Proposal Preparation and Submission

e-Course Workbook

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SPONSORED PROGRAMS, OFFICE OF RESEARCH
UNIVERSITY OF CALIFORNIA, DAVIS
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Learning Objectives

After today’s class you should:

• Understand the **proposal process**.
• Know the information needed to **start preparing a proposal**.
• Know how to **submit a proposal to Sponsored Programs**.
• Know how to **check the status of your proposal** after it has been submitted to Sponsored Programs.
• Know what to do when the **proposal is approved/ready for submission**.

Common Acronyms

• BAA: Broad Agency Announcement
• BUA: Biological Use Approval
• CGA: Contracts and Grants Accounting
• COI: Conflict of Interest
• F&A: Facilities & Administrative rates; also referred to as indirect cost rate (IDC or ICR) or “overhead”
• FOA: Funding Opportunity Announcement
• IACUC: Institutional Animal Care and Use Committee
• IP: Intellectual Property
• IPF: Internal Processing Form in Cayuse SP
• IRB: Institutional Review Board
• PI: Principal Investigator
• RCI: Research Compliance and Integrity
• RCR: Responsible Conduct of Research
• RFA: Request for Applications
• RFP: Request for Proposals
• SBIR: Small Business Innovation Research
• SPO: Sponsored Programs unit in the Office of Research
• STTR: Small Business Technology Transfer
Funding Process at UC Davis

Funding Process Overview

Investigator has an idea, looks for funding opportunities → PI writes proposal → Department helps prepare details → Proposal sent to Sponsored Programs Office

Sponsored Programs reviews for campus compliance, sponsor compliance and terms & conditions → Proposal sent through Sponsored Programs to funding agency → Agency reviews proposal & decides whether or not to fund → Sponsored Programs reviews terms and conditions for conformity with UC policy and negotiates as needed

Sponsored Programs accepts award on behalf of the Regents → Department sets up the fund with Contracts & Grants Accounting → PI conducts research, spends award → Department monitors expenditures

Award ends & Final Reports are submitted → Sponsored Programs, in association with Contracts and Grants Accounting, completes close-out → PI uses results to develop more proposals

Sponsored Programs Functions

The Sponsored Programs Office (SPO) is responsible for:

- Reviewing and submitting proposals,
- Negotiating and accepting awards on behalf of the Regents and
- Drafting, negotiating, and executing (outgoing) Subawards for collaborative research.
Sponsored Programs Structure

Executive Director
Research Administration

Associate Director
Proposals

Assistant Director
Subawards and Negotiations

Associate Director
Awards

Team Leader

CAES, CBS, COE, Law, OR, SOE, UNEX

Team Leader

CLS, SOM, SON, SVM

Team Leader

eRA Analyst & Cayuse Help Desk

Proposal Intake Desk

Training Officer

Closeout Analyst

SPO Facilitation Team

Proposal Process Timeline

5 - 7 days before deadline
• Full proposal package arrives in SPO for review

2 - 3 days before deadline
• PI/Department incorporates SPO feedback
• PI/Department finalizes proposal package

1 - 2 days before deadline
• Submit final proposal to sponsor
• Note: SPO submits electronic proposals
Proposal Types
The proposal or application process may involve one or multiple phases that require submission of proposal materials. A sponsor may require submission of a letter of intent, preliminary proposal and/or full proposal/application.

Letters of Intent
Letters of Intent (LOIs) provide basic applicant and application information and are often used by sponsors to manage the review process. LOIs must be submitted to SPO if:

- Sponsor requires institutional approval; or
- Sponsor requires agreement to terms and condition at proposal stage; or
- Budget is required.

Pre-Proposals
Preliminary proposals or pre-proposals provide applicant and application information, project summary and other documents as requested by the sponsor. Sponsors often use pre-proposals to manage the review process or invite for full application. Similar to an LOI, submit a pre-proposal to SPO if the sponsor requires:

- Institutional approval; or
- Agreement to terms and condition at proposal stage; or
- Budget.

Full Proposals
Full proposals are the full application to the sponsor. It may be the only or the last phase of the proposal submission process. Always submit full proposals to SPO.

Types of Research and Other Sponsored Activity
The type of activity being performed in the project determines the Facilities and Administration (F&A) rate that should be applied to the budget. Identify the type of activity by reading the scope of work or asking the Principal Investigator (PI) if it is unclear. UC Davis' federal negotiated F&A rates are based on the following Activity Types.

Basic Research
Basic research aims to increase knowledge. The primary goal of the investigator is a fuller knowledge or understanding of the subject under study, rather than a clear or direct practical application. The end product is usually a report, although experimental hardware may be involved.

Example: Exploring alternative means of administering medicine other than by oral consumption. Discovering that medicine can be absorbed through the skin.

Applied Research
Applied research activity normally occurs after a period of basic research. It attempts to determine and expand the potentialities of new scientific discoveries or improvements in technology, materials, processes, methods, devices and technologies, and attempts to advance the state of the art.

Example: Clinical trials are developed to administer nicotine into the human body via patches.

Developmental Research
Developmental research is concerned with the systematic use of scientific and technical knowledge in the design, development, testing or evaluation of potential new products or services.

Example: Patches are developed and determinations made regarding types of medicines that can be absorbed via the skin, in what volume, etc.
Training
Training is the instruction of University students and/or employees in research or in the techniques or practices pertinent to a particular academic discipline. Training support is generally awarded in the form of individual fellowships (with stipends) or as institutional grants to conduct an entire training program.

Example: A fellowship given to a medical student to specialize in clinical research.

Public Service
Public service funding supports organizing, establishing, providing or enhancing the delivery of services to both University and/or non-University audiences.

Examples: Musical or dramatic productions, tutorial services to potential university students or the rehabilitation of drug users.

Other Sponsored Activities
Other sponsored activities are services/activities that the University provides or makes available which do not fit within the categories of research, training, or public service.

Examples: Support to organize conferences or symposia or to create or maintain research infrastructure, such as database to equip a newly built laboratory.

Award Types/Funding Mechanisms
Funding sponsors utilize various funding mechanisms, also referred to as award types. Correctly determining the award type is critical as this may affect the budget and other proposal components. Read the program and sponsor guidelines to determine the award type. Common award types include grants, contracts, cooperative agreements, gifts, Subawards and industry-sponsored clinical trials.

Grants
A grant is a type of financial assistance awarded to conduct research or other programs as specified in an approved proposal. Grants contains the following elements:

- The statement of work allows the PI significant freedom to change the emphasis within the general area of work as the project progresses.
- There is no substantial involvement anticipated between the sponsor and recipient during performance of the activity.
- Deliverables are minimal, consisting mainly of reports.
- Benefits of the project are to accrue to the nation and the world.

Grants often use the cost-reimbursement method of payment, thus any unexpended balance at the completion of the project is usually returned to the sponsor.

Contracts
A contract is an agreement to acquire services or perform research or other services that primarily benefit the sponsor. For an award to be considered a contract, it normally must contain all of the following elements:

- Detailed financial and legal requirements included with a specific statement of work.
- A specific set of deliverables and/or reports to the sponsor.
- Separate accounting procedures.
- Legally binding contract clauses.

Cost-Reimbursement
Under cost-reimbursement contracts, the sponsor agrees to give UC Davis actual dollars in an amount exactly equal to what UC Davis spends on allowable costs. If there is a limit to the contract amount, UC Davis must notify the sponsor if it appears all funds will be spent prior to completion of the work. The sponsor may decide to add more money to allow completion of the approved scope of work. Because the work is usually associated with the PI’s “reasonable efforts”, it poses the least risk to the University and, therefore, is the most desirable method of contracting. Unexpended balances are returned to the sponsor.
**Fixed Price/Rate**
Under a fixed price/rate contract, UC Davis agrees to provide a service or deliver a product at a fixed payment amount regardless of the actual costs. If the project costs more than what was proposed and agreed to, UC Davis absorbs the additional costs. On rare occasions, the University may be able to renegotiate the costs. Fixed price/rate agreements place the University at a greater risk. Any unexpended balance at the conclusion of a fixed price/rate contract remains with the University.

**Cooperative Agreements**
A cooperative agreement is similar to a grant, except that the sponsor has significant involvement in the project. The sponsor’s staff may actively participate in the programmatic design and, once awarded, will continue to actively participate or have substantial involvement in project activities.

**Gifts**
A gift is defined as a unilateral transfer of money, property or other assets by a donor to the recipient for the recipient’s ownership and use. The donor makes no claims on the recipient in connection with the gift. Gifts are processed and managed through the UC Davis [Office of University Development](#) and should not be submitted to SPO for review.

Gifts normally have the following characteristics:
- Significant freedom for the PI to change the emphasis within a general area of work.
- No deliverables are involved.
- Separate accounting procedures are not required.
- The donor has no audit rights.

**Subawards**
Subaward in this context refers to when UC Davis is a subrecipient on another institution’s proposal. For example, the University of Southern California is preparing a proposal in response to a funding opportunity from the NIH and has invited UC Davis to participate in a substantive way. At UC Davis, incoming subawards are treated the same as other incoming awards. Incoming subawards are classified as either a UC Multiple Campus Awards (MCAs) or subawards to non-UC campuses. A MCA is a form of subaward in that one UC campus or division transfers funds to another. The fund assignment for UC intercampus awards are based on the prime sponsor. UC campuses are reimbursed monthly via Intercampus Transfer of Funds (TOF).

UC Davis must prepare and submit a proposal to the organization (Prime Applicant) submitting the prime proposal. This proposal must be routed through SPO with internal forms and include, at a minimum:
- UC Davis’ scope of work,
- UC Davis’ budget and budget Justification,
- CVs of UC Davis key personnel and
- Other sponsor documents as required.

SPO will also need a copy of the prime sponsor guidelines as well as any communication from the proposing organization. The final proposal package will include a letter of institutional support or subrecipient commitment form from UC Davis.

**Clinical Trial Contracts with Private Pharmaceutical Companies**
A clinical trial combines research with the testing of practical applications in biomedicine. Clinical Trials are usually funded by pharmaceutical companies seeking approval of new pharmaceutical products or treatments by the Food and Drug Administration (FDA) and are usually fixed-rate agreements.

Human subject clinical trial contracts with private pharmaceutical companies are handled by [UC Davis Health Systems Clinical Trials Contracts](#). All other clinical trials are handled by [SPO](#) in the Office of Research.
Sponsor Types

Each sponsor type is subject to different policies and regulations that impact the format and content of a proposal. UC Davis commonly receives funding from federal, State of California and local government, non-profit and for-profit sponsors.

Federal

All federal agencies must comply with the requirements of the U.S. Office of Management and Budget (OMB) in developing the grant/contract policies incorporated in the awards issued to institutions such as UC Davis. The OMB Circular that most directly impacts grant proposal budget preparation is OMB Uniform Guidance. While each federal sponsor must adhere to OMB circulars, OMB permits each sponsor to implement the requirements that best suit their needs, which may result in differences from sponsor to sponsor. Also, a single sponsor may have multiple variations of a policy to cover specific grant programs, so it is important to read all of the sponsor specific guidelines and policies for proposal budget and/or re-budgeting limitations and prepare your budget accordingly.

When applying to a federal sponsor, note the following:

- Use UC Davis’ federally-negotiated F&A rate unless a non-standard rate is explicitly stated in the program announcement or other sponsor guidelines.
- Budget items must be reasonable, allowable and allocable.
- Most Federal proposals are submitted electronically via Cayuse 424.
- Legally binding contract clauses may be included in a Request for Proposals (RFP) and must be reviewed prior to submission. Contact SPO (proposals@ucdavis.edu) early regarding a federal contract proposal or other proposal with terms and conditions listed in the guidelines.

State and Local Government

State of California and local government proposals usually result in contracts. Often the program officer at the State or government agency and PI have discussions independent of SPO, and an informal or draft budget is submitted without SPO review and approval. That budget, often incorporated into the contract, may not be fully costed, so SPO may need to renegotiate the budget to secure full costs, including the full F&A. If unsuccessful, the difference in F&A must be taken from the direct costs. For this reason, SPO recommends the PI’s discussion with a sponsor’s program officer be limited to programmatic issues, and that draft budgets be submitted for SPO review before submission to the sponsor.

When applying to a State or local government agency, note the following:

- State and local government contract terms are restrictive and require prior approval for the smallest changes in the project or budget. Care should be taken in preparing the budget to minimize the need for post-award re-budgeting.
- Unless a special exception is requested from UCOP for the particular agency/program, the full applicable rate for the project being conducted must be requested. Not all State programs are eligible to receive a waiver from UCOP - even if the program guidelines limit indirect costs.

Non-Profit

While many non-profit sponsors reflect the general principles set out in federal guidelines, they are not restricted by the OMB circulars. Many non-profit sponsors implement their own policies, creating a wide range of regulatory and procedural compliance requirements. Charges not allowable on federal proposals may be allowable on foundation proposals. However, the reverse may also be true. Closely, read all of their program and sponsor guidelines.

Non-profit sponsors often limit or even prohibit the F&A (or indirect) cost rate applied. UC Davis may, but not always, accept reduced F&A rates based on the non-profit, philanthropic status as documented in the organization’s written policy. This exception is processed by a SPO analyst and reviewed by the University of California Office of the President (UCOP).
Most awards from for-profit sponsors are issued in the form of a contract. Sponsored Programs will review and negotiate the terms and conditions in consultation with the PI prior to submission to assure that terms are acceptable and comply with Federal and State laws and research policies, as well as University policies.

When applying to a for-profit entity, note the following:

- Contract terms are restrictive and often require prior approval for changes in the project or budget. Care should be taken in preparing the budget to minimize the need for post-award re-budgeting.
- F&A rates for proposals with for-profit sponsors should use the appropriate UC Davis Federally Negotiated Rate.
- Sponsor may limit the purchase of equipment or maintain title to equipment purchased after project completion.
- Confidentiality agreements that require the recipient of sponsor information to keep that information in confidence may be required.
- Cost-sharing is generally not allowed; therefore, all associated faculty and staff effort should be charged to for-profit projects.

**F&A Costs**

UC Davis’ negotiated F&A rates should be used unless otherwise indicated by the sponsor. In addition to the F&A rate, there are multiple indirect costs bases that are used. An indirect cost base is the amount of direct costs to which indirects must be applied.

Common indirect cost bases used as UC Davis are:

- **Modified Total Direct Costs (MTDC):** Certain costs such as, equipment and subawards to other UC campuses, are not subject to indirects and are excluded from the F&A/indirect cost base. All negotiated rates at UC Davis are applied on a MTDC base, and the specific excluded costs are listed in the federally negotiated rate agreement. Non-profit sponsors also often require an MTDC base, but may define MTDC differently than the federal government. For example, a private foundation may limit indirect costs to 10% of all direct costs excluding personnel.
- **Total Direct Costs (TDC):** Total Direct Costs are calculated the same as MTDC. However, there are no direct cost exclusions other than subawards to other UC campuses. Because a TDC base differs from the base defined in our federally negotiated rate agreement, it should only be used if the sponsor specifically requires it.
- **Total Costs (TC):** As with TDC, only use TC as an indirect cost base if the sponsor specifically requires it or is silent on the base type (e.g., “10% indirect costs.”). When using a TC base, F&A is applied to the total project costs (direct + indirect.) Note that subawards to other UC campuses are always excluded from the F&A base regardless of the base type.
Getting Started

Sponsor and Program Guidelines

Most sponsors provide a written call for proposals that will serve as a roadmap for the proposal submission. Calls for proposals are used by both public and private sponsors, and may be called a variety of different things, including:

- Program Announcements (PA)
- Broad Agency Announcements (BAA)
- Request for Applications (RFA)
- Request for Proposals (RFP)

Identify and carefully read all of the relevant sponsor and program guidelines. Additionally, sign-up for email alerts from the sponsor if they are available, and check for updates in the call for proposals regularly as sponsors sometimes change their guidelines after they have been issued.

The guidelines will assist you in determining important information, such as:

- Proposal submission deadlines and method
- Institutional and PI eligibility, including whether there are any limits to the number of proposals a PI or institution may submit
- Funding limitations including maximum dollars that can be requested, F&A restrictions, and any other funding details
- Application forms and formatting
- Required proposal components

SPO recommends reviewing guidelines two or three times, using the Call for Proposals Checklist. This checklist helps identify important information in a call for proposals and is also helpful when reviewing a sponsor’s general guidelines. Use highlighting pens, sticky notes and flags to tag instructions or guidance of importance.

Take the proposal guidelines seriously! Sponsors may return proposals without review if all the guidelines are not met. Also, provide Sponsored Programs with all guidelines when submitting the proposal in Cayuse SP.

Common Sponsor Guidelines

While the sponsor guidelines must be read each time a proposal is being prepared, there are some common sponsor guidelines – such as:

1. PI Eligibility
   - Sponsors may limit PI eligibility based on their career stage, such as offering opportunity specifically to early or established investigators.

2. Limited Submissions
   - Sponsors may limit the number of applications an institution may submit. In these cases, internal pre-proposals must be submitted to the Limited Submissions Program in the Office of Research before submitting a proposal to SPO. Once an investigator is selected through the Limited Submissions Program, they will proceed with routing the application as usual, submitting through Cayuse SP to Sponsored Programs for review.

3. Submission Method
   - Sponsors will indicate the method for submitting applications, including if electronic submission is allowed or required and which electronic Research Administration system(s) (eRA) should be used.
     - Cayuse 424 is required for all Grants.gov submissions except:
       i. NSF FastLane/Research.gov should be used for NSF
       ii. ASSIST may be used for NIH
       iii. NASA NSPIRES should be used for NASA
   - Other sites may be used as mandated by the RFA/sponsor guidelines (e.g., EERE for some DOE submissions)
Tips and Tricks

- Always check the requirements/guidelines.
  - Even if you have submitted a proposal to the specific program and or sponsor before.
  - Sponsors frequently update their guidelines.
- Read all guidelines carefully.
  - Review two to three times.
  - Including the links to other guidelines/instructions.
- Email proposals@ucdavis.edu to clarify complexities.
- Create a timeline.
- Create a checklist.
- Subscribe to Sponsor listservs.

Additional Notes:
Activity 1: Call for Proposals

Use the request for proposals (RFP) from the National Institutes of Health (NIH) on the following pages to answer e-Course questions.
Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations
National Institute of Environmental Health Sciences (NIEHS (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) Research Project Grant

Announcement Type

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

Scientific Merit Review
June/July 2018, June/July 2019, June/July 2020

Advisory Council Review
October 2018, October 2019, October 2020

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), 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/)). 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/) to track your application. Check with your institutional officials regarding availability.


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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](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) 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)

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](https://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](https://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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System (DUNS)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number,
applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be
used for all registrations, as well as on the grant application.

- **System for Award Management (SAM)** ([https://www.sam.gov/portal/public/SAM/](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.

- **eRA Commons** ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](//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** ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82300](//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](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](//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)).

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), 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.


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

Page Limitations  
All page limitations described in the SF424 Application Guide and the Table of Page Limits (//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](https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-001.html) 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](https://grants.nih.gov/grants/guide/rfa-files/RFA-ES-18-001.html)
holiday (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 (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 (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. (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 (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 (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 (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 (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.
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)). 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 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 (http://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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

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., CTSAs, 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 (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 (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 (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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

Appeals (//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:
- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
3. Anticipated Announcement and Award Dates

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

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (http://grants.nih.gov/grants/guide=url_redirect.htm?id=11158) 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


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) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)


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

Scientific/Research Contact(s)
Carol Shreffler, PhD
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3322
Email: 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

Financial/Grants Management Contact(s)
Ashley Singh
National Institute of Environmental Health Sciences (NIEHS)
Telephone: 984-287-3323
Email: ashley.singh@nih.gov

Section VIII. Other Information

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.
Preparing and Submitting the Proposal to Sponsored Programs

Determine Institution and Principal Investigator Eligibility

Check the sponsor and programs guidelines to determine if the institution (UC Davis) and the PI are eligible to apply to the funding program.

Institutional Eligibility

In some cases, sponsors place restrictions on what types of institutions are eligible to apply for funding or how many proposals an eligible institution may submit. UC Davis is eligible to apply for funding if the guidelines state that Academic Institutions and/or 503c institutions may apply. If the sponsor limits the number of proposals/applications an institution may submit, the Principal Investigator must first apply to the UC Davis Limited Submissions Program. After being selected by the Limited Submissions Program as the campus applicant, the Principal Investigator must submit his/her proposal to SPO for review before submitting to the sponsor.

Principal Investigator Eligibility

UC policy (PPM 230-01 and PPM 230-02) states that only qualified members of the Academic Senate and appointees in other eligible title groups listed in the UC Academic Senate policy may submit proposals without the need for an exception. View the UC Davis Academic Personnel Attributes Chart for assistance in determining if a person has PI status by policy or needs an exception. In addition, a sponsor may have principal investigator eligibility requirements that need to be met, such as requiring the principal investigator to be a Young Investigator. Sponsor-specific principal investigator eligibility requirements can typically be found in the funding announcement. If the principal investigator is eligible to apply based on the sponsor requirements but does not have PI status at UC Davis, complete and upload Form 105 as Proposal Attachment before submitting the Cayuse SP Proposal/Internal Processing Form (IPF).

Coordinate the Proposal

Although PIs are ultimately responsible for the accuracy and quality of the content of their proposal, departmental contract ad grant administrators assist in organizing and creating the required information and documents.

1. Gather the necessary information, such as the RFP and all other guidelines from the sponsor.
2. Get organized for the proposal preparation process by:
   a. Coordinating tasks with the PI. Use the New Proposal Questions checklist to help get started.
   b. Determining the relevant sponsor and university requirements, such as the required proposal components and institutional approvals.
   c. Establishing deadlines for the necessary components.
      i. Consider creating a checklist or timeline to track who is responsible for and the status of the necessary proposal components.
3. Prepare and collect all proposal components.
   a. Remember that consistency is critical. Do not re-use components, such as budgets and biosketches, from previous proposals.
   b. If the proposal includes (outgoing) subawards, collect the necessary subaward components before submitting the proposal to SPO.
4. Review the draft proposal before submitting it for SPO review.
   a. Ensure all required documents and other information are included. Use the Proposal Preparation Checklist.
   b. Review for formatting, page limits, etc. as SPO does not provide that level of review.
   c. Compare the budget forms to the budget justification to ensure they match
5. Submitting your proposal to SPO initiates coordination process with our office.
   a. The assigned SPO proposal analyst will review the proposal and provide feedback.
   b. The PI and contract and grant administrator review and incorporate SPO feedback.
   c. Once SPO has approved the proposal for submission and the PI provides concurrence that the proposal is final, SPO generally submits the proposal to the sponsor.
Standard Proposal Components

The program and sponsor guidelines will indicate the required proposal components and formatting. Pay special attention to all sponsor guidelines, as failure to do so can result in rejection of the proposal. Common proposal components that may be required by a sponsor include a cover page, abstract, project description, budget and budget justification, biosketches, references, facilities and resources, current and pending support, appendices, representations and certifications, subaward materials if outgoing subawards are included, Financial Conflicts of Interest (COI) items and other internal documents.

Cover Page
The cover page may also be called a face page, proposal title page, signature page or possibly another name, depending on the sponsor. Most granting agencies have standard forms or formats that should be used. If a standard form is not required, a title or face page should contain enough information to clearly identify the proposed project. Sponsored Programs has an optional cover page to use if one is not provided by the sponsor.

Abstract
The abstract is also referred to as a project summary. The abstract is an overview or summary of the project. Many granting agencies give specific instructions for the format and content of the abstract. Generally, it should be able to stand alone as a description of the project. The abstract should describe what will be done, how it will be done, the anticipated results and this significance of the project.

Project Description
The project description, research strategy or narrative is often referred to as the “body” of the proposal. Most agencies have specific guidelines or instructions for preparing and submitting this section of the proposal. These guidelines often detail the requested content and required formatting such as number of pages, margin size, and font type.

Budget and Justification
The budget should reflect the PI’s best estimate of the actual cost of conducting the scope of work. This includes the materials and supplies as well as indirect costs. Most agencies have specific budget forms or formats. The project description and the budget should be consistent with each other - that is, funds for activities described in the narrative should be requested in the budget.

Biosketches (CV)
Some proposal guidelines require a specialized format for biographical sketches of key personnel and other important collaborators who will be working on the project. Some agencies impose a page limitation for each biographical sketch.

References
It is recommended that the PI list full references for any citations made in the body of the proposal. Some agency guidelines require specific formats.

Facilities and Resources
This section describes equipment, labs or other resources that are already available to the PI for the project. It should explain why the physical facilities, resources and equipment described make this an advantageous location for the project.

Current and Pending Support
Many sponsors require, and closely review, a current listing of pending proposals and funded awards for all key personnel at time of proposal or time of award. It is important that the PI’s time does not exceed available research effort or a maximum of 100% effort. Federal sponsors are also concerned with the sources of funding, so PIs should ensure all sources are detailed.

Appendices
It is important to determine if a sponsor allows appendices to be submitted with the proposal. Some agencies (the National Science Foundation and National Institutes of Health, for example) restrict the submission of appendices, or have specific guidelines for inclusion with a proposal. Some agencies restrict the types and/or numbers of items that may be included.
Representations and Certifications

Some federal sponsors require that applicants provide assurances or sign certifications of compliance with a variety of Federal Policies whether or not they are applicable to the project. Examples include regulations regarding civil rights, lobbying, drug-free workplace, debarment and suspension and procurement integrity. Certifications are also required for COI and, under the Pro Children act of 1994, verification that smoking is prohibited in buildings where services are provided to children younger than 18. All assurances must be certified by an authorized individual, such as a Sponsored Programs analyst or associate director.

Standard Subaward Materials

If UC Davis is submitting a proposal that includes a subaward to another institution, the proposal package submitted for SPO review must include the following for each subaward:

1. Appropriate Subrecipient Commitment Form
   a. Multi-Campus Commitment Form if the subrecipient is another UC campus.
   b. Federal Demonstration Partnership (FDP) Subrecipient Pilot – Supplemental Project Information Form if the subrecipient is included among the list of institutions participating in the FDP Expanded Clearinghouse.
   c. Subrecipient Commitment Form if the subrecipient is a non-UC and non-FDP Member subaward institution.

2. Subrecipient’s statement of work (SOW), including a clear and detailed description of the work to be performed, the proposed timelines and deliverables.

3. Subrecipient’s Budget and Budget Justification, including the subrecipient’s direct and indirect costs, calculated in accordance with sponsor guidelines using the subrecipient’s approved F&A and fringe benefit rates, and verifying any committed cost sharing.

4. If the subrecipient does not have a current federally negotiated F&A rate in place they have the following options:
   a. Use a de minimis F&A rate of 10% MTDC,
   b. Negotiate a F&A rate with their Cognizant Federal Agency (must be approved at time of proposal to use at time of proposal) or
   c. Elect not to charge F&A.

5. If the proposal is for a Federal contract (not a grant or cooperative agreement):
   a. Sole Source Justification - Completion of this form is mandatory when proposing subcontract(s) under a federal contract for sponsored activity and the subcontract is being issued without seeking multiple bids OR if subaward was not included in the original proposal submitted to sponsor under a grant or cooperative agreement. See Uniform Guidance Section 200.324 or the Federal Acquisition Regulation 6.302-1 for additional guidance.
   b. Any additional elements that may be required by UCD’s sponsor for inclusion in the proposal.

View the Handbook for Submitting a Proposal with Subawards for detailed instructions on preparing and submitting the proposal to SPO in Cayuse SP and to the sponsor in Cayuse 424.

Financial Conflict of Interest (COI) Requirements

Some sponsors, such as federal agencies, require disclosures of financial conflicts of interest. The Research Compliance and Integrity (RCI) within the Office of Research is responsible for managing the COI process at UC Davis.

All financial COI disclosures are filed online in the e-COI system.

1. Form 800 is required at the proposal stage for proposal to government, non-PHS and some other sponsors if human subjects are involved.
2. PHS COI and Online Training are required for awards from Public Health Science (PHS) agencies and some other sponsors. This is verified at the award stage.
3. Form 700-U is required for awards from non-government/private sponsors, such as private foundations, industry and for-profit universities. This form should be submitted at the just-in-time and award stages or before requesting and Advance Account (pre-award spending).
Other Internal Proposals Documents

Other internal documents/forms may be required. Example of other documents are:

1. Letter of Support for cost-share commitments. View guidance for submitting proposals that involve cost sharing for the specific documentation requirements.

2. From 105 to request exception to PI status.

3. Informed Participation/Special Individual Agreement if there are terms and conditions that would generally not be acceptable to UC Davis (or the Regents). Work with your PI to facilitate signatures when requested by Sponsored Programs. Request this form from your SPO analyst if needed.

4. Protocol Certification form may be requested by the assigned SPO analyst if the proposal involves human or vertebrate animals.

Develop the Budget

Creating the project budget is generally the most time consuming and complicated part of the proposal preparation process for a department administrator. Work with the PI to find out what needs to be included in the budget: personnel, equipment, travel, supplies, fees, subcontracts, etc. Once you are given some rough parameters, generate a first draft of the budget and forward it to the PI for review. Review the Preparing a Proposal Budget Toolkit for detailed guidance.

Keep the following compliance points in mind when you’re completing the budget:

- Charging Practices
  - Regardless of whether the funding is from a federal, other government, or private sponsor, you must adhere to the applicable Charging Practices.
  - Are the costs on the budget allowable and allocable? OMB Uniform Guidance provides guidance on both the allowability and allocability of expense items on grants.
  - For more details about charging practices, consider taking the Costing Principles class training offered by Extramural Funds Accounting.

- Indirect Costs
  - Apply the applicable federally negotiated indirect cost rate, UC negotiated state rate, or work with Sponsored Programs to determine if requesting a waiver from the University of California Office of the President (UCOP) is appropriate.
  - It is the policy of the University to recover the full costs of doing research (UC Davis PPM 230-03). To request an exception to the negotiated rates, a request must be sent by the Office of Research, Sponsored Programs to UCOP for review. UCOP has specific guidelines for requesting waivers, and not all projects qualify for consideration. For example, projects funded by for-profit sponsors do not qualify under most circumstances.

Budget Justification

Once the budget is final, generate the budget justification based on the budget figures. Generate a first draft and forward it to the PI for review and approval. This may take several reiterations. Consider completing our two-part proposal budget series: the online class Preparing a Proposal Budget: Concepts and the in-person class Preparing a Proposal Budget: Lab and/or budget training sessions. Visit the Training page for more information about these courses and training sessions.
Submiting to Sponsored Programs

Prepare the Proposal Package for Submission

Review our Proposal Preparation page for more help with preparing and submitting proposal packages to SPO for review in Cayuse SP. Note that if you are submitting to a federal sponsor, the proposal/application should be submitted to the sponsor in Cayuse 424, FastLane (NSF), NSPIRES (NASA), or ASSIST (NIH).

The proposal package should include:

1. Proposal cover page
2. Proposal guidelines
3. Proposal scope of work
4. Budget spreadsheet
5. Budget justification, if required by the sponsor
6. Other applicable internal documents
   a. Cost Share Commitment letters/emails: Review the guidance for submitting proposals/IPFs that involve cost sharing document to determine the required documentation for each type of cost-sharing.
   b. Exception to PI Eligibility
7. Electronic application package, if applicable
   a. Follow agency guidelines for electronic submission and allow ample time for the registration process if needed. New registrations can take several days.
   b. Remember that even if the proposal submission system will allow a PI or department staff member to submit the proposal to the sponsor, UC policy still requires that the proposal be processed through SPO prior to submission to a sponsor.
   c. Ensure there is at least one contact person available prior to the to address any last minute submission issues.
8. Additional sponsor-specific items, if applicable
9. Subaward information, if applicable
   a. The subcontracting institution will need to provide a scope of work, budget, budget justification, commitment form and any other required documents. Refer to our Subawards webpage for additional guidance.
10. Compliance documents, if applicable
    a. Some sponsors require that project personnel complete a financial disclosure form. The disclosures may be filed online.
       i. Form 800 must be completed by all senior personnel on proposals to the National Science Foundation, projects where the sponsor has adopted federal financial disclosure regulations and projects with human subjects. It is required to be completed at the proposal stage per federal guidelines. Failure to complete at time of proposal could result in withdrawal of the proposal or delay award processing.
       ii. Form PHS is required to be completed by all investigators on Public Health Service (PHS) projects, including those funded by NIH and CDC. Other non-federal sponsors such as the American Cancer Society have adopted its use as well, as indicated in program guidelines. A complete list sponsors requiring Form PHS is available on the Office of Research website.
       iii. Find details about the disclosure requirements by visiting the Conflicts of Interest in Research page. This page provides guidance about which forms must be completed for your project, as well as links to policies, regulations and forms. For further details about financial disclosure forms, you should contact the Research Compliance and Integrity unit.

Use the Proposal Preparation Checklist to ensure the required items for SPO review are included.
Submit the Proposal to SPO

For proposals to receive a full review by Sponsored Programs, they must be received **5-7 business days** prior to requested return/submission date.

1. Complete the Internal Processing Form (IPF)/Proposal in Cayuse SP.
   - Complete all *applicable* fields in Cayuse SP; even if they are not indicated as a required field.

2. Upload the Proposal Attachments in Cayuse SP and give your SPO analyst access to the proposal in the sponsor’s submission system, if applicable. Use the Proposal Preparation Checklist to ensure the required items for SPO review are included.

3. At a minimum, SPO needs access to the following for the proposal to be assigned for review:
   - Proposal Scope of Work
   - Budget Spreadsheet
   - Budget Justification, if required by the sponsor
   - Subcontractor information
   - Other internal documents, as required

4. Once the proposal package is ready to submit for approval by the department chair and/or dean’s office and review by SPO, submit the proposal for routing.
   - If the proposal involves the School of Medicine or the College of Veterinary Medicine, the Dean will need to approve your proposal before it can be reviewed by Sponsored Programs. Please keep this in mind when considering submission deadlines.
Activity 2: IPF

Use the project scenario below to answer e-Course questions 11-17.

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salary Support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI salary at 100% for year 1</td>
<td>$5,000</td>
<td>$2,500</td>
</tr>
<tr>
<td>PI salary at 50% for year 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U. of Australia Subaward</td>
<td>$3,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>EZ Research Oven</td>
<td>$5,001</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Supplies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chocolate Chip Cookies</td>
<td>$0*</td>
<td>$0*</td>
</tr>
<tr>
<td>Other Cookie Ingredients</td>
<td>$759</td>
<td>$999</td>
</tr>
<tr>
<td><strong>Indirect Costs</strong></td>
<td>Use the federally negotiated F&amp;A rate</td>
<td>Use the federally negotiated F&amp;A rate</td>
</tr>
</tbody>
</table>

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.
  - I will submit the UC Davis subaward proposal to ACME Labs and ACME Labs will submit the full proposal to NIH.
    My subaward proposal is due to ACME on November 11, 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!
Sponsored Programs Proposal Review

The assigned SPO analyst will review the proposal package to ensure adherence to campus and sponsor requirements. Additionally, the analyst will also review any terms and conditions that must be agreed to at the proposal stage to ensure they are acceptable to the University and to the PI.

Campus Requirements

To determine adherence to campus requirements, SPO reviews the following. Required items are indicated with an asterisk (*). The other items on this list are recommended at the time of proposal submission.

1. **IPF Certifications and Authorizations** *
   a. The Lead PI and co-PIs must certify the proposal.
   b. The unit head of the administering unit/department and all involved senior personnel listed on the Investigators/Research Team tab must authorize the proposal.
   c. The deans of the Schools of Medicine or Veterinary Medicine must also authorize the proposal if it involves senior personnel from their school.
   d. The sponsor may require a minimum level of effort be committed by the PI.

2. **Budget Information** *
   a. The F&A rate and base should be correct and accurately applied.
   b. The calculations should be accurate, including benefits and Graduate student fees and nonresident tuition.
   c. The costs should be allowable and allocable.
   d. The budget and budget justification should match.
   e. The subaward/subcontract costs should be accurate.
   f. Cost-sharing documentation, if applicable.

3. **Scope of Work** *
   a. The activity type determines the F&A rate to apply to the budget.
   b. The final scope of work* must be received before the proposal is submitted to the sponsor.

4. **Subaward/Subcontractor Items**, if applicable
   a. The subrecipient(s) is/are identified on the Subcontractor tab of the IPF.
   b. All necessary items must be provided.

Sponsor Compliance

SPO reviews the following to determine sponsor compliance. Required items are indicated with an asterisk.

1. **Eligibility** *
   a. The PI and institution must be eligible to apply for funding under the program. If the PI is not eligible to undertake sponsor research, Form 105-A is required.
   b. If the program is a Limited Submission, the SPO analyst will ensure the PI was selected through the Limited Submission Process.

2. **Sponsor and Program Administrative Guidelines** *
   a. Required Proposal Components per sponsor guidelines.
   b. Draft Scope of Work* must be submitted before submitting the IPF for routing and approval.
   c. Other items are required before submission to the sponsor.
   d. Note that SPO does not review formatting, the table of contents, page margins, font or pitch, line spacing, characters per inch, page limitation, spelling or grammar.

3. **Regulatory Compliance**, if applicable, as entered on the IPF
   a. IRB Approval
   b. IACUC approval
   c. BUA approval, if rDNA or pathogenic agents
   d. Stem Cell Use approval
4. Financial COI Items
   a. Form 700-U, if applicable
   b. Form 800, if applicable*
   c. PHS COI and Online Training*

Terms and Conditions

In order for SPO to determine if the sponsor requires terms and conditions be agreed to at the time of proposal, SPO will review the sponsor and program administrative guidelines* as follows:

1. Terms and conditions must be acceptable to the UC Regents and to the PI.
2. If there are any potentially problematic terms, SPO will request Informed Participation.*

Next Steps

Once the proposal/Cayuse SP Internal Processing Form (IPF) is submitted for routing, check the routing and approval status in Cayuse SP.

- View the Approvals tab of the IPF to see who has/has not certified and authorize the IPF.
- Find the assigned SPO analyst. The SPO analyst is listed in the Specialists field. The first person listed is the assigned SPO proposal analyst. The second person listed, if applicable, is the assigned SPO award analyst.
- View the Notes tab for notes from SPO regarding outstanding items, etc.

Sponsored Programs will review the proposal package and notify the PI and department administrator when the proposal is approved for submission if the PI is submitting the proposal to the sponsor or when it has been submitted (by SPO) to the sponsor.

Please ensure that there is at least one contact person available (e.g., department administrator or PI) prior to the sponsor deadline. There are often small errors, such as page limits exceeded or missing information, which will cause a proposal to be automatically rejected by a sponsor’s proposal submission system. In these cases, proposal analysts in SPO will work quickly to alert the contact person, so the issue can be resolved.
Resources

Policy Links

- UCOP RAO-95-01: [http://researchmemos.ucop.edu/index.php/site/memoDetail/memo_id/RAO-95-01](http://researchmemos.ucop.edu/index.php/site/memoDetail/memo_id/RAO-95-01)

Websites and Online Systems

- Cayuse SP and 424: [https://ucdavis.cayuse424.com](https://ucdavis.cayuse424.com)
- eCOI System: [https://or-forms.ucdavis.edu/](https://or-forms.ucdavis.edu/)
- Grants Facilitation Unit, School of Medicine: [https://www.ucdmc.ucdavis.edu/medresearch/grant_facilitation.html](https://www.ucdmc.ucdavis.edu/medresearch/grant_facilitation.html)
- Grant Writing Resources: [https://research.ucdavis.edu/resources/grantwriting/](https://research.ucdavis.edu/resources/grantwriting/)
- Interdisciplinary Research Support unit, Office of Research: [https://research.ucdavis.edu/offices/irs/](https://research.ucdavis.edu/offices/irs/)
- Office of Research Website: [http://research.ucdavis.edu](http://research.ucdavis.edu)
- Sponsored Programs Research Administration Kiosk (SPARK) Website: [http://spark.ucdavis.edu/training/](http://spark.ucdavis.edu/training/)
- SDPS Classes Offered by Sponsored Programs: [https://research.ucdavis.edu/proposals-grants-contracts/spo/spo-training/](https://research.ucdavis.edu/proposals-grants-contracts/spo/spo-training/)
- Training Sessions at Research Park: [https://research.ucdavis.edu/proposals-grants-contracts/spo/spo-training/](https://research.ucdavis.edu/proposals-grants-contracts/spo/spo-training/)
- UC Davis Limited Submissions Program: [https://research.ucdavis.edu/proposals-grants-contracts/funding-opportunities/limited-submission/](https://research.ucdavis.edu/proposals-grants-contracts/funding-opportunities/limited-submission/)

Documents, Toolkits and Handbooks

- Proposal Preparation and Submission Toolkit:
Sponsored Programs Forms