

Proposal Preparation and Submission

Activity Packet

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Proposal Preparation and Submission: Activity 1

Call for Proposals

Instructions

1. Work alone or in groups.
2. Read the following RFA.
3. Complete the Activity 1 worksheet in the Activity Workbook (starting on page 3).

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

Funding Opportunity Title

Outstanding New Environmental Scientist (ONES) Award (R01 Clinical Trial Optional)

Activity Code

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

Announcement Type

Reissue of [RFA ES-15-020 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-15-020.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-15-020.html)

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-ES-18-001

Companion Funding Opportunity

None

Number of Applications

Only one application per School or College within a University will be accepted. See [Section III. 3. Additional Information on Eligibility](#).

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

93.113

Funding Opportunity Purpose

The Outstanding New Environmental Scientist (ONES) Award is intended to identify the most talented Early Stage Investigators (ESIs) who intend to make a long-term commitment to research in the Environmental Health Sciences and assist them in launching an innovative research program focused on the understanding of environmental exposure effects on people's health.

Key Dates

Posted Date

October 25, 2017

Open Date (Earliest Submission Date)

January 27, 2018

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Date(s)

February 27, 2018; February 28, 2019; February 28, 2020, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11112)

Scientific Merit Review

June/July 2018, June/July 2019, June/July 2020

Advisory Council Review

October 2018, October 2019, October 2020

(<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>)

Earliest Start Date

December 2018, December 2019, December 2020

Expiration Date

February 29, 2020

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

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

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-ES-18-001\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-ES-18-001) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Research Objectives

An essential element of the mission of the National Institute of Environmental Health Sciences (NIEHS) is the support and career promotion of the next generation of exceptionally talented and creative new scientists who will further the understanding of the impact of environmental exposures on human health. The NIEHS

supports a number of training and fellowship programs for pre and postdoctoral training, and mentored career development awards for faculty in the early stages of their career development. Along with these training and career development programs, NIEHS initiated a program of research grants for Early Stage Investigators, The Outstanding New Environmental Scientist (ONES) Award, that is designed to identify the best new biomedical investigators across the spectrum of science supported by the NIEHS (i.e., including basic mechanistic, clinical and population based researchers) and facilitate their establishing a vibrant, independent research program in the environmental health sciences. NIEHS uses this FOA to support the NIEHS goal of assuring a continuing cadre of productive environmental health science investigators.

Research Goals and Scope

The ONES program is designed to identify outstanding scientists at the formative stages of their career and assist them in launching an innovative research program with a defined impact in the environmental health sciences. These R01 research grants are targeted for researchers who are defined by the NIH as Early Stage Investigators (see http://grants.nih.gov/grants/new_investigators/index.htm ([//grants.nih.gov/grants/new_investigators/index.htm](http://grants.nih.gov/grants/new_investigators/index.htm))).

The ONES program is designed to be highly competitive, and only a limited number are awarded per year.

Research programs supported by this announcement seek to promote career advancement of the most highly creative and promising new scientists who intend to make a long-term career commitment to research in the mainstream of the environmental health sciences, and bring innovative, ground-breaking research initiatives and thinking to bear on the problems of how environmental exposures affect human health.

The ONES Program is specifically targeted to Early Stage Investigators and program goals include career promotion as well as the scientific project proposed. Applications for the ONES program differ from standard R01 applications in that applicants must describe plans for the active participation of an external advisory committee to provide consultation and feedback, commitment by the institution to actively support the research program development of the Program Director/Principal Investigator (PD/PI), and a plan for career enhancement which will provide a strong foundation for future research endeavors. See Section IV.2 for detailed application instructions.

Research projects proposed in response to this FOA will be expected to have a defined impact on the environmental health sciences and be responsive to both the mission of the NIH and, specifically, to the mission of the NIEHS and the NIEHS 2012-2017 Strategic plan, [Advancing Science, Improving Health: A Plan for Environmental Health Sciences Research](#). (http://www.niehs.nih.gov/about/strategicplan/strategicplan2012_508.pdf) This plan sets out a set of strategic themes and strategic goals that have been identified as priority areas for the field of environmental health sciences. These reflect both the mission of the NIEHS, which is to discover how the environment affects people in order to promote healthier lives, and the vision of NIEHS to provide global leadership for innovative research that improves public health by preventing disease and disability.

A variety of scientific disciplines, including basic, mechanistic, clinical, epidemiological, computational, engineering, and/or health risk communication approaches, can be used to advance the NIEHS Strategic Plan. Applicants should consult the strategic plan to ensure that the research proposed in their application addresses the goals and priority areas of the NIEHS.

Applications submitted in response to this FOA must have a research focus on exposure -health related responses from environmental agents within the mission interest of the NIEHS. The Strategic Plan emphasizes that environmental exposures within the primary mission interest of NIEHS may both manifest effects through direct toxicities and as an element in combined exposures in the totality of all types of human exposure experiences throughout the lifespan, the exposome.

Environmental agents which are considered of primary interest for NIEHS include: industrial chemicals or manufacturing byproducts, metals, pesticides, herbicides, air pollutants and other inhaled toxicants, particulates or fibers, fungal, and bacterial or biologically derived toxins. Agents that are considered within

the primary mission responsibility of other NIH Institutes and Centers include, but are not limited to: alcohol, chemotherapeutic agents, radiation that is not a result of an ambient environmental exposure, smoking, except when considered as a secondary smoke exposure as a component in the indoor environment (particularly in children), drugs of abuse, pharmaceuticals, dietary nutrients, and infectious or parasitic agents. Applications which focus entirely or primarily on these exposure factors will be considered nonresponsive to this announcement and will not proceed to review. However, it is appropriate to include these factors as part of research to define effects of the exposome, and these factors may be a part of applications focused on the totality of a person's environmental exposure. Applicants are strongly encouraged to contact NIEHS Scientific/Research staff prior to submission to determine if their project meets the goals of the ONES program.

It is anticipated that the ONES program will be evaluated on a continuing basis by the NIEHS, to assess the impact of the program on the portfolio of the NIEHS, and on the progression of the awardees' careers. Metrics to be used include, but are not limited to: publications, including numbers, impact factors, citations of publications; academic promotion of the PD/PIs; invited talks at national/international symposia; students and postdoctoral fellows trained in the PD/PI's laboratory; honors and awards received by the PD/PI; committee service of the PD/PI; and subsequent grant support awarded. The design of the program evaluation will be determined by the Program Analysis Branch of the Division of Extramural Research and Training. PD/PIs awarded ONES grants will be requested to provide information for the evaluation during the period of the award.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Resubmission

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

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s)

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIEHS intends to fund an estimate of 5-6 awards, corresponding to a total of \$3.0 million, for each of fiscal years 2018, 2019, 2020. Future year amounts will depend on annual appropriations.

Award Budget

The budget for direct costs is composed of two elements - research direct costs and career enhancement costs. For most applications, the budget for direct costs should be limited to \$250,000 per year. With

strong justification, research projects which have inherently higher costs may request direct costs of up to \$400,000 per year. Career enhancement direct costs are limited to \$250,000, which can be distributed over the 5-year award period. Note: the total direct cost budget (research plus career enhancement) may not exceed \$475,000 in any year of the award.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11118](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118)), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](http://fedgov.dnb.com/webform) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number,

applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.

- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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

To be eligible for this award, applicants must have a Ph.D., M.D., or equivalent graduate degree.

PD(s)/PI(s) must be NIH defined Early Stage Investigators. See <https://grants.nih.gov/policy/early-investigators/index.htm>

In addition, PD/PI's must have faculty appointments which are tenure track or equivalent, generally at the level of Assistant Professor, Research Assistant Professor, and have demonstrated outstanding abilities in basic, clinical, quantitative, or population-based research. Individuals must have established research independence from a mentor, and have dedicated, independent laboratory space or access to the clinical, population-based and/or public health research resources which will allow them to conduct the research proposed in the grant application as the lead, independent PD/PI.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Only one application per school or college within a university will be accepted. For example, within a university, one application can be submitted from each of the schools of medicine, public health, arts and sciences, etc. If more than one application from the same grantee entity is submitted, none will be reviewed.

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

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

PD(s)/PI(s) who have a scientifically distinct R01 application pending at the time of the ONES application due date are eligible to submit a ONES application for a different project. However, since the ONES is limited to ESIs who do not have R01 support, PD(s)/PI(s) who receive a fundable score and accept funding for the regular R01 prior to the award of the ONES grant are not eligible to receive the ONES award.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Janice B. Allen, Ph.D.
Scientific Review Officer

Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3232
Fax: 301-451-5715
Email: Allen9@niehs.nih.gov (<mailto:Allen9@niehs.nih.gov>)

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Other Attachments: The PD/PI is expected to form an external advisory committee. Names of Advisory Committee members should not be listed in the application. This FOA uses the just in time concept for the External Advisory Committee members and potential members should not be contacted until after the review to avoid potential conflict situations in review. The application should indicate the areas of expertise and scientific and anticipated input, and any critical considerations in the selection of members, at the time of submission. As part of the just in time information prior to funding, the applicant will be asked to name the Advisory Committee members, and ask each to provide a letter outlining his/her expected role and the expertise to be provided to the PD/PI's research and career experiences.

NIEHS suggests an Advisory Committee structure such as the following: At least three scientists, two of whom are external to the Department, (one external to the University or Institution). One member should have research expertise to provide input into the exposure proposed for study, and one should be an individual who can provide input into either the translation of the research to human or clinical studies, or in the case of population studies, to the relevant exposure biology research findings in model systems.

The Advisory Committee is expected to meet at least annually to provide ongoing assessment of the progress of the research, to discuss future research goals, aims, and ideas, and to provide research career guidance to the awardee during the five years of the grant. It is expected that face-to-face meetings of the Advisory Committee will be convened at least twice during the five-year grant period (once in years 1-2, and once in years 3-4).

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed. The instructions for the biographical sketch should be followed. The Personal Statement should explicitly address the PD/PI's career track vision and long term research interests/objectives in the environmental health sciences.

Modular or R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed. The budget is to consist of two elements:

Element #1: Most PD/PIs should request up to \$250,000 in direct costs in all five years to conduct the research project. This budgetary level is expected to apply to most laboratory-based projects and those epidemiology and patient-oriented studies primarily involving secondary analysis. The PD/PI should budget sufficient travel costs within this amount to present the results of the research at a scientific meeting devoted directly to research in the environmental health sciences which is widely attended by other NIEHS grantees.

For research applications where the PD/PI can provide strong justification for research support above the base level of \$250,000, direct costs of up to \$400,000 may be requested. Examples where this higher budgetary level might be justified include epidemiologic studies including the active recruitment or follow-up of a new cohort, patient oriented research studies, and studies which involve especially expensive methodology. Increasing the scope of research is not a sufficient rationale for requesting the higher budgetary level. Since the purpose of the ONES grant is to further the career of ESIs, listing of previous mentors as co-investigators on the research project is also strongly discouraged, particularly if salary is requested. If these are included, a strong justification for their specific role in the conduct of the research should be provided. The independent research of the PD/PI, the role of the previous mentor and the focus on a new hypothesis should be made clear in the Research Strategy section of the application.

Element #2: In addition, the PD/PI may request a total of up to \$250,000 to be distributed over the five-year period, for a combination of equipment, resource development, career enhancement experiences and dissemination of research results. Equipment or resource development expenses must be justified on the basis of research proposed in the experimental plan or by the long-term research goals in environmental health sciences section of the research strategy. Career enhancement activities may include such items as short courses, visits to laboratories of other scientists, Gordon Conferences, and other enrichment activities. The Career Enhancement budget should include travel costs for external members of the advisory committee and may provide for a consulting fee to members of the advisory committee who are external to the department. In addition, the PD/PI should budget for travel to the NIEHS campus in Research Triangle Park each year to participate in a research symposium.

PD/PIs are expected to devote at least 6-person months per year to the grant. However, if during the tenure of this grant, should the PD/PI be successful in obtaining funding through another R01 or similar award, the effort on the ONES award may be negotiated with the NIEHS program staff down to no less than 3.6-person-months per year. In addition, the awardees' departments are encouraged to provide an additional 25% release time from clinical, teaching, and administrative duties in order to allow the awardees to devote a larger percentage of time to research efforts

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Research Strategy: In the research strategy section of the application, as part of the discussion of significance, applicants should specifically address the importance of the problem or critical barrier to progress relative to improved knowledge of how environmental exposures affect human health.

Applications that propose to study only model compounds must provide a clear, reasonable and specific description as to how research on the model compound will lead to a better understanding of the mechanisms involved in responses to specific environmental agents which are included in the mission responsibility of the NIEHS.

All applications should include a timeline for the proposed research and a schedule for the Advisory Committee meetings.

Letters of Support: The Chair of the Department where the PD/PI holds the primary academic appointment should provide a letter describing any tangible research support which has been committed to the PD/PI. This may include start up packages provided to the investigator, salary commitment, protected time for research, space and equipment allocations, core facilities which will be made available without charge-back, specialized training and mini-sabbatical experiences to promote career enhancement, etc. In addition, the letter should discuss the departmental commitment to protected research time for the applicant.

If a previous postdoctoral or research mentor remains in the same Institution as the PD/PI, a letter should be included in the application which outlines the respective roles of the applicant and the former research mentor in the design and conduct of the proposed research. The research mentor should also indicate how the proposed research program is expected to be independent from the research directions of his/her laboratory.

The strength of the institutional commitment will be considered a factor in the review of the application.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide

Appendix:

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

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

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

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

4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal](#)

[holiday \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11142\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

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

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11144\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

Important reminders:

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

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

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

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by National Institute of Environmental Health Sciences ([NIEHS \(http://www.niehs.nih.gov\)](http://www.niehs.nih.gov)). Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the Referral Office by email at [Allen9@niehs.nih.gov \(mailto:Allen9@niehs.nih.gov\)](mailto:Allen9@niehs.nih.gov) when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

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

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? How will the proposed research significantly advance knowledge in a defined problem in the environmental health sciences, specifically in terms of understanding the underlying disease processes relevant to environmental exposures, the human biology involved in the cause, prevention, or moderation of disease, or the population burden attributable to the exposure?

In addition, for applications proposing clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to

a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Based on the future goals section and the biographical sketch, does the PD/PI have the potential to make important research discoveries? Does the PD/PI demonstrate a long-term commitment to environmental health sciences research?

In addition, for applications proposing clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Are the anticipated results expected to lead to major research advances in the environmental health sciences or have important implications for clinical or environmental public health?

In addition, for applications proposing clinical trials

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

Approach

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

In addition, for applications proposing clinical trials

Does the application adequately address the following, if applicable?

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are

the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

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

In addition, for applications proposing clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

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

Specific to applications proposing clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSA, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not applicable

Revisions

Not applicable

Additional Review Considerations

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

Applications from Foreign Organizations

Not applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIEHS, in accordance with [NIH peer review policy and procedures](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

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

[Appeals](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html>) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Environmental Health Sciences Council. The following will be considered in making funding decisions:

- o Scientific and technical merit of the proposed project as determined by scientific peer review.
- o Availability of funds.

- Relevance of the proposed project to program priorities.
- Programmatic and geographic balance

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

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

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

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

Additionally, ICs may specify any special reporting requirements for the proposed clinical trial to be included under IC-specific terms and conditions in the NoA. For example: If the proposed clinical trial has elevated risks, ICs may require closer programmatic monitoring and it may be necessary to require the awardee to provide more frequent information and data as a term of the award (e.g., to clarify issues, address and evaluate concerns, provide documentation). All additional communications and information related to programmatic monitoring must be documented and incorporated into the official project file. Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA. ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov>). NIH expects registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that the application as well as all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols. Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11157](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157)) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11159](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159)). More information is provided at [Award Conditions and Information for NIH Grants](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11158](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158)).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html> (<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

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

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

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

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

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsr.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11170\)](http://www.fsr.gov) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11171\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Finding Help Online: <http://grants.nih.gov/support/> ([//grants.nih.gov/support/](http://grants.nih.gov/support/)) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82301](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301)) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

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

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

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

Telephone: 301-945-7573

Scientific/Research Contact(s)

Carol Shreffler, PhD

National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984-287-3322

Email: shreffl1@niehs.nih.gov (<mailto:shreffl1@niehs.nih.gov>)

Peer Review Contact(s)

Janice B. Allen, PhD

National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984-287-3232

Email: Allen9@niehs.nih.gov (<mailto:Allen9@niehs.nih.gov>)

Financial/Grants Management Contact(s)

Ashley Singh

National Institute of Environmental Health Sciences (NIEHS)

Telephone: 984-287-3323

Email: ashley.singh@nih.gov (<mailto:ashley.singh@nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11163](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163)) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11164](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?10-27-17) ([/grants/guide/WeeklyIndex.cfm?10-27-17](http://grants/guide/WeeklyIndex.cfm?10-27-17))

[NIH Funding Opportunities and Notices](http://grants/guide/index.html) ([/grants/guide/index.html](http://grants/guide/index.html))

Proposal Preparation and Submission: Activity 2

Internal Processing Form

Instructions

1. Work alone or in groups.
2. Read the write-up from the Principal Investigator.
3. Complete the Activity 2 worksheet in the Activity Workbook (starting on page 5)

Project Information:

Title: Randomized Cookie-Eating: Man vs. Animal

Project Dates: 01/01/2018-12/31/2019

Research Team

Principal Investigator: Elizabeth Lemon

Home Department: Nutrition, College of Agricultural and Environmental Sciences

Abstract

This study will research the impact on consumption of cookies based on varying levels of chocolate chip deliciousness in those cookies. Cows and humans will consume the cookies. Half of the cow and human study population will eat cookies with regular chocolate chips. The other half of the population will eat cookies with chocolate chips made from cocoa mutated to include UC Davis' proprietary *extradelicious* recombinant deoxyribonucleic acid. We will also send a sample of both cookies to our collaborators for them to conduct parallel research that will be included in our study.

Budget

Category	Year 1	Year 2
<i>Salary Support</i>		
PI salary at 100% for year 1	\$5,000	\$2,500
PI salary 50% for year 2		
U. of Australia Subcontract	\$3,000	\$3,000
EZ Research Oven	\$5,001	\$0
<i>Supplies</i>		
Chocolate Chip Cookies	\$0*	\$0*
Other Cookie Ingredients	\$759	\$999
<i>Indirect Costs</i>	?? (Dear SPO: just take what the feds say)	?? (Dear SPO: just take what the feds say)

Other Notes:

- Half of the study will take place in my garage at my home in Natomas, California, and the rest will be conducted at the Dairy Teaching and Research Facility at UC Davis.
- This is ground-breaking research. I have never even submitted a funding application for this work before today.
- I am submitting to ACME Labs, Inc. for a proposal they will submit in response to the “response to the “Pilot and Feasibility Clinical and Translational Research Studies in Digestive Diseases and Nutrition (R21 Clinical Trial Optional)” call (PA-18-099) from the National Institutes of Health (<https://grants.nih.gov/grants/guide/pa-files/PA-18-099.html>). The application is due to the sponsor by November 15, 2017.
- My grad students, the Spunkmeyer triplets, Otis, Keebler, and Amos (“Famous”), will really be running the study, I’m just going to oversee their design and implementation of the study, and I’ll probably ‘test’ their cookies.

**The chocolate chips cost \$1,000,000, but we will donate them because this is important research. 75% of the chocolate chips will be used in year 1 and 25% year in year 2. The chocolate chips technically belong to the Department of Uninnovative Science, but they weren’t using them, so somebody that’s not me took them because I think their Department Chair Chris Dye-Hixenbaugh would approve. Don’t ask me about it – talk to my Department Chair Shanna Nation Jose – she’s the real brains here!*

COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN:
 ORGANIZATION:
 University of California (UCD)
 Davis Campus

DATE:06/27/2017
 FILING REF.: The preceding
 agreement was dated
 06/21/2016

Davis, CA

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: INDIRECT COST RATES

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

EFFECTIVE PERIOD

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE (%)</u>	<u>LOCATION</u>	<u>APPLICABLE TO</u>
PRED.	07/01/2013	06/30/2014	54.50	On-Campus	Organized Res.
PRED.	07/01/2014	06/30/2015	55.50	On-Campus	Organized Res.
PRED.	07/01/2015	06/30/2016	56.50	On-Campus	Organized Res.
PRED.	07/01/2016	06/30/2018	57.00	On-Campus	Organized Res.
PRED.	07/01/2013	06/30/2018	26.00	Off-Campus	Organized Res.
PRED.	07/01/2013	06/30/2014	37.00	On-Campus	Other Spons Act
PRED.	07/01/2013	06/30/2014	24.00	Off-Campus	Other Spons Act
PRED.	07/01/2014	06/30/2015	38.00	On-Campus	Other Spons Act
PRED.	07/01/2014	06/30/2015	24.50	Off-Campus	Other Spons Act
PRED.	07/01/2015	06/30/2016	38.50	On-Campus	Other Spons Act
PRED.	07/01/2015	06/30/2016	24.50	Off-Campus	Other Spons Act
PRED.	07/01/2016	06/30/2018	39.00	On-Campus	Other Spons Act
PRED.	07/01/2016	06/30/2018	25.00	Off-Campus	Other Spons Act
PRED.	07/01/2013	06/30/2018	50.00	On-Campus	Instruction
PRED.	07/01/2013	06/30/2018	26.00	Off-Campus	Instruction
PRED.	07/01/2013	06/30/2018	22.70	Primate Ctr	Core Grant (1)
PRED.	07/01/2013	06/30/2018	54.40	Primate Ctr	Non-Core Fed(1)
PRED.	07/01/2013	06/30/2018	8.00	Off-Campus	IPA (2)

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE (%)</u>	<u>LOCATION</u>	<u>APPLICABLE TO</u>
PROV.	07/01/2018	Until Amended		(3)	

*BASE

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

- (1) Primate Center - see Section II: Special Remarks.
- (2) Intergovernmental Personnel Act Agreements.
- (3) Use the same rates and conditions as those cited for fiscal year ending June 30, 2018.