

# Department of Health and Human Services

## Part 1. Overview Information

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### Participating Organization(s)

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

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### Components of Participating Organizations

National Institute of Environmental Health Sciences ([NIEHS \(http://www.niehs.nih.gov\)](http://www.niehs.nih.gov))

National Institute of Nursing Research ([NINR \(http://www.ninr.nih.gov\)](http://www.ninr.nih.gov))

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### Funding Opportunity Title

Research to Action: Assessing and Addressing Community Exposures to Environmental Contaminants (R01)

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### Activity Code

[R01 \(http://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

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### Announcement Type

Reissue of [PA-12-153 \(http://grants.nih.gov/grants/guide/pa-files/PA-12-153.html\)](http://grants.nih.gov/grants/guide/pa-files/PA-12-153.html)

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### Related Notices

- [February 9, 2016 \(http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-005.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-005.html) - Notice of Change to PA-16-083. See Notice [NOT-ES-16-005 \(http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-005.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-005.html).
  - [NOT-OD-16-004 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html) - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)
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### Funding Opportunity Announcement (FOA) Number

PA-16-083

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### Companion Funding Opportunity

None

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### Number of Applications

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

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

93.113, 93.361

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**Funding Opportunity Purpose**

This Funding Opportunity Announcement encourages applications using community-engaged research methods to investigate the potential health risks of environmental exposures of concern to the community and to implement an environmental public health action plan based on research findings. The overall goal is to support changes to prevent or reduce exposure to harmful environmental exposures and improve the health of a community.

## Key Dates

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**Posted Date**

January 13, 2016

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**Open Date (Earliest Submission Date)**

May 5, 2016

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

Not Applicable

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**Application Due Date(s)**

Standard dates ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11111](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11111)) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications ([http://grants.nih.gov/grants/guide/pa-files/PA-16-083.html#Application Types Allowed](http://grants.nih.gov/grants/guide/pa-files/PA-16-083.html#Application%20Types%20Allowed)) allowed for this funding opportunity announcement are due on these dates.

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.

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**AIDS Application Due Date(s)**

Not Applicable

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**Scientific Merit Review**

Standard dates ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113)) (<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>) apply

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**Advisory Council Review**

Standard dates ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113)) (<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>) apply

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## Earliest Start Date

[Standard dates \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11113\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

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## Expiration Date

May 8, 2019

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## Due Dates for E.O. 12372

Not Applicable

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## Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/\)](http://grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. [Learn more \(http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2\)](http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm#2).

**Apply Online Using ASSIST**

**Apply Using Downloadable Forms**

Problems accessing or using ASSIST should be directed to the [eRA Service Desk \(http://grants.nih.gov/grants/ElectronicReceipt/support.htm#desk\)](http://grants.nih.gov/grants/ElectronicReceipt/support.htm#desk).

Problems downloading forms should be directed to [Grants.gov Customer Support \(http://www.grants.gov/contactus/contactus.jsp\)](http://www.grants.gov/contactus/contactus.jsp).

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## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### **Purpose**

This Funding Opportunity Announcement (FOA) encourages community-engagement projects designed to investigate the potential health risks of environmental exposures of concern to a community and to implement an environmental public health action plan based on research findings. Projects supported under this program are expected to employ community-engaged research methods to not only conduct research but also to seamlessly translate research findings into public health action. This announcement reflects NIEHS goals in bi-directional communications and in supporting research to address environmental health disparities and environmental justice concerns.

The Research to Action program is part of the National Institute of Environmental Health Sciences (NIEHS) "Partnerships for Environmental Public Health" (PEPH) network (<http://www.niehs.nih.gov/research/supported/dert/programs/peph/> (<http://www.niehs.nih.gov/research/supported/dert/programs/peph/>)). The PEPH network encompasses a variety of research, communication, and training/educational activities to identify, prevent, reduce, or eliminate environmental exposures that lead to adverse health outcomes in communities. PEPH meetings involve grantees from many NIEHS programs, including Research to Action, and allow opportunities for networking, interaction and collaboration across programs.

This announcement also reflects the National Institute of Nursing Research's (NINR's) ongoing investment in clinical, biological, and translational research programs in many areas, including chronic illness, symptom management, disease prevention, and patient-focused health programs that encourage and enable individuals to become guardians of their own well-being. These investments are based on the perspective that the science of health encompasses the investigation of multiple health determinants, including environmental factors and its impact on the health promotion and self-management behavior of individuals within their communities. NINR seeks to support research that promotes health equity and eliminates health disparities by investigating the interplay of behavioral, biological, and environmental determinants of health and wellness for all populations, including underserved and resource-limited communities.

Community engagement (CE) lies on a continuum that reflects the level of involvement of community members, or representatives of specific subpopulations, in the research. The continuum of involvement ranges from community consent to research to full participation and shared leadership of community members in the research design and implementation. Community based participatory research (CBPR) is a recognized approach of Community Engaged Research (CEnR).

For the purpose of this FOA, CE is defined as 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 development of the research questions and research design; the translation and dissemination of study results; the development and implementation of an environmental action plan; and the development of methods for evaluating the success of the project. In addition, for the purpose of this FOA, CEnR should entail the involvement of sufficient numbers of individuals to adequately represent all segments of their community. By the involvement of larger numbers of community members, CEnR can more effectively align with a community's shared vision and values, create an inclusive environment, nurture collaboration, build community capacity to sustain interventions and implementation plans, and increase health and environmental literacy among those involved.

All studies must be motivated by expressed concerns of a community and the need for scientifically-based information to develop or test the environmental public health action element of the project. The research

element of projects may include descriptive research (for example, to characterize sources of exposures, measure exposure levels, or the prevalence of exposure-related health conditions among members of the community and the community itself), as well as hypothesis-driven studies designed to improve understanding of the exposure-health outcome relationship.

The environmental public health action element may include a variety of education, communication, prevention, or behavioral change activities. This element should be evidence-based, incorporating knowledge gained through the research element of the project, and targeted towards supporting change that will improve the health of a community or decrease the prevalence of local exposure-related health conditions. Additionally, each project team is encouraged to implement an evaluation of project processes and, when possible, outcomes. The evaluation element could provide systematic information that can be used to strengthen the project over the life cycle and to assess the effectiveness and impact of the project.

## Background

Protecting the public from environmental health risks requires both the generation of science-based information about exposure occurrences and exposure-health relationships, as well as the translation of such information into actions to reduce or eliminate exposure, prevent disease, and promote health. The distinctive needs of individual communities are key for identifying environmental health problems and devising appropriate disease and exposure prevention or remediation tactics. Furthermore, by fostering community-researcher partnerships, vital information that has been identified by the community about exposures and disease prevalence can be used by the researchers to identify the linkages between such exposures and disease and to develop preventive strategies to promote health and reduce risk of disease across the populations at highest risk. Placing an emphasis on equitable partnerships between community and researcher in environmental public health research also ensures that:

- Communities will have a role in identifying and defining problems and risks related to environmental exposures and stressors that are of greatest importance to them.
- Communities will receive the scientific and financial support necessary to conduct high quality research in partnership with investigators that will accurately characterize the distributions and sources of environmental exposures and exposure-health relationships in their community, and empower all involved to take action to reduce potential health risks.
- Communities will actively participate with researchers and public health professionals in developing effective strategies for training/education, communication, remediation and prevention in response to environmental threats in order to reduce or eliminate such exposures and to improve health outcomes.
- Communities will ensure that strategies and education are provided in accessible, culturally sensitive formats and developed at a literacy level and language appropriate for members of that community.

CeNR is particularly vital in addressing environmental justice issues. Environmental justice refers to the need to remedy the unequal burden of exposure and disease borne by socioeconomically disadvantaged persons (e.g. populations defined as minority, low income, or American Indian/Alaska Native tribes). Geographic location and socioeconomic status play important roles in environmental exposure of these sub-populations as does multigenerational exposures. In addition, the lack of resources for early identification of the effects of toxic agents, or the means to address known exposures, may lead to an increased disease burden among people who are economically least able to cope with it. Research to identify and characterize environmental exposures that disproportionately burden these sub-populations can lead to public health action that will reduce the associated health disparities. Furthermore, active participation of community members in the formulation of environmental health research questions and in the conduct and translation of research findings can help community members better understand the associated health risks and empower them to make informed decisions or to initiate local activities to prevent ongoing chronic and/or cumulative exposures that disproportionately affect them.

## Objectives and Scope

In 2009, and again in 2012, the NIEHS initiated the Research to Action programs to bring together environmental health researchers and community members to assess and address environmental public health issues of greatest concern to their communities. Currently funded projects are addressing a variety of environmental health issues and include a diverse set of communities. A description of currently funded grants under the Research to Action program can be found at:

<http://www.niehs.nih.gov/research/supported/dert/programs/peph/prog/rta/index.cfm>  
(<http://www.niehs.nih.gov/research/supported/dert/programs/peph/prog/rta/index.cfm>).

This FOA intends to expand the number and scope of projects supported through the NIEHS Research to Action program. The two main objectives of this initiative, however, remain the same: 1) to conduct research to collect and characterize information about environmental health concerns of significance to a community and 2) to develop and implement a strategy to translate and disseminate research findings to community members, public health professionals and/or policymakers to support an action that will ultimately promote the reduction of exposure and reduce the health impact from environmental stressors.

To meet these stated objectives, applicants should propose CEnR projects that incorporate three elements - research, community engagement and public health action. A third, optional element is evaluation. These three elements are discussed further below.

### **Community-engagement**

All projects should include, at a minimum, one health researcher with a background in environmental research and member(s) of affected communities or representatives of community-based organization(s) (CBOs)..

Project teams are also encouraged to incorporate expertise in social science, evaluative methods, and communications and be comprised of, and co-developed by, researchers and community members. The projects developed by these partners should be focused on environmental agents or diseases that have been identified by the community as potential or existing public health issues.

Because participation of the affected community is essential for both the identification of environmental health risks to be studied and formulation of research and translation plans, it is expected that fully incorporating equitable input from both researchers and community members is a priority throughout the entire research process. Furthermore, the partnership between the researcher and CBO(s) should appropriately draw upon the unique strengths that each brings to the partnership.

For purposes of this FOA, "community" refers to populations and groups affected by, or with a shared interest in, environmental exposures and related health outcomes. Populations may be defined by socioeconomic status, geography, exposure(s), race, ethnicity, gender, age, occupation, religion, sexual orientation, disability, illness, or other health condition. The term "community-based organization" (or CBO) is broadly defined. The CBO does not need to be a formally recognized organization, such as a non-profit organization, but should be an established community group(s) or network(s) with a common interest in a particular environmental health concern and that includes representatives of the community. Of note, the involvement of more than one CBO may be necessary to represent the interests and concerns of all members of the community (e.g., the distinct needs of different age groups or diseases, the cultural constraints related to a particular ethnic or religious sub-population.)

Responsibilities of the research partner and community partner include, but are not limited to, collaborating on (a) determining what information and research questions the proposed study can and cannot provide and address, (b) identifying the most appropriate research design and methodology, (c) ensuring research findings are translated effectively into public health action, and (d) helping translate and communicate study findings to community members in appropriate and accessible formats.

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 preliminary data from previous research in the community. Capacity

building activities to develop training and educational programs, or to establish a new community-researcher partnership, would not be considered appropriate for this FOA.

## Research Element

The objective of this element is to support research that will increase knowledge of how environmental exposures impact health and disease in communities. This can include descriptive studies intended to increase understanding of exposure levels, sources or prevalence of exposure-related health conditions among the community, or hypothesis-driven studies designed to improve understanding of the exposure-health outcome relationship. A key requirement is that research findings should be used to directly inform a public health implementation action plan. Furthermore, while it is anticipated that research will entail primary data collection, projects should build upon previous research conducted with the community and existing findings, and may also take advantage of existing data sources if such resources can adequately address the research question(s) co-developed by the researcher-community partnership team and produce the new information needed for a public health action plan for implementation and sustainability. Projects are encouraged that include the use of methodologies for integrating local knowledge about the environment or locally gathered data, such as Tribal Ecological Knowledge and/or citizen science efforts, along with traditional research approaches.

For purposes of this FOA, “environmental exposure” is broadly defined and can include a variety of environmental contaminants. This does not include exposures to infectious diseases, poorly built or maintained housing, or other aspects of the built environment related solely to social conditions (e.g, poverty, food deserts, density, noise and/or violence). Instead, projects should focus on environmental exposures that meet all of 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 environmental agent(s) with potential widespread exposure.
- The researcher and community is lacking information needed to support the proposed public health action, such as data on exposure levels, sources, or potential health effects.

The type of research study proposed should be motivated by existing needs identified by the community and lead to an environmental public health implementation action plan. Specific examples of research topics that are of interest for this FOA include, but are not limited to:

- The cumulative health impact of exposure to multiple environmental stressors on health risks (e.g., the cumulative health effects of exposure to multiple endocrine disruptors; the combined effect/interaction between physical, social, and neighborhood-level environmental stressors; interactive effects of genetics, diet, and environmental exposures on health).
- The burden on human health from hazardous pollutants or health conditions associated with a known toxic waste site, nuclear facility, chemical plant, or resource extraction site (e.g., mine or hydraulic fracturing site) where, for example, a new school, housing development, or community center is to be built.
- Exposure to mixtures of toxic substances and associated health impacts among populations that may experience higher exposure or particular sensitivity to exposure (e.g., emergency response personnel exposed to disaster recovery or mitigation sites).
- The impact of climate change on particularly vulnerable communities or populations (e.g., those living in coastal or flood prone communities, tribal communities, the elderly, and children)
- Applications that consider interactions between environmental contaminant exposures and the social or physical environment or infectious diseases (as a potential modifier of the health risk associated with exposure to an environmental chemical) are encouraged. However, applications that focus on the social/physical environment or infectious disease alone will not be considered responsive to this initiative.

## Public Health Action Element

For the purposes of this FOA, public health action includes campaigns, programs, interventions, and policies intended to elicit a change in behavior or practice that will lead to the prevention of disease and disability and promote the health of a population. Public health action may be targeted at the individual, neighborhood, or community level, or developed as models that have national public health practice application. Participation of the affected community in identifying the most effective public health action plan is essential.

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
- Local, regional, or national strategies to raise policymaker awareness of the link between environmental/occupational exposures and adverse health outcomes or to test the effectiveness of a particular intervention.
- Local, state or tribal programs that address management of symptoms related to an already exposed population.
- Collaborations with public health laboratories to develop and implement 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.

Applicants should develop strategies that translate the findings from the research element of the study to action. The strategy should be designed to help support or promote action that will result in the prevention or reduction of exposure among community members at the local, regional or national level, ultimately leading to improved health outcomes and quality of life. Examples of possible public health action strategies include, but are not limited to:

- Develop and implement community-based, culturally sensitive 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.
- Develop and implement exposure reduction/pollution prevention strategies.
- Develop informational materials and risk communication strategies to educate policymakers about potential sources of exposure and the associated potential health risks and economic burden resulting from such exposures.
- Establish and implement community-based training to increase environmental health literacy, and/or health promotion (i.e., increase awareness of affected communities at the local, regional and /or national level).
- Develop targeted community-based training for local policymakers, disaster and emergency response personnel, and for specific segments of the affected community (e.g., trainings developed for implementation by local educators for K-12 students).
- Develop and implement medical and continuing medical education training modules in conjunction with local providers to educate health care and public health professionals on the role of the environmental exposure under investigation 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.

## Evaluation Element

Evaluations help community-research partners assess the effectiveness and impact of their projects as well as the 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 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-research 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 processes (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).
- Examples of potential measures for evaluating the project's outcomes may include:
- 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 involve 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) is also encouraged for evaluation planning (see the Evaluation Metrics Manual, Chapter 7 at

[http://www.niehs.nih.gov/research/supported/assets/docs/a\\_c/peph\\_evaluation\\_metrics\\_manual\\_11513\\_508.pdf](http://www.niehs.nih.gov/research/supported/assets/docs/a_c/peph_evaluation_metrics_manual_11513_508.pdf) ([http://www.niehs.nih.gov/research/supported/assets/docs/a\\_c/peph\\_evaluation\\_metrics\\_manual\\_11513\\_508.pdf](http://www.niehs.nih.gov/research/supported/assets/docs/a_c/peph_evaluation_metrics_manual_11513_508.pdf)) for more information on logic models).

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

## Section II. Award Information

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### Funding Instrument

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

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### Application Types Allowed

New  
Renewal  
Resubmission

The [OER Glossary](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11116](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116)) and the SF424 (R&R) Application Guide provide details on these application types.

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## Funds Available and Anticipated Number of Awards

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

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## Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

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## Award Project Period

The maximum project period is 5 years.

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

# Section III. Eligibility Information

## 1. Eligible Applicants

### Eligible Organizations

#### Higher Education Institutions

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

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

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

#### Nonprofits Other Than Institutions of Higher Education

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

#### For-Profit Organizations

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

#### Governments

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

## Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

## 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](#)

([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118](http://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](#) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html>) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](#) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](#) (<https://www.sam.gov/portal/public/SAM/>) (formerly CCR) – 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](#) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](#) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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](#) (<http://www.grants.gov/web/grants/applicants/organization-registration.html>) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

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

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

an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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

Community based organizations (CBOs) and community partners in research (e.g., representatives of communities that are affected by the issue of concern) are encouraged to apply and to collaborate with academic investigators as Key Personnel on the project.

## 2. Cost Sharing

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

## 3. Additional Information on Eligibility

### Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

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

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at [Grants.gov](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11127](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127)).

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), including [Supplemental Grant Application Instructions](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82216) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82216](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82216)) 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.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=41137](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137)).

### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11133](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133)) must be followed.

## Instructions for Application Submission

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

### SF424(R&R) Cover

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

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

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

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

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

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

All instructions in the SF424 (R&R) Application Guide must be followed. Projects that include representatives of Community-based organizations (CBOs) and/or community members as Key Personnel and who will serve as research partners with the academic investigators are encouraged.

For researcher(s) on the project, describe any history of conducting research that explores the links between environmental exposures and health. In addition, describe any past interactions between the researcher and the community including appropriate CBO(s) which demonstrate a strong equitable partnership. This can include, but is not limited to, prior training and education of researchers in community based participatory methodologies and communication techniques; prior training and experience related to research capacity among community members; and established means for obtaining effective input from a community on matters such as priority areas of environmental public health and plausible research and research translation approaches.

For CBO or community members on the project, describe any history of working directly and regularly with the affected community and provide evidence that the community partners adequately represent the range of interests and concerns of the affected community.

### R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed. Projects that include CBOs and/or community members as Key Personnel must include compensation for the level of effort of these research partners in the budget.

- Describe the roles of both the researcher(s) and community participant(s) in the project

### R&R Subaward Budget

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

### PHS 398 Cover Page Supplement

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

### PHS 398 Research Plan

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

#### Research Strategy

- Applications are expected to demonstrate both strong scientific capabilities and strong community collaboration, trust, and shared leadership and support.
- Define the relevant community or communities of interest using a set of tangible and explicit criteria (e.g., a common interest, cultural or geographic identity, characteristic, exposure(s) or health condition).
- Describe proposed interactions and identify the specific translational approaches that are feasible, relevant, and culturally sensitive for that community and that will provide effective dissemination of findings, education, and/or trainings for all segments of the community.

- Explain why the research findings to be obtained in the project are vital to support the planned environmental public health action.
- Explain how their proposed public health strategy will lead to action with the community.

Additionally, applicants are encouraged to

- Include a management plan that describes the collaboration between the researchers and the community members. Describe how appropriate input of all partners will be achieved. The collaboration between the academic researchers and the community members or community organizations to be involved in the research should be established prior to submission of the application and the structure of the collaboration fully 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.
- 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 support for implementation of the project from the community, (e.g., public health department, public schools, church or youth organizations, etc).
- Demonstrate that a community representative/CBO speaks on behalf of the community and include letters of support from each organization to be involved in the research (e.g., representatives of an established public health CBO, church, and 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.

**Appendix:** Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

#### **Planned Enrollment Report**

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

#### **PHS 398 Cumulative Inclusion Enrollment Report**

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

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

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

## **4. Submission Dates and Times**

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday](#) ([http://www.opm.gov/Operating\\_Status\\_Schedules/fedhol/2010.asp](http://www.opm.gov/Operating_Status_Schedules/fedhol/2010.asp)), the application deadline is automatically extended to the next business day.



Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](http://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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](http://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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

## 6. Funding Restrictions

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

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11143\)](http://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 [Applying Electronically \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### Important reminders:

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

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

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

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

### **Requests of \$500,000 or more for direct costs in any year**

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact [NIH program staff \(http://grants.nih.gov/grants/guide/pa-files/PA-13-302.html#\\_Section\\_VII\\_Agency\)](http://grants.nih.gov/grants/guide/pa-files/PA-13-302.html#_Section_VII_Agency) at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

### **Post Submission Materials**

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-13-030 \(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html).

## **Section V. Application Review Information**

### **1. Criteria**

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

For this particular announcement, note the following:

The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the [mission of the NIH \(http://www.nih.gov/about/mission.htm\)](http://www.nih.gov/about/mission.htm).

### **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 there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

#### **Investigator(s)**

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

#### **Innovation**



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

## **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators 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 children, justified in terms of the scientific goals and research strategy proposed?

## **Environment**

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

## **Additional Review Criteria**

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

### **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the six 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 six 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

### **Inclusion of Women, Minorities, and Children**

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 children 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](http://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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](http://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**

Not Applicable

## **Additional Review Considerations**

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

### **Applications from Foreign Organizations**

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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11153\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

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

As part of the scientific peer review, all applications:

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

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](http://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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11156\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

## 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

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

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

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

### 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](http://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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#)

([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159)). More information is provided at [Award Conditions and Information for NIH Grants \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. 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. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html> (<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

## Cooperative Agreement Terms and Conditions of Award

Not Applicable

## 3. Reporting

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

A final progress report, 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

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

See the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11171\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

## 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 registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)  
Finding Help Online: <http://grants.nih.gov/support/> (<http://grants.nih.gov/support/>) (preferred method of contact)  
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support \(http://www.grants.gov/web/grants/support.html\)](http://www.grants.gov/web/grants/support.html) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

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

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

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

Telephone: 301-710-0267

### Scientific/Research Contact(s)

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National Institute of Environmental Health Sciences (NIEHS)

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### Peer Review Contact(s)

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

### Financial/Grants Management Contact(s)

Molly Puente

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Email: [wertzr@mail.nih.gov](mailto:wertzr@mail.nih.gov) (<mailto:wertzr@mail.nih.gov>)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11163\)](http://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\* \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11164\)](http://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\* \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](http://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.

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[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?01-15-16\)](/grants/guide/WeeklyIndex.cfm?01-15-16)  
[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)

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National Institutes of Health (</grants/oer.htm>)  
Office of Extramural Research



(<http://www.hhs.gov/>)

Department of Health  
and Human Services (HHS)



(<http://www.usa.gov/>)

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