COVID-19 Update: 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
Science to Achieve Results (STAR) Program

ASSESSMENT TOOLS FOR BIOTECHNOLOGY PRODUCTS

This is the initial announcement of this funding opportunity.

Funding Opportunity Number: EPA-G2020-STAR-C1, Assessment Tools for Biotechnology Products
Funding Opportunity Number: EPA-G2020-STAR-C2, Early Career: Assessment Tools for Biotechnology Products

Catalog of Federal Domestic Assistance (CFDA) Number: 66.509

Solicitation Opening Date: ***May 6, 2020***
Solicitation Closing Date: ***July 15, 2020*****:11:59:59** pm Eastern Time

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Access Standard STAR Forms (https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms)
View research awarded under previous solicitations (https://www.epa.gov/research-grants/research-grant-areas)

SUMMARY OF PROGRAM REQUIREMENTS

Synopsis of Program:
The United States Environmental Protection Agency (EPA), as part of its Science to Achieve Results (STAR) program, is seeking applications proposing research to support the development of improved science-based human health and environmental risk assessments of new biotechnology products, including those developed through synthetic biology, genome editing, and metabolic engineering.

This solicitation provides the opportunity for the submission of applications for projects that may involve human subjects research. 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. 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 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). All

applications must include a Human Subjects Research Statement (HSRS, as described in Section IV.C.6.c of this solicitation), and 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.

Guidance and training 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

The STAR Program's goal is to stimulate and support scientific and engineering research that advances EPA's mission to protect human health and the environment. It is a competitive, peer-reviewed, extramural research program that provides access to the nation's best scientists and engineers in academic and other nonprofit research institutions. STAR funds research on the environmental and public health effects of air quality, environmental changes, water quality and quantity, hazardous waste, toxic substances, and pesticides.

In addition to regular awards, this solicitation includes the opportunity for early career awards. The purpose of the early career award is to fund research projects smaller in scope and budget by early career PIs. It is expected that the majority of the research will be performed by early career investigators. Further, it is expected that significant resources will be allotted to early career investigators to perform the research. Please see Section III of this Request for Applications (RFA) for details on the early career eligibility criteria.

Award Information:
Anticipated Type of Award: Grant
Estimated Number of Awards: Approximately 7 awards, 4 regular and 3 early career awards
Anticipated Funding Amount: Approximately $4.4 million total for all awards
Potential Funding per Award: Up to a total of $760,000 for regular awards, and up to a total of $453,333 for early career awards, including direct and indirect costs, with a maximum duration of 3 years. Cost-sharing is not required. Applications with budgets exceeding the total award limits will not be considered.

Eligibility Information:
Public and private nonprofit institutions/organizations, public and private institutions of higher education, and hospitals located in the U.S., state and local governments, Federally Recognized Indian Tribal Governments, and U.S. territories or possessions are eligible to apply. Special eligibility criteria apply to the early career award portion of this RFA. See full announcement for more details.

Application Materials:
To apply under this solicitation, use the application package available at Grants.gov (for further submission information 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.

If your organization is not currently registered with Grants.gov, you need to allow approximately one month to complete the registration process. Please note that the registration process also requires that your organization have a unique entity identifier (e.g., 'DUNS number') and a current registration with the System for Award Management (SAM) and the process of obtaining both could take a month or more. 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 submission deadline. This registration, and electronic submission of your application, must be performed by an authorized representative of your organization.

If you do not have the technical capability to utilize the Grants.gov application submission process for this solicitation, see Section IV.A below for additional guidance and instructions.

Agency Contacts:
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Eligibility Contact: Ron Josephson; phone: 202-564-7823; email: josephson.ron@epa.gov
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I. FUNDING OPPORTUNITY DESCRIPTION

A. Introduction

Research solicited in this RFA will support the development of improved science-based human health and environmental risk assessments of novel biotechnology products. Recent advances in synthetic biology methods can be used to create substances and life forms not found in nature, which may in turn be used to make biotechnology products. Oversight of biotechnology products is shared between the EPA, the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA). Research solicited in this RFA will support the development of improved science-based human health and environmental risk assessments of novel synthetic biology products. For the purposes of this RFA, biotechnology products of interest include: industrial or consumer chemicals; pesticides (including pesticide intermediates); and new microbes used in biomass conversion for chemical production, microbial fuel cells, mining and resource extraction, building materials, waste remediation and pollution control, and non-pesticidal agriculture applications (e.g., biofertilizers, weather and climate modification). Robust and efficient evaluation and monitoring tools are needed to ensure these biotechnology products' safety and to assure public trust (Morton et al., 2019). Some examples of appropriate risk assessment tools include models, bioinformatic systems, and field-based and *in vitro* methods (SCENIHR, 2015). This research will help inform high-priority research areas identified by the EPA Office of Research and Development (ORD) and included in the Chemical Safety for Sustainability (CSS) National Research Program. The EPA currently supports CSS-related research grants resulting from previous solicitations. Information regarding current research can be found on EPA's Research Grants website at https://www.epa.gov/research-grants/.

In addition to regular awards, this solicitation includes the opportunity for early career awards. The purpose of the early career award is to fund research projects smaller in scope and budget by early career PIs. Please see Section III of this RFA for details on the early career eligibility criteria.

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). 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(a)(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

Synthetic biology, genome editing, and metabolic engineering, along with a wide range of other transformational tools and techniques, are enabling the development of entirely new generations of synthetic biology (referred to as "synbio" in this RFA) biotechnology products (NAS, 2017). For the purposes of this RFA, synthetic biology is defined as an interdisciplinary area that applies bioengineering tools to biology in order to fabricate a wide range of biotechnology products. Research solicited in this RFA will support the development of improved science-based human health and environmental risk assessments of novel synthetic biology products. Information and effective tools are needed to evaluate and monitor parameters such as long-term stability, persistence, efficacy, and reliability of synthetic biology products in order to assess any potential unintended human and ecological impacts (U.S.A.C.E., 2019). Better understanding of how synthetic biology products interact at both the cellular and systems levels will allow for

informed decisions on the safety and efficacy of novel products of biotechnology, now increasingly available for industrial and commercial applications (NAS, 2017).

To realize the potential benefits of synthetic biology while avoiding unintended consequences that may adversely impact public health and the environment, it is crucial to better comprehend the underpinning science and to develop appropriate assessment technologies. (Gronvall, 2017; U.S.A.C.E., 2019; NAS, 2017). Innovative risk assessment tools are needed to evaluate these new products (NAS, 2017). The manufacturing, agricultural, and biomedical benefits of these varied products will depend on robust evaluation approaches and monitoring capabilities to ensure their safety and to assure public trust (Jones et al., 2019; Trump et al., 2018; U.S.E.P.A., 2017; Gronvall, 2017).

One rapidly expanding application area of biotechnology is modification of the genetic makeup of plants, animals, and microbes, which themselves then become valuable products (CRS, 2019). Traditional breeding and selection techniques, or early methods of genetic engineering, have been surpassed by developments in synthetic biology that have enabled unprecedented advances in the number and types of products being developed. Novel new techniques, such as CRISPR-Cas9 (CRS, 2018) and other genome engineering technologies, have transformed and accelerated the creation and production of the next generation (EBRC, 2019) of agricultural (e.g., genetically engineered products that qualify as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act-FIFRA), medical, and industrial materials (e.g., microbial biotechnology-derived substances are considered new chemicals under the Toxic Substances Control Act-TSCA). United States law mandates that risk assessment of a product is based on its end use, including biotechnology products (U.S. EPA, 2019 and 2017).

For the purposes of this RFA: synbio organisms are whole organisms that have been engineered using synthetic biology; synbio components are synthetic biology constructs that may be used or deployed outside of a living organism; synthetic biology constructs and by-products are new or redesigned biological entities or novel biomolecules not derived from extant organisms (e.g., enzymes, genetic circuits, atypical nucleotides, noncanonical amino acids, and cells); biocontainment methodologies prevent unintended proliferation of genetically modified organisms in the environment; and genetic restriction technologies are methods that impede transgene movement. Additionally, “synthetic genetic constructs” are defined as new biological entities, not directly derived from extant organisms, such as enzymes, genetic circuits, and cells or the redesign of existing biological systems for useful purposes. “Genetic restriction technologies” are defined as methods that impede transgene movement.

Novel synthetic biology products present new challenges to the assessment of potential human health and environmental risk. For example, risk assessment efforts currently rely largely on existing databases of known substances, but new products have no such data. Empirical and modeling research efforts will help inform risk assessments of emerging biotechnology products, especially where comparisons to previously developed products are limited (U.S. EPA, 2017). This RFA solicits research to inform development of assessment tools to better understand the characteristics and interactions of synbio organisms, components, and their biocontainment strategies, and to characterize potential risks to human health and the environment.

For synthetically engineered organisms and components, there are 4 general questions that must be addressed regarding risk assessment:

1. Is there a hazard? (Hazard identification);
2. How likely is the hazard to occur? (Quantifying the probability of occurrence; identifying likely hazard exposure scenarios);
3. What is the severity of hazard resulting from specific levels of exposure? (Quantifying effects)
4. Is there an effect above and beyond what might occur with a native, unmodified organism, or one with similar traits which was developed using older, more established, technologies?

C. Authority and Regulations

The authority for this RFA and resulting awards is contained in the Toxic Substances Control Act, 15 U.S.C. 2609, Section 10, as amended by P.L. 106-74 and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136r, Section 20, as amended by P.L. 106-74.

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. Generally, a project must address the causes, effects, extent, prevention, reduction and elimination of air pollution, water pollution, solid/hazardous waste pollution, toxic substances control or pesticide control, depending on which statute(s) is 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 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 announcement support EPA's FY 2018-22 Strategic Plan (https://www.epa.gov/planandbudget/strategicplan.html). Activities to be funded under this announcement support Goal 3: Greater Certainty, Compliance, and Effectiveness, Objective 3.3: Prioritize Robust Science, of EPA's FY 2018-22 Strategic Plan. Awards made under this announcement will further EPA's priorities supporting robust science for chemical safety.

All applications must be for projects that support the goal and objective identified above. 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 priorities described above.

The Agency is soliciting research that proposes the development of tools to evaluate, monitor and assess risk, as well as potential outcomes from the use of synthetic biology products. Examples of tools include models, bioinformatic systems, field-based and *in vitro* methods supporting risk assessments of synthetic biology products.

Applicants should address at least one of the three research areas, including at least one subtopic, described below. Applications may respond to one research area or integrate across two or three research areas. Applications should clearly indicate which research area(s) the application is addressing. Applications that address more than one research area will not necessarily be rated more highly than those that address just one of the areas. This RFA does not support any research which could also be used to facilitate intentional harm to public health and safety, agricultural crops and other plants, animals, the environment, material (including food, water, supplies, or material of any kind), or national security. For the purposes of this RFA, biotechnology products of interest include: industrial or consumer chemicals; pesticides (including pesticide intermediates); and new microbes used in biomass conversion for chemical production, microbial fuel cells, mining and resource extraction, building materials, waste remediation and pollution control, and non-pesticidal agriculture applications (e.g., biofertilizers, weather and climate modification).

1. **Long-term stability, persistence, efficacy, and reliability of microbial biocontainment strategies, microbial synthetic genetic constructs, or microbial genetic restriction technologies:**

    a. Long-term stability, persistence, and reliability of synbio microbial biocontainment strategies (e.g., xenonucleic acids, noncanonical amino acids, recoded microorganisms) for synbio microorganisms. For the purposes of this RFA, biocontainment methodologies are those that prevent unintended proliferation of genetically modified organisms in the environment.
    b. Stability and persistence of synthetic genetic constructs in microbes (e.g., are synthetic transgenes eliminated from viral, bacterial, algal or fungal genomes over time?). For the purposes of this RFA, "synthetic genetic constructs" are defined as new biological entities, not directly derived from extant organisms, such as enzymes, genetic circuits, and cells or the redesign of existing biological systems for useful purposes.
    c. Efficacy of genetic restriction technologies or orthogonal gene constructs in precluding horizontal gene transfer from synthetic microorganisms. Horizontal gene transfer is a process in which organisms exchange genetic material with other species. For the purposes of this RFA, "genetic restriction technologies" are defined as methods that impede transgene movement. Particularly with self-

replicating microbial systems, re-engineered cells may produce undesired consequences if they escape or overwhelm their intended host environment.

2. **Ecological effects/impacts of synbio organisms or by-products that are released into the environment:**

    a. Survival, persistence, and unintended ecological effects of synbio microorganisms, plants and animals.
    b. Unintended environmental effects/potential impacts of synthetic microorganisms, plants and animals such as: bacteriophages, plant viruses, entomopathogens, bacterial or fungal colonizers, (e.g., rhizobia, other nitrogen-fixing bacteria, mycorrhizae), higher plants, mosquitoes, or rodents.

3. **Risks to human health from novel biomolecules produced using metabolic or genetic pathways by organisms used as manufacturing bioreactors. Much work regarding toxicity and allergenicity of new protein domains relies on bioinformatics that use existing databases of known toxins and allergens. These databases, or the literature, do not apply to biomolecules made by synbio organisms.** Methods and models are needed to determine potential physiological responses, such as:
    a. Adverse responses, including protein toxicity/allergenicity, biosynthetically produced proteins, atypical nucleotides, or noncanonical amino acids (i.e., non-standard amino acids and possibly other ligands),
    b. Predictive toxicity motif detection in instances where noncanonical amino acids are incorporated into peptides/proteins,
    c. Synbio microorganism colonization of the human microbiome.

Potential outputs expected from the research funded under this RFA may include:

- Tools and methods able to assess and monitor the effects of synthetic biotechnology products.
- Methods and models able to identify and quantify probable outcomes, sources of uncertainty, and trace cause and effect pathways.
- New or redesigned systems able to generate information on synthetic biology products and components that help determine potential adverse human and ecological effects.
- Advanced, useful evaluation and monitoring methods to assess risk to human health and the environment of beneficial synthetic biology products.

Potential outcomes expected from the research funded under this RFA may include:

- Improved understanding of risks to human health and the environment from synthetic biotechnology production processes.
- Better identification of key connections in the continuum between the production of synthetic biotechnology products and intermediate substances with potential adverse outcomes in humans.

To the extent practicable, research applications must embody innovation. Innovation for the purposes of this RFA is defined as the process of making changes; a new method, custom or

device. Innovative research can take the form of wholly new applications or applications that build on existing knowledge and approaches for new uses. Research applications must include a discussion on how the proposed research is innovative (see Section IV.C.6.a). Reviewers will draw from the above-mentioned innovation definition in the review/evaluation process of research applications (see Section V.A).

E. References

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Congressional Research Service, *Major Agricultural Trade Issues in the 116th Congress, https://crsreports.congress.gov,* May 20, 2019.

Drinkwater et al, Synthetic Biology Project, *Creating A Research Agenda for the Ecological Implications of Synthetic Biology*, Joint Workshops by the MIT Program on Emerging Technologies and the Wilson Center's Synthetic Biology Project, SYNBIO May 7, 2014.

Engineering Biology Research Consortium, *Engineering Biology; A Research Roadmap for the Next-Generation Bioeconomy*, June 2019, https://roadmap.ebrc.org/.

European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, Scientific Committee on Health and Environmental Risks, Scientific Committee on Consumer Safety, *Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology*, doi:10.2875/590512.

Evans, B. et al, *Transgenic Aedes aegypti Mosquitoes Transfer Genes into a Natural Population,* Scientific Reports, volume 9, Article number: 13047, September 10, 2019.

Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products. June 11, 2019 https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/

Gronvall, G. *Maintaining US Leadership in Emerging Biotechnologies to Grow the Economy of the Future*. Health Security. Volume: 15 Issue 1: February 1, 2017.

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U.S. Army Corps of Engineers, Engineer Research and Development Center (2019). *Synthetic Biology: Research Needs for Assessing Environmental Impacts*. ERDC/EL TR-19-10. http://dx.doi.org/10.21079/11681/33681

USDA, FDA, EPA (2020) The Unified Website for Biotechnology Regulation; https://www.usda.gov/media/press-releases/2020/01/09/usda-fda-epa-launch-website-biotechnology-regulationU.S. EPA, Environmental Protection Agency (2019). *Regulation of Biotechnology under TSCA and FIFRA*; available at https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra.

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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).

Please note: Early career awards will not accommodate a Multiple PI application. Early career awards shall be submitted as a single Lead PI application. Special eligibility criteria apply to the early career portion of this RFA. Please see Section III of this RFA for details on the early career eligibility criteria. The application must include an early career verification (see "Early Career Verification" in Section IV.C.6.e).

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.6.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.

II. AWARD INFORMATION

It is anticipated that a total of approximately $4.4 million 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 7 awards (4 regular and 3 early career) under this RFA. Requests for amounts in excess of a total of $760,000 for regular awards and a total of $453,333 for early career awards, including direct and indirect costs, 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.

EPA intends to award only grants under this announcement.

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

III. ELIGIBILITY INFORMATION

A. Eligible Applicants

Public and private nonprofit institutions/organizations, public and private institutions of higher education, and hospitals located in the U.S., state and local governments, Federally Recognized Indian Tribal Governments, and U.S. territories or possessions are eligible to apply. Profit-making firms and individuals are not eligible to apply.

Non-profit organization, as defined by 2 CFR 200.70, means any corporation, trust, association, cooperative or other organization that: (1) is operated primarily for scientific, educational, service, charitable or similar purposes in the public interest; (2) is not organized primarily for profit; and (3) uses its net proceeds to maintain, improve and/or expand its operations. Note that 2 CFR 200.70 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 non-profit organization(s) as defined by 2 CFR 200.70, public or nonprofit Institutions of Higher Education are, nevertheless, eligible to submit applications under this RFA. Hospitals operated by state, tribal, or local governments or that meet the definition of nonprofit at 2 CFR 200.70 are also eligible to apply as nonprofits or as instrumentalities of the unit of government depending on the applicable law. For-profit colleges, universities, trade schools, and hospitals are ineligible. Nonprofit organizations described in Section 501(c) (4) of the Internal Revenue Code that lobby are not eligible to apply.

Foreign governments, international organizations, and non-governmental international organizations/institutions are not eligible to apply.

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.

The early career awards will support research performed by PIs with outstanding promise at the Assistant Professor or equivalent level. Principal investigators from applicant institutions applying for the early career portion of the RFA must meet the following additional eligibility requirements:

1. Hold a doctoral degree in a field related to the research being solicited by the closing date of the RFA;
2. Be untenured at the closing date of the RFA; and
3. By the award date, be employed in a tenure-track position (or tenure-track-equivalent position) as an assistant professor (or equivalent title) at an institution in the U.S., its territories, or possessions. Note: For a position to be considered a tenure-track-equivalent position, it must meet all of the following requirements: (1) the employing department or organization does not offer tenure; (2) the appointment is a continuing appointment; (3) the appointment has substantial educational responsibilities; and (4) the proposed project relates to the employee's career goals and job responsibilities as well as to the goals of the department/organization.

The application must include an early career verification (see "Early Career Verification" in Section IV.C.6.e).

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

Institutional cost-sharing is not required.

C. Other

Applications must substantially comply with the application submission instructions and requirements set forth in Section IV of this announcement or they will be rejected. In addition, where a page limitation is expressed in Section IV with respect to parts of the application, pages in excess of the page limit will not be reviewed. In addition, applications must be submitted

through Grants.gov as stated in Section IV of this announcement (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 announcement. Applicants are responsible for following the submission instructions in Section IV of this announcement (see Section IV.F. "Submission Instructions and Other Submission Requirements" for further information) to ensure that their application is submitted timely. Applications submitted after the submission deadline will be considered late and deemed ineligible without further consideration unless the applicant can clearly demonstrate that it was late due to EPA mishandling or because of technical problems associated with Grants.gov or relevant SAM.gov system issues. An applicant's failure to timely submit their application through Grants.gov because they did not timely or properly register in SAM.gov or Grants.gov will not be considered an acceptable reason to consider a late submission.

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.

Applications deemed ineligible for funding consideration will be notified within fifteen calendar days of the ineligibility determination.

IV. APPLICATION AND SUBMISSION INFORMATION

Additional provisions that apply to this solicitation and/or awards made under this solicitation, including but not limited to those related to confidential business information, contracts and subawards under grants, and proposal assistance and communications, can be found at https://www2.epa.gov/grants/epa-solicitation-clauses.

These, and the other provisions that can be found at the website link, are important, 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 communicate with the EPA contact listed in this solicitation to obtain the provisions.

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

A. Grants.gov Submittal Requirements and Limited Exception Procedures

Applicants, except as noted below, must apply electronically through Grants.gov under this funding opportunity based on the grants.gov instructions in this announcement. If an applicant does not have the technical capability to apply electronically through grants.gov because of limited or no internet access which prevents them from being able to upload the required application materials to Grants.gov, the applicant must contact OMS-ARM-OGDWaivers@epa.gov or the address listed below in writing (e.g., by hard copy, email) *at least 15 calendar days prior to the submission deadline under this announcement* to request approval to submit their application materials through an alternate method.

Mailing Address:
OGD Waivers
c/o Jessica Durand
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Ave., N. W.
Mail Code: 3903R
Washington, DC 20460

Courier Address:
OGD Waivers
c/o Jessica Durand
Ronald Reagan Building
1300 Pennsylvania Ave., N.W.
Rm # 51278
Washington, DC 20004

In the request, the applicant must include the following information:
Funding Opportunity Number (FON)
Organization Name and Unique Entity Identifier (e.g., DUNS)
Organization's Contact Information (email address and phone number)
Explanation of how they lack the technical capability to apply electronically through Grants.gov because of: 1) limited internet access or 2) no internet access which prevents them from being able to upload the required application materials through Grants.gov.

EPA will only consider alternate submission exception requests based on the two reasons stated above and will timely respond to the request -- all other requests will be denied. If an alternate submission method is approved, the applicant will receive documentation of this approval and further instructions on how to apply under this announcement. Applicants will be required to submit the documentation of approval with any initial application submitted under the alternative method. In addition, any submittal through an alternative method must comply with all applicable requirements and deadlines in the announcement including the submission deadline and requirements regarding application content and page limits (although the documentation of approval of an alternate submission method will not count against any page limits).

If an exception is granted, it is valid for submissions to EPA for the remainder of the entire calendar year in which the exception was approved and can be used to justify alternative submission methods for application submissions made through December 31 of the calendar year in which the exception was approved (e.g., if the exception was approved on March 1, 2020, it is valid for any competitive or non-competitive application submission to EPA through December 31, 2020). Applicants need only request an exception once in a calendar year and all exceptions will expire on December 31 of that calendar year. Applicants must request a new exception from required electronic submission through Grants.gov for submissions for any succeeding calendar year. For example, if there is a competitive

opportunity issued on December 1, 2019 with a submission deadline of January 15, 2020, the applicant would need a new exception to submit through alternative methods beginning January 1, 2020.

Please note that the process described in this section is only for requesting alternate submission methods. All other inquiries about this announcement must be directed to the Agency Contact listed in Section VII of this announcement. Queries or requests submitted to the email address identified above for any reason other than to request an alternate submission method will not be acknowledged or answered.

B. Application Package Information

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

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 SF424 are included with the form. However, note that EPA requires that the entire requested dollar amount appear on the SF424, not simply the proposed first year expenses. The form must contain the signature of an authorized representative of the applying organization.

Applicants are required to provide a unique entity identifier (e.g., 'DUNS number') when applying for federal grants or cooperative agreements. Organizations may receive a unique entity identifier, at no cost, by calling the dedicated toll-free request line at 1-866-705-5711, or visiting the website at: https://www.dnb.com.

2. Key Contacts

The applicant must complete the "Key Contacts" form found in the Grants.gov application package. An "Additional Key Contacts" form is also available at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms. The Key Contacts form should also be completed for major 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. Table of Contents
Provide a list of the major subdivisions of the application indicating the page number on which each section begins.

5. 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 should 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).

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.

6. Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, Early Career Verification 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 the STAR 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) Innovation: Describe how your project shifts current research or engineering paradigms by using innovative theoretical concepts, approaches or methodologies, instrumentation or interventions applicable to one or more fields of research.

(4) 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.

(5) 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.

(6) 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 American National Standard ASQ/ANSI E4:2014: Quality management systems for environmental information and technology programs—Requirements

with guidance for use, approved February 4, 2014. 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 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).

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

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

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

Human subjects research supported by the EPA is governed by EPA Regulation 40 CFR Part 26 (Protection of Human Subjects). This includes the Common Rule at subpart A and prohibitions and additional protections for pregnant women and fetuses, nursing women and children at subparts B, C and D. While retaining the same notation, subparts B, C and D are substantively different in 40 CFR Part 26 than in the more commonly cited 45 CFR 46. Particularly noteworthy is that research meeting the regulatory definition of intentional exposure research found in subpart B is prohibited by that subpart in pregnant women, nursing women and children. Research meeting the regulatory definition of observational research (any research that

is not intentional exposure research) found in subparts C and D is subject to the additional protections found in those subparts for pregnant women and fetuses (subpart C) and children (subpart D). These subparts also differ markedly from the language in 45 CFR 46. For more information, please see: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0.

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

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

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

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

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

Complete all items below for studies involving human subjects.

Protection of Human Subjects (*Adapted from National Institutes of Health Supplemental Instructions for PHS 398 and SF424 (R&R) II-10)

1. Risks to Human Subjects
    a. Human Subjects Involvement, Characteristics and Design
        • Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
        • Describe the characteristics of the subject population, including their anticipated number, age range and health status, if relevant.
        • Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
        • Explain the rationale for the involvement of special vulnerable populations, such as pregnant women, children or others who may be considered vulnerable populations.
        • If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subject's protection, describe and justify the selection of an intervention's dose, frequency and administration.
        • List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed and protected.
    b. Sources of Materials
        • Describe the research material obtained from living individuals in the form of specimens, records or data.
        • Describe any data that will be collected from human subjects for the project(s) described in the application.
        • Indicate who will have access to individually identifiable private information about human subjects.
        • Provide information about how the specimens, records and/or data are collected, managed and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.
    c. Potential Risks
        • Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal or other), and assess their likelihood and seriousness to the human subjects.
        • Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.
2. Adequacy of Protection Against Risks
    a. Recruitment and Informed Consent
        • Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

• Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

b. Protections Against Risk

• Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data and assess their likely effectiveness.

• Research involving vulnerable populations, as described in the EPA regulations, Subparts B-D, must include additional protections. Refer to EPA guidance:

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

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

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

• Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials must include a general description of the plan for data and safety monitoring of the clinical trials and adverse event reporting to the IRB, the 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. Early Career Verification (1 page)

For early career awards, provide the following statement in your application package verifying that you meet the early career eligibility requirements:
"I verify that:
1. I hold a doctoral degree in a field related to the research being solicited by the closing date of the RFA;
2. I am untenured at the closing date of the RFA, and
3. I am, or expect to be, employed in a tenure-track position (or tenure-track-equivalent position) as an assistant professor (or equivalent title) at an institution in the U.S., its territories, or possessions by the award date."

Note: For a position to be considered a tenure-track-equivalent position, it must meet all of the following requirements: (1) the employing department or organization does not offer tenure; (2) the appointment is a continuing appointment; (3) the appointment has substantial educational responsibilities; and (4) the proposed project relates to the employee's career goals and job responsibilities as well as to the goals of the department/organization.

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

7. Budget and Budget Justification

a. Budget

Prepare a master budget table using "SF-424A Budget Information for Non-Construction Programs" (aka SF-424A), available in the Grants.gov electronic application package and also at https://www.epa.gov/research-grants/research-funding-opportunities-how-apply-and-required-forms. Only complete "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).

Applicants may not use subagreements to transfer or delegate their responsibility for successful completion of their EPA assistance agreement. Please refer to https://www2.epa.gov/grants/epa-solicitation-clauses#Contracts and Subawards if your organization intends to identify specific contractors, including consultants and subawardees in your application.

Please note that institutional cost-sharing is not required.

b. Budget Justification *[3 pages in addition to the Section IV.C.6 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. The budget justification should not exceed three consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

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

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

Below is a sample computation for Personnel:

Position/Title	**Annual Salary**	**% of Time Assigned to Project**	**Year 1**	**Year 2***	**Year 3***	**Total**
Project Manager	$70,000	50%	$35,000	$36,050	$37,132	$108,182
Env. Specialist	$60,000	100%	$60,000	$61,800	$63,654	$185,454
Env. Health Tech	$45,000	100%	$45,000	$46,350	$47,741	$139,091
Total Personnel			**$140,000**	**$144,200**	**$148,527**	**$432,727**

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

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

(2) 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.

(3) 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. 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 STAR program progress reviews (estimate for two days in Washington, D.C.) and a final workshop to report on results.

Below is a sample computation for Travel:

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

(4) 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).

(5) 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.

(6) 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 200.317-200.326. Please see https://www2.epa.gov/grants/epa-solicitation-clauses#Contracts and Subawards for more details.**

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.

(7) 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://www2.epa.gov/grants/epa-solicitation-clauses#Contracts and Subawards 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.**

(8) Indirect Costs: For additional information pertaining to indirect costs, please see the IDC Competition Clause at Additional Provisions for Applicants Incorporated into the Solicitation.

8. 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).

9. 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.

10. 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://www2.epa.gov/grants/epa-solicitation-clauses#Contracts and Subawards.

b. Funding Opportunity Number(s) (FON)

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

Applicants must select the FON corresponding to either the regular award or the early career award. It is the responsibility of the applicant to identify the proper FON. Failure to do so could result in an inappropriate peer review assignment. **Each application must be submitted using a single FON.**

The Funding Opportunity Numbers for this RFA are:

EPA-G2020-STAR-C1, Assessment Tools for Biotechnology Products
EPA-G2020-STAR-C2, Early Career: Assessment Tools for Biotechnology Products

c. Confidentiality

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: **July 15, 2020**, 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 STAR 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 STAR 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 technical capability 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. Preparing for Submission: The electronic submission of your application must be made by an official representative of your institution who is registered with Grants.gov and is authorized to sign applications for Federal assistance. For more information on the registration requirements that must be completed in order to submit an application through Grants.gov, go to https://www.grants.gov/ and click on "Register" at the top right corner of the page. If your organization is not currently registered with Grants.gov, please encourage your office to designate an Authorized Organization Representative (AOR) and ask that individual to begin the registration process as soon as possible. Please note that the registration process also requires that your organization have a unique entity identifier (e.g., 'DUNS' number) and a current registration with the System for Award Management (SAM) and the process of obtaining both could take a month or more. 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 submission deadline. Registration on Grants.gov, SAM.gov and unique entity identifier assignment is FREE.

Applicants need to ensure that the AOR who submits the application through Grants.gov and whose unique entity identifier (e.g., DUNS number) is listed on the application is an AOR for the applicant listed on the application. Additionally, the DUNS number listed on the application must be registered to the applicant organization's SAM account. If not, the application may be deemed ineligible.

To begin the application process under this grant announcement, go to https://www.grants.gov/ and click on "Applicants" on the top of the page and then "How to Apply for Grants" from the drop-down menu and then follow the instructions accordingly. Please note: To apply through Grants.gov, you must use Adobe Reader software and download the compatible Adobe Reader version. For more information about Adobe Reader, to verify compatibility, or to download the free software, please visit https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html.

You may also be able to access the application package for this announcement by searching for the opportunity on https://www.grants.gov/. Go to https://www.grants.gov/ and click "Search Grants" at the top of the page and enter the Funding Opportunity Number, EPA-G2020-STAR-C1, or EPA-G2020-STAR-C2, or the CFDA number that applies to the announcement (66.509), in the appropriate field under "Basic Search Criteria" and click the Search button.

Note: All applications must now be submitted through Grants.gov using the "Workspace" feature. Information on the Workspace feature can be found at the Grants.gov Workspace Overview Page.

2. Acknowledgement of Receipt: The complete application must be transferred to Grants.gov no later than 11:59:59 pm Eastern Time on the solicitation closing date (see "Submission Dates and Times"). Applications submitted through Grants.gov will be time and date stamped

electronically. Grants.gov provides an on-screen notification of successful initial transfer as well as an email notification of successful transfer from Grants.gov to EPA. 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.***

3. Application Package Preparation: Your organization's AOR must submit your complete application package electronically to EPA through Grants.gov (https://www.grants.gov/) no later than **July 15, 2020**, 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.

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 (f) 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: Only complete "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 (click on "Add Mandatory Project Narrative"): Attach a single electronic PDF file labeled "Application" that contains the items described in Section IV.C.4. through IV.C.10.a [Table of Contents, Abstract, Research Plan, Quality Assurance Statement, Human Subjects Research Statement, Scientific Data Management Plan, Early Career Verification (for early career awards), 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, place them before the

EPA Form 4700-4, Preaward Compliance Review Report for All Applicants and Recipients Requesting EPA Financial Assistance (Section IV.C.3.).

Once the application package has been completed, the "Submit" button should be enabled. If the "Submit" button is not active, please call Grants.gov for assistance at 1-800-518-4726. 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. Investigators should save the completed application package with two different file names before providing it to the AOR to avoid having to re-create the package should submission problems happen, or a revised application needs to be submitted. Note: Revised applications must be submitted before the solicitation closing date and time.

4. Submitting the application: The application package must be transferred to Grants.gov by an AOR. The AOR should close all other software before attempting to submit the application package. Click the "submit" button of the application package. Your Internet browser will launch and a sign-in page will appear. ***Note: Minor problems are not uncommon with transfers to Grants.gov. It is essential to allow sufficient time to ensure that your application is submitted to Grants.gov BEFORE 11:59:59 pm Eastern Time on the solicitation closing date.*** The Grants.gov support desk operates 24 hours a day, seven days a week, except Federal Holidays.

A successful transfer will end with an on-screen acknowledgement. For documentation purposes, print or screen capture this acknowledgement. If a submission problem occurs, reboot the computer – turning the power off may be necessary – and re-attempt the submission.

Note: Grants.gov issues a "case number" upon a request for assistance.

5. Transmission Difficulties: If transmission difficulties that result in a late transmission, no transmission or rejection of the transmitted application are experienced and following the above instructions do not resolve the problem so that the application is submitted to Grants.gov by the deadline date and time, follow the guidance below. The Agency will make a decision concerning each late submission on a case-by-case basis as to whether it should be forwarded for peer review. All emails, as described below, are to be sent to jones.debram@epa.gov with the FON in the subject line.

Be aware that EPA will only consider accepting applications that were unable to transmit due to Grants.gov or relevant www.Sam.gov system issues or for unforeseen exigent circumstances, such as extreme weather interfering with internet access. Failure of an applicant to submit timely because they did not properly or timely register in SAM.gov or Grants.gov is not an acceptable reason to justify acceptance of a late submittal.

Please note that if the application you are submitting is greater than 70 MB in size, please call or send an email message to the Electronic Submissions Contact listed for this RFA. The Agency may experience technical difficulty downloading files of this size from Grants.gov. Therefore, it is important that the Agency verify that the file can be downloaded. The Agency will provide alternate submission instructions if the file cannot be downloaded.

(a) If you are experiencing problems resulting in an inability to upload the application to Grants.gov, it is essential to call Grants.gov for assistance at 1-800-518-4726 before the application deadline. 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. Be *sure* to obtain a case number from Grants.gov. If the problems stem from unforeseen exigent circumstances unrelated to Grants.gov, such as extreme weather interfering with internet access, contact Debra M. Jones (jones.debram@epa.gov).

(b) Unsuccessful transfer of the application package: If a successful transfer of the application cannot be accomplished even with assistance from Grants.gov due to electronic submission issues or unforeseen exigent circumstances, send an email message to Debra M. Jones (jones.debram@epa.gov) by 11:59:59 pm Eastern Time on the solicitation closing date. The email message must document the problem and include the Grants.gov case number as well as the entire application in PDF format as an attachment.

(c) Grants.gov rejection of the application package: If a notification is received from Grants.gov stating that the application has been rejected for reasons other than late submittal, promptly send an email to Debra M. Jones (jones.debram@epa.gov) with the FON in the subject line within one business day of the closing date of this solicitation. The email should include any materials provided by Grants.gov and attach the entire application in PDF format.

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

V. APPLICATION REVIEW INFORMATION

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 electronic copies of all applications, as well as a full set of abstracts for the 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 will read the full set of abstracts and entire application package for each application they are assigned. They 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.

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 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 their 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, research needs and special considerations specified by the RFA.

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 (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. Other Factors:

   Innovation: The degree to which the application demonstrates that the research will challenge and seek to shift current research or engineering paradigms by using innovative theoretical concepts, approaches or methodologies, instrumentation or interventions applicable to one or more fields of research.

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 research is relevant to EPA's priorities (as described in Goal 3: Greater Certainty, Compliance, and Effectiveness, Objective 3.3: Prioritize Robust Science, of the EPA's FY2018-2022 Strategic Plan) supporting robust science for Chemical Safety.

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.

4. The degree to which the research has the potential to strengthen the scientific basis for risk assessment.

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 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 that were similar in size and scope to the proposed project.

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. Brief description of the grant/cooperative agreement
5. A description of how the agreement is similar in size and scope to the proposed project and whether or not it was successfully managed and completed; if not successfully managed and completed, provide an explanation
6. 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
7. 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
8. Total (all years) grant/cooperative agreement dollar value
9. Project period
10. 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. 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.6.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.

G. Additional Provisions for Applicants Incorporated into the Solicitation

Additional provisions that apply to this solicitation and/or awards made under this solicitation including the clause on Reporting and Use of Information Concerning Recipient Integrity and Performance can be found at EPA Solicitation Clauses. These, and the other provisions that can be found at the website link, are important, 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 communicate with the EPA contact listed in this solicitation to obtain *the provisions*.

VI. AWARD ADMINISTRATION INFORMATION

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 Grant Competition Dispute Resolution Procedures. 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

Additional provisions that apply to this solicitation and/or awards made under this solicitation, including but not limited to those related to unique entity identifier, SAM, copyrights, disputes, and administrative capability, can be found at https://www2.epa.gov/grants/epa-solicitation-clauses.

These, and the other provisions that can be found at the website link, are important, 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 communicate with the EPA contact listed in this solicitation to obtain the provisions.

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: Barbara Klieforth; phone: 202-564-7723; email: klieforth.barbara@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