OVERVIEW INFORMATION

U.S. Environmental Protection Agency
Office of Science Advisor, Policy and Engagement
Office of Research and Development

NATIONAL PRIORITIES: EVALUATION OF ANTIMICROBIAL RESISTANCE IN WASTEWATER AND SEWAGE SLUDGE TREATMENT AND ITS IMPACT ON THE ENVIRONMENT

This is the initial announcement of this funding opportunity.

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I. FUNDING OPPORTUNITY DESCRIPTION

For Updates and Additional Information see https://www.epa.gov/research-grants/research-funding-opportunities.
View research awarded under previous solicitations at https://www.epa.gov/research-grants/research-grant-areas.

A. Introduction

In recent years, concern has increased about the occurrence of antibiotic resistant bacteria (ARB) and antibiotic resistant genes (ARGs) that could make it more difficult to treat certain infections in animals and people. Wastewater treatment facilities are believed to be potential receptors and sources for ARB and ARGs and can act as a bridge to the environment. This RFA seeks research that will address knowledge gaps in the occurrence, fate and transport, and persistence of antimicrobial resistant organisms and genes found in municipal wastewater effluent and biosolids. The RFA also requests research on combined sewer overflows, septic systems, and small wastewater systems. Research should provide a better understanding of the impact of ARB and ARGs on receiving waters including information on the relative contribution of ARB and ARGs from wastewater as compared to other sources such as animal agriculture, animal husbandry, hospital sources, and direct industrial sources. Research should also support the development of frameworks and methodologies for quantifying risk related to AMR in treated wastewater discharge, water reuse, and biosolids (and biosolids products) land application and beneficial use. Research results should improve our understanding of the nature, extent, selection, and removal of ARB and ARGs found in municipal wastewater effluent and biosolids.

The Office of Research and Development's (ORD) Consolidated Research/Training/Fellowships program supports research and development to: (1) determine the environmental effects of air quality, drinking water, water quality, hazardous waste, toxic substances, and pesticides; (2) identify, develop, and demonstrate effective pollution control techniques; (3) perform risk assessments to characterize the potential adverse health effects of human exposures to environmental hazards; and (4) facilitate training and program participant support in these areas.

Awards made under this program further EPA's priorities supporting robust science for air quality, safe and sustainable water resources, sustainable and healthy communities, chemical safety, and human health risk assessment. The national priorities competition under this program supports high-priority water quality and availability research.

EPA recognizes that it is important to engage all available minds to address the environmental challenges the Nation faces. At the same time, EPA seeks to expand the environmental conversation by including members of communities which may have not previously participated in such dialogues to participate in EPA programs. For this reason, EPA strongly encourages all eligible applicants identified in Section III, including minority serving institutions (MSIs), to apply under this opportunity.

For purposes of this solicitation, the following are considered MSIs:

1. Historically Black Colleges and Universities, as defined by the Higher Education Act (20 U.S.C. § 1061(2)). A list of these schools can be found at Historically Black Colleges and Universities;

2. Tribal Colleges and Universities (TCUs), as defined by the Higher Education Act (20 U.S.C. § 1059c(b)(3) and (d)(1)). A list of these schools can be found at American Indian Tribally Controlled Colleges and Universities;

3. Hispanic-Serving Institutions (HSIs), as defined by the Higher Education Act (20 U.S.C. § 1101a(a)(5)). A list of these schools can be found at Hispanic-Serving Institutions;

4. Asian American and Native American Pacific Islander-Serving Institutions; (AANAPISIs), as defined by the Higher Education Act (20 U.S.C. § 1059g(b)(2)). A list of these schools can be found at Asian American and Native American Pacific Islander-Serving Institutions; and

5. Predominately Black Institutions (PBIs), as defined by the Higher Education Act of 2008, 20 U.S.C. 1059e(b)(6). A list of these schools can be found at Predominately Black Institutions.

B. Background

The genetic adaptability of microbes along with the prevalence of antimicrobial medicines have created a global health problem due to ARB and ARGs that could make it harder to treat certain infections in animals and people. Given rapid evolution and selection, ARB and ARGs can move between the environment, humans, and animals, which makes predicting where and when resistance occurs difficult. Antimicrobial resistance (AMR) has been identified by the World Health Organization (WHO) as one of the greatest threats to human health. Furthermore, both WHO and the U.S. Centers for Disease Control (CDC) have identified antibiotic resistance as a high priority research area. To further illustrate, according to a 2019 CDC report, every year 2.8 million resistant infections in the United States cause 35,900 deaths. From an economic

standpoint, a direct estimate for treating six, common, multidrug-resistant pathogens is $4.6 billion a year (CDC, 2019). Given the scale and complexity of the problem, a "One Health" approach which recognizes the interdependencies between people and animals, but also acknowledges the importance of the ecosystems and environment, has been put into practice by multiple health organizations internationally (CDC, 2022). This approach emphasizes strong collaboration between animal and human health sectors as well as collaboration between different disciplines at different scales (regional, national, international) to prevent and control emerging diseases. Within the one health approach, the natural and engineered water environments have increasingly been shown to play significant roles in AMR evolution and spread. A recent National Academy of Sciences report (NAS, 2022) emphasized the need for improved guidance for assessing antimicrobial resistance in discharges from wastewater treatment given their importance as a link between anthropogenic contamination and the environment.

Wastewater treatment facilities are believed to be one of the major potential receptors and sources for ARB and ARGs. These facilities typically discharge to aquatic environments and act as both a barrier as well as a potential source of pollutant discharge to the environment. They receive a mix of pathogens, resistant genes, and antimicrobial drug residues from multiple points in the collection system, including wastewater from industry, households, and hospitals, all of which contribute to a high density of pathogens that enter the plant. The selective pressure of residual antimicrobial drugs coupled with gene transfer between microorganisms at the plant can potentially lead to the proliferation of ARB and ARGs during wastewater treatment processes. Operational conditions in treatment processes may promote the proliferation of ARB resulting in higher fractions in treated wastewaters relative to raw wastewater or in finished biosolids or biosolids products, which are ready to be applied to land.

Despite recent studies investigating treatment, operational conditions, and environmental occurrence of AMR (Gerrity et al., 2018, Wengroth et al., 2021), further information is needed to characterize the occurrence and significance of AMR found in treated and discharged municipal wastewater effluent, especially effluent used for reuse applications. Reported AMR selection and removal efficiencies in wastewater treatment systems have been highly variable, most likely due to the impact of the treatment mechanism, operational parameters and setting, and other still unknown factors. New research and controlled studies are needed to better understand the key technology (conventional and advanced); operational and site-specific parameters that affect AMR occurrence and growth, such as wastewater parameters, antimicrobial concentrations, operational conditions, dry or wet weather flow; and mechanisms responsible for attenuation such as photo-reactivation. Similarly, significant knowledge gaps exist on the potential occurrence, mechanism, and timing of genetic mobilization of ARGs between microbial communities in wastewater reclamation facilities and the human health implications that may be present in potable water reuse. The conditions that result in horizontal gene transfer of ARGs from bacteria in the environment to pathogenic bacteria found in clinical infections are also not well understood. Research in these areas should support development of effective mitigation measures.

Along with treated effluent, sewage sludge has the potential to concentrate significant amounts of ARB and ARGs from sewage. Sludge processing prior to land application or use as fertilizer includes multiple unit processes to reduce pathogens and vector attraction. Biosolids, the resulting byproduct from sludge, is, in many cases, applied to land where it can potentially spread ARB and ARGs into the environment. A better understanding of the impact of various in-plant biosolids treatment processes on the fate of AMR in biosolids is needed. Furthermore, research on potential new biosolids management mitigation practices may be needed to reduce or remove AMR within treatment processes. The transfer of ARGs found in biosolids applied to soils and harvested crops as well as from the use of biosolids products such as compost and heat-treated pellets has also not been well-investigated. In addition, more information is needed on the horizontal transfer of mobile ARGs (resistome) in biosolids to human pathogens and commensals and their potential role in the spread of AMR from the environment to human pathogens (Law et.al., 2021). Such research may inform the potential development of new management practices to protect public health.

Other sources of ARB and ARGs reaching the environment due to wastewater treatment processes include combined sewer overflows (CSOs) and non-point sources such as septic systems. Untreated sewer sediments and wastewater containing ARB and ARGs may be discharged to surface water during storm events (Eramo et al., 2017). Similarly, aging or inadequate wastewater collection systems along with septic systems are potential non-point sources of ARB and ARGs to the environment (Damashek et al., 2022). More information on non-point sources and CSOs is needed to determine the relative contributions of AMR from these sources.

As treated wastewater is typically discharged to aquatic environments, these environments are potential exposure routes to transmit resistant pathogens and genes to humans and animals via irrigation, recreational use, or drinking water exposure. Furthermore, wastewater biosolids, manure, surface water, and reclaimed wastewater are routinely applied to crops and agricultural land, exposing soils and plants to the antimicrobials, ARB, and ARGs. Soils can serve as reservoirs of AMR, facilitating the maintenance and spread of ARGs within their microbiome and among plant-associated bacteria (Christou et al., 2017; Tyrell et al., 2019). Vegetable crops can become contaminated through contact with the soil or directly via irrigation water, thereby serving as a potential route of human exposure (Hölzel et al., 2018). Recreational contact with contaminated surface waters may also result in AMR infections, as evidenced by epidemiological studies demonstrating elevated ARB colonization among exposed groups (Leonard et al. 2018; Søraas et al. 2013). Contaminated drinking water has likewise been associated with increased risk of ARB carriage (Coleman et al., 2012). Although drinking water treatment processes are generally effective in reducing ARB and ARGs, both have nevertheless been detected in treated drinking water (Sanganyado and Gwenzi 2019).

Given the multiple exposure routes for AMR, knowledge is needed to inform public health and environmental impact implications and to establish appropriate frameworks for quantifying risk

related to AMR in treated wastewater discharge, water reuse, and land applied biosolids. In addition, it is not clear if, and to what extent, the level of AMR in the environment is due to the presence of AMR in the raw sewage influent (including those that receive untreated hospital waste), the proliferation of AMR during wastewater treatment, subsequent gene transfer in the environment, and other AMR sources that are completely unrelated to municipal wastewater such as animal agriculture or husbandry, direct discharges, and commercial or industrial sources. As such, the significance of the discharge of wastewater and use of biosolids on the presence of AMR should be assessed and compared with other sources of AMR in different watersheds, which can inform decision-making and risk assessments. Research is also needed to track and understand how ARGs are propagated in wastewater microbial communities and how ARGs can be transferred from wastewater sources to environmental bacteria and potentially on to pathogenic microorganisms in the environment.

C. Authority and Regulations

The authorities for this RFA and resulting awards are contained in the Clean Water Act, 33 U.S.C. 1254, Section 104(b)(3), the Safe Drinking Water Act, 42 U.S.C. 300j-1, Section 1442, and the Consolidated Appropriations Act, 2023, Public Law 117-328.

For research with an international aspect, the above statutes are supplemented, as appropriate, by the National Environmental Policy Act, Section 102(2)(F).

Note that a project's focus is to consist of activities within the statutory terms of EPA's financial assistance authorities; specifically, the statute(s) listed above. Further note applications dealing with any aspect of or related to hydraulic fracking will not be funded by EPA through this program.

Additional applicable regulations include: 2 CFR Part 200, 2 CFR Part 1500, and 40 CFR Part 40 (Research and Demonstration Grants).

D. Specific Research Areas of Interest/Expected Outputs and Outcomes

Note to applicant: The term "output" means an environmental activity, effort, and/or associated work products related to an environmental goal or objective, that will be produced or provided over a period of time or by a specified date. The term "outcome" means the result, effect, or consequence that will occur from carrying out an environmental program or activity that is related to an environmental or programmatic goal or objective.

The activities to be funded under this solicitation support EPA's FY 2022-2026 Strategic Plan (https://www.epa.gov/planandbudget/strategicplan). Awards made under this solicitation will support Goal 5: Ensure Clean and Safe Water for All Communities, Objective 5.1: Ensure Safe Drinking Water and Reliable Water Infrastructure and Objective 5.2: Protect and Restore Waterbodies and Watersheds, of the Plan. All applications must be for projects that support the goal(s) and objective(s) identified above. Awards made under this announcement will further the

goals of the Consolidated Research/Training/Fellowships program by furthering EPA's priorities ensuring clean and safe water for safe and sustainable water resources by promoting high-priority water quality and availability research. The agency is seeking applications proposing innovative research to address knowledge gaps on the occurrence, fate and transport, and persistence of antimicrobial resistant organisms and genes found in municipal wastewater effluent and biosolids.

EPA also requires that grant applicants adequately describe environmental outputs and outcomes to be achieved under assistance agreements (see EPA Order 5700.7A1, Environmental Results under Assistance Agreements, https://www.epa.gov/grants/epa-order-57007a1-epas-policy-environmental-results-under-epa-assistance-agreements). Applicants must include specific statements describing the environmental results of the proposed project in terms of well-defined outputs and, to the maximum extent practicable, well-defined outcomes that will demonstrate how the project will contribute to the goal(s) and objective(s) described above.

The Agency is soliciting research that will address knowledge gaps on the occurrence, fate and transport, and persistence of antimicrobial resistant organisms and genes found in municipal wastewater effluent and biosolids. Note that the research should be national in scope; it should also focus on water quality (by looking at the impact of ARB and ARGs in wastewater effluent on receiving waters used for drinking water, recreation, support of ecosystems, and other purposes) and water availability (to the extent that improving water quality increases the amount of safe drinking water to the public). The proposed research will provide new information needed to determine the removal efficiency of ARB and ARGs in wastewater treatment plants, national estimates of AMR discharges to U.S. surface waters via treated wastewater, and an increased ability to understand and identify potential public health and ecosystem risks from ARB and ARGs in receiving waters. The proposed research should support or contribute to the ability to conduct risk assessments and eventually estimate risk of infection for drinking water, recreational water, and occupational exposures. Additionally, it should facilitate comparison of AMR impacts from treated wastewater effluent and biosolids compared to other non-municipal wastewater sources (e.g., animal agriculture, hospital wastes, other industrial sources, and untreated wastewater discharges).

Given the lack of standardized methods, applicants should also clearly describe selected AMR targets and methods proposed, as well as how they best characterize AMR and address the proposed study objectives. Current work to standardize methods in the literature are Liguori et al., (2022) and The Water Research Foundation (2023) which include frameworks for AMR monitoring of wastewater, recycled water, and surface water. Franklin et al. (2020), provides an overview of common contemporary molecular methods available for analyzing AMR in surface waters and associated rationales for selection of methods dependent on the study outcome. Specifically, with respect to molecular methods, the Minimum Information for Publication of Quantitative Real-Time Polymerase Chain Reaction Experiments (MIQE) guidelines include minimum information necessary for evaluating quantitative polymerase chain reaction (qPCR) experiments and directions for researchers to develop and publish research using qPCR methods.

The proposed research should account for these and other sources of methods standardization to ensure that project data and results are transferrable and generalizable given their specific objective. Last, research should be planned in the context of existing literature, leveraging existing data sources to the extent possible, and focusing data collection on outstanding needs.

There are two distinct areas of research covered by this solicitation. EPA encourages applicants to focus on only one research area. However, applications that address more than one research area will not be deemed ineligible but will not necessarily be rated more highly than those that address just one. In addition, applications that are not national in scope may not be rated as highly as those that are. The proposed research project should be as responsive as possible to as many of the research questions listed under the selected research area; however, applicants are not required to respond to all the research questions or limit the research scope to these questions. Applications should clearly indicate which research area is being addressed.

Research Areas

Research Area 1: Understanding the selection and removal of antimicrobial resistant genes and bacteria throughout wastewater and biosolids treatment trains. The goal of this research area is to better understand the contribution of different wastewater treatment processes on the potential proliferation or removal efficiency of ARB and ARGs. Emphasis should be placed on unit processes and treatment trains that are broadly representative of U.S. wastewater treatment plants (WWTPs), including both large and small systems discharging to surface water, groundwater, and waterbodies with varying designated uses (e.g., water supply, primary contact recreation, aquatic life, and water reuse). Results should fill knowledge gaps in the understanding of the fate of AMR in different conventional and advanced municipal wastewater treatment processes. Additionally, research should support the development of national-scale estimates of ARB and ARG discharges from WWTP effluents, and support comparison to other non-municipal wastewater sources. These estimates should be generated such that they are compatible with relevant monitoring programs such as the National Antimicrobial Resistance Monitoring System (NARMS) and National Wastewater Surveillance System (NWSS). Note that this research area also requests information to better understand how sludge treatment processes effect ARB and ARGs found in biosolids.

The following are suggested research questions to be considered. Applicants are encouraged to consider other significant questions that need to be investigated to meet the objectives of this research area:

- What are the key operational and site-specific parameters impacting AMR selection, growth, and removal in conventional and advanced treatment processes and sewage sludge treatment processes? In addition to operational and site-specific parameters, this includes aspects such as physiochemical wastewater parameters, antibiotic concentrations, operational conditions, dry or wet weather flow, as well as mechanisms responsible for attenuation that impact AMR.

- What key knowledge gaps need to be addressed on the removal of ARB and ARGs by oxidation and disinfection processes and on the impact of typical doses used on AMR of final treated wastewater?
- How do combinations of conventional and advanced treatment processes impact the removal of AMR and what current knowledge gaps need to be addressed?
    - How can ARB and ARG levels be controlled within treatment processes?
- How do WWTP characteristics such as size of system, types of treatment processes, location, and treatment train configuration affect ARB, ARG, and AMR residue levels in WWTP effluent?
    - How effective is conventional and advanced treatment (including chlorination, UV treatment, ozonation, and advanced oxidation processes) in removing ARB and ARGs?
    - What is the occurrence, mechanism, and timing of genetic mobilization of ARGs between microbial communities in wastewater reclamation facilities?
    - What are the differences between wastewater systems of the same size using different treatment trains?
- What are the levels of ARB and ARGs in influent as compared to levels in effluent?
- How do WWTPs vary nationally regarding removal efficiencies of ARB and ARGs?
    - What are the impacts of watershed geography, temperature, and socioeconomic aspects on ARB and ARG levels in effluent?
    - What are the differences in ARB and ARGs in effluent across different treatment trains?
- What is the impact from different influent wastewaters such as municipal dominated vs systems including commercial and/or industrial sources, and hospitals on ARB, ARG, and antimicrobial levels in effluent?
    - How does this impact loadings and selection or removal within the individual treatment processes?
- What is the impact of different biosolids treatment processes such as anaerobic digestion, lime stabilization, heat drying, and composting on AMR?
    - How do different operational factors affect AMR in biosolids?
    - How well do these biosolids processes impact antimicrobial residues?

Research Area 2: Understanding the environmental burden and public health impact of antimicrobial resistant genes and bacteria from different municipal wastewater sources on downstream applications and from biosolids use on the environment. Multiple wastewater sources of AMR, including municipal effluents, land-applied biosolids, septic systems, and untreated sewage overflows may contribute to AMR levels in receiving waters that are used for recreation, aquatic life, ecosystem services, and planned and de facto reuse. New information is needed to characterize the different wastewater sources so that the relative contributions can be determined and compared to other sources such as agriculture. Moreover, this research area includes the development and demonstration of risk assessment models (e.g., of acute human

exposure risks, ecological impacts, and the development of novel resistances among pathogens). Study design should therefore facilitate the use of generated data in risk assessments and relative source contribution studies.

The following are suggested research questions to be considered. Applicants are encouraged to consider other significant questions that need to be investigated to meet the objectives of this research area:

- What is the relative significance of wastewater effluent as a source of ARB and ARGs in receiving waters compared to other non-wastewater sources such as animal agriculture, animal husbandry, hospital sources, direct industrial sources, etc.?
    - What is the relative contribution of ARB and ARGs from wastewater effluent (secondary treated and disinfected), combined sewer overflows (CSOs), septic systems, and small systems such as lagoon systems, to receiving surface waters?
    - What is the impact from gene transfer in the environment, compared to other non-wastewater related pathways such as natural development, animal husbandry, animal agriculture, and others?
- How can effluent measurements be used to estimate human health risks associated with water reuse (potable, non-potable, de facto), primary contact recreation, and other potential exposures?
- What is the significance of AMR from land applied biosolids on human and animal health and the environment?
    - What is the role of biosolids (Class A and Class B) on the spread of AMR to the environment?
    - What is the impact on food crops? On domesticated and wild animals?
    - How do land applied biosolids transfer ARGs to human pathogens?
- What are appropriate mitigation and management practices that reduce the AMR risk from land applied biosolids?
- What are the appropriate frameworks for quantifying risk related to AMR in treated wastewater discharge, water reuse, and biosolids and land application?

Expected Outputs/Outcomes

Expected Outputs: Some examples of desirable outputs are listed below:

- Bench, pilot, or full-scale testing at wastewater facilities and biosolids land application sites.
- Knowledge development on risk from effluent discharge and biosolids land application and other beneficial uses.
- Development of appropriate frameworks and methodologies for quantifying risk related to AMR in treated wastewater discharge, water reuse, and biosolids (and biosolids products) land application and beneficial use.

- Assessment of the significance of the wastewater discharge sources and biosolids use on AMR proliferation in the environment in comparison to other non-wastewater sources in different watersheds.
- Research and testing reports and peer reviewed publications pertaining to the research areas listed above.
- Workshops and webinars to disseminate information to states and utilities.
- Guidance documents for utilities and states including targets and ways to integrate with other networks.
    - Guidance to mitigate the sources of ARB and ARGs, particularly those that may persist and/or accumulate in the environment.
- Risk assessments along with development of risk models and source apportionment studies.
- Data on wastewater effluent quality as impacted by various processes and geographical variation.
- Survey frameworks for the longitudinal monitoring of AMR in wastewater effluents.
- Guidance on effective treatment processes and operational configurations for the management of ARB and ARGs in wastewater.

Expected Outcomes:

- Better understanding of the nature, extent, selection, and removal of ARB and ARGs found in municipal wastewater effluent and biosolids as well as the conditions associated with their occurrence and growth.
- Improved understanding of the environmental burden and public health impact of ARB and ARGs from different municipal wastewater sources on downstream applications and from biosolids use on the environment.
- Better planning and increased ability for States, municipalities, and wastewater treatment facilities to identify and manage human health and ecosystem risks from ARB and ARGs.

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F. Special Requirements

It is EPA Policy to ensure that the results of EPA-funded extramural scientific research are accessible to the public to the greatest extent feasible consistent with applicable law; policies and Orders; the Agency's mission; resource constraints; and U.S. national, homeland and economic security. This entails maximizing, at no charge, access by the public to peer-reviewed, scientific research journal publications or associated author manuscripts, and their underlying digital research data, created in whole or in part with EPA funds, while protecting personal privacy; recognizing proprietary interests, confidential business information, and intellectual property rights; and avoiding significant negative impact on intellectual property rights, innovation, and U.S. competitiveness.

Applications submitted under this announcement shall include a Scientific Data Management Plan (SDMP) that addresses public access to EPA-funded scientific research data. See the SDMP clause in Section IV for details on the content of an SDMP. Applicants will also be asked to provide past performance information on whether journal publications or associated author manuscripts, and the associated underlying scientific research data and metadata, under prior assistance agreements were made publicly accessible. These items will be evaluated prior to award.

Reasonable, necessary and allocable costs for data management and public access may be included in extramural research applications and detailed in the budget justification described in Section IV.

Agency policy and ethical considerations prevent EPA technical staff and managers from providing applicants with information that may create an unfair competitive advantage. Consequently, EPA employees will not review, comment, advise, and/or provide technical assistance to applicants preparing applications in response to EPA RFAs. EPA employees cannot endorse any particular application.

Multiple Investigator applications may be submitted as: (1) a single Lead Principal Investigator (PI) application with Co-PI(s) or (2) a Multiple PI application (with a single Contact PI). If you choose to submit a Multiple PI application, you must follow the specific instructions provided in Sections IV and V of this RFA. For further information, please see the EPA Implementation Plan for Policy on Multiple Principal Investigators (https://www.epa.gov/research-grants/research-grants-guidance-and-policies).

This solicitation provides the opportunity for the submission of applications for projects that may involve human subjects research. All applications must include a Human Subjects Research Statement (HSRS; described in Section IV.C.5.iii.c of this solicitation). If the project involves human subjects research, it will be subject to an additional level of review prior to funding decisions being made as described in Sections V.D and V.F of this solicitation.

These awards may involve the collection of "Geospatial Information," which includes information that identifies the geographic location and characteristics of natural or constructed features or boundaries on the Earth or applications, tools, and hardware associated with the generation, maintenance, or distribution of such information. This information may be derived from, among other things, a Geographic Positioning System (GPS), remote sensing, mapping, charting, and surveying technologies, or statistical data.

G. Additional Provisions for Applicants Incorporated into the Solicitation

Additional provisions that apply to sections III, IV, V, and VI of this solicitation and/or awards made under this solicitation, can be found at EPA Solicitation Clauses. These provisions are important for applying to this solicitation and applicants must review them when preparing applications for this solicitation. If you are unable to access these provisions electronically at the website above, please contact the EPA point of contact listed in this solicitation (usually in Section VII) to obtain the provisions.

II. AWARD INFORMATION

It is anticipated that a total of approximately $9,500,000 will be awarded under this announcement, depending on the availability of funds, quality of applications received, and other

applicable considerations. The EPA anticipates funding approximately 4 awards under this RFA. Requests for amounts in excess of a total of $2,375,000 in federal funds per award, including direct and indirect costs, will not be considered. In addition, a minimum 25% non-federal cost share/match of the federal funds awarded, which may include in-kind contributions (see Section III.B. for more details), is required. For example, if an applicant requests $2,375,000 in EPA funds, a minimum of $593,750 must be included. Including matching, total project costs can exceed $2,968,750 (if the applicant proposes more than the minimum required non-federal cost share/match), however, the federally-funded portion of the budget must not exceed $2,375,000. Applications which do not include the minimum 25% non-federal cost share/match will not be considered. The total project period requested in an application submitted for this RFA may not exceed 3 years.

The EPA reserves the right to reject all applications and make no awards, or make fewer awards than anticipated, under this RFA. The EPA reserves the right to make additional awards under this announcement, consistent with Agency policy, if additional funding becomes available after the original selections are made. Any additional selections for awards will be made no later than six months after the original selection decisions.

In appropriate circumstances, EPA reserves the right to partially fund applications by funding discrete portions or phases of proposed projects. If EPA decides to partially fund an application, it will do so in a manner that does not prejudice any applicants or affect the basis upon which the application, or portion thereof, was evaluated and selected for award, and therefore maintains the integrity of the competition and selection process. Awards may be fully or incrementally funded, as appropriate, based on funding availability, satisfactory performance, and other applicable considerations.

EPA intends to award only grants under this announcement.

Under a *grant,* EPA scientists and engineers are not permitted to be substantially involved in the execution of the research. However, EPA encourages interaction between its own laboratory scientists and grant Principal Investigators after the award of an EPA grant for the sole purpose of exchanging information in research areas of common interest that may add value to their respective research activities. This interaction must be incidental rather than substantial to achieving the goals of the research under a grant. Interaction that is "incidental" does not involve resource commitments by EPA.

III. ELIGIBILITY INFORMATION

Note: Additional provisions that apply to this section can be found at EPA Solicitation Clauses.

A. Eligible Applicants

This solicitation is available to public and private nonprofit institutions and public and private universities and colleges located in the United States and its territories or possessions. Foreign

entities, U.S. States, territories and possessions, the District of Columbia, State and local government departments, and Federally Recognized Indian Tribal Governments of the U.S., are not eligible to apply under this RFA. Profit-making firms and individuals are not eligible to receive assistance agreements from the EPA under this program.

Consistent with the definition of Nonprofit organization at 2 CFR § 200.1, the term nonprofit organization means any corporation, trust, association, cooperative, or other organization that is operated mainly for scientific, educational, service, charitable, or similar purpose in the public interest and is not organized primarily for profit; and uses net proceeds to maintain, improve, or expand the operation of the organization. Note that 2 CFR § 200.1 specifically excludes Institutions of Higher Education from the definition of non-profit organization because they are separately defined in the regulation. While not considered to be a nonprofit organization(s) as defined by 2 CFR § 200.1, public or nonprofit Institutions of Higher Education are, nevertheless, eligible to submit applications under this RFA. Hospitals that meet the definition of nonprofit at 2 CFR § 200.1 are also eligible to apply as nonprofits. Hospitals operated by state, tribal, or local governments or that are instrumentalities of the unit of government depending on the applicable law are not eligible to apply. For-profit colleges, universities, trade schools, and hospitals are ineligible.

Nonprofit organizations that are not exempt from taxation under section 501 of the Internal Revenue Code must submit other forms of documentation of nonprofit status; such as certificates of incorporation as nonprofit under state or tribal law. Nonprofit organizations exempt from taxation under section 501(c)(4) of the Internal Revenue Code that lobby are not eligible for EPA funding as provided in the Lobbying Disclosure Act, 2 U.S.C. 1611.

National laboratories funded by Federal Agencies (Federally-Funded Research and Development Centers, "FFRDCs") may not apply. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization. An award recipient may provide funds through its assistance agreement from the EPA to an FFRDC for research personnel, supplies, equipment, and other expenses directly related to the research.

Federal Agencies may not apply. Federal employees are not eligible to serve in a principal leadership role on an assistance agreement. Federal employees may not receive salaries or augment their Agency's appropriations through awards made under this program unless authorized by law to receive such funding.

The applicant institution may enter into an agreement with a Federal Agency to purchase or utilize unique supplies or services unavailable in the private sector to the extent authorized by law. Examples are purchase of satellite data, chemical reference standards, analyses, or use of instrumentation or other facilities not available elsewhere. A written justification for federal involvement must be included in the application. In addition, an appropriate form of assurance

that documents the commitment, such as a letter of intent from the Federal Agency involved, should be included.

Potential applicants who are uncertain of their eligibility should contact Ron Josephson in ORD, phone: 202-564-7823, email: josephson.ron@epa.gov.

B. Cost sharing

Each applicant must contribute a minimum non-federal cost share/match of 25% of the federal funds awarded. This is equivalent at a minimum to 20% of the total project costs.

For example, if an applicant requests $2,375,000 in EPA funds, a minimum of $593,750 must be included. Including matching, total project costs can exceed $2,968,750 (if the applicant proposes more than the minimum required non-federal cost share/match), however, the federally-funded portion of the budget must not exceed $2,375,000.

If the applicant is successful, the resultant assistance agreement will display cost share as a percentage of total project costs. Cost share may include in-kind contributions. In order to be eligible for funding consideration, applicants must demonstrate in their applications how they will meet the required minimum 25% cost share/match in accordance with 2 CFR § 200.306.

The cost share/match may be provided in cash or can come from in-kind contributions, such as the use of volunteers and/or donated time, equipment, etc., subject to the regulations governing matching fund requirements at 2 CFR § 200.306. Cost share/matching funds are considered grant funds and are included in the total award amount.

All contributions, including cash and third party in-kind, shall be accepted as cost sharing or matching when such contributions meet all of the following criteria: (1) Are verifiable from the non-Federal entity's records; (2) Are not included as contributions for any other Federal award; (3) Are necessary and reasonable for proper and efficient accomplishment of project or program objectives; (4) Are allowable under Subpart E—Cost Principles of 2 CFR Part 200; (5) Are not paid by the Federal Government under another Federal award, except where the Federal statute authorizing a program specifically provides that Federal funds made available for such program can be applied to matching or cost sharing requirements of other Federal programs; (6) Are provided for in the approved budget when required by the Federal awarding agency; and (7) Conform to other provisions of 2 CFR Part 200, as applicable.

Any restrictions on the use of grant funds (examples of funding restrictions are described in Section IV.E of this announcement) also apply to the use of cost share/matching funds.

C. Other

All applications will be reviewed for eligibility and must meet the eligibility requirements described in Sections III.A., B., and C. to be considered eligible. Applicants deemed ineligible for funding consideration as a result of the threshold eligibility review will be notified within 15 calendar days of the ineligibility determination.

a. Applications must substantially comply with the application submission instructions and requirements set forth in Section IV of this solicitation or else they will be rejected. However, where a page limit is expressed in Section IV with respect to the application, or parts thereof, pages in excess of the page limitation will not be reviewed. Applicants are advised that readability is of paramount importance and should take precedence in application format, including selecting a legible font type and size for use in the application.

b. In addition, initial applications must be submitted through Grants.gov as stated in Section IV of this solicitation (except in the limited circumstances where another mode of submission is specifically allowed for as explained in Section IV) on or before the application submission deadline published in Section IV of this solicitation. Applicants are responsible for following the submission instructions in Section IV of this solicitation to ensure that their application is timely submitted. Please note that applicants experiencing technical issues with submitting through Grants.gov should follow the instructions provided in Section IV, which include both the requirement to contact Grants.gov and email a full application to EPA prior to the deadline.

c. Applications submitted outside of Grants.gov will be deemed ineligible without further consideration unless the applicant can clearly demonstrate that it was due to EPA mishandling or technical problems associated with Grants.gov or SAM.gov. An applicant's failure to timely submit their application through Grants.gov because they did not timely or properly register in SAM.gov or Grants.gov will not be considered an acceptable reason to consider a submission outside of Grants.gov.

If an applicant submits more than one application under this announcement, each application must be submitted separately, and the scope of work proposed in each application must be significantly different from the other application(s) in order for them to all be deemed eligible. If applications are submitted with scopes of work that do not significantly differ, then EPA will only accept the most recently submitted application and all other applications will be deemed ineligible.

In addition, applications which do not provide the required non-federal cost share/match will be deemed ineligible. Also, applications exceeding the funding limits or project period described herein will be rejected without review. See Section II. Further, applications that fail to demonstrate a public purpose of support or stimulation (e.g., by proposing research which primarily benefits a Federal program or provides a service for a Federal agency) will not be funded.

IV. APPLICATION AND SUBMISSION INFORMATION

Note: Additional provisions that apply to this section can be found at EPA Solicitation Clauses.

Formal instructions for submission through Grants.gov are in Section F.

A. Grants.gov Submittal Requirements and Limited Exception Procedures

Applicants must apply electronically through Grants.gov under this funding opportunity based on the grants.gov instructions in this announcement. If your organization has no access to the internet or access is very limited, you may request an exception for the remainder of this calendar year by following the procedures outlined here. Please note that your request must be received at least 15 calendar days before the application due date to allow enough time to negotiate alternative submission methods. Issues with submissions with respect to this opportunity only are addressed in section *F. Submission Instructions and Other Submission Requirements* below.

B. Application Package Information

Use the application package available at Grants.gov (see Section IV.F. "Submission Instructions and Other Submission Requirements"). Note: With the exception of the current and pending support form (available at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms), all necessary forms are included in the electronic application package. Make sure to include the current and pending support form in your Grants.gov submission.

C. Content and Form of Application Submission

The application is made by submitting the materials described below. **Applications must contain all information requested.**

1. Standard Form 424

The applicant must complete Standard Form 424, Application for Federal Assistance. Instructions for completion of the SF-424 are included with the form. However, note that EPA requires that the entire requested dollar amount appear on the SF-424, not simply the proposed first year expenses. **Note that a minimum 25% non-federal cost share/match of the federal funds awarded must be included.** The form must contain the signature of an authorized representative of the applying organization.

2. Key Contacts, EPA Form 5700-54

The applicant must complete the "Key Contacts" form found in the Grants.gov application package. An "Additional Key Contacts" form is also available at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms. The Key Contacts form should also be completed for major subawards (i.e., principal investigators). Do not include information for consultants or other contractors. Please make certain that all contact information is accurate.

For Multiple PI applications: The Additional Key Contacts form ***must*** be completed (see Section I.F. for further information). *Note: The Contact PI must be affiliated with the institution submitting the application. EPA will direct all communications related to scientific, technical, and budgetary aspects of the project to the Contact PI; however, any information regarding an application will be shared with any PI upon request.* The Contact PI is to be listed on the Key Contact Form as the Project Manager/Principal Investigator (the term Project Manager is used on the Grants.gov form, the term Principal Investigator is used on the form located at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms). For additional PIs, complete the Major Co-Investigator fields and identify PI status next to the name (e.g., "Name: John Smith, Principal Investigator").

3. EPA Form 4700-4, Preaward Compliance Review Report for All Applicants and Recipients Requesting EPA Financial Assistance (For tips on completing the form see: https://www.epa.gov/grants/tips-completing-epa-form-4700-4.)

4. SF-424A Budget Information - Non-Construction Programs

Prepare a master budget table using Standard Form 424A, Budget Information for Non-Construction Programs, available in the Grants.gov electronic application package. Provide the federal funds being requested and non-federal cost share being contributed in "Section A-Budget Summary" under the "New or Revised Budget" heading. In "Section B-Budget Categories", provide the object class budget category (a. - k.) amounts for each budget year under the "Grant Program, Function or Activity" heading. Each column reflects a separate budget year. For example, Column (1) reflects budget year 1. The total budget will be automatically tabulated in column (5).

Please note that a minimum 25% non-federal cost-share/match of the federal funds awarded is required. Cost shared amounts must be listed in the SF-424A and described in the budget justification.

Applicants may not use subawards to transfer or delegate their responsibility for successful completion of their EPA assistance agreement. Note: Prior to naming a contractor (including consultants) or subrecipient in your application as a "partner", please carefully review Section IV.d, "Contracts and Subawards", of EPA's Announcement Clauses that are incorporated by reference in this announcement (See Section I.G). EPA expects recipients of funding to comply with competitive procurement contracting requirements as well as EPA's rule on Participation by

Disadvantaged Business Enterprises in EPA Programs in 40 CFR Part 33. The Agency does not accept justifications for sole source contracts for services or products available in the commercial marketplace based on a contractor's role in preparing an application.

5. Project Narrative, submitted using Project Narrative Attachment Form and prepared as described below:

i) Table of Contents

Provide a list of the major subdivisions of the application indicating the page number on which each section begins.

ii) Abstract (1 page)

The abstract is a very important document in the review process. Therefore, it is critical that the abstract accurately describes the research being proposed and conveys all the essential elements of the research. Also, the abstracts of applications that receive funding will be posted on EPA's Research Grants website.

The abstract must include the information described below (a-h). Examples of abstracts for current grants may be found on EPA's Research Grants website.

a. Funding Opportunity Title and Number for this application.

b. Project Title: Use the exact title of your project as it appears in the application. The title must be brief yet represent the major thrust of the project. Because the title will be used by those not familiar with the project, use more commonly understood terminology. Do not use general phrases such as "research on."

c. Investigators: For applications with multiple investigators, state whether this is a single Lead PI (with co-PIs) or Multiple PI application (see Section I.F.). For Lead PI applications, list the Lead PI, then the name(s) of each co-PI who will significantly contribute to the project. For Multiple PI applications, list the Contact PI, then the name(s) of each additional PI. Provide a website URL or an email contact address for additional information.

d. Institution(s): In the same order as the list of investigators, list the name, city and state of each participating university or other applicant institution. The institution applying for assistance must be clearly identified.

e. Project Period and Location: Show the proposed project beginning and ending dates and the performance site(s)/geographical location(s) where the work will be conducted.

f. Project Cost: Show the total funding requested from the EPA (include direct and indirect costs for all years) as well as the non-federal cost share. Indicate how you will meet the required match requirement.

g. Project Summary: Provide three subsections addressing: (1) the objectives of the study (including any hypotheses that will be tested), (2) the experimental approach to be used (a description of the proposed project) and (3) the expected results (outputs/outcomes) of the project and how it addresses the research needs identified in the solicitation, including the estimated improvement in risk assessment or risk management that will result from successful completion of the proposed work.

h. Supplemental Keywords: Without duplicating terms already used in the text of the abstract, list keywords to assist database searchers in finding your research. A list of suggested keywords may be found at: https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms.

iii) Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, and References

a. Research Plan (15 pages)

Applications should focus on a limited number of research objectives that adequately and clearly demonstrate that they meet the RFA requirements. Explicitly state the main hypotheses that you will investigate, the data you will create or use, the analytical tools you will use to investigate these hypotheses or analyze these data and the results you expect to achieve. Research methods must be clearly stated so that reviewers can evaluate the appropriateness of your approach and the tools you intend to use. A statement such as: "we will evaluate the data using the usual statistical methods" is not specific enough for peer reviewers.

This description must not exceed fifteen (15) consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. While these guidelines on page size, point type and margins establish the minimum type size requirements, applicants are advised that readability is of paramount importance and should take precedence in selection of an appropriate font for use in the application.

The description must provide the following information:

(1) Objectives: List the objectives of the proposed research and the hypotheses being tested during the project, and briefly state why the intended research is important, how it supports the Agency's research priorities and how it fulfills the requirements of the solicitation. This section should also include any background or introductory information that would help explain the objectives of the study. If this application is to expand upon research supported by an existing or former assistance agreement awarded under an EPA

program, indicate the number of the agreement and provide a brief report of progress and results achieved under it.

(2) Approach/Activities: Outline the research design, methods, and techniques that you intend to use in meeting the objectives stated above.

(3) Expected Results, Benefits, Outputs and Outcomes: Describe the expected outputs and outcomes resulting from the project. This section should also discuss how the research results will lead to solutions to environmental problems and improve the public's ability to protect the environment and human health. A clear, concise description will help ORD and peer reviewers understand the merits of the research.

(4) Project Management: Discuss other information relevant to the potential success of the project. This should include facilities, personnel expertise/experience, project schedules with associated milestones and target dates, proposed management, interactions with other institutions, etc. If applicable, provide resources available to specific investigator(s), such as additional research space or personnel and in-kind contributions that support the research activity for use on the project/proposal being proposed. Describe the approach, procedures, and controls for ensuring that awarded grant funds will be expended in a timely and efficient manner and detail how project objectives will be successfully achieved within the grant period. Describe how progress toward achieving the expected results (outputs and outcomes) of the research will be tracked and measured. Applications for multi-investigator projects must identify project management and the functions of each investigator in each team and describe plans to communicate and share data.

(5) Appendices may be included but must remain within the 15-page limit.

b. Quality Assurance Statement (3 pages)

For projects involving environmental data collection or processing, conducting surveys, modeling, method development, or the development of environmental technology (whether hardware-based or via new techniques), provide a Quality Assurance Statement (QAS) regarding the plans for processes that will be used to ensure that the products of the research satisfy the intended project objectives. Follow the guidelines provided below to ensure that the QAS describes a system that complies with EPA Quality Standards found at: https://www.epa.gov/quality/agency-wide-quality-program-documents. Do not exceed three consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

NOTE: If selected for award, applicants will be expected to provide additional quality assurance documentation.

Address each applicable section below by including the required information, referencing the specific location of the information in the Research Plan or explaining why the section does not apply to the proposed research. (Not all will apply)

(1) Identify the individual who will be responsible for the quality assurance (QA) and quality control (QC) aspects of the research along with a brief description of this person's functions, experience and authority within the research organization. Describe the schedule and type of assessments to be conducted along with the corrective action process for each assessment proposed. Describe the organization's general approach for conducting quality research. *(QA is a system of management activities to ensure that a process or item is of the type and quality needed for the project. QC is a system of activities that measures the attributes and performance of a process or item against the standards defined in the project documentation to verify that they meet those stated requirements).*

(2) Discuss project objectives, including quality objectives, any hypotheses to be tested, and the quantitative and/or qualitative procedures that will be used to evaluate the success of the project. Include any plans for peer or other reviews of the study design or analytical methods.

(3) Address each of the following project elements as applicable:

(a) Collection of new/primary data:
*(**Note:** In this case the word "sample" is intended to mean any finite part of a statistical population whose properties are studied to gain information about the whole. If certain attributes listed below do not apply to the type of samples to be used in your research, simply explain why those attributes are not applicable).*

(i) Discuss the plan for sample collection and analysis. As applicable, include sample type(s), frequency, locations, sample sizes, sampling procedures, and the criteria for determining acceptable data quality (e.g., precision, accuracy, representativeness, completeness, comparability, or data quality objectives).

(ii) Describe the procedures for the handling and custody of samples including sample collection, identification, preservation, transportation, and storage, and how the accuracy of test measurements will be verified.

(iii) Describe or reference each analytical method to be used, any QA or QC checks or procedures with the associated acceptance criteria and any procedures that will be used in the calibration and performance evaluation of the analytical instrumentation.

(iv) Discuss the procedures for overall data reduction, analysis, and reporting. Include a description of all statistical methods to make inferences and conclusions, acceptable error rates and/or power, and any statistical software to be used.

(b) Use of existing/secondary data (i.e., data previously collected for other purposes or from other sources):

(i) Identify the types of secondary data needed to satisfy the project objectives. Specify requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable.

(ii) Specify the source(s) of the secondary data and discuss the rationale for selection.

(iii) Establish a plan to identify the sources of the secondary data in all deliverables/products.

(iv) Specify quality requirements and discuss the appropriateness for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable.

(v) Describe the procedures for determining the quality of the secondary data.

(vi) Describe the plan for data management/integrity.

(c) Method development:
*(**Note:** The data collected for use in method development or evaluation should be described in the QAS as per the guidance in section 3A and/or 3B above).*

Describe the scope and application of the method, any tests (and measurements) to be conducted to support the method development, the type of instrumentation that will be used, and any required instrument conditions (e.g., calibration frequency), planned QC checks and associated criteria (e.g., spikes, replicates, blanks) and tests to verify the method's performance.

(d) Development or refinement of models:
*(**Note:** The data collected for use in the development or refinement of models should be described in the QAS as per the guidance in section 3A and/or 3B above).*

(i) Discuss the scope and purpose of the model, key assumptions to be made during development/refinement, requirements for code development, and how the model will be documented.

(ii) Discuss verification techniques to ensure the source code implements the model correctly.

(iii) Discuss validation techniques to determine that the model (assumptions and algorithms) captures the essential phenomena with adequate fidelity.

(iv) Discuss plans for long-term maintenance of the model and associated data.

(e) Development or operation of environmental technology:
*(**Note:** The data collected for use in the development or evaluation of the technology should be described in the QAS as per the guidance in section 3A and/or 3B above).*

(i) Describe the overall purpose and anticipated impact of the technology.

(ii) Describe the technical and quality specifications of each technology component or process that is to be designed, fabricated, constructed, and/or operated.

(iii) Discuss the procedure to be used for documenting and controlling design changes.

(iv) Discuss the procedure to be used for documenting the acceptability of processes and components and discuss how the technology will be benchmarked and its effectiveness determined.

(v) Discuss the documentation requirements for operating instructions/guides for maintenance and use of the system(s) and/or process(s).

(f) Conducting surveys:
(***Note:** The data to be collected in the survey and any supporting data should be described in the QAS as per the guidance in section 3A and/or 3B above).*

(i) Discuss the justification for the size of the proposed sample for both the overall project and all subsamples for specific treatments or tests. Identify and explain the rational for the proposed statistical techniques (e.g., evaluation of statistical power).

(4) Discuss data management activities (e.g., record-keeping procedures, data-handling procedures, and the approach used for data storage and retrieval on electronic media). Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used.

c. EPA Human Subjects Research Statement (HSRS) (4 pages)

Human subjects research supported by the EPA is governed by EPA Regulation 40 CFR Part 26 (Protection of Human Subjects). This includes the Common Rule at subpart A and prohibitions and additional protections for pregnant women and fetuses, nursing women and children at subparts B, C and D. While retaining the same notation, subparts B, C and D are substantively

different in 40 CFR Part 26 than in the more commonly cited 45 CFR 46. Particularly noteworthy is that research meeting the regulatory definition of intentional exposure research found in subpart B is prohibited by that subpart in pregnant women, nursing women and children. Research meeting the regulatory definition of observational research (any research that is not intentional exposure research) found in subparts C and D is subject to the additional protections found in those subparts for pregnant women and fetuses (subpart C) and children (subpart D). These subparts also differ markedly from the language in 45 CFR 46. For more information, please see: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0.

Procedures for the review and oversight of human research subject to 40 CFR Part 26 are also provided in EPA Order 1000.17A (https://www.epa.gov/osa/epa-order-100017-policy-and-procedures-protection-human-research-subjects-epa-conducted-or). These include review of projects for EPA-supported human research by the EPA Human Subjects Research Review Official (HSRRO). Additional requirements must be met and final approval must be received from the HSRRO before the human subjects' portion of the research can begin. When reviewing human observational exposure studies, EPA Order 1000.17A requires the HSRRO to apply the principles described in the SEAOES document (https://nepis.epa.gov/Exe/ZyPDF.cgi/P10012LY.PDF?Dockey=P10012LY.PDF) and grant approval only to studies that adhere to those principles.

All applications submitted under this solicitation must include a HSRS as described below. For more information about what constitutes human subjects research, please see: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0. For information on the prohibition on the inclusion of vulnerable subjects in intentional exposure research, please see: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0.

Human Subjects Research Statement (HSRS) Requirements

If the proposed research **does not** involve human subjects as defined above, provide the following statement in your application package as your HSRS: "The proposed research does not involve human subjects." Applicants should provide a clear justification about how the proposed research does not meet the definition (for example, all samples come from deceased individuals OR samples are purchased from a commercial source and provided without identifiers, etc.).

If the proposed research **does** involve human subjects, then include in your application package a HSRS that addresses each applicable section listed below, referencing the specific location of the information in the Research Plan, providing the information in the HSRS or explaining why the section does not apply to the proposed research. (Not all will apply). Please note that even research that has been determined to be exempt from the human subjects regulations by an IRB must be reviewed by the EPA HSRRO. Therefore, consider exempt research to include human subjects work for this EPA solicitation. Do not exceed **four** consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. The factors below are not intended to be exhaustive of all those needed for the HSRRO to provide the final approval

necessary for research to be conducted but provide a basis upon which the human subjects oversight review may begin.

NOTE: Researchers must provide evidence of an assurance on file with the U.S. Department of Health and Human Services (HHS) or other Federal Agency that it will comply with regulatory provisions in the Common Rule. In special circumstances where there is no such assurance, EPA will work with investigators to obtain an assurance from HHS or another source.

Complete all items below for studies involving human subjects.
Protection of Human Subjects (Adapted from National Institutes of Health Supplemental Instructions for PHS 398 and SF424 (R&R) II-10)

1. Risks to Human Subjects
    a. Human Subjects Involvement, Characteristics and Design
        • Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
        • Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.
        • Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
        • Explain the rationale for the involvement of special vulnerable populations, such as pregnant women, children, or others who may be considered vulnerable populations.
        • If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subject's protection, describe and justify the selection of an intervention's dose, frequency, and administration.
        • List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.
    b. Sources of Materials
        • Describe the research material obtained from living individuals in the form of specimens, records, or data.
        • Describe any data that will be collected from human subjects for the project(s) described in the application.
        • Indicate who will have access to individually identifiable private information about human subjects.
        • Provide information about how the specimens, records, and/or data are collected, managed and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.
    c. Potential Risks

• Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
• Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

2. Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

• Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
• Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

b. Protections Against Risk

• Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data and assess their likely effectiveness.
• Research involving vulnerable populations, as described in the EPA regulations, Subparts B-D, must include additional protections. Refer to EPA guidance:

Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women
https://www.epa.gov/osa/basic-information-about-human-subjects-research-0

Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA
https://www.epa.gov/osa/basic-information-about-human-subjects-research-0

Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA
https://www.epa.gov/osa/basic-information-about-human-subjects-research-0

• Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials must include a general description of the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the Data and Safety Monitoring Board (DSMB) (if one has been established for the trial), the EPA and others, as appropriate, to ensure the safety of subjects.

3. Potential Benefits of the Proposed Research to Human Subjects and Others

• Discuss the potential benefits of the research to research participants and others.
• Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
• Please note that financial compensation of subjects is not considered to be a benefit of participation in research.

4. Importance of the Knowledge to be Gained
• Discuss the importance of the knowledge to be gained as a result of the proposed research.
• Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Note that an Interventional Study (or Clinical Trial) is a clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes; the assignments are determined by the study protocol.

d. Scientific Data Management Plan (2 pages)

Applications submitted in response to this solicitation must include a Scientific Data Management Plan (SDMP) that addresses public access to EPA-funded scientific research data by including the information below:

(1) If the proposed research described in the application is expected to result in the generation of scientific research data, the application must include a Scientific Data Management Plan (SDMP) of up to two single-spaced pages (this is in addition to any application page limits described in Section IV of this solicitation that apply to other parts of the application package) describing plans for providing long-term preservation of, and public access to, the scientific research data and accompanying metadata created and/or collected under the award (including data generated under subawards and contracts) funded in whole or in part by EPA. The SDMP should indicate that recipients will make accessible, at a minimum, scientific research data and associated metadata underlying their scientific research journal publications funded in whole or in part by EPA. SDMPs should reflect relevant standards and community best practices for data and metadata and make use of community-accepted repositories whenever practicable. The contents of the SDMP (or absence thereof) will be considered as part of the application review process for selected applicants as described in Section V and must be deemed acceptable for the applicant to receive an award. The SDMP should include the following elements (Note: If any of the items listed below do not apply, please explain why):

i. Types of scientific research data and metadata expected to be generated and/or collected under the award.
ii. The location where the data will be publicly accessible.
iii. The standards to be used for data/metadata format and content.

iv. Policies for accessing and sharing data including provisions for appropriate protection of privacy, security, intellectual property, and other rights or requirements consistent with applicable laws, regulations, rules, and policies.
v. Plans for digital data storage, archiving, and long-term preservation that address the relative value of long-term preservation and access along with the associated costs and administrative burden.
vi. Description of how data accessibility and preservation will enable validation of published results or how such results could be validated if data are not shared or preserved.
vii. Roles and responsibilities for ensuring SDMP implementation and management (including contingency plans in case key personnel leave the project).
viii. Resources and capabilities (equipment, connections, systems, software, expertise, etc.) requested in the research application that are needed to meet the stated goals for accessibility and preservation (reference can be made to the relevant section of the research application's budget justification).
ix. If appropriate, an explanation as to why data accessibility and/or preservation are not possible.

(2) If the proposed research is not expected to result in the generation of scientific research data, provide the following statement (not subject to any application page limits described in Section IV of this solicitation) in your application as the SDMP: "The proposed research is not expected to result in the generation of scientific research data." If scientific research data are generated after award, the recipient agrees to update the statement by providing EPA with a revised SDMP (see content of SDMP described above) describing how scientific research data and accompanying metadata created and/or collected under the award (including data generated under subawards and contracts) will be preserved and, as appropriate, made publicly accessible.

e. References: References cited are in addition to other page limits (e.g., research plan, quality assurance statement).

iv) Budget Justification *[3 pages in addition to the Section IV.C.5.iii page limitations]*

Identify the amount requested for each budget category and describe the basis for calculating the personnel, fringe benefits, travel, equipment, supplies, contractual support, and other costs identified in the SF-424A. **Cost shared amounts must be described in the budget justification under each applicable category.** The budget justification should not exceed three consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. EPA provides detailed guidance on preparing budgets and budget justifications in the Agency's Interim General Budget Development Guidance for Applicants and Recipients of EPA Financial Assistance.

Budget information must be supported at the level of detail described below:

a. Personnel: List all staff positions by title. Give annual salary, percentage of time assigned to the project, total cost for the budget period, project role, and specify any annual cost of living adjustments. Compensation paid for employees engaged in grant activities must be consistent with payments for similar work within the applicant organization. Note that for salaries to be allowable as a direct charge to the award, a justification of how that person will be directly involved in the project must be provided. General administrative duties such as answering telephones, filing, typing, or accounting duties are not considered acceptable.

Below is a sample computation for Personnel:

Position/Title	**Annual Salary**	**% of Time Assigned to Project**	**Year 1**	**Year 2***	**Year 3***	**Total**
Project Manager	$70,000	50%	$35,000	$36,050	$37,132	$108,182
Env. Specialist	$60,000	100%	$60,000	$61,800	$63,654	$185,454
Env. Health Tech (cost share)	$45,000	100%	$45,000	$46,350	$47,741	$139,091
Total Personnel Request			**$95,000**	**$97,850**	**$100,786**	**$293,636**
Total Personnel Cost Share			**$45,000**	**$46,350**	**$47,741**	**$139,091**
Total Personnel (EPA + Cost Share)			**$140,000**	**$144,200**	**$148,527**	**$432,727**

***There is a 3% increase after Year 1 for all personnel for cost of living adjustments.**

Note this budget category is limited to persons employed by the applicant organization ONLY. Those employed elsewhere are classified as subawardees, program participants, contractors, or consultants. Contractors and consultants should be listed under the "Contractual" budget heading. Subawards made to eligible subrecipients are listed under the "Other" budget heading. Participant support costs such as stipends or travel assistance for trainees (e.g., interns or fellows) are listed under the "Other" budget heading.

b. Fringe Benefits: Identify the percentage used and the basis for its computation. Fringe benefits are for the personnel listed in budget category (a) above and only for the percentage of time devoted to the project. Fringe benefits include but are not limited to the cost of leave, employee insurance, pensions and unemployment benefit plans. The

applicant should not combine the fringe benefit costs with direct salaries and wages in the personnel category.

Below is a sample computation for Fringe Benefits:

Position/Title	**Base Fringe % Rate**	***Year 1***	***Year 2****	***Year 3****	**Total**
Project Manager	47.22%	$16,527	$17,022	$17,533	$51,082
Env. Specialist	50.83%	$30,498	$31,413	$32,355	$94,266
Project Manager (cost share)	49.16%	$22,122	$22,786	$23,469	$68,377
Total Fringe Benefits Request					$145,348
Total Fringe Benefits Cost-share					$68,377
Total Fringe (EPA + Cost Share)					$213,725

***An annual inflation rate of 3% has been factored into years 2 and 3 of the fringe benefits.**

c. Travel: In a table format, specify the estimated number of trips, purpose of each trip, number of travelers per trip, destinations, and other costs for each type of travel for applicant employees. Travel costs for program participants should be specified in the "Other" budget category. Explain the need for any travel, paying particular attention to travel outside the United States. Foreign travel includes trips to Mexico and Canada but does not include trips to Puerto Rico, the U.S. territories or possessions. **If EPA funds will not be used for foreign travel, the budget justification must expressly state that the applicant will not use EPA funds for foreign travel without approval by EPA.** Include travel funds for annual progress reviews (estimate for two days in Washington, D.C.) and a final workshop to report on results.

Below is a sample computation for Travel:

Purpose of Travel	**Location**	**Item**	**Computation**	**Cost**
EPA Progress Review	Washington DC	Lodging	4 people x $100 per night x 2 nights	$800
		Airfare	4 people x $500 round trip	$2,000
		Per Diem	4 people x 50 per day x 2 days	$400
Total Travel				**$3,200**

d. Equipment: Identify all tangible, non-expendable personal property to be purchased that has an acquisition cost of $5,000 or more per unit and a useful life of more than one year. Equipment also includes accessories and services included with the purchase price necessary for the equipment to be operational. It does not include: (1) equipment planned

to be leased/rented; or (2) separate equipment service or maintenance contracts. Details such as the type of equipment, cost, and a brief narrative on the intended use of the equipment for project objectives are required. Each item of equipment must be identified with the corresponding cost. Particular brands of equipment should not be identified. General-purpose equipment (office equipment, etc.) must be justified as to how it will be used on the project. (Property items with a unit cost of less than $5,000 are considered supplies).

e. Supplies: "Supplies" are tangible property other than "equipment" with a per item acquisition cost of less than $5,000. Include a brief description of the supplies required to perform the work. Costs should be categorized by major supply categories (e.g., office supplies, computing devices, monitoring equipment) and include the estimated costs by category.

f. Contractual: List the proposed contractual activities along with a brief description of the scope of work or services to be provided, the proposed duration of the contract/procurement, the estimated cost, and the proposed procurement method (competitive or non-competitive). **Any procurement of services from individual consultants or commercial firms (including space for workshops) must comply with the competitive procurement requirements of 2 CFR Part 200.317-200.327. Please see https://www.epa.gov/grants/epa-solicitation-clauses for more details.** EPA provides detailed guidance on procurement requirements in the Agency's Best Practice Guide for Procuring Services, Supplies, and Equipment Under EPA Assistance Agreements.

   Examples of Contractual costs include:

   i. Consultants – Consultants are individuals with specialized skills who are paid at a daily or hourly rate. EPA's participation in the salary rate (excluding overhead) paid to individual consultants retained by recipients or by a recipient's contractors or subcontractors is limited to the maximum daily rate for a Level IV of the Executive Schedule (formerly GS-18), to be adjusted annually.
   ii. Speaker/Trainer Fees – Information on speakers should include the fee and a description of the services they are providing.

g. Other: List each item in sufficient detail for the EPA to determine the reasonableness of its cost relative to the research to be undertaken. "Other" items may include equipment rental, telephone service and utilities and photocopying costs. Note that subawards, such as those with other universities or nonprofit research institutions for members of the research team, are included in this category. **Provide the total costs proposed for subawards as a separate line item in the budget justification and brief description of the activities to be supported for each subaward or types of subawards if the subrecipients have not been identified.** Subawards may not be used to acquire services from consultants or commercial firms. Please see https://www.epa.gov/grants/epa-

solicitation-clauses for more details. The "Other" budget category also includes participant support costs such as stipends or travel assistance for trainees (e.g. interns or fellows). **Provide the total costs proposed for participant support costs as a separate line item in the budget justification and brief description of the costs. If EPA funds will not be used for foreign travel by program participants, the budget justification must expressly state that the applicant will not use EPA funds for foreign travel without approval by EPA.**

Below is a sample computation for Other:

Item	Description	Year 1	Year 2	Year 3	Total
Publication costs	The costs incurred will be for dissemination of results in peer reviewed journal publications.	$0	$3,000	$3,000	$6,000
Tuition Cost-share	Graduate students (2)	$15,000	$15,000	$15,000	$45,000
Subaward to X University	To conduct all work related to evaluation of experimental mouse models	$100,000	$100,000	$100,000	$300,000
Subaward to Y University – cost share	To conduct fish models	$20,000	$20,000	$20,000	$60,000
Other: Participant Support Costs	Participant Incentives (100 x $25)				$2,500
Other: Participant Support Cost-Share	Participant Incentives (100 x $25)				$2,500
Total Publication Request					$6,000
Total Tuition– Cost Share					$45,000
Total Subaward Request					$300,000
Total Subaward– Cost Share					$60,000
Total Participant Support Request					$2,500
Total Participant Support– Cost Share					$2,500
Total Other Request					$308,500

Total Other – Cost Share	$107,500
Total Other (EPA + Cost Share)	$416,000

h. Indirect Costs: For additional information pertaining to indirect costs, please see the IDC Competition Clause at EPA Solicitation Clauses.

v) Resumes

Provide resumes for each investigator identified by the applicant who will contribute in a substantive, meaningful way to the scientific development or execution of the research and development project. Investigators typically do not include undergraduate and graduate students. The resume is not limited to traditional materials but should provide materials to clearly and appropriately demonstrate that the investigator has the knowledge needed to perform their component of the proposed research. The resume for each individual must not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

In addition to professional preparation (e.g., educational degrees), the resume should also include organizational affiliations and academic, professional or institutional appointments, whether or not remuneration is received, and whether they are full-time, part-time, or voluntary.

Alternative to a standard resume, you may use a profile such as an NIH BioSketch that can be generated in SciENcv (see https://grants.nih.gov/grants/forms/biosketch.htm for information on the BioSketch; also see https://www.nlm.nih.gov/pubs/techbull/so13/so13_sciencv.html for information on SciENcv). These materials should generally conform to the requirements for a resume (e.g., content and page number).

vi) Current and Pending Support

Current and pending support information is used to assess the capacity of the individual to carry out the research as proposed and helps assess any potential scientific and budgetary overlap/duplication, as well as overcommitment with the project being proposed. Complete a current and pending support form (provided at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms) for each investigator identified by the applicant who will contribute in a substantive, meaningful way to the scientific development or execution of the research and development project. Investigators typically do not include undergraduate and graduate students. Include all current and pending support regardless of source. Investigators will certify that the information contained in their current and pending support form is current, accurate, and complete. For applications selected for funding, EPA will require investigators to update, as needed, their current and pending support disclosure prior to award and at any subsequent time the agency determines appropriate during the term of the award.

Current and pending research support means all resources made available, or expected to be made available, to an individual in support of the individual's research and development efforts, regardless of: (i) whether the source of the resource is foreign or domestic; (ii) whether the resource is made available through the entity applying for a research and development award or directly to the individual; or (iii) whether the resource has monetary value. Current and pending research support also includes in-kind contributions requiring a commitment of time and directly supporting the individual's research and development efforts, such as the provision of office or laboratory space, equipment, supplies, employees, or students.

Consistent with the Guidance for Implementing National Security Presidential Memorandum 33 (NSPM-33) on National Security Strategy for United States Government-Supported Research and Development, investigators are required to disclose contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if an individual receives direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Investigators must also report other foreign government sponsored or affiliated activity. Note that non-disclosure clauses associated with these contracts are not acceptable exemptions from this disclosure requirement.

Investigators should disclose current or pending participation in, or applications to, programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. This disclosure is limited to those that are associated directly or indirectly with a foreign government (i.e., foreign governments or foreign government instrumentalities or entities).

Investigators should also disclose paid consulting that falls outside of their appointment or separate from the institution's agreement; in-kind contributions not intended for use on the project/proposal being proposed; visiting scholars funded by an entity other than your own institution; students and postdoctoral researchers funded by an entity other than your own institution; and travel supported/paid by an entity other than your own institution to perform research activities with an associated time commitment.

In accordance with Section 223(a)(1) of the *William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021* (42 USC 6605(a)(1)), investigators are required to certify that the information provided in their current and pending support form is current, accurate, and complete. Each investigator who provides a pending and support form must also provide a certification attesting that the information contained in the form is current, accurate, and complete.

False representations may be subject to prosecution and liability pursuant to, but not limited to, 18 U.S.C. §§ 287, 1001, 1031 and 31 U.S.C. §§ 3729-3733 and 3802.

Note to all prospective applicants requiring multiple Current and Pending Support Form pages: Due to a limitation in Adobe Acrobat's forms functionality, additional pages cannot be directly inserted into the original PDF form and preserve the form data on the subsequent pages. Multiple page form submissions can be created in Acrobat 8 and later using the "PDF Package" option in the "Create PDF from Multiple Files" function. If you have an earlier version of Adobe Standard or Professional, applicants will need to convert each PDF page of the form to an EPS (Encapsulated Post Script) file before creating the PDF for submission. The following steps will allow applicants with earlier versions of Adobe Standard or Professional to create a PDF package:

1. Populate the first page of the PDF and save it as an EPS (Encapsulated Post Script) file.
2. Reopen the form and populate it with the data for page 2. Save this page as a different EPS file. Repeat for as many pages as necessary.
3. Use Acrobat Distiller to convert the EPS files back to PDF.
4. Open Acrobat Professional and combine the individual pages into a combined PDF file.

vii) Applicant Current and Pending Support Certification

The applicant's Authorized Organization Representative (AOR) is required to provide a certification that each individual employed by the organization and identified on the proposal as an investigator has been made aware of the certification requirements identified in the *William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021,* Section 223(a)(1) (42 USC 6605(a)(1)).

False representations may be subject to prosecution and liability pursuant to, but not limited to, 18 U.S.C. §§ 287, 1001, 1031 and 31 U.S.C. §§ 3729-3733 and 3802.

viii) Guidelines, Limitations, and Additional Requirements

a. Letters of Intent/Letters of Support

Letters of intent to provide resources for the proposed research or to document intended interactions are limited to one brief paragraph committing the availability of a resource (e.g., use of a person's time or equipment) or intended interaction (e.g., sharing of data, as-needed consultation) that is described in the Research Plan. EPA employees are not permitted to provide letters of intent for any application.

Letters of support do not commit a resource vital to the success of the application. A letter of support is written by businesses, organizations, or community members stating their support of the applicant's proposed project. EPA employees are not permitted to provide letters of support for any application.

Note: Letters of intent or support must be part of the application; letters submitted separately will not be accepted. Any letter of intent or support that exceeds one brief paragraph (excluding letterhead and salutations), is considered part of the Research Plan and is included in the 15-page Research Plan limit. Any transactions between the successful applicant and parties providing letters of intent or support financed with EPA grant funds are subject to the contract and subaward requirements described here https://www.epa.gov/grants/epa-solicitation-clauses.

b. Funding Opportunity Number(s) (FON)

At various places in the application, applicants are asked to identify the FON.

The Funding Opportunity Number for this RFA is:
EPA-G2023-ORD-F1, National Priorities: Evaluation of Antimicrobial Resistance in Wastewater and Sewage Sludge Treatment and its Impact on the Environment

By submitting an application in response to this solicitation, the applicant grants the EPA permission to make limited disclosures of the application to technical reviewers both within and outside the Agency for the express purpose of assisting the Agency with evaluating the application. Information from a pending or unsuccessful application will be kept confidential to the fullest extent allowed under law; information from a successful application may be publicly disclosed to the extent permitted by law.

D. Submission Dates and Times

Applications **must be transferred to Grants.gov no later than 11:59:59 pm Eastern Time** on the solicitation closing date. Applications transferred after the solicitation closing date and time will be deemed ineligible without further consideration. EPA will not accept any changes to applications after the solicitation closing date.

It should be noted that this schedule may be changed without prior notification because of factors not anticipated at the time of announcement. In the case of a change in the solicitation closing date, a new date will be posted on EPA's Research Grants website (https://www.epa.gov/research-grants) and a modification posted on Grants.gov.

Solicitation Closing Date: **August 16, 2023,** 11:59:59 pm Eastern Time (applications ***must*** be submitted to Grants.gov by this time, see Section IV.F "Submission Instructions and Other Submission Requirements" for further information).

NOTE: Customarily, applicants are notified about evaluation decisions within six months of the solicitation closing date. Awards are generally made 9-12 months after the solicitation closing date.

E. Funding Restrictions

The funding mechanism for all awards issued under ORD solicitations will consist of assistance agreements from the EPA. All award decisions are subject to the availability of funds. In accordance with the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301 et seq., the primary purpose of an assistance agreement is to accomplish a public purpose of support or stimulation authorized by federal statute, rather than acquisition for the direct benefit or use of the Agency. In issuing a grant, the EPA anticipates that there will be no substantial EPA involvement in the design, implementation, or conduct of the research. However, the EPA will monitor research progress through annual reports provided by grantees and other contacts, including site visits (as needed), with the Principal Investigator(s).

EPA award recipients may incur allowable project costs 90 calendar days before the Federal awarding agency makes the Federal award. Expenses more than 90 calendar days pre-award require prior approval of EPA. All costs incurred before EPA makes the award are at the recipient's risk. EPA is under no obligation to reimburse such costs if for any reason the recipient does not receive a Federal award or if the Federal award is less than anticipated and inadequate to cover such costs.

If you wish to submit applications for more than one EPA funding opportunity you must ensure that the research proposed in each application is significantly different from any other that has been submitted to the EPA or from any other financial assistance you are currently receiving from the EPA or other federal government agency.

Collaborative applications involving more than one institution must be submitted as a single administrative package from one of the institutions involved.

Each proposed project must be able to be completed within the project period and with the initial award of funds. Applicants should request the entire amount of money needed to complete the project. Recipients should not anticipate additional funding beyond the initial award of funds for a specific project.

Coalitions

Groups of two or more eligible applicants may choose to form a coalition and submit a single application under this RFA; however, one entity must be responsible for the grant. Coalitions must identify which eligible organization will be the recipient of the grant and which eligible organization(s) will be subrecipients of the recipient (the "pass-through entity"). *Subawards* must be consistent with the definition of that term in 2 CFR 200.1 and comply with EPA's Subaward Policy. The pass-through entity that administers the grant and subawards will be accountable to EPA for proper expenditure of the funds and reporting and will be the point of contact for the coalition. As provided in 2 CFR 200.332, subrecipients are accountable to the pass-through entity for proper use of EPA funding.

For-profit organizations are not eligible for subawards under this grant program but may receive procurement contracts. Any contracts for services or products funded with EPA financial assistance must be awarded under the competitive procurement procedures of 2 CFR Part 200 and/or 2 CFR Part 1500, as applicable. The regulations at 2 CFR 1500.10 contain limitations on the extent to which EPA funds may be used to compensate individual consultants. Refer to the Best Practice Guide for Procuring Services, Supplies, and Equipment Under EPA Assistance Agreements for guidance on competitive procurement requirements and consultant compensation. Do not name a procurement contractor (including a consultant) as a "partner" or otherwise in your application unless the contractor has been selected in compliance with competitive procurement requirements.

F. Submission Instructions and Other Submission Requirements

Please read this entire section before attempting an electronic submission through Grants.gov.

If you do not have the appropriate internet access to utilize the Grants.gov application submission process for this solicitation, see Section IV.A above for additional guidance and instructions.

Note: Grants.gov submission instructions are updated on an as-needed basis. Please provide your Authorized Organizational Representative (AOR) with a copy of the following instructions to avoid submission delays that may occur from the use of outdated instructions.

1. SAM.gov (System for Award Management) Registration Instructions: Organizations applying to this funding opportunity must have an active SAM.gov registration. If you have never done business with the Federal Government, you will need to register your organization in SAM.gov. If you do not have a SAM.gov account, then you will create an account using login.gov[1] to complete your SAM.gov registration. SAM.gov registration is FREE. The process for entity registrations includes obtaining Unique Entity ID (UEI), a 12-character alphanumeric ID assigned an entity by SAM.gov, and requires assertions, representations and certifications, and other information about your organization. Please review the Entity Registration Checklist for details on this process.

If you have done business with the Federal Government previously, you can check your entity status using your government issued UEI to determine if your registration is active. SAM.gov requires you renew your registration every 365 days to keep it active.

Please note that SAM.gov registration is different than obtaining a UEI only. Obtaining an UEI only validates your organization's legal business name and address. Please review the Frequently

[1] Login.gov a secure sign in service used by the public to sign into Federal Agency systems including SAM.gov and Grants.gov. For help with login.gov accounts you should visit http://login.gov/help.

Asked Question on the difference for additional details.

Organizations should ensure that their SAM.gov registration includes a current e-Business (EBiz) point of contact name and email address. The EBiz point of contact is critical for Grants.gov Registration and system functionality.

Contact the Federal Service Desk for help with your SAM.gov account, to resolve technical issues or chat with a help desk agent: (866) 606-8220. The Federal Service desk hours of operation are Monday – Friday 8am – 8pm ET.

2. Grants.gov Registration Instructions: Once your SAM.gov account is active, you must register in Grants.gov. Grants.gov will electronically receive your organization information, such as e-Business (EBiz) point of contact email address and UEI. Organizations applying to this funding opportunity must have an active Grants.gov registration. Grants.gov registration is FREE. If you have never applied for a federal grant before, please review the Grants.gov Applicant Registration instructions. As part of the Grants.gov registration process, the EBiz point of contact is the only person that can affiliate and assign applicant roles to members of an organization. In addition, at least one person must be assigned as an Authorized Organization Representative (AOR). Only person(s) with the AOR role can submit applications in Grants.gov. Please review the Intro to Grants.gov-Understanding User Roles and Learning Workspace – User Roles and Workspace Actions for details on this important process.

Please note that this process can take a month or more for new registrants. Applicants must ensure that all registration requirements are met in order to apply for this opportunity through Grants.gov and should ensure that all such requirements have been met well in advance of the application submission deadline.

Contact Grants.gov for assistance at 1-800-518-4726 or support@grants.gov to resolve technical issues with Grants.gov. Applicants who are outside the U.S. at the time of submittal and are not able to access the toll-free number may reach a Grants.gov representative by calling 606-545-5035. The Grants.gov Support Center is available 24 hours a day 7 days a week, excluding federal holidays.

3. Application Submission Process: To begin the application process under this grant announcement, go to Grants.gov and click the red "Apply" button at the top of the view grant opportunity page associated with this opportunity.

The electronic submission of your application to this funding opportunity must be made by an official representative of your organization who is registered with Grants.gov and is authorized to sign applications for Federal financial assistance. If the submit button is grayed out, it may be because you do not have the appropriate role to submit in your organization. Contact your organization's EBiz point of contact or contact Grants.gov for assistance at 1-800-518-4726 or support@grants.gov.

Applicants need to ensure that the Authorized Organization Representative (AOR) who submits the application through Grants.gov and whose UEI is listed on the application is an AOR for the applicant listed on the application. Additionally, the UEI listed on the application must be registered to the applicant organization's SAM.gov account. If not, the application may be deemed ineligible.

Please submit all of the application materials described below using the Grants.gov application package accessed using the instructions above.

The application package consists of the following mandatory documents.

(a) Application for Federal Assistance (SF 424): Complete the form except for the "competition ID" field.

(b) EPA Key Contacts Form 5700-54: Complete the form. If additional pages are needed, see (e) below.

(c) EPA Form 4700-4, Preaward Compliance Review Report for All Applicants and Recipients Requesting EPA Financial Assistance: Complete the form.

(d) SF-424A, Budget Information for Non-Construction Programs:
Provide the federal funds being requested and non-federal cost share being contributed in "Section A-Budget Summary" under the "New or Revised Budget" heading. In "Section B-Budget Categories," provide the object class budget category (a. - k.) amounts for each budget year under the "Grant Program, Function or Activity" heading. Each column reflects a separate budget year.

(e) Project Narrative Attachment Form: Attach a single electronic PDF file labeled "Application" that contains the items described in Section IV.C.5.i through IV.C.5.viii.a (Table of Contents, Abstract, Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, References, Budget Justification, Resumes, Current and Pending Support, Applicant Current and Pending Support Certification, and Letters of Intent/Support) of this solicitation. *In order to maintain format integrity, this file must be submitted in Adobe Acrobat PDF.* Please review the PDF file for conversion errors prior to including it in the electronic application package; requests to rectify conversion errors will not be accepted if made after the solicitation closing date and time. If Key Contacts Continuation pages (see https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms) are needed, attach them using the Project Narrative Form.

4. Application Submission Deadline: Your organization's AOR must submit your complete application package electronically to EPA through Grants.gov no later than **August 16, 2023**, 11:59:59 pm Eastern Time. Please allow for enough time to successfully submit your application

and allow for unexpected errors that may require you to resubmit.

Applications submitted through Grants.gov will be time and date stamped electronically. Please note that successful submission of your application through Grants.gov does not necessarily mean your application is eligible for award. Any application submitted after the application deadline time and date deadline will be deemed ineligible and not be considered.

5. Technical Issues with Submission: If applicants experience technical issues during the submission of an application that they are unable to resolve, follow these procedures **before** the application deadline date:

a. Contact Grants.gov Support Center **before** the application deadline date.

b. Document the Grants.gov ticket/case number.

c. Send an email with the FON (EPA-G2023-ORD-F1) in the subject line to electronic-grant-submissions@epa.gov **before** the application deadline time and date and **must** include the following:
i. Grants.gov ticket/case number(s)
ii. Description of the issue
iii. The entire application package in PDF format.

Without this information, EPA may not be able to consider applications submitted outside of Grants.gov. Any application submitted after the application deadline time and date deadline will be deemed ineligible and **not** be considered.

Please note that successful submission through Grants.gov or email does not necessarily mean your application is eligible for award.

EPA will make decisions concerning acceptance of each application submitted outside of Grants.gov on a case-by-case basis. EPA will only consider accepting applications that were unable to submit through Grants.gov due to Grants.gov or relevant SAM.gov system issues or for unforeseen exigent circumstances, such as extreme weather interfering with internet access. Failure of an applicant to submit prior to the application submission deadline date because they did not properly or timely register in SAM.gov or Grants.gov is not an acceptable reason to justify acceptance of an application outside of Grants.gov.

V. APPLICATION REVIEW INFORMATION

Note: Additional provisions that apply to this section can be found at EPA Solicitation Clauses.

A. Peer Review

All eligible grant applications are reviewed by appropriate external technical peer reviewers based on the criteria and process described below. This review is designed to evaluate each

application according to its scientific merit. The individual external peer reviewers include non-EPA scientists, engineers, social scientists, and/or economists who are accomplished in their respective disciplines and proficient in the technical subjects they are reviewing.

Prior to the external technical peer review panel meeting, all reviewers will receive access to electronic copies of all applications. Each application will be assigned to a minimum of three primary peer reviewers, one of whom will be assigned the role of Rapporteur. Each reviewer will be assigned up to approximately 10 applications on which to serve as a primary reviewer. During the review period leading up to the panel meeting, primary reviewers read the entire application package for each application they are assigned. The primary reviewers will also prepare a written individual evaluation for each assigned application that addresses the peer review criteria described below and rate the application with a score of Excellent, Very Good, Good, Fair, or Poor. To promote a better panel discussion, all reviewers must, at a minimum, read the abstracts of all applications.

At the beginning of the panel meeting, each primary reviewer will report their ratings for the applications they reviewed. Those applications receiving at least two ratings of *Very Good* or one rating of *Excellent* from among the primary reviewers will then be further discussed by the entire panel in terms of the peer review criteria below. In addition, if there is one *Very Good* rating among the primary reviewers of an application, the primary reviewer, whose initial rating is the *Very Good*, may request discussion of the application by the peer review panel. All other applications will be declined for further consideration.

After the discussion of an application by the panel, the primary reviewers may revise their initial ratings and if they do so, this will also be documented. The final ratings of the primary reviewers will then be translated by EPA into the final peer review score (Excellent, Very Good, Good, Fair or Poor) for the application. This is reflected in a peer review results document developed by the Rapporteur which combines the individual initial and final evaluations of the primary reviewers and captures any substantive comments from the panel discussion. This score will be used to determine which applications undergo the internal relevancy and past performance review discussed below. A peer review results document is also developed for applications that are not discussed. However, this document is a consolidation of the individual primary reviewer initial evaluations, with an average of the scores assigned by the primary reviewers.

Peer reviewers consider an application's merit based on the extent to which the application demonstrates the criteria below. Criteria are listed in descending order of importance (i.e., Criteria 1 has the heaviest weight).

1. **Research Merits** (subcriteria are in descending order of importance):

    a. The degree to which the application demonstrates that the research is original and contributes to the scientific knowledge in the topic area. And the degree to which the

application demonstrates that the project (and its approach) is defensible and technically feasible, and uses appropriate and adequate research methods.

b. The degree to which the application demonstrates that the project results will produce benefits to the public (such as improvements to the environment or human health) and will be disseminated to enhance scientific and technological understanding.

2. **Responsiveness**: The degree to which the application demonstrates that the research is responsive to the objectives and research areas of interest specified by the RFA, including whether the research is national in scope and whether it addresses at least one of the two research areas described in Section I.D.

3. **Project Management** (subcriteria are equally weighted):

   a. **Investigators**: The degree to which the application demonstrates that the Principal Investigator(s) and other key personnel have the appropriate qualifications to effectively perform the project (including research training, demonstrated knowledge of pertinent literature, experience and publication records).

   b. **Management**: The degree to which the application demonstrates that the project will be adequately managed to ensure the timely and successful achievement of objectives using appropriate project schedules and milestones. And the degree to which the application demonstrates the applicant will adequately track and measure progress toward achieving expected results (outputs and outcomes).

   c. **Quality Assurance (QA)**: The degree to which the application includes an appropriate and adequate QA Statement.

   d. **Resources and Cost Controls**: The degree to which the application demonstrates that the facilities, equipment and budget are appropriate, adequate, and available. And the degree to which the application demonstrates that well-defined and acceptable approaches, procedures and controls are used to ensure timely and efficient expenditure of awarded grant funds.

B. Relevancy Review

Applications receiving final peer review scores of Excellent or Very Good will then undergo an internal relevancy review, as described below, conducted by experts from the EPA, including individuals from the Office of Research and Development (ORD) and program and regional offices involved with the science or engineering proposed. All other applications are

automatically declined. The purpose of the relevancy review is to ensure an integrated research portfolio for the Agency and help determine which applications to recommend for award.

Prior to the relevancy review panel meeting, all relevancy reviewers will receive electronic copies of all applications that passed peer review as well as a full set of abstracts for the applications. Each application will be assigned to a minimum of three primary relevancy reviewers, one of whom will be assigned the role of Rapporteur. Each reviewer will be assigned up to approximately 10 applications on which to serve as a primary relevancy reviewer. During the review period leading up to the relevancy review panel meeting, all reviewers will be instructed to read the full set of abstracts and the entire application package for each application they are assigned. They will also prepare a written individual evaluation for each assigned application that addresses the relevancy review criteria described below and rate the application with a score of A, high relevance to EPA mission; B, relevant to EPA mission; C, moderately relevant to EPA mission; D, possibly relevant to EPA mission; or E, not relevant to EPA mission.

All applications that pass peer review will be discussed by the relevancy review panel with the Rapporteur initiating the discussion. If the primary relevancy reviewers revise their initial scores after the discussion by the panel they will document the reasons for the revisions. After the discussion, the primary relevancy reviewers will provide their final score for the applications they are assigned. The final ratings of the primary reviewers will then be translated by EPA into the final relevancy review score (A, B, C, D, or E) for the application.

The final relevancy review score (A, B, C, D, or E) and final peer review score (Excellent or Very Good) will be used to place each application in one of 6 ranking tiers: Tier 1 = A/Excellent; Tier 2 = A/Very Good or B/Excellent; Tier 3 = B/Very Good or C/Excellent; Tier 4 = C/Very Good or D/Excellent; Tier 5 = D/Very Good; Tier 6 = E/Excellent or E/Very Good.

The internal relevancy review panel will assess the relevancy of the proposed research to the EPA's mission and priorities based on the following criteria that are listed in descending order of importance (i.e., Criteria 1 has the heaviest weight):

1. The degree to which the proposed science/research is relevant to EPA's priorities as described in this solicitation and Goal 5: Ensure Clean and Safe Water for All Communities, Objective 5.1: Ensure Safe Drinking Water and Reliable Water Infrastructure, and Objective 5.2: Protect and Restore Waterbodies and Watersheds, of EPA's FY2022-2026 Strategic Plan.

2. The degree to which results (i.e., outputs/outcomes) of the research have broad application or affect large segments of society.

3. The degree to which the research is designed to produce data and methods that can immediately and/or with little to no translation be utilized by the public, states, and tribes to better assess or manage environmental problems.

C. Past Performance History Review

Those applicants who received final scores of Excellent or Very Good as a result of the peer review process will also be asked to provide additional information for the past performance history review pertaining to the proposed Lead PI's (in the case of Multiple-PI applications, the Contact PI's) "Past Performance and Reporting History." The applicant must provide the EPA with information on the proposed Lead/Contact PI's past performance and reporting history under prior Federal agency assistance agreements (assistance agreements include grants and cooperative agreements but not contracts) in terms of: (i) the level of success in managing and completing each agreement, (ii) history of meeting the reporting requirements and documenting progress towards achieving the expected results (outputs/outcomes) under each agreement, and (iii) whether journal publications or author manuscripts associated with the journal publications, and the associated underlying scientific research data and metadata, resulting from those agreements were made publicly accessible.

This information is required only for the proposed Lead/Contact PI's performance under Federal assistance agreements performed within the last five years.

Past performance history review scores are satisfactory (S), nothing to report (NTR) or unsatisfactory (U). For purposes of consideration of an award, scores of S will be considered favorable, NTR will be considered neither favorable nor unfavorable and scores of U will be considered unfavorable and unlikely to result in an award recommendation. Scores of S and U must be justified by the reviewer, with scores of U clearly documented to explain why past performance history cannot be considered satisfactory.

The specific information required for each agreement is shown below and must be provided within one week of EPA's request. A maximum of three pages will be permitted for the response; excess pages will not be reviewed. **Note: If no prior past performance information and/or reporting history exists, you will be asked to so state.**

1. Name of Awarding Agency
2. Grant/Cooperative agreement number
3. Grant/Cooperative agreement title
4. Grantee Institution
5. Brief description of the grant/cooperative agreement
6. A discussion on whether the agreement was successfully managed and completed; if not successfully managed and completed, provide an explanation
7. Information relating to the proposed Lead/Contact PI's past performance in reporting on progress towards achieving the expected results (outputs/outcomes) under the agreement and meeting reporting requirements under the agreement. Include the history of submitting acceptable and timely progress/final technical reports, describe how progress towards achieving the expected results was reported/documented and if such progress was not being made, provide an explanation of whether and how this was reported

8. Information relating to whether journal publications or author manuscripts associated with the journal publications, and the associated underlying scientific research data and metadata, resulting from those agreements were made publicly accessible (and if not, explain why not; or explain why this requirement does not apply) to the extent permissible under applicable laws and regulations
9. Total (all years) grant/cooperative agreement dollar value
10. Project period
11. Technical contact (project officer), telephone number and Email address (if available)

In evaluating applicants under the past performance history factor, EPA will consider the information provided by the applicant and may also consider relevant information from other sources, including information from EPA files and from current/prior grantors (e.g., to verify and/or supplement the information provided by the applicant). **If you do not have any relevant or available past performance or past reporting information, please indicate this in your response and you will receive a nothing to report (NTR) score for these factors assuming EPA does not have any information in its files or from other sources that can be considered. If you do not provide any response for these items, you may receive an unsatisfactory (U) score for these factors.**

The past performance history review will be conducted by the EPA and will assess the following criteria which are of equal weight:

1. History of successfully managing and completing these prior Federal assistance agreements, including whether there is a satisfactory explanation for any lack of success.

2. History in meeting reporting requirements under the prior agreements and reporting progress toward achieving results (outputs/outcomes) under these agreements, including the proposed Lead/Contact PI's history of submitting acceptable and timely progress/final technical reports that adequately describe the progress toward achieving the expected results under the agreements. Any explanation of why progress toward achieving the results was not made will also be considered.

3. History of whether journal publications or author manuscripts associated with the journal publications, and the associated underlying scientific research data and metadata, resulting from these prior assistance agreements were made publicly accessible, and if not whether the Lead/Contact PI adequately explained why not, or the Lead/Contact PI explained why the requirement does not apply.

D. Human Subjects Research Statement (HSRS) Review

Applications being considered for funding after the Relevancy and Past Performance Review that involve human subjects research studies will have their HSRS reviewed prior to award. The local EPA Human Subjects Officer (HSO) will review the information provided in the HSRS and the

Research Plan to determine if the ethical treatment of human subjects is described in a manner appropriate for the project to move forward. The HSO may consult with the EPA Human Subjects Research Review Official (HSRRO) as appropriate. The HSRRO may determine that an application cannot be funded if it is inconsistent with EPA's regulations at 40 CFR Part 26.

E. Evaluation of the Scientific Data Management Plan

EPA will evaluate the merits of the SDMPs for those applications recommended for award. The SDMPs for those applications not recommended for award will not be reviewed. The SDMPs of all applications recommended for award will be evaluated to ensure they are appropriate and adequate (e.g., describe the types of scientific research data and metadata to be collected and/or generated under the proposed research award and include plans for providing long-term preservation of, and public access to, the scientific research data and metadata). SDMPs that indicate the proposed research will not result in the generation and/or collection of scientific research data will also be evaluated to ensure the proposed research will not result in the generation and/or collection of scientific research data and therefore not require a more comprehensive SDMP. Applicants may be contacted regarding their SDMP if additional information is needed or if revisions are required prior to award. If upon review of the SDMP, EPA identifies any issues with the plan, EPA will raise these issues to the applicant, so they may be addressed. Applicants with an unsatisfactory SDMP will not receive an award.

F. Funding Decisions

Final funding decisions are made by the ORD selection official based on the ranking tier, the past-performance history review, the evaluation of the SDMP, and, where applicable, the assessment of the applicant's human subjects research (see Section IV.C.5.iii.c). In addition, in making the final funding decisions, the ORD selection official may also consider program balance, potential duplication of effort, disclosure of support, and available funds. Applicants selected for funding will be required to provide additional information listed below under "Award Notices." The application will then be forwarded to EPA's Grants and Interagency Agreement Management Division for award in accordance with the EPA's procedures.

VI. AWARD ADMINISTRATION INFORMATION

Note: Additional provisions that apply to this section can be found at EPA Solicitation Clauses.

A. Award Notices

Customarily, applicants are notified about evaluation decisions within six months of the solicitation closing date. Applicants to be recommended for funding will be required to submit additional certifications and an electronic version of the revised project abstract. They may also be asked to provide responses to comments or suggestions offered by the peer reviewers and/or submit a revised budget. EPA Project Officers will contact the Lead PI/Contact PI to obtain these

materials. Before or after an award, applicants may be required to provide additional quality assurance documentation.

The official notification of an award will be made by the Agency's Grants and Interagency Agreement Management Division. Applicants are cautioned that only a grants officer is authorized to bind the Government to the expenditure of funds; preliminary selection by the ORD selection official does not guarantee an award will be made. For example, statutory authorization, funding or other issues discovered during the award process may affect the ability of EPA to make an award to an applicant. The award notice, signed by an EPA grants officer, is the authorizing document and will be provided through electronic or postal mail.

B. Administrative and National Policy Requirements

Expectations and responsibilities of ORD grantees and cooperative agreement recipients are summarized in this section, although the terms grants and cooperative agreements are used interchangeably.

1. Meetings

Principal Investigators will be expected to budget for, and participate in, All-Investigators Meetings (also known as progress reviews) approximately once per year with EPA scientists and other grantees to report on research activities and discuss issues of mutual interest.

2. Approval of Changes after Award

Prior written approval of changes may be required from EPA. Examples of these changes are contained in 2 CFR 200.308. Note: prior written approval is also required from the EPA Award Official for incurring costs more than 90 calendar days prior to award.

3. Human Subjects

A grant applicant must agree to comply with all applicable provisions of EPA Regulation 40 CFR Part 26 (Protection of Human Subjects). In addition, grant applicants must agree to comply with EPA's procedures for oversight of the recipient's compliance with 40 CFR Part 26, as given in EPA Order 1000.17A (Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research). As per this Order, no human subject may be involved in any research conducted under this assistance agreement, including recruitment, until the research has been approved or determined to be exempt by the EPA Human Subjects Research Review Official (HSRRO) after review of the approval or exemption determination of the Institutional Review Board(s) (IRB(s)) with jurisdiction over the research under 40 CFR Part 26. Following the initial approvals indicated above, the recipient must, as part of the annual report(s), provide evidence of continuing review and approval of the research by the IRB(s) with jurisdiction, as required by 40 CFR 26.109(e).

Guidance for investigators conducting EPA-funded research involving human subjects may be obtained here:

https://www.epa.gov/osa/basic-information-about-human-subjects-research-0
https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr26_main_02.tpl

4. Data Access and Information Release
EPA's requirements associated with data access and information release as well as copyrights, may be accessed here: https://www.epa.gov/grants/epa-solicitation-clauses.

Congress, through OMB, has instructed each federal agency to implement Information Quality Guidelines designed to "provide policy and procedural guidance...for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." The EPA's implementation may be found at https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information. These procedures may apply to data generated by grant recipients if those data are disseminated as described in the Guidelines.

5. Reporting
A grant recipient must agree to provide annual performance progress reports, with associated summaries, and a final report with an executive summary. The summaries will be posted on EPA's Research Grants website. The reports and summaries should be submitted electronically to the Technical Contact named in Section VII of this announcement.

A grant recipient must agree to provide copies of, or acceptable alternate access to (e.g., web link), any peer reviewed journal article(s) resulting from the research during the project period. In addition, the recipient should notify the ORD Project Officer of any papers published after completion of the grant that were based on research supported by the grant. ORD posts references to all publications resulting from a grant on EPA's Research Grants website.

6. Acknowledgement of EPA Support
EPA's full or partial support must be acknowledged in journal articles, oral or poster presentations, news releases, interviews with reporters and other communications. The acknowledgement to be included in any documents developed under this agreement that are intended for distribution to the public or inclusion in a scientific, technical or other journal will be provided in the award's terms and conditions.

VII. AGENCY CONTACTS

Further information, if needed, may be obtained from the EPA contacts indicated below. Information regarding this RFA obtained from sources other than these Agency Contacts may not be accurate. Email inquiries are preferred.

Technical Contact: Ben Packard; phone: 202-564-7673; email: packard.benjamin@epa.gov
Eligibility Contact: Ron Josephson; phone: 202-564-7823; email: josephson.ron@epa.gov
Electronic Submissions Contact: electronic-grant-submissions@epa.gov