period.

Shared responsibilities of the team include, but are not limited to, (a) determining what information and research questions the proposed study can and cannot provide and address, (b) identifying the most appropriate research design, methodology, and budgetary needs, (c) helping communicate study findings to community members in appropriate and accessible formats, and (d) ensuring research findings are translated effectively into public health action. Community partners serving as co-investigators is strongly encouraged. The use of the multiple PD/PIs leadership plan is strongly encouraged, when feasible and appropriate.

Element #2: Research

The objective of this element is to support research that will 1) increase knowledge of how environmental exposures impact health and disease in communities and 2) directly inform a public health implementation action plan (see Element #3). Proposed studies must be motivated by the expressed concerns of a community (see Element #1). Research may include:

- Discovery/exploratory-based studies intended to fill research gaps by characterizing sources of exposures, measure exposure levels, or the prevalence of exposure-related health conditions among members of the community and the community itself.
- Hypothesis-driven studies designed to improve understanding of the exposure-health outcome relationship.

For this FOA, "environmental exposure" is broadly defined and can include a variety of environmental/occupational contaminants such as heavy metals, pesticides, chemicals, extreme heat and other extreme weather conditions, etc. Exposures to infectious diseases, poorly built or maintained housing, or the neighborhood/social environmental conditions (for example poverty, food deserts, density, noise and/or violence) without an environmental co-exposure are outside the scope of this FOA.

Projects should focus on environmental exposures that meet all the following criteria:

- The exposure(s) is considered a significant environmental health issue of concern to the community.
- The exposure(s) is suspected to be associated with a health effect that has a large public health burden, disproportionately impacts the community of interest (such as environmental justice issues) and/or is an emerging or re-emerging/legacy environmental agent(s) with potential widespread exposure.

- The researcher and community are lacking information needed to support the proposed public health action, such as data on exposure levels, sources, or potential health effects.

Specific examples of research topics that are of interest for this FOA include, but are not limited to:

- Cumulative health impacts of exposure to multiple environmental/occupational stressors on health risks.
  Examples include, but are not limited to, examination of long-term health effects from exposure to multiple endocrine disruptors; the combined effect/interaction between physical, social, and neighborhood-level environmental stressors; diet, and environmental/occupational exposures on health.
- Burden on human health from land use and planning decisions.
  For example, understanding health impacts from siting a new school, housing development, or community center near a known location of a toxic waste site, nuclear facility, chemical plant, or energy resource extraction site (such as oil drilling, hydraulic fracturing, mining, etc).
- Exposure to mixtures of toxic substances and associated health impacts among populations that may experience higher exposure or particular sensitivity to exposure (for example emergency response personnel exposed to disaster recovery or mitigation sites).
- Health impacts from climate change.
  Research in partnership with communities or populations most at risk of the impacts of extreme weather (for example coastal or flood prone communities, tribal communities, the elderly, and children). Could include research on impact of climate change on traditional food sources and practices and resulting health consequences.
- Disproportionate impact of emerging and ongoing exposures affecting the health of a community and its residents. Exposures can include, for example, chemicals in personal care products, microplastics, PFAS/PFOAs, and legacy exposures such as lead or other heavy metals.

While it is anticipated that research will entail primary data collection, projects could build upon previous research conducted with the community and existing findings. Proposals may also take advantage of existing data sources assuming such resources can adequately address the research question(s) and produce new information needed for a public health action plan. Projects that propose to include methodologies for integrating local knowledge about the environment or locally gathered data (such as Tribal Ecological Knowledge approaches and/or citizen science efforts) along with traditional research approaches, are encouraged. Projects evaluating the intersection of SDOH with environmental exposures are strongly encouraged to utilize the Social Determinants of Health Collection of the PhenX Toolkit (www.phenxtoolkit.org).

Element #3: Public Health Action

The environmental public health action element incorporates knowledge gained through the research element of the project. This evidence-based plan should be designed to support change that improves the health of a community through a reduction of exposure levels and ultimately leading to improved quality of life. Ideally, this environmental public health action plan should be multi-level, creating lasting public health impact from the individual to the population level. The National Institute on Minority Health and Health Disparities (NIMHD) Minority Health and Health Disparities Research Framework is one example of a multi-level framework (https://www.nimhd.nih.gov/about/overview/research-framework/ (https://www.nimhd.nih.gov/about/overview/research-framework/)) that could guide a public health action plan. Applicants applying to this FOA may also wish to consider the incorporation of implementation science theories, models, frameworks, and outcomes. Applicants can refer to the NIEHS Implementation Science in Environmental Health website for resources (https://www.niehs.nih.gov/research/supported/translational/implementation/index.cfm (https://www.niehs.nih.gov/research/supported/translational/implementation/index.cfm)).

Community members should be co-developers of this public health action plan. For the purposes of this FOA, examples of environmental public health action include, but are not limited to:

- Campaigns to change individuals' behaviors that will lead to exposure reduction.
- Educational programs for community health care providers about the health risks associated with a prevalent environmental exposure in their community.
- Innovative application of social media and other mobile technologies to promote bi-directional communications with community partners and to effectively communicate findings to all segments of affected populations.
- Communication training for researchers to more effectively engage with community partners and disseminate research findings in culturally appropriate ways.
- Local, regional, or national strategies to raise policymaker awareness of the link between environmental/occupational exposures and adverse health outcomes.
- Evidence-based communications about recognizing, mitigating or preventing local environmental risks.
- Community programs that focus on health promotion and disease prevention related to health risks in environmental exposures.
- Community programs that enhance the quality of life in individuals with chronic disease related to environmental exposures.
- Community-based, culturally appropriate communication and outreach programs to educate community members about potential sources of exposure, the potential associated health risks, and how they might reduce their exposure.
- Exposure reduction or prevention strategies.

- Risk communication strategies that use informational materials to educate policymakers about potential sources of exposure and the associated potential health risks and economic burden resulting from such exposures.
- Community-based training to increase environmental health literacy, and/or health promotion
- Focused community-based training for local policymakers, disaster and emergency response personnel, or for specific segments of the affected community (such as local K-12 educators, community health workers/promotores de salud, faith-based leaders, etc.).
- Medical and continuing medical education training modules in conjunction with local providers to improve awareness and environmental health literacy among health care and public health professionals on the role of the environmental exposure in disease etiology or exacerbation. Education modules may be developed or adapted to address the specific educational needs of nurses, occupational therapists, lay community health workers, and other health care specialties.

Element #4: Evaluation (optional)

Evaluations help community-university partners assess the effectiveness and impact of their projects as well as factors that led to program success (or failure). In addition, evaluations can supply ongoing, systematic information that strengthens projects during their life cycle. Evaluations should be designed to reflect program goals, milestones, and objectives.

The NIEHS PEPH program has developed an Evaluation Metrics Manual to serve as a resource for applicants in developing and implementing an evaluation plan for environmental public health research projects. The complete Evaluation Metrics Manual can be accessed electronically at: http://www.niehs.nih.gov/pephmetrics (http://www.niehs.nih.gov/pephmetrics). Key areas addressed in the Manual include community-university partnerships, the translation and dissemination of messages based on research findings, education and training, and capacity building. Applicants are encouraged to review the Evaluation Metrics Manual for guidance on development of an evaluation plan or to include evaluation scientific expertise on the study team.

Examples of potential measures for evaluating the project's success (activities and outputs) may include:

- Number, type, and/or location of interactions among various partners in the project.
- Number, cost, content, and/or level of community involvement in development and dissemination of education and training information.
- Number of people (community members, researchers, and health care providers) trained to use a specific approach or tool).
- Number and/or type of additional support/resources CBOs and Communities are able to garner after completion of training activities.
- Proportion of participants reporting attitudinal changes based on the usefulness of materials developed, increases in awareness, knowledge and behavior related to environmental exposure examined by the project.
- Proportion of participants reporting lower exposure to hazardous contaminant targeted by the program.
- The number of local or regional policies or public health practices that were informed by the project’s efforts.

Applicants are encouraged to include social scientists in the development of these quantitative and qualitative tools to assess progress and programmatic achievements. Applicants are encouraged to implement evaluation during any and all phases of the study. The development and use of a project logic model(s) are also encouraged for evaluation planning (see the Evaluation Metrics Manual, Chapter 7 at https://www.niehs.nih.gov/research/supported/assets/docs/j_q/peph_evaluation_metrics_manual_chapter_7_508.pdf (https://www.niehs.nih.gov/research/supported/assets/docs/j_q/peph_evaluation_metrics_manual_chapter_7_508.pdf) for more information on logic models). In addition, the PEPH Evaluation Metrics Manual, applicants may wish to use the Environmental Health Translational Research Framework to describe how their research will address research gaps and inform practice. The Translational Research Framework and supporting resources can be found online. (https://www.niehs.nih.gov/research/programs/translational/framework-details/index.cfm (https://www.niehs.nih.gov/research/programs/translational/framework-details/index.cfm))

Capacity Building

Since this FOA requires demonstrated community-university partnerships, proposals solely focused on capacity building activities to establish a new community-university partnership, or to develop training and educational programs, will not be considered responsive to this FOA. However, educational and training activities that complement the engagement, research, and public health action efforts, as well as help to sustain the project beyond the funding period, would be responsive. If a capacity building activity is included in this proposal, we strongly encourage it to be focused in limited-resourced environments such as academic institutions and CBOs in AI/AN Tribal Nation or environmental justice fence line communities, and amongst early career researchers from these communities. Capacity building activities could include:

- Bi-directional training component to enhance established partnerships between academic institutions and community-based organizations working to advance health equity.
- Implementation of training component to improve institutional capacity of CBOs to apply for and manage NIH grants and sustain interventions to address placed-based environmental health concerns.
- Implementation of activities or programs to strengthen the ability of community members or CBOs to conduct and sustain citizen science to advance environmental health equity in their own communities.

Partnerships for Environmental Public Health

As noted, the Research to Action program is a critical part of the PEPH Network. Therefore, participation in PEPH events is encouraged. PEPH meetings involve grantees from many NIEHS programs, including Research to Action, and allow opportunities for networking, interaction, and collaboration across programs. In addition, Research to Action projects are expected to add materials and tools to the PEPH Resource Center, which is a central repository of materials and resources developed by grantees within the PEPH Network.

NIMHD

The mission of the NIMHD is to lead scientific research to improve minority health and reduce health disparities. NIMHD focuses on all aspects of health and health care for racial and ethnic minority populations in the U.S. and the full continuum of health disparity causes as well as the interrelation of these causes. NIMHD projects must include a focus on one or more of the following populations that NIH-designates as experiencing health disparities (https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html) in the United States and its territories: African Americans, Latinos/Hispanics, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and Pacific Islanders, less privileged socioeconomic groups, underserved rural populations, and sexual and gender minorities. NIMHD encourages projects that use approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities (see the NIMHD Research Framework, https://www.nimhd.nih.gov/about/overview/research-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework.html), for more information). NIMHD is particularly interested in studies focusing on issues related to climate change and environmental justice for this FOA. Studies using animal models or exclusively basic science, or studies based outside the U.S. or its territories will not be supported by NIMHD under this FOA. Applications are required to involve a formal collaboration with a CBO serving one or more populations that experiences health disparities.
Potential research topics include, but are not limited to the following among populations that experience health disparities:

- Integrated interventions to prevent or reduce the impact of environmental exposures
- Studies to address food deserts and structural barriers associated with food insecurity
- Examine the combined effects or interactions of environmental exposures and structural racism and discrimination

Applications Not Responsive to the FOA:

- Proposals focused solely on capacity building to establish new partnerships.
- Proposals that do not address all three of the required elements of the Research to Action FOA.
- Proposals with research focused on exposures to infectious diseases, poorly built or maintained housing, or the neighborhood/social environmental conditions (for example poverty, food deserts, density, noise and/or violence) without an environmental co-exposure.

Non-responsive applications will be withdrawn without review. All interested applicants are strongly encouraged to consult with the NIEHS Scientific/Research contacts for this FOA prior to submitting a proposal.
See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources (https://researchmethodsresources.nih.gov/) website for information about developing statistical methods and study designs.

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
Renewal
Resubmission
Revision

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

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

Award Budget

Application budgets are limited to $500K Direct Cost.

Award Project Period

The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this 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 not** 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.

- System for Award Management (SAM)– (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her 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, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

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

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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

Not Applicable

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.

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

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:

Research Strategy

Element #1: Community Engagement

- Significance: Define the relevant community or communities of interest using a set of tangible and explicit criteria (for example, a common interest, cultural or geographic identity, characteristic, exposure(s) or health condition).
- Approach: Demonstrate both strong scientific capabilities and strong collaboration, trust, and shared leadership and financial support with the proposed community partners/organizations. Describe and justify the specific roles that individuals, organizations, and advisory board members will play in the project and confirm that the time and effort proposed for community partners and organizational efforts reasonably reflect their involvement in the project.

Element #2: Research

- Significance: Describe the hypothesis or problem that will be addressed. Describe how the proposed community partners collaborated with the investigators to develop the research questions and goals for the project.
- Approach: Explain the study design, methodology, and other approaches that will be deployed to address the problem. Describe proposed community interactions and identify the specific research translation approaches – such as, but not limited to, reporting back research results – that are feasible, relevant, and culturally appropriate for the community and that will provide effective dissemination of findings, education, and/or trainings for all segments of the community.
- Innovation: Clearly and concisely state the innovation of your approach. If proposed methodology may be considered standard, describe what is unconventional and innovative about the approach.

Element #3: Public Health Action

- Significance: Outline the proposed public health action plan and explain why the project's research findings are vital to supporting the plan. Explain how their proposed public health strategy will lead to action that will improve the health of a community, prevent, or reduce the exposure(s) among community members at the local, regional or national level, or ultimately lead to improved health outcomes and quality of life.
- Approach: Explain the approach(es) and methodology used to develop and implement the public health action plan. Describe how the findings will/could be generalizable or transferable to other settings, implemented, adapted, scaled up, or disseminated to other communities facing similar environmental health issues. Explain how proposed public health actions have been designed for sustainability.
- Innovation: Clearly and concisely state the innovation of your approach. If proposed methodology may be considered standard, describe what is unconventional and innovative about the approach.

Additionally, applicants are encouraged to

- Include a multiple PI/PD plan, especially if the project is proposing a community partner as a CO-PI.
- Include a management plan that describes the collaboration between the university partners and the community partners. Describe how appropriate input of all partners will be achieved and sustained. The structure of the collaboration could be described in the management plan. Given the demographics of some communities, this may entail the involvement of more than one CBO, or more than one representative of a community, particularly if the community is identified through its exposure risk or poverty status and includes members of different racial and/or ethnic sub-populations. If other partner groups are included in the proposal, this management plan should reflect those additional project partners.
- If the project proposes the optional Evaluation Element (#4), it is recommended to include a summary plan for evaluating the project's processes and outcomes. The plan should describe the evaluation questions to be assessed; evaluation metrics that will be measured to answer evaluation questions; who, when, and how such data will be collected; and how data will be analyzed and incorporated into the ongoing study design.

Letters of Support:

- Demonstrate broad community support for implementation of the project (for example, the involvement of local or regional public health departments, public schools, churches or youth organizations, etc.).
- Demonstrate that community representatives/CBOs speak on behalf of the community. Letters of support should come from each organization to be involved in the proposed project (for example representatives of an established public health department, CBO, church, and/or representatives of local youth organizations).

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.

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

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/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 fieldof 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 FOA 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 components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

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

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 of the partner community(-ies). 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.

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?

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?

In addition, for applications involving clinical trials

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

Innovation

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

In addition, for applications involving clinical trials

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

Approach

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

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

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?

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.

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

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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 following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview); and (3) Genomic Data Sharing Plan (GDS) (https://sharing.nih.gov/genomic-data-sharing-policy).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). 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.

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 appropriate national Advisory Council or Board. 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 (https://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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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 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.

Should the applicant organization successfully compete for an award, 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 (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

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

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

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

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the

designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

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)

Educational and outreach materials (such as fact sheets, videos, podcasts, curriculum, slide sets, etc.) developed as part of these awards and reported in the annual progress report must be entered into the Partnerships for Environmental Public Health (PEPH) Resource Center (https://connect.niehs.nih.gov/peph/index.cfm?fuseaction=peph.landing (https://connect.niehs.nih.gov/peph/index.cfm?fuseaction=peph.landing)). Awardees will be given login instructions.

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 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) 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)

Liam O'Fallon
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3298
Email: ofallon@niehs.nih.gov (mailto:ofallon@niehs.nih.gov)

Deborah E. Linares, PhD
National Institute on Minority Health and Health Disparities (NIMHS)
Phone: 301-402-2516
Email: deborah.linares@nih.gov (mailto:deborah.linares@nih.gov)

Deborah E. Linares, PhD
National Institute on Minority Health and Health Disparities
Phone: 301-402-2516
Email: deborah.linares@nih.gov (mailto:deborah.linares@nih.gov)

Peer Review Contact(s)

Not Applicable

Financial/Grants Management Contact(s)

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

Priscilla Grant, JD
National Institute on Minority Health and Health Disparities (NIMHD)
Phone: 301-594-8412
E-mail: pg38h@nih.gov (mailto:pg38h@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?07-15-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

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