<u>COVID-19 Update:</u> EPA is providing flexibilities to applicants experiencing challenges related to COVID-19. Please see the **Flexibilities Available to Organizations Impacted by COVID-19** clause in Section IV of EPA's Solicitation Clauses.

OVERVIEW INFORMATION

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

NATIONAL PRIORITIES: RESEARCH ON DISINFECTANTS, DISINFECTION BY-PRODUCTS (DBPs), AND OPPORTUNISTIC PATHOGENS IN DRINKING WATER DISTRIBUTION SYSTEMS

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-grant-areas.

A. Introduction

Ensuring clean and safe drinking water is important for protecting human health and the environment. Opportunistic pathogen and disinfection by-product (DBP) contaminants in drinking water distribution systems remains a water quality issue that is prevalent across the Nation. More information is needed on the occurrence of DBPs and opportunistic pathogens, along with identifying environmental conditions and niches favorable to colonization, microbial growth, and propagation in drinking water distribution systems. This research will help inform water infrastructure management and risk-mitigation practices to ensure safe drinking water. This National Priorities Request for Applications (RFA) will solicit innovative research to address knowledge gaps on the occurrence of pathogens and DBPs in drinking water distribution systems across the United States.

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

In recent years, concern has increased about opportunistic pathogen and disinfection by-product (DBP) contaminants in drinking water distribution systems. Water quality in drinking water distribution systems may degrade based on the way water is treated or not treated prior to entering the system, and because of reactions and other physical actions that occur in a distribution system (National Research Council, 2007). The occurrence of microbial pathogens is associated with contaminated storage facilities, backflow, cross-connections, and low and negative pressure incidents (Nygard et al. 2007). These contamination events can lead to gastrointestinal and other illnesses. It was estimated about 7.15 million waterborne illnesses occurred in 2014 (Collier et al., 2021). Health departments reported almost 10,000 cases of Legionnaire's Disease to the Centers for Disease Control and Prevention (CDC) in 2018 (CDC, 2020), a nearly 10-fold increase since 2000. The disinfectants needed to control these pathogens can cause problems of their own by reacting with natural organic matter, bromide, and other contaminants to form DBPs. Many DBPs are carcinogenic, neurotoxic, genotoxic, mutagenic,

and teratogenic (Richardson et al. 2007). More research is needed to address knowledge gaps on the occurrence of pathogens and DBPs in drinking water distribution systems.

Drinking water distribution systems connect water treatment plants or water sources (in the absence of treatment) to customers via a network of pipes, storage facilities, valves, and pumps. In addition to providing water for domestic use, distribution systems supply water for fire protection, agricultural, institutional, and commercial uses. Distribution systems represent most of the physical infrastructure for water systems and serve as the final barrier against contamination. Distribution systems must be operated and maintained to reduce the risk of contamination from external sources (e.g., storage tanks, backflows, cross connections, and pressure transient events) or internal sources (e.g., microbial growth or corrosion within the system). In larger distribution systems, disinfectant booster stations may also be present to maintain an effective disinfectant residual in the treated water. Finished water storage facilities are another important part of drinking water distribution systems. These are used to equalize pressure during periods of high-water demand and serve as backup supplies during emergencies. Water storage facilities are typically unpressurized and contain large volumes of water. EPA's 6th Drinking Water Infrastructure Needs Survey and Assessment (USEPA, 2018) estimated needs of \$312.6 billion to replace or repair aging and/or deteriorating pipelines and another \$47.6 billion to construct, rehabilitate, or cover water storage tanks and reservoirs over a 20-year period. In addition to physical infrastructure improvements, utilities and communities in the U.S. need better information on how best to manage water quality in drinking water distribution systems, especially in communities where drinking water quality may not be adequately maintained due to resource constraints. Distribution systems with health-based violations may benefit from this research and can be found at EPA's SDWIS Federal Report Search (USEPA, 2017).

The National Academy of Science (National Research Council, 2007) report on assessing and reducing risks in distribution systems concluded that research on eradicating waterborne disease is still needed and efforts to minimize water residence times, maintain positive water pressure, and evaluate water storage facilities should be made by utilities to ensure the delivery of safe drinking water. A subsequent report recognized progress in some areas but identified additional research needs (NAS, 2016). The outcomes of the research under this solicitation aim to provide information to enable better risk mitigation.

In addition to maintaining and improving drinking water distribution systems infrastructure, the optimization of water quality within the systems must also be a high priority. The interactions between disinfectants, biofilms, scales, opportunistic pathogen propagation and growth, and DBPs (including their precursors) are complex and can vary from system to system. More research is needed to evaluate the occurrence and concentrations of opportunistic pathogens on a national scale as well as the factors that affect their occurrence and fate in drinking water distribution systems and how their occurrence varies from system to system. These factors should consider that opportunistic pathogens have higher concentrations at certain times of the year.

Adding disinfectants to drinking water to control disease-causing microorganisms is an important step to protect human health (Gibson and Bertrand, 2021). Disinfectant residuals in drinking water distribution systems serve to protect against microbial contaminants, act as an indicator of distribution system upset, and limit growth of heterotrophic bacteria and *Legionella* within the distribution system. Under EPA's Surface Water Treatment Rule (USEPA, 1989), drinking water systems must maintain a minimum of 0.2 mg/L disinfectant residual concentration in water entering the distribution system. Within the distribution system, the water system must maintain a detectable disinfectant residual in at least 95 percent of the samples collected (note that some states have numerical requirements for residual concentrations within the distribution system). Sample collection/monitoring for disinfectant residuals must be conducted throughout the distribution system at the same times and locations as those used for the Revised Total Coliform Rule monitoring and continuously at the entry point. Small systems (serving <3,300 people) can take one to four grab samples per day. EPA compiled national-level compliance monitoring data for disinfectant residuals as part of its Six-Year Review 3 process (USEPA, 2016a).

The process of adding disinfectants for maintaining residuals in drinking water infrastructure is referred to as secondary disinfection to differentiate this process from initial, or primary, disinfection for eliminating microbial contaminants during the treatment process (Furatian et al., 2021). In the U.S., free chlorine, chloramines, and chlorine dioxide are used for secondary disinfection. Free chlorine is typically generated from chlorine gas or sodium hypochlorite generated on- or off-site by the utility and is the most common form of secondary disinfection. The second most used secondary disinfectant by utilities (less than one-third) is chloramines (AWWA Disinfection Committee, 2018; AWWA Disinfection Committee, 2021). Many systems, primarily smaller groundwater systems, add no secondary disinfectant (Gibson and Bertrand, 2021).

However, despite the presence of a disinfectant in the distribution system, levels of disinfectant residuals can be decreased by disinfectant demand, providing an opportunity for microbial growth. Microorganisms of distribution system concern, due to their prevalence in treated water and link to human illness, include the following genera: *Legionella*, Mycobacteria, and *Pseudomonas*. These genera are part of a broad range of microorganisms that can be opportunistic pathogens, meaning they typically cause disease in only people with underlying health conditions.

- Legionella causes the disease legionellosis. It is estimated that in 2014 there were 9,000 to 14,000 U.S. cases from all water exposures per year (Collier et al., 2021). This number is believed to be higher today and it is now the most commonly reported cause of drinking waterborne outbreaks (LeChevallier, 2019). Legionella can be found in approximately 50% of large building water systems and 10–30% of home water systems in the United States (Kool et al 1999). Legionella is of particular interest to this RFA.
- Mycobacteria causes a wide variety of infections and diseases. Collier et al. (2021) estimated that in 2014 there were 97,000 Non-tuberculosis Mycobacteria (NTM) infections with 3,800 deaths. Treatment of NTM infections generates \$1.53 billion in direct healthcare costs.

• *Pseudomonas* pneumonia was estimated to cause 15,000 hospitalizations and 750 deaths in 2014. While *Pseudomonas* septicemia was estimated to cause 13,000 cases generating \$214 million in direct healthcare costs (Collier et al., 2021).

Opportunistic pathogens are known to occur and multiply in premise plumbing, and some are ubiquitous in water environments (e.g., *Pseudomonas*). However, the introduction of pathogens may begin within the drinking water distribution system, where it can seed the system for growth at the point of introduction or elsewhere. More research is needed on the occurrence of opportunistic pathogens and to evaluate the factors that contribute to their growth and propagation in distribution systems. There are known environmental conditions and vectors that support the survival of these microorganisms in the distribution system and in premise plumbing (e.g., inadequate residual, presence of amoeba, corrosion particles, nutrients, and biofilms). Therefore, control of opportunistic pathogens and their vectors (e.g., amoeba) within distribution systems can play an important role in minimizing public health risks resulting from colonized drinking water systems. Several studies show the presence of opportunistic pathogens in distribution systems (Falkinham et al., 2001; Wang et al., 2012; Lu et al., 2016; King et al., 2016; Qin et al., 2017; LeChevallier, 2019;) and storage tanks (Lu et al., 2015), however these studies are of a relatively small number of distribution systems.

To control microbial growth in distribution systems, secondary disinfection is used in drinking water distribution systems. However, simply increasing disinfectant concentrations may cause unintended consequences; a balance needs to be achieved to limit the formation of DBPs while controlling pathogenic microorganisms in the distribution system. EPA currently regulates a subset of DBPs including four trihalomethanes (THM4; referred to as TTHM in EPA regulations) and five haloacetic acids (HAA5). These types of DBPs form when water containing precursors (e.g., natural organic matter, bromide, and iodide) is disinfected. EPA compiled national-level occurrence and associated parametric data for regulated DBPs as part of its Six-Year Review 3 process including treatment information (USEPA, 2016b). Switching to chloramines can help to produce lower levels of regulated THM4 and/or HAA5, however, chloramine disinfection may lead to the increased formation of other unregulated DBPs such as haloacetonitriles (HANs) or n-nitrosodimethylamine (NDMA) as well as increased concerns for nitrification. As part of the Unregulated Contaminant Monitoring Rule (UCMR2), national-level occurrence data were collected about NDMA and 5 other nitrosamines, with summary-level information compiled by EPA (USEPA, 2016c). Several studies have found that many emerging unregulated DBPs may be more cytotoxic and genotoxic than those currently regulated (Allen et al., 2022; Richardson et al. 2007; Wagner et al. 2017; Plewa et al. 2017; and Liu et al. 2019) however information is lacking about the national-level occurrence of these DBPs. Given the new information on the potential toxicity of emerging DBPs, additional information is needed about the occurrence and concentrations of unregulated DBPs (for example, within groups such as haloacetonitriles and iodinated acids) as well as their co-occurrence with regulated DBPs such as THM4 and HAA5 and among groups of unregulated DBPs.

Given the importance of occurrence of both pathogens and DBPs from public water systems, communicating occurrence data (such as elevated levels), is an important consideration. Developing a response protocol for the occurrence based on various concentrations, and

engaging stakeholders on monitoring and communications plans may be necessary. Other researchers have provided examples of steps to include in a communication (LeChevallier, Version 2.7.20). In this example, communications could have procedures that differ based on the frequency of occurrence and concentration level found, including taking no action; notifying the environmental/public health regulator; issuing public notification to boil tap water; and advising the elderly and immunocompromised to avoid showers and situations where water is aerosolized.

C. Authority and Regulations

The authorities for this RFA and resulting awards are contained in the Safe Drinking Water Act, 42 U.S.C. 300j-1, Section 1442 and the Consolidated Appropriations Act, 2022, Public Law 117-103.

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, 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 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 of opportunistic pathogens and DBPs that will ensure safe drinking water and reliable water infrastructure.

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 in the occurrence of opportunistic pathogens and DBPs along with identifying environmental conditions and niches favorable to colonization, microbial growth, and propagation in drinking water distribution systems.

EPA is interested in applications that address both of the following research areas (i.e., pathogens and DBPs). The proposed research should be national in scope and address environmental problems associated with both water quality (by looking at the impact of pathogens and DBPs in drinking water systems) and availability (to the extent that improving water quality increases the amount of safe drinking water to the public). Applications that do not address both research areas or are not national in scope may not be rated as highly as those that address both research areas and are national in scope. Bulleted sub-topics are also listed under each research area for applicants to consider in shaping their research project. Applicants are not required, but are encouraged, to respond to all of the bulleted sub-topics described below.

The research under this RFA should also take into account current studies including experience with existing projects, and engagement with key stakeholders and water managers working on pathogen and DBP occurrence in distribution systems. Applications should consider the biotic and abiotic interactions that strongly affect the ecosystem which in turn will impact the microbial structure (including colonization, propagation and growth of opportunistic pathogen) and ecological processes. These range from intraspecific to interspecific interactions, and from simple short-term interactions to intricate long-term ones. Abiotic factors, including disinfectants, the availability of nutrients, DBPs, and temperature, among other factors, have been demonstrated to be important in determining the community patterns of water microbial communities. Applicants should also consider appropriate communications about occurrence data generated from this research.

Research Areas:

Research Area 1: Evaluation of opportunistic pathogens in drinking water distribution systems.

The main objective of this research area is to determine the occurrence and concentration of opportunistic pathogens in the distribution system along with related parameters that may influence their growth or presence. Applicants should focus their research efforts on *Legionella*, as it is the most prevalent, but additional opportunistic pathogens such as Mycobacteria or *Pseudomonas* may also be evaluated. Applicants should also address detection, identification, quantification, and viability of pathogenic organisms in storage facilities and distribution systems including vector organisms (e.g., amoebae for *Legionella*). Additionally, the research should identify the environmental conditions and niches most favorable to pathogen colonization and

propagation to help later identify strategies to control pathogens in the system and mitigate future growth in the system. The proposed research should be field focused with analyses performed on samples from existing drinking water distribution systems. To address concerns about risk-risk tradeoff (e.g., pathogens versus DBPs), some of the data should come from the same public water systems (PWSs) for both microbials and DBPs.

Possible sub-topics in this research area are listed below for applicants to employ in shaping their research project. Although encouraged, applicants are not required to include all the sub-topic examples or limit their research scope to these examples.

Subtopics:

- Identification of niches and locations of relatively high pathogen concentration in the distribution system (e.g., storage facility sediments, biofilms, dead zones).
- Diversity and distribution of opportunistic pathogens in distribution systems along with related parameters (e.g., heterotrophic bacteria).
- Characteristics of the opportunistic pathogen population (e.g., diversity, distribution, and viability) as a function of different size utilities (based on population served), distribution systems size, geographic location, water temperature, seasonal changes, primary and secondary disinfectant types (e.g., chlorine vs. chloramine), disinfectant concentrations, organic matter and nutrients entering the distribution system, and DBP concentrations (if available).
- Identification of chemical and physical parameters in the distribution systems that lead to favorable conditions for opportunistic pathogens (e.g., water age, water pressure, water temperature, pH, assimilable organic carbon, areas of high/low water demand, turbidity, disinfectant residuals, corrosion control, infrastructure conditions).
- Consider distribution system interrelation between the selling water system and the consecutive system; public water systems and building water systems; and buildings with at risk populations (e.g., hospitals, nursing homes, schools).

Research Area 2: Evaluation of DBPs.

The main objective of this research area is to focus on identifying the occurrence and concentrations of unregulated DBPs in actual drinking water distribution systems including storage facilities and distribution systems as well as their co-occurrence with DBPs. Related parameters including disinfectant concentrations and treatment types should be determined, to help later identify conditions that minimize DBP formation while maintaining effective control of opportunistic pathogens. While a distribution system modeling component may be included, emphasis should be placed on actual distribution system field sampling. To address concerns about risk-risk tradeoff (e.g., pathogens versus DBPs), some of the data should come from the same PWSs for both microbials and DBPs.

Possible sub-topics in this research area are listed below for applicants to employ in shaping their research project. Although encouraged, applicants are not required to include all the sub-topic examples or limit their research scope to these examples.

Subtopics:

- In addition to individual DBP quantification, measurements may also include bulk measures of DBP formation to frame the extent of DBP formation in water samples. Examples include total organic halogen (TOX) quantification along with further speciation of TOX into the halogen specific methods of total organic bromine (TOBr) and total organic iodine (TOI).
- A variety of distribution systems may be sampled including systems from different size utilities (based on population served), in different climates, those conveying water with different types and concentrations of disinfectant residuals, varying residence times from treatment to representative locations, and from consecutive systems. Consecutive systems of varying sizes and varying distribution line distances may be considered. Also, consider the influence of disinfectant type on mixture of DBPs.
- Consider different types of inorganic and organic source water influences that serve as DBP precursors such as bromide and total organic carbon (TOC), wastewater, algal matter, wildfires, and power plant discharges, along with drought conditions.
- Research may include quantification of DBPs in different points in the distribution system as water moves through the system.
- Identification of characteristics of distribution systems that lead to elevated DBP levels (e.g., water age, pipe types, storage facilities, as well as the types and levels of inorganic and organic matter entering the distribution system).
- Identification of treatment train characteristics and its operation that are associated with DBP levels (e.g., pre-oxidation/pre-disinfection, TOC removal, disinfectant use, biofiltration).

Expected Outputs and Outcomes:

The proposed research will provide new information needed to determine the extent of opportunistic pathogen and DBP contamination in drinking water distribution systems which will be helpful for informing a better understanding about how to control them.

Any methods, approaches, and models developed from this research should be scientifically robust and transparently convey uncertainties in the analyses. Models should be non-proprietary, open-source and based on open-access data.

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

- Reports and peer reviewed publications pertaining to the research areas listed above.
- Workshops and webinars to disseminate information (including interim data sets) to states, utilities, and other researchers.
- Planning/guidance documents to mitigate and reduce risks associated with opportunistic pathogens and DBPs in distribution systems.
- A communication plan to appropriately convey findings with partners, particularly if the findings include elevated levels of contaminants.

- Risk communication materials and tools that translate scientific results into easily understandable outreach and education materials for water management professionals and the public.
- Identification of key areas within the distribution system that are in need of attention to control chemical and biological contaminants of concern.
- Occurrence data about opportunistic pathogens in distribution systems, organized with unique system identifiers and optionally by Public Water System Identification Number (PWSID), along with parametric data about the conditions and locations most amenable to pathogen growth and propagation.
- Occurrence data about unregulated DBPs in distribution systems organized with unique system identifiers and optionally by PWSID, along with parametric data about co-occurrence with regulated DBPs and the conditions relevant to DBP formation.
- Descriptions of analytical methods used (e.g., culture methods, extraction protocols, instrumentation, standard operating procedures).
- Tools to optimize distribution system water quality that can be incorporated by water system operators in achieving compliance.

Expected Outcomes:

- A better understanding of the nature and extent of opportunistic pathogens and DBPs in
 distribution systems as well as the conditions associated with their occurrence and
 growth/formation. This research will enable better planning to mitigate and reduce risks
 associated with pathogens and DBPs in distribution systems, and ultimately maximize the
 overall protection of public health from potential risks associated with DBP and
 opportunistic pathogen exposure in drinking water.
- Improved protection of public health from risks posed by pathogens resulting in cleaner and safer drinking water.

Collaboration/Engagement Plan

A collaboration/engagement plan is required. See Section IV.C.5.iii.e. Collaboration and cooperative partnerships are strongly encouraged in the design and execution of the proposed research. Therefore, applications must include a Collaboration/Engagement Plan. Applications must, at minimum, describe how: a) applicants will work in partnership with appropriate partners (e.g., states, tribes, and utilities) to effectively design and implement the proposed project; b) to the extent possible, coordinate with and/or complement other projects or activities being performed by others that will result in a greater positive impact; and c) demonstrate how the proposed project will address the needs and concerns of relevant partners including how appropriate parties will be engaged to enhance the project's effectiveness and/or efficiency.

The collaboration/engagement plan must:

• Describe the type of collaboration/engagement proposed and what role it will play in the overall project including the degree of partner input or engagement in the conceptualization, hypothesis/question development, design, methods, analyses, and implementation of the research. This includes describing how the project addresses

- engagement with states, tribes, and utilities, to ensure their meaningful participation with respect to the design, project planning, and performance of the project.
- Describe how the collaboration/engagement will enhance the overall impact of the project such that the project results are useable by state/local agencies and utilities. This includes the capacity of the project to more effectively communicate risk and translate scientific results into easily understandable outreach and education materials.
- Describe how activities of the project will be coordinated with related or complementary projects and studies.
- Describe how the collaboration/engagement will materialize during project performance. Describe the partner(s) intent to participate in the proposed research including evidence of support of an active partnership with states, tribes, and utilities, (e.g., letter(s) of intent or support from state or local government agencies, water utility managers, site managers or operators). Any letters demonstrating evidence of collaboration and support should be included as part of Section IV.C.5.vii.a. Letters of Intent/Letters of Support.

Applicants that do not plan on collaborating/engaging with other groups in project performance must still include a collaboration/engagement plan in their application describing how they will be able to effectively perform and complete the project without such collaboration/engagement.

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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. EPA's *Policy for Increasing Access to Results of EPA-Funded Extramural Scientific Research* may be accessed at: https://www.epa.gov/research/non-epa-researcher-requirements. Terms and conditions implementing this policy may be accessed at: https://www.epa.gov/research/non-epa-researcher-requirements.

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 as discussed in EPA's *Policy for Increasing Access to Results of EPA-Funded Extramural Scientific Research*, 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.

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 <u>Subaward Policy</u>. 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.

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 <u>EPA Solicitation Clauses</u>. 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 \$8,492,000 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 \$2,123,000 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 \$2,123,000 in EPA funds, a minimum of \$530,750 must be included. Including matching, total project costs can exceed \$2,653,750 (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 \$2,123,000. 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 may award both grants and cooperative agreements 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.

Where appropriate, based on consideration of the nature of the proposed project relative to the EPA's intramural research program and available resources, the EPA may award cooperative agreements under this announcement. A cooperative agreement is an assistance agreement that is used when there is substantial federal involvement with the recipient during the performance of an activity or project. EPA awards cooperative agreements for those projects in which it expects to have substantial interaction with the recipient throughout the recipient's performance of the project. When addressing a research question/problem of common interest, collaborations between EPA scientists and the institution's principal investigators are permitted under a cooperative agreement. These collaborations may include data and information exchange; providing technical input to experimental design and theoretical development; coordinating extramural research with in-house activities; the refinement of valuation endpoints; in accordance with 2 CFR 200.317 and 2 CFR 200.318, as appropriate, review of proposed procurements, reviewing qualifications of key personnel, and/or review and comment on the content of printed or electronic publications prepared; and joint authorship of journal articles on these activities. Note EPA does not have the authority to select employees or contractors employed by the recipient and the final decision on the content of reports rests with the recipient. EPA will negotiate the precise terms and conditions of "substantial involvement" as part of the award process. Applications may not identify EPA cooperators, specific interactions between EPA's investigators and those of the prospective recipient for cooperative agreements will be negotiated at the time of award.

Potential applicants should contact Jacquelyn Bell; phone: 202-564-4811; email: bell.jacquelyn@epa.gov regarding questions pertaining to EPA's substantial involvement.

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. The institution, organization, or governance receiving the award 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. However, salaries for permanent FFRDC employees may not be provided through this mechanism.

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 \$2,123,000 in EPA funds, a minimum of \$530,750 must be included. Including matching, total project costs can exceed \$2,653,750 (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 \$2,123,000.

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 <u>Grants.gov</u> 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 <u>Grants.gov</u> or <u>SAM.gov</u>. An applicant's failure to timely submit their application through <u>Grants.gov</u> because they did not timely or properly register in <u>SAM.gov</u> or <u>Grants.gov</u> 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 order to be deemed eligible, the application must include a Collaboration/Engagement Plan (see Section IV.C.5.iii.e) that demonstrates collaboration/engagement with partners in the design and execution of the proposed research or how the applicant will be able to effectively perform and complete the project without such collaboration/engagement.

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 term described herein will be rejected without review. 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**.

Access Standard Forms at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms.

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 <u>Grants.gov</u> 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 <u>here</u>. 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 <u>Grants.gov</u> (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.

An email will be sent by ORD to the Lead/Contact PI and the Administrative Contact (see below) to acknowledge receipt of the application and transmit other important information. The email will be sent from receipt.application@epa.gov; emails to this address will not be accepted. If you do not receive an email acknowledgement within 10 calendar days of the submission closing date, immediately inform the Electronic Submissions Contact shown in this solicitation. Failure to do so may result in your application not being reviewed. See Section IV.F. "Submission Instructions and Other Submission Requirements" for additional information regarding the application receipt acknowledgment.

C. Content and Form of Application Submission

The application is made by submitting the materials described below. Applications must contain all information requested and be submitted in the formats described.

1. Standard Form 424

The applicant must complete Standard Form 424. 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.

This program is eligible for coverage under E.O. 12372, "Intergovernmental Review of Federal Programs." An applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed

in applying for assistance, if the State has selected the program for review. EPA financial assistance programs and activities subject to intergovernmental review that have been selected for review under State single point of contact procedures are identified at https://www.epa.gov/grants/epa-financial-assistance-programs-subject-executive-order-12372-and-section-204-demonstration. Applicants for programs or activities subject to Intergovernmental Review that have not been selected for State single point of contact review must provide directly affected State, areawide, regional, and local entities at least 60 days to review their application following notification by EPA that the application has been selected for funding as provided by 40 CFR 29.8(a) and (c).

2. Key Contacts

The applicant must complete the "Key Contacts" form found in the <u>Grants.gov</u> 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 sub-agreements (i.e., primary 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 (available at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms).

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

Prepare a master budget table using "SF-424A Budget Information for Non-Construction Programs" (aka SF-424A), available in the <u>Grants.gov</u> 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 subagreements to transfer or delegate their responsibility for successful completion of their EPA assistance agreement. Please refer to https://www.epa.gov/grants/epa-solicitation-clauses if your organization intends to identify specific contractors, including consultants, or subrecipients in your 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, Collaboration/Engagement 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. 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/ZvPDF.cgi/P10012LY.PDF?Dockey=P10012LY.PDF) and grant

(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 <u>does not</u> 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 <u>does</u> 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 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. Collaboration/Engagement Plan (5 pages, not including letters of intent/support)

Provide a plan to detail strategies for promoting and/or obtaining collaboration/engagement and support from appropriate partners such as states, tribes, and utilities. Applicants should document the following:

- Describe the type of collaboration/engagement proposed and what role it will play in the overall project including the degree of partner input or engagement in the conceptualization, hypothesis/question development, design, methods, analyses, and implementation of the research. This includes describing how the project addresses engagement with states, tribes, and utilities, to ensure their meaningful participation with respect to the design, project planning, and performance of the project.
- Describe how the collaboration/engagement will enhance the overall impact of the project such that the project results are useable by state/local agencies and utilities. This includes the capacity of the project to more effectively communicate risk and translate scientific results into easily understandable outreach and education materials.
- Describe how activities of the project will be coordinated with related or complementary projects and studies.
- Describe how the collaboration/engagement will materialize during project performance. Describe the partner(s)' intent to participate in the proposed research including evidence of support of an active partnership (e.g., letter(s) of intent or support from, state or tribal government agencies, utility managers, site managers or operators). Any letters demonstrating evidence of collaboration and support should be included as part of Section IV.C.5.vii.a Letters of Intent/Letters of Support.
- Applicants that do not plan on collaborating/engaging with other groups in project performance should describe how they will be able to effectively perform and complete the project without such collaboration/engagement.
- Allocate appropriate resources as needed to the research partners to ensure success of the collaboration, e.g., delineating funds under the project's budget for partner participation. Examples include:
 - i. travel/stipends for partners to participate in advisory group meetings, workshops, and focus groups,
 - ii. subawards to eligible organizations for their involvement in the proposed research.

EPA requires that estimated amounts for subawards and individual participant support costs be classified as "Other" for the purposes of the budget table (aka SF-424A). Please see (EPA Solicitation Clauses) for EPA guidance on competition for contractors (including consulting

contracts) and acceptable noncompetitive subawards. Applicants may provide subawards to partners to enhance project effectiveness and/or efficiency. Note that applicants, not EPA, will select their subawardees and the applicants must demonstrate in their application that the organization(s) or other groups are willing to accept the subaward and have the capacity to effectively administer and perform the agreement. The selected applicant who proposes to make subawards, including those to partners must follow proper procedures in making subawards and will be expected to make the subawards consistent with their application.

f. 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), 8.5×11 -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	% of Time	Year 1	Year 2*	Year 3*	Total
	Salary	Assigned to				
		Project				
Project	\$70,000	50%	\$35,000	\$36,050	\$37,132	\$108,182
Manager						
Env.	\$60,000	100%	\$60,000	\$61,800	\$63,654	\$185,454
Specialist						
Env. Health	\$45,000	100%	\$45,000	\$46,350	\$47,741	\$139,091
Tech (cost						
share)						

Total	\$95,000	\$97,850	\$100,786	\$293,636
Personnel				
Request				
Total	\$45,000	\$46,350	\$47,741	\$139,091
Personnel				
Cost Share				
Total	\$140,000	\$144,200	\$148,527	\$432,727
Personnel				
(EPA + Cost				
Share)				

*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 (1) 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:

	Base Fringe %	Costs				
Position/Title	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						
Total Fringe Benefits Cost-share						
Total Fringe (EPA + Cost Share)						

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	Location	Item	Computation	Cost
Travel				
EPA Progress	Washington	Lodging	4 people x \$100 per night x 2	\$800
Review	DC		nights	
		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/epasolicitation-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:

		Cost			
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					
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 <u>EPA Solicitation Clauses</u>.

v) Resumes

Provide resumes for each investigator and important co-worker. You may include resumes from staff of subawardees such as universities. Do not include resumes of consultants or other contractors. 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.

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

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 and important co-worker. Do not include current and pending support for consultants or other contractors. Include all current and pending research regardless of source.

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) 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. Letters of intent are to be included as an addition to the budget justification documents. 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-G2022-ORD-H1, National Priorities: Research on Disinfectants, Disinfection By-Products (DBPs), and Opportunistic Pathogens in Drinking Water Distribution Systems

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 closing date and time will be returned to the sender without further consideration. EPA will not accept any changes to applications after the 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 31, 2022, 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.

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. <u>SAM.gov</u> (<u>System for Award Management</u>) <u>Registration Instructions:</u> 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 <u>login.gov</u>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

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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.

other information about your organization. Please review the <u>Entity Registration Checklist</u> 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 <u>Frequently</u> 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 <u>Federal Service Desk</u> 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 <u>Grants.gov</u> for assistance at 1-800-518-4726 or <u>support@grants.gov</u> 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 <u>Grants.gov</u> 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.vii.a (Table of Contents, Abstract, Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, Collaboration/Engagement Plan, References, Budget Justification, Resumes, Current and Pending Support, 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 <u>Grants.gov</u> no later than **August 31, 2022,** 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.

- <u>5. Technical Issues with Submission: If</u> applicants experience technical issues during the submission of an application that they are unable to resolve, follow these procedures <u>before</u> 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-G2022-ORD-H1) in the subject line to Debra M. Jones (jones.debram@epa.gov) <u>before</u> 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 <u>Grants.gov</u> or relevant <u>SAM.gov</u> 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 <u>not</u> an acceptable reason to justify acceptance of an application outside of Grants.gov.

While it is advisable to retain copies of these Grants.gov acknowledgements to document submission, the only official documentation that the application has been received by ORD is the email acknowledgement sent by ORD to the Lead/Contact PI and the Administrative Contact.

This email will be sent from receipt.application@epa.gov; emails to this address will not be accepted. If an email acknowledgment from receipt.application@epa.gov has not been received within 10 calendar days of the solicitation closing date, immediately inform the Electronic Submissions Contact shown in this solicitation. Failure to do so may result in your application not being reviewed.

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 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.

4. Collaboration/Engagement Plan (subcriteria are equally weighted):

- a. The degree to which the Plan clearly describes the type of collaboration/engagement proposed, and what role it will play in the overall project including the degree of partner input or engagement in the conceptualization, hypothesis/question development, design, methods, analyses and implementation of the research. This includes the degree to which the Plan addresses engagement with states, tribes, and utilities, to ensure their meaningful participation with respect to the design, project planning, and performance of the project. If an applicant does not plan on collaborating/engaging with other groups in project performance, the degree to which the Plan clearly describes how the applicant will be able to effectively perform and complete the project without such collaboration/engagement will be evaluated.
- b. The degree to which the Plan clearly describes how the collaboration/engagement will: 1) enhance the overall impact of the project such that project results are useable by state/local agencies and utilities; and 2) effectively communicate risk and translate scientific results into easily understandable outreach and education materials. If an applicant does not plan on collaborating/engaging with other groups in project performance, the degree to which the Plan clearly describes how the aforementioned activities will be effectively performed and completed without such collaboration/engagement will be evaluated.
- c. The degree to which the Plan clearly describes how project activities will be coordinated with related or complementary projects and studies.
- d. The degree to which the Plan clearly describes how the proposed collaboration/engagement will materialize during the project along with evidence of the partner(s)' intent to participate. If an applicant does not intend to collaborate/engage with respect to the project, then the applicant will be evaluated based on how well it demonstrates that it can effectively perform and complete the project without such collaboration/engagement.

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, 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 Granting 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 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. Disputes

Assistance agreement competition-related disputes will be resolved in accordance with the dispute resolution procedures published in 70 FR (Federal Register) 3629, 3630 (January 26, 2005) which can be found at <u>Grant Competition Dispute Resolution Procedures</u>. Copies of these procedures may also be requested by contacting the person listed in Section VII of the announcement. Note, the FR notice references regulations at 40 CFR Parts 30 and 31 that have been superseded by regulations in 2 CFR parts 200 and 1500. Notwithstanding the regulatory changes, the procedures for competition-related disputes remains unchanged from the procedures described at 70 FR 3629, 3630, as indicated in 2 CFR Part 1500, Subpart E.

C. 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: Jacquelyn Bell; phone: 202-564-4811; email: bell.jacquelyn@epa.gov Eligibility Contact: Ron Josephson; phone: 202-564-7823; email: josephson.ron@epa.gov Electronic Submissions Contact: Debra M. Jones; phone: 202-564-7839; email: jones.debram@epa.gov