

# **Pre-Award Administration for Sponsored Projects**



University of Colorado  
Denver | Anschutz Medical Campus

## **Pre-Award Administration for Sponsored Projects**

Course Description: This course reviews the pre-award phase by examining sponsor requirements, university policies and procedures, proposal development, and the sponsor selection process.

### Objectives:

After completion of this course, you will be able to:

1. Explain the roles and responsibilities of a research administrator in the pre-award phase
2. Analyze a funding opportunity notice
3. Build a proposal in InfoEd
4. Develop a proposal budget in InfoEd
5. Apply the university's routing and submission procedures to a proposal
6. Describe the sponsor review and award process

## **TABLE OF CONTENTS**

### **1. The Pre-Award Phase**

- 1.1 Overview of the Pre-Award Phase
- 1.2 Types of Sponsored Projects
- 1.3 Overview of the University's Pre-Award Process

### **2. Funding and Research Development**

- 2.1 Locating Funding Opportunities
- 2.2 Types of Proposals and Applications
- 2.3 Funding Opportunity Announcements
- 2.4 Exercise – Reviewing a Funding Opportunity Announcement

### **3. Proposal Development**

- 3.1 InfoEd
- 3.2 Roles and Responsibilities During Proposal Development
- 3.3 Project Management
- 3.4 Proposal Components
- 3.5 Narrative Review
- 3.6 Exercise – Developing a Proposal Timeline

### **4. Budget Development**

- 4.1 The Role of the Research Administrator in the Budget Development Process
- 4.2 The Budget's Role in the Award Lifecycle
- 4.3 The Budget Development Process
- 4.4 Exercise: Calculating Salaries
- 4.5 Cost Sharing or Matching
- 4.6 Program Income
- 4.7 Payment Types
- 4.8 Foreign Currency Conversion
- 4.9 Exercise – Developing a Budget

### **5. Application Routing and Submission Process**

- 5.1 Routing a Proposal to OGC
- 5.2 Purpose of Routing
- 5.3 Xenia Email
- 5.4 OGC Review
- 5.5 Submitting the Proposal to the Sponsor
- 5.6 Exercise - Completing the Routing Form

### **6. Sponsor Review and Award Process**

- 6.1 Sponsor Review and Evaluation
- 6.2 Just-in-Time Requests
- 6.3 Award Process

Appendix A - Acronyms

Appendix B - Glossary

Appendix C - Elements of a Federal Funding Opportunity Announcement  
Appendix D - Institutional Information  
Appendix E - Overview of InfoEd ERA  
Appendix F - Routing Form  
Appendix G - NIH Information  
Appendix H - Sample Assistances Listing (CFDA) Program Description  
Appendix I - Federal Funding Opportunity Announcement  
Appendix J - Sample Non-Federal Funding Opportunity Announcement  
Appendix K – OGC Organizational Chart

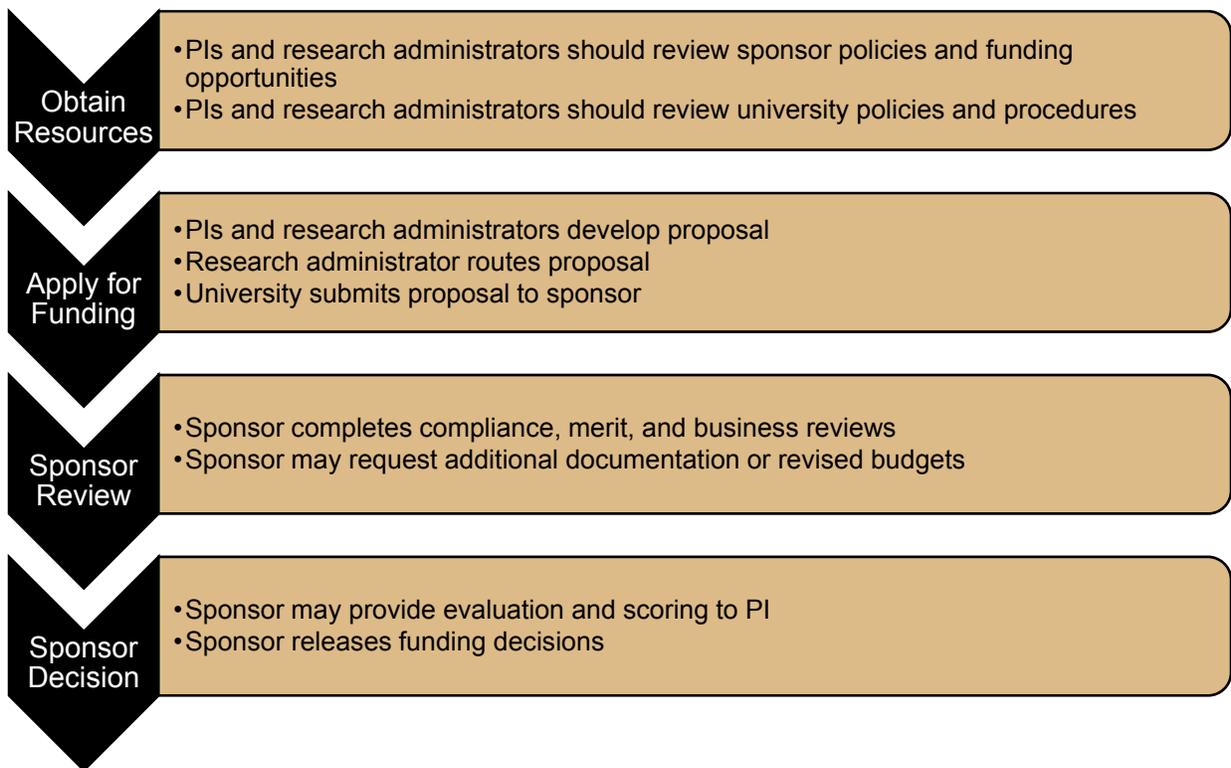
# 1. The Pre-Award Phase

## 1.1 Overview of the Pre-Award Phase

The **pre-award** phase of the sponsored project lifecycle encompasses all activities leading to a sponsor making an award.<sup>1</sup> The major activities during the pre-award phase include:

- Locating funding sources
- Developing the project proposal
- Preparing the budget
- Following university procedures to route the proposal
- Submitting the proposal to the sponsor
- Responding to sponsor requests
- Receiving sponsor decisions

The following graphic depicts the pre-award phase.



The length of the pre-award phase will vary depending on the sponsor. On average, the time between submitting a proposal and receiving a sponsor’s decision may take between three and nine months.

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<sup>1</sup> See Appendix G on page 81 for pre-award information pertaining to the NIH.

## **1.2 Types of Sponsored Programs**

Sponsored programs fund a variety of projects. The following list identifies some of the types of funding programs the university applies for and receives.

- **Research grants and contracts** are faculty research projects designed to expand the body of scientific knowledge and to develop new technologies.
- **Training grants** provide funding to develop or enhance research training opportunities, usually for pre- or post-doctoral work. Training grants generally provide funding for stipend and tuition support.
- **Instructional grants** are designed to improve and enhance the quality of teaching.
- **Career development awards** are usually provided to new researchers to foster their research opportunities.
- **Fellowships** generally provide support to pre- and post-doctoral students at various to obtain individualized, mentored research training.
- **Conference and travel grants** help provide funding for recipients to attend conferences or to travel for research and training.
- **Equipment grants** provide funding for researchers to obtain necessary equipment for their studies.
- **Clinical trials** fund the evaluation of medications or medical devices on a population.
- **Non-research project grants** fund a variety of non-research based activities.
- **Construction grants** fund the construction, modernization, or major alterations and renovations of facilities.



### **Significance**

Before developing an application proposal, it is critical to review the program's eligibility criteria, funding restrictions, and other requirements.

## **1.3 Overview of the University's Pre-Award Process**

The university has a decentralized process in which administrative units and the Office of Grants and Contracts (OGC) each have specific responsibilities in the pre-award phase.<sup>2</sup>

The following graphics depicts the routing and submission process when the department is submitting the proposal to the sponsor.

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<sup>2</sup> See Appendix K on page 114 for an organizational chart for OGC.



The following flowchart depicts the routing and submission process when OGC is submitting the proposal to the sponsor.



Each administrative unit has its own internal processes for managing sponsored projects. The following list summarizes general pre-award responsibilities for research administrators, though the exact responsibilities will vary by administrative unit:

- Works collaboratively with faculty, postdocs, students, and staff members on all aspects of pre-award grant administration in the development, preparation, and submission of proposals, including but not limited to:
  - Reviewing all funding opportunity announcement documents, sponsor requirements, document instructions, and related information and disseminating synthesized information to principal investigators (PIs)
  - Working with PIs and personnel to develop submission timeline and determine responsible personnel for proposal development activities.
  - Assisting PIs with budget development and advising on revisions necessary to meet sponsor requirements
  - Assisting with the development and formatting of attachments such as: biosketches, current or pending support lists, conflict of interest certifications, and other support documents
  - Coordinating required institutional signatures on application documents as needed.
  - Reviewing applications prior to submission, ensuring that all sponsor and university guidelines and requirements are met
  - Routing submission through OGC and serving as a liaison between OGC and the PI, and facilitating the resolution of errors as needed until final submission
  - Facilitating timely responses to requests for further information from sponsors, including Just-In-Time requests
  - Monitoring progress report deadlines and coordinate timely preparation and submission of such reports
- Facilitating the execution of industry-funded contracts and development of clinical trial budgets

- Facilitating the execution of subawards
- Assisting with the preparation of project-specific budgets, including proper application of indirect (F&A) costs
- Maintaining a database with internal and external funding opportunities related to faculty research areas and keep investigators informed of upcoming deadlines
- Developing guidance documents relating to processes and policies of grant submissions.



**Resource**

OGC's Pre-Award website is located at:

<http://www.ucdenver.edu/research/OGC/awardadmin/preaward/Pages/default.aspx>

The following table provides an overview of the sponsored projects process at the university and the typical role of the research administrator during the pre-award phase.

<b>Pre-Award Activities</b>	<b>Principal Investigator</b>	<b>Administrative Unit</b>	<b>OGC</b>	<b>Role of the Research Administrator</b>
Identifies funding opportunities	X			May assist PIs in locating funding opportunities; may direct PIs to the Office of Research Development and Education (ORDE)
Prepares proposal documents	X	X		Develops proposal budget; assists PIs as needed with other documents
Routes proposal to OGC through InfoEd		X		Assembles and uploads required documents in InfoEd
Reviews proposal for compliance with sponsor terms and conditions and university policies		X	X	Addresses questions from OGC; works with PIs to address OGC comments and revises proposal documents
Submits applications based on sponsor and university requirements	X	X	X	Ensures proposal is complete and submitted before deadline; notifies OGC when proposal is ready for submission, if OGC is submitting the application
Responds to "Just-in-Time" requests	X	X	X	Works with PIs to provide requested documents
Reviews Notice of Awards and negotiates terms and conditions, as applicable	X	X	X	Reviews award terms and conditions

## 2. Funding and Research Development

### 2.1 Locating Funding Opportunities

While PIs are typically responsible for identifying or locating sponsored funding opportunities, research administrators should be prepared to provide assistance when needed.

At the university, the Office of Research Development and Education (ORDE) provides services and resources to assist PIs in identifying funding opportunities and preparing proposals. Research administrators can direct PIs to ORDE for:

- Training and seminars for proposal development
- Personalized searches for funding opportunities
- Strategy sessions
- Opportunities for forming and sustaining collaborative opportunities
- Proposal development resources



#### **Resource**

The Office of Research Development and Education is found at:  
<http://www.ucdenver.edu/research/ORDE/Pages/default.aspx>

For federal awards, 2 CFR 200 (Uniform Guidance) requires federal awarding agencies to post information about grant programs on two websites:

- **Assistance Listings.**<sup>3</sup> Formerly known as the Catalog of Federal Domestic Assistance (CFDA), the Assistance Listings is the governmentwide database containing information about federal financial assistance programs. Information about federal programs contained in the Assistance Listings includes:
  - An overview of the program
  - Criteria for Applying
  - Financial Information
  - Compliance Requirements
  - Contact Information

The Assistance Listings is a resource that can be used to identify potential program opportunities; however, the Assistance Listings does not indicate when an agency is accepting applications or conducting funding competitions.

All federal financial assistance programs are required to have a five digit CFDA number. The format of the CFDA number is XX.XXX, with the first two digits indicating the awarding agency and the last three digit suffix indicating the

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<sup>3</sup> See Appendix H on page 84 for an example of an Assistances Listing program description.

program. The CFDA number is listed in the award terms and conditions and must be included on subawards.

- **Grants.gov.** 2 CFR 200 requires federal agencies to post competitions for grants and cooperative agreements on Grants.gov. On the website, each agency must post both a synopsis of the competition and the full funding opportunity announcement. Grants.gov prominently displays the closing date for competitions. Unless exigent circumstances exist, 2 CFR 200 requires federal agencies to post funding opportunities at least 30 days before the deadline. The Department of Health and Human Services (HHS) provides forecasted grant opportunities on Grants.gov to help applicants better prepare for future competitions.

In addition to the two required locations, many federal agencies also post funding opportunities on their websites.



#### **Resources**

The Assistance Listings is located at:

<https://beta.sam.gov/>

Grants.gov is located at:

<https://www.grants.gov/>

There is not a standard location for locating non-federal funding opportunities. Suggested resources include:

- The Foundation Center's Foundation Directory Online (FDO)
- ORDE
- Professional research associations websites and list serves
- Websites of corporate and non-profit sponsors

#### **Non-Federal Sponsors for the University**

The following list identifies some of the non-federal sponsors that provide funding to the university:

- American Heart Association
- Bill & Melinda Gates Foundation
- Colorado Health Foundation
- Genetech
- Gilead Sciences
- Pfizer

## **2.2 Types of Proposals and Applications**

There are a variety of proposal types that may be submitted to sponsors. The following list identifies and explains some of the different proposal types that sponsors may require.

- **Pre-Application.** Some sponsors may require a pre-application before an application may be submitted for consideration. Sponsors use pre-applications to evaluate potential projects and invite selected applicants to submit a formal proposal. Pre-applications are generally a brief abstract detailing what the PI plans to do, how the PI will conduct the project, and why the project has merit. Some sponsors may also require a budget. Sponsors may use a variety of names for pre-applications, including: pre-proposal, preliminary proposal, letter of intent, or white papers.
- **Funding Opportunity Announcement (FOA).** Sponsors solicit proposals by publishing specific program announcements. PIs develop a proposal in response to the sponsor's guidelines established in the announcement.
- **Unsolicited Proposals.** PIs may submit a proposal to a sponsor that is not within a scope of any issued funding opportunity announcement, but is within the scope of the sponsor's activities. The willingness of sponsors to respond or accept unsolicited proposals varies. Unsolicited proposals, also called investigator-initiated proposals, generally compete for available sponsor funding.
- **Limited Solicitations.** Sponsors may announce funding opportunities limiting the number of proposals that may be submitted from the university. The university requires interested PIs to notify the Office of Vice Chancellor for Research (OVCR) before submitting a proposal. If the number of PIs wishing to apply to a given grant program exceeds the number of applications the university is allowed to submit, the OVCR's office will conduct an internal selection process. PIs must submit a proposed project summary to OVCR and an ad hoc committee will select the proposals that best meet the program's criteria. The PIs selected by the ad hoc committee may formally submit their proposal to the sponsor. Research Administrators should carefully review the funding opportunity to determine how the sponsor defines "limited submission."
- **Continuation or Non-Competing Continuation Proposals.** Frequently, federally sponsored awards are distributed on a year-to-year or incremental basis. Though the award may have been approved for a project period covering multiple years, the PI must submit a continuation proposal to receive annual funding allotments. Continued funding is usually based on availability of funds, project performance, and compliance with sponsor requirements.
- **Renewal, Competing Continuation, or Competitive Renewal Proposals.** A renewal proposal requests funds to continue a project beyond the initially funded project period. Renewal proposals compete for funds with all other applications and must be developed as fully as though the PI is applying for the first time. Renewal proposals may pursue the same long-term goals, but with new specific aims or objectives.

### **2.3 Funding Opportunity Announcements**

A **funding opportunity announcement** (FOA) is a mechanism many sponsors use to invite applicants to apply for funding. Sponsors may use a variety of names in lieu of FOA, including:

- Notice of Funding Opportunity (NOFO), which is the phrase 2 CFR 200 uses
- Request for Funding Application (RFA)
- Notice of Funding Availability (NOFA)
- Solicitations

For federal awards, 2 CFR 200 mandates each federal awarding agency use a governmentwide template for funding announcements. The use of a standard template is meant to improve the ability of potential applicants to readily identify key information.<sup>4</sup> The federal template is organized as follows:

- Section 1: Program Description
- Section 2: Federal Award Information
- Section 3: Eligibility Information
- Section 4: Application and Submission Information
- Section 5: Application Review Information
- Section 6: Federal Award Administration Information
- Section 7: Federal Awarding Agency Contact
- Section 8: Other Information

For non-federal awards, the information contained in a funding opportunity announcement may vary. Some sponsors may provide extensive information, while other sponsors may use a basic or underdeveloped announcement providing limited information. In these situations, research administrators may need to research the sponsor's policies, or contact the sponsor or OGC for additional assistance. Developing a proposal without adequate information regarding the sponsor's requirements may significantly delay submission and potentially require the university to decline the award.

The funding opportunity will identify the required elements of the proposal and the proposal should be submitted. Failure to adhere to the requirements in the funding announcement may result in the sponsor rejecting the proposal. For example, the NIH states that "applications containing one or more biosketches that do not conform to the required format may be withdrawn."

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<sup>4</sup> See Appendix C on page 65 for a summary of the required information in each section of a federal FOA.

### Example – Types of NIH Funding Announcements

The following table identifies the different types of funding announcements from the NIH.

<b>Type of Funding Announcement</b>	<b>Description</b>
Parent Announcement	<ul style="list-style-type: none"><li>• Broad announcement allowing applicants to submit an investigator-initiated (unsolicited) application for a specific activity code</li><li>• Many NIH institutes and centers participate</li><li>• Usually ongoing for 3 to 5 years</li><li>• Standard due dates</li><li>• Approximately 80% of NIH budget</li></ul>
Program Announcements (PAs)	<ul style="list-style-type: none"><li>• Issued by one or more Institutes and Centers to highlight areas of scientific interest</li><li>• Encourage applications for new or ongoing program</li><li>• Usually ongoing for 3 years</li><li>• Uses standard due dates</li><li>• Types of PAs:<ul style="list-style-type: none"><li>○ PAS: with set-aside funds</li><li>○ PAR: special receipt, referral, and/or review considerations</li></ul></li></ul>
Request for Applications (RFA)	<ul style="list-style-type: none"><li>• FOAs issued by one or more Institutes or Centers to highlight well-defined areas of scientific interest to accomplish specific program objective.</li><li>• Indicate anticipated number of awards and funding</li><li>• Usually single due date</li><li>• Institute/Center usually convenes review panel</li></ul>
Request for Proposal (RFP)	<ul style="list-style-type: none"><li>• Solicits contract proposals</li><li>• Usually has one receipt date, identified in the RFP solicitation</li></ul>

### **Example – Funding Announcement Identifies Rejection and Withdrawal Criteria**

In a 2018 funding opportunity announcement, the Department of Defense (DOD) outlined automatic and potential disqualifications:

The following will result in administrative rejection of the application:

- Pre-application was not submitted
- Project Narrative exceeds page limit
- Project Narrative is missing
- Budget is missing

The following may result in administrative withdrawal of the application:

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm)
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process
- Submission of the same research project to different funding opportunities within the same program and fiscal year
- The application proposes an observational study involving human subjects or a clinical trial

### **Example – American Heart Association Required Documents**

The American Heart Association outlines the requirements for proposal documents for the Established Investigator award on its webpage. The requirements for the proposal include:

- Abbreviated Proposal (10 pages)
- Biographical Sketch/Bibliography (5 pages)
- Budget Justification Form – Word template (2 pages)
- Literature Cited (no page limit)
- Research Project Environment Form – Word template (2 pages)
- Vertebrate Animal Subjects (no page limit)
- Collaborating Investigator's Bio-Sketch (5 pages)
- Collaborating Investigator's Letter (5 pages)
- Consultant's Letter (5 pages)
- Department Head's Letter (5 pages)
- Reference Letter (3 count, 4 pages each)

### **Activity – Comparing A Federal FOA to a Non-Federal FOA**

Compare the federal funding announcement example in Appendix I on page 93 to the non-federal funding announcement example in Appendix J on page 111

1. What differences do you see between the two examples?
2. If you were reviewing a funding announcement and had questions about the sponsor's requirements, what would you do?



#### **Significance**

The format of funding opportunities varies depending on the sponsor. Regardless of the source of funding and the award type, there are critical items that should be carefully identified and reviewed, including:

- Application deadlines
- Expiration date of funding opportunity
- Eligibility requirements
- Award type / mechanism
- Cost sharing or matching requirements
- Funding restrictions
- Required applications forms
- Indirect (F&A) cost rate allowability
- Application requirements
- Review criteria
- Anticipated award date
- Submission requirements

## **2.4 Exercise – Reviewing a Funding Opportunity Announcement**

Background: Dr. Ellen Sirleaf is a faculty member in the School of Public Health and has informed you of her plans to apply for funding through the NIH Exploratory/Development Research Grant Program (R21) Parent Announcement from the National Institutes of Environmental Health Sciences, an institute under the NIH.

Dr. Sirleaf will study the link between Cholangiocarcinoma (CCA), bile duct cancer, and koi pla, a dish made of raw fish, in northeast Thailand. Dr. Sirleaf's proposal does not include any subrecipients. The majority of the project's work will be conducted at Anschutz Medical Campus.

This is Dr. Sirleaf's first time applying for a R21 award and she has asked you for your guidance.

Directions: For this exercise, assume Dr. Sirleaf's project is eligible for the award. Review the funding opportunity announcement in Appendix I on page 93 and answer the following questions.

1. What are the possible due dates for the proposal?
2. Describe the budget constraints on this award.
3. What is the maximum period of performance for this award?
4. Are there any special considerations for the content and form of the application package?
5. Describe the extent of funding restrictions for this program.

## **3. Proposal Development**

### **3.1 InfoEd**

**InfoEd eRA** (InfoEd) is the university's grants management system.<sup>5</sup> The university uses InfoEd to track proposals and award information. InfoEd also provides system-to-system proposal submission, such as through Grants.gov. InfoEd is required for the internal routing and approval of sponsored research proposals. The system is also used for:

- Human subjects protocol submission, review, and tracking
- Conflict of interest submission, review, and tracking
- Reporting



#### **Resources**

Training opportunities and resources for InfoEd, including step-by-step directions for creating a proposal in the system, can be found at:

<http://www.ucdenver.edu/research/RIT/era/Pages/default.aspx>

### **3.2 Roles and Responsibilities During Proposal Development**

The university uses a decentralized model for administering sponsored awards, therefore, the exact pre-award responsibilities will vary by administrative unit. The following list is not meant to be an exhaustive list, but rather to highlight common responsibilities.

During proposal development, a research administrator commonly has the following responsibilities:

- Manage the development and submission of the proposal
- Develop the budget
- Ensure the proposal is compliant with sponsor requirements
- Assemble the proposal in InfoEd
- Ensure proper university routing and sponsor submission of the proposal
- Identifying sources of required cost sharing

The PI is responsible for:

- Developing the technical or scientific portion of the proposal
- Obtaining necessary approvals
- Identifying subrecipients and ensuring subrecipient statements of work, budget, and budget justification are received on time

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<sup>5</sup> See Appendix E on page 73 for an overview of InfoEd.

### **3.3 Project Management**

In many administrative units, the research administrator is responsible for managing the proposal development process by:

- Identifying required elements of the proposal
- Developing a detailed project schedule
- Communicating all internal and external deadlines
- Ensuring all deadlines are met

#### **Identify Required Elements of the Proposal**

A research administrator should review the funding opportunity announcement to determine the required proposal elements and to identify who is responsible for completing each element. Typically, the PI will be responsible for the scientific and technical aspects of the proposal and the research administrator will be responsible for the budget development and for compiling the proposal elements.

Items to consider when reviewing a funding announcement:

- What is the sponsor's policy on accepting indirect (F&A) cost rates?
- What research regulatory compliance documentation, such as conflict of interest certifications or approved protocols, are required and when does the sponsor require those documents? If the sponsor requires the documentation with proposal, then additional time will need to be built into the schedule in order to obtain the necessary approvals.
- Does the sponsor allow for subawards? Obtaining the necessary documents from subrecipients can be a lengthy process, and this time needs to be reflected in a project schedule.
- Does the sponsor require cost sharing or matching?

#### **Develop a Detailed Project Schedule**

Identifying university and sponsor deadlines is critical when developing a project schedule. The amount of time between a sponsor announcing a funding opportunity and the deadline to submit an application can greatly vary. Some federal sponsors, such as the NIH, have standing deadlines to submit proposals for certain funding programs; while other sponsors may provide potential applicants less than a month to submit proposals.

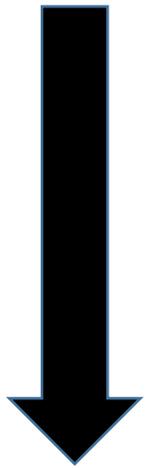
One of the most important factors impacting a project timeline is determining who is responsible for submitting the proposal. The following table explains how the timeline is impacted based on the responsible party for submitting the proposal.

Responsible for Submitting Proposal	Requirement
OGC is submitting the proposal to the sponsor	<ul style="list-style-type: none"> <li>• For the initial review, OGC must receive the proposal by the end of the 12th business day prior to the submission deadline</li> <li>• The final electronic version must be in InfoEd by 4:00pm on the 4th business day prior to the submission deadline. Notification must be sent to <a href="mailto:eapp.xenia@ucdenver.edu">eapp.xenia@ucdenver.edu</a> when the application is ready for submission.</li> <li>• If the application is submitted by a method other than InfoEd, such as through a sponsor-specific portal, the email notification must include the application file or the application must be ready in the applicable sponsor portal. Additionally, research administrators must ensure OGC has access to the application in the sponsor portal.</li> </ul>
The Department is submitting the proposal to the sponsors	<ul style="list-style-type: none"> <li>• OGC must receive the routing package 5 full business days prior to the submission deadline</li> </ul>

The following tables provide summarized timeline of the major activities that need to be completed before a proposal is submitted to a sponsor. To develop an effective project schedule, research administrators should work backwards from the sponsor deadline.



OGC Submits Proposal	
Days Before Deadline	Actions
Sponsor Deadline	OGC will submit proposal
4 Business Days	Finalize all proposal documents in InfoEd and route to OGC
After OGC Review	Revise proposal
12 Business Days	Routed proposal received by OGC for initial Review
12+ Business Days	<ul style="list-style-type: none"> <li>• Assemble proposal documents in InfoEd</li> <li>• Obtain regulatory compliance documents, if applicable</li> <li>• Obtain subrecipient documents, if applicable</li> <li>• Budget development</li> <li>• Proposal development</li> <li>• Develop project timeline</li> <li>• PI notifies research administrator of intent to apply</li> </ul>



Department Submits Proposal	
Days Before Deadline	Actions
Sponsor Deadline	•Submit proposal to sponsor
After OGC Review	•Revise proposal
5 Business Days	•Routed proposal received by OGC for review
5+ Business Days	•Assemble proposal documents in InfoEd •Obtain regulatory compliance documents, if applicable •Obtain subrecipient documents, if applicable •Budget development •Proposal development •Develop project timeline •PI notifies research administrator of intent to apply

When developing a project timeline, a research administrator should consider the following:

- While the budget development process can occur in conjunction with the project narrative, the final budget will need to be compared with the final project narrative to ensure the two documents are aligned
- OGC will need time to review and process the application documents, which generally takes around five business days
- When routing a proposal to OGC, the project narrative is not required
- Obtaining subrecipient documents may take longer than anticipated, therefore additional time should be allocated into the project timeline for potential delays
- Project timelines should reflect each PI's work style; some PIs may provide significant advanced notice that they plan to apply for an award, while others may provide very little notice
- Always allocate time for worst case scenarios
- Actions will take longer to complete than anticipated
- Most sponsors provide no exceptions to application deadlines

#### Communicate Deadlines to the PI

After the initial project deadline has been developed, the research administrator should discuss the important milestone deadlines with the PI and adjust the schedule as necessary. The deadlines should also be communicated to the subrecipients, if applicable.

#### Ensure Deadlines Are Met

It is important to understand each PI's work style. Some PIs may appreciate friendly reminders of upcoming deadlines, while others may be less inclined to take kindly to periodic reminders. One aspect of being a research administrator is learning what works best with each PI.

Some deadlines can be treated as flexible, and a research administrator may build in time into the project schedule knowing that a PI or subrecipient may routinely miss a deadline. However, the deadline to submit a proposal to a sponsor is almost never flexible, and sponsors may reject a proposal that is late by even a few minutes.

### **Types of Due Dates for Proposals**

Sponsors may classify due dates in a variety of ways. The following list identifies and explains some due date terminology used by sponsors.

- **Deadlines** – hard cut off dates for submission to an opportunity
- **Target Dates** – soft cut off dates in which late submissions may get reviewed with on-time proposals or may be held by the sponsor until the next review cycle; research administrator should treat target due dates as hard deadlines
- **Submission Windows**- designated periods of time during which proposals will be accepted by a sponsor
- **Rolling or Continuous Deadline** – allows for proposal submission at any time

### **3.4 Proposal Components**

The format and content of a proposal depends upon the sponsor's requirements. The following list identifies and explains common proposal sections.

- **Cover page or proposal form.** Most proposals include a form that requires institutional information and relevant project data. Most federal agencies require the use of the SF-424, for non-research awards, or the SF-424 (R&R) for research awards. Commonly requested information for the proposal form include:
  - Institutional information<sup>6</sup>
  - Identification of the sponsor's program, such as funding opportunity announcement and, for federal awards, the CFDA number
  - Project title
  - Project start and ending dates
  - PI information
  - Amount of requested project funding
  - Authorized Organization Representative (AOR) contact information and signature.
- **Abstract or proposal summary.** The abstract summarizes the major aspects of the proposed project, including the proposed project's hypothesis, specific aims, objectives, significance, and expected results. Most sponsors limit the length of the abstract.
- **Project Narrative.** The project description describes the project, its purpose, relevance, and implementation. Each sponsor has specific guidelines for this portion of the proposal, including page limitations and formatting requirements. Common sections in the project description include:

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<sup>6</sup> See Appendix D on page 69 for a list of commonly requested information about the university.

- Introduction
- Specific aims or objectives
- Background
- Research strategy and description
- Plan of work
- Timeline
- **Bibliography or references cited.** This section should contain all references cited in the proposal, including the PI's own publications. The required format will vary by sponsor.
- **Biographical Sketch (BioSketch).** Sponsors often require biographical sketches for all senior and key personnel, including: PIs, co-investigators, and other significant contributors. Sponsors have different format, naming conventions, and content requirements, but will typically request the education background, appointments, research experience, and publications for each key individual.
- **Budget and budget justification.** Sponsors typically request a detailed budget that identifies cost categories and an accompanying justification for each cost.
- **Facilities and other resources.** This section provides information on the facilities and other resources available for use on the project, such as: lab or office space; library resources, equipment, or unpaid personnel. Sponsors use this section to evaluate the capability of available university resources to perform the proposed project.
- **Data Management.** This section details how the PI will share their research data, including: primary data, samples, physical collections, and other supporting materials created or gathered.
- **Current and pending support.** PIs may need to identify all current funding, as well as proposals that have been submitted. The purpose of this section is for the sponsor to ensure that the researcher is not overcommitted and to determine whether the proposed scope of work overlaps with other projects in the researcher's portfolio. PIs that fail to disclose duplicative proposals on federal awards may face administrative, civil, or criminal sanctions.
- **Compliance documents.** Depending on the sponsor and the type of proposed project, the PI may need to submit a variety of compliance documents. Sponsors may require this information at the time of the proposal or as a condition of funding. Compliance documents may include:
  - Institutional Review Board (IRB) approval for human subject research
  - Verification of Human Subjects Training
  - Institutional Animal Care and Use Committee (IACUC) approval
  - Institutional Biosafety Committee approval for recombinant DNA research
  - Conflict of Interest documentation
  - Compliance with federal disability laws
  - Sponsor and program-specific requirements
- **Attachments and appendices.** Some sponsors may allow for the inclusion of appendices with the proposal. PIs may include figures, charts, protocols,

representations and certifications, and letter of support, as well as other supplemental material. Appendices cannot be used to circumvent the page limitations of the project description. Sponsors may limit what items can be included in the appendices.

**Example – Cornell Settles \$2.6 Million Fraud Lawsuit**

In 2009, Weill Cornell Medicine settled a \$2.6 million fraud lawsuit due to a PI failing to disclose on NIH applications the full extent of her research activities. The government alleged that the PI's failure to disclose other grants she received allowed her to over-commit her professional time in violation of NIH guidelines. The funding in question related to eight NIH awards and one Defense Department award totaling more than \$13 million over a 12-year period.

**3.5 Narrative Review**

While a research administrator is not expected to evaluate a project narrative for scientific merit, it is essential that a compliance review and budget analysis is completed. The following list identifies what a research administrator should do when reviewing a project narrative:

- Verify that the proposal format adheres to sponsor requirements, such as page length and formatting
- Compare the project narrative to the budget to confirm alignment
- Ensure all required documents are completed, including commitment forms and subrecipient documents
- Proofread for typos and grammatical errors

### 3.6 Exercise – Developing a Proposal Timeline

Background: Dr. Sirleaf informs you on December 20, 2018 that she will be submitting her R21 proposal on the Cycle I due date, February 16, 2019. Since this is a NIH proposal, OGC is responsible for submission.

Directions: Answer the following questions to assist you in developing a project management timeline for this proposal.

December 2018							January 2019							February 2019						
Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
						1			1	2	3	4	5						1	2
2	3	4	5	6	7	8	6	7	8	9	10	11	12	3	4	5	6	7	8	9
9	10	11	12	13	14	15	13	14	15	16	17	18	19	10	11	12	13	14	15	16
16	17	18	19	20	21	22	20	21	22	23	24	25	26	17	18	19	20	21	22	23
23	24	25	26	27	28	29	27	28	29	30	31			24	25	26	27	28		
30	31																			

1. Use the funding opportunity announcement to identify the required elements for the proposal.

2. Identify the key dates for this proposal:

- a. Submission to NIH: \_\_\_\_\_
- b. Final Submission to OGC: \_\_\_\_\_
- c. Initial Submission to OGC: \_\_\_\_\_

## **4. Budget Development**

### **4.1 The Role of the Research Administrator in the Budget Development Process**

A proposal has two distinct elements: a project narrative and a budget. PIs will develop the project narrative, as they have the scientific expertise regarding the proposed project and they are ultimately responsible for the project's implementation. In many administrative units, the research administrator is responsible for developing a project's budget in collaboration with the PI and other project personnel.

### **4.2 The Budget's Role in the Award Lifecycle**

A **budget** is an estimate of the costs for conducting a project. By translating planned activities into dollar amounts, the budget transforms concepts, objectives, and strategies into executable plans. A successful application depends upon the sponsor's review of both the budget and project narrative. As a result, the budget and project narrative must represent a consistent, unified plan. Since the responsibilities for the budget and project narrative are split between the research administrator and the PI, coordination and communication are vital.

The budget must give an accurate estimation of all costs that are necessary and reasonable for the project.<sup>7</sup> Sponsors will evaluate the budget to determine if the project can be performed with the requested level of funding, the allocated personnel, and the amount of resources. Budget details usually reveal whether a proposed project has been carefully planned and is ultimately feasible.

A well-developed budget can increase the potential of receiving funding by:

- Demonstrating credibility
- Clarifying the project narrative

Likewise, a poorly-developed budget will raise concerns during the sponsor's review and may result in denied funding. Common problems associated with a budget that may concern sponsors include:

- Not identifying all associated costs
- Requesting funding for costs normally borne by the university
- An inflated project budget or a budget that is not cost-effective
- Inaccurate calculations
- Inadequate cost justifications
- Incorporating costs not tied to the project's objectives
- Including unallowable costs

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<sup>7</sup> Financial Services offers a course entitled Cost Principles for Sponsored Projects that provides detailed coverage of allowable costs.

The budget is a critically important aspect of both the pre-award and post-award phases. If a sponsor funds a project, then the approved budget will guide the project in the post-award phase. Underestimating costs or not including enough resources may limit the success of a project.



**Significance**

The budget becomes an integral part of the project. The decisions made in the pre-award phase will continue through the life of the project.

Developing a budget requires practice, skill, and luck. Underestimating a budget will cause problems in the post-award phase, and overestimating, or padding, a budget will cause sponsors to look negatively upon a proposal.

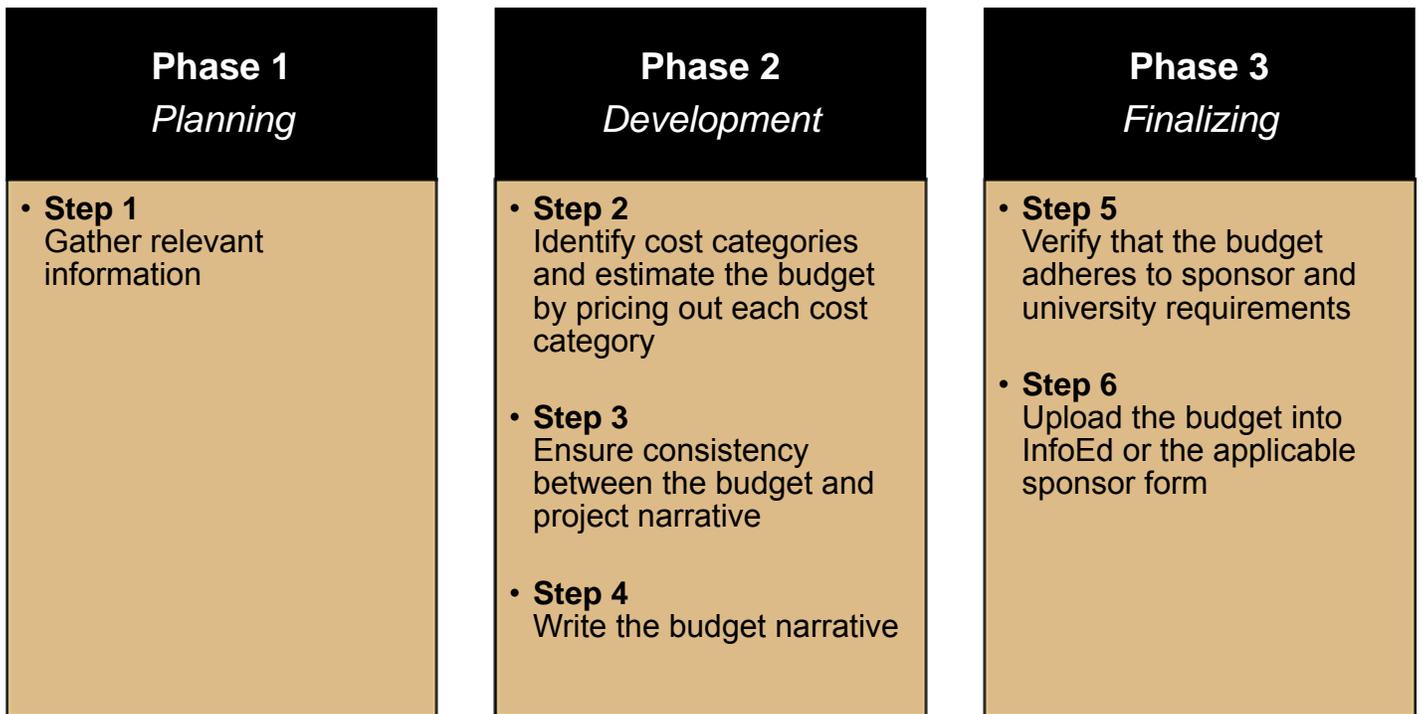
Another consideration when developing a budget is that most sponsors will probably not provide funding for the entire requested amount. This requires reducing budgeted amounts when the award is made, which may potentially alter the scope of work.

The following table identifies questions that each of the major actors lifecycle should ask regarding the budget throughout the award lifecycle.

Phase	PI	Research Administrator	OGC	Sponsor
Pre-Award	<ul style="list-style-type: none"> <li>How much will it cost do to this project?</li> </ul>	<ul style="list-style-type: none"> <li>Is the budget accurate and reasonable?</li> <li>Does the budget address the project's needs</li> <li>Does the budget adhere to sponsor requirements?</li> </ul>	<ul style="list-style-type: none"> <li>Does the budget adhere to sponsor requirements?</li> <li>Is cost sharing involved?</li> <li>Is the correct indirect (F&amp;A) cost rate applied?</li> </ul>	<ul style="list-style-type: none"> <li>Is the budget aligned with the project scope?</li> <li>Does the budget adhere to sponsor requirements?</li> <li>Is there funding available for this project?</li> </ul>
	Award	<ul style="list-style-type: none"> <li>How will budget cuts affect this project?</li> </ul>	<ul style="list-style-type: none"> <li>What cost categories should be reduced?</li> </ul>	<ul style="list-style-type: none"> <li>Has the updated budget been submitted?</li> </ul>
Post-Award	<ul style="list-style-type: none"> <li>Are the costs compliant with sponsor and university requirements?</li> <li>Are all costs allocable, allowable, necessary and reasonable?</li> <li>Are effort commitments being met?</li> <li>Is prior approval needed for carryforward, rebudgeting, and no-cost extension requests?</li> <li>Do budget changes reflect a change in scope?</li> </ul>	<ul style="list-style-type: none"> <li>Are the costs compliant with sponsor and university requirements?</li> <li>Are all costs necessary, reasonable, and allocable to the project?</li> <li>Are project costs adhering with the budget?</li> <li>Is prior approval needed for carryforward, rebudgeting, and no-cost extension requests?</li> <li>Do budget changes reflect a change in scope?</li> </ul>	<ul style="list-style-type: none"> <li>Are the costs compliant with sponsor and university requirements?</li> <li>Are all costs necessary, reasonable, and allocable to the project?</li> <li>Are project costs adhering with the budget?</li> <li>Is prior approval needed for carryforward, rebudgeting, and no-cost extension requests?</li> <li>Do budget changes reflect a change in scope?</li> <li>Do the costs match the approved budget on the financial reports?</li> </ul>	<ul style="list-style-type: none"> <li>Are the costs compliant with sponsor and university requirements?</li> <li>Are all costs necessary, reasonable, and allocable to the project?</li> <li>Are project costs adhering with the budget?</li> <li>Should prior approval be granted?</li> <li>Do budget changes reflect a change in scope?</li> <li>Was cost sharing or matching requirements met?</li> </ul>

### 4.3 The Budget Development Process

The following graphic depicts the budget development process.



#### Step 1: Gather Relevant Information

The first step in the budget development process is to gather all relevant information. Pertinent information includes:

- **Funding announcement and sponsor guidelines.** The funding announcement should be reviewed to identify:
  - Allowable costs and funding restrictions
  - Cost sharing or matching requirements
  - Budget format requirements
  - Funding ranges and average funding levels
  - Indirect (F&A) cost policy
- **Questions to ask the PI.** Communicating with the PI is essential in developing the budget. Questions a research administrator should ask a PI during the initial budget planning stage include:
  - What is the scope of work?
  - Who is the sponsor?
  - Where will the work be performed?
  - Will there be any subrecipients?
  - Will you hire any consultants?
  - Who are the personnel and what percent of effort will they commit?
  - What resources will be needed?
  - Will travel be necessary, and is the travel foreign or domestic?
  - Are human and/or animal subjects involved?
  - Will the project include tuition reimbursement?

- **Institutional and personnel information.** Information vital to developing the budget include:
  - The university’s indirect (F&A) cost rates
  - Salary for personnel
  - Fringe benefit rates
  - Travel reimbursement rates
- **Budget format.** The funding announcement should identify the requirements for the budget. Most sponsors will require a detailed budget that identifies a breakdown of costs associated with each cost category.

### **NIH Modular Budgets**

The National Institutes of Health (NIH) allows the use of modular budgets for certain programs. NIH requires them on new, renewal, and resubmission applications, as well as for revisions for the following grants and their cooperative agreement equivalents that request up to a total of \$250,000 of direct costs per year (excluding consortium indirect (F&A) costs), regardless of whether the application is an investigator-initiated application or is one submitted in response to a PARFA:

- Research Project Grants Program (R01/U01)
- Small Grant Program (R03)
- Exploratory/Development Research Grant Award (R21/UH2)
- Clinical Trial Planning Grant Program (R34/U34)
- Academic Research Enhancement Awards (R15/UA5)

The modular grant budget uses specific modules, or increments, in which direct costs are requested. Rather than submitting detailed line-item budgets, funds are required in “modules” of \$25,000, up to \$250,000 a year. A typical modular grant application will request the same number of modules in each year; however, exceptions are permitted for purchases, such as equipment, or activity that occurs only in certain years of the project.

Information on the Modular Budget format is available on the [NIH Modular Grant Application](#) page.

## Step 2: Identify Cost Categories

The funding opportunity announcement should identify the cost categories the sponsor requires for the budget. Typical cost categories include:

- Personnel
- Fringe Benefits
- Travel
- Equipment
- Supplies
- Contractual (Consultants)
- Subawards(Outgoing Subcontracts)
- Trainee Support Costs
- Other Direct Costs
- Indirect (F&A) Costs

For each budget category, sponsors only expect estimated costs; however, if the project is funded, sponsors typically only allow limited rebudgeting to occur without seeking prior approval.

### *Personnel*

Personnel refers to the wages and salaries for university employees, and prospective employees, directly involved in the project. All personnel should be listed and the amount of effort for each employee needs to be identified. For most proposals at the university, salaries and wages constitute the vast majority of the budget.

Salaries for personnel are calculated based on the effort a person will devote to the project. Because effort may vary over the life of a project, for budgeting purposes, effort should be determined based on an anticipated average over each project year.

For the personnel category, research administrators must:

- Verify any sponsored imposed salary caps or limitations
- Follow university policy on naming prospective employees on proposals
- Use percentage of effort or person-months to reflect effort
- Follow appropriate sponsor guidelines and requirements

Some sponsors may allow for budgets to include inflationary increases. When determining inflationary increases, it is critical to follow sponsor guidelines.

### **NIH Salary Cap**

Effective January 7, 2018, the NIH salary cap is \$189,600. For personnel on a 9-month appointment, research administrators need to convert the 9-month salary to a 12-month base to verify the salary cap is not exceeded.

Information about the salary cap can be found at:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html>

### **NSF Two-Month Rule**

As a general rule, the National Science Foundation (NSF) limits the salary compensation requested in the proposal budget for senior personnel to no more than two months of their institutional base salary in any one year. This limit includes salary compensation received from all NSF-funded grants; therefore, the total amount of salary paid from all NSF awards cannot exceed two months unless explicitly approved by NSF.

### **Salary and Percent of Effort**

The method to calculate salary requests and percent of effort depends on their appointments. Employees at the Denver Campus are on a 9-month schedule with the potential for summer salary, whereas most employees at Anschutz Medical Campus are on a 12-month schedule.

Use the following equations to calculate salary and effort.

#### 12-month salary:

- $\% \text{ of effort} * 12 \text{ months} = \text{person months (calendar year)}$
- $\% \text{ of effort} * \text{Institutional Base Salary} = \text{Proposed Salary}$

#### 9-month salary:

- $\% \text{ of effort} * 9 \text{ months} = \text{person months (academic year)}$
- $\% \text{ of effort} * \text{Institutional Base Salary} = \text{Proposed Salary}$

#### Summer salary:

- $\% \text{ of effort} * 3 \text{ months} = \text{person months (summer term)}$
- $\text{Institutional Base Salary} / 9 \text{ months} * 3 \text{ months} = \text{Summer Salary}$
- $\% \text{ of effort} * \text{Summer Salary} = \text{Proposed Summer Salary}$

The NIH provides a Percent of Time and Effort to Persons Months Calculator at:

[https://grants.nih.gov/grants/policy/person\\_months\\_conversion\\_chart.xls](https://grants.nih.gov/grants/policy/person_months_conversion_chart.xls)

### **Part-Time University Appointments**

The effort and salary proposed for part-time employees must be based on their part-time appointment. Budget calculations should use the actual salary the university pays the employee.

For example, 10% of a 0.5 FTE 12 month appointment equals 0.6 (CY) person months. (12 calendar months \* 0.5 FTE \* 0.1 effort = 0.6 (CY) person months).

The budget justification should state: "The employee is committing 1.2 calendar months of a 50% appointment."

In the proposal, personnel need to be classified as either:

- Senior/Key personnel, or
- Other personnel

### **Senior/Key Personnel Definition**

The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salary or compensation under the award. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. Zero percent effort or “as needed” are not acceptable levels of involvement for those designated as senior/key personnel.

Most sponsors require a biographical sketch of individuals classified as senior or key personnel, and sponsors will evaluate the merits of a proposal by reviewing the submitted biographical sketches. Additionally, key personnel must complete annual conflict of interest disclosures. In the post award phase, sponsor prior approval is generally required when replacing an individual classified as key personnel.

Individuals may also be classified as “other significant contributors,” which means they are contributing to the project, but are not committing any specified measurable effort. These individuals are typically presented at “effort of zero person months” or “as needed.” Other significant contributors are not listed in the budget section of InfoEd, but are listed in the personnel section.

### *Fringe Benefits*

Fringe benefits are the cost of benefits paid to the personnel working on the grant. The classifications are based on the employee’s job code and work location, as listed in the Human Capital Management (HCM) system. Research administrators need to verify an employee’s job code, salary, and associated fringe benefit rates in the HCM system. It is important to note that some sponsors may only allow a portion of the university’s fringe benefits rate to be included in the budget.

The following fringe benefit rates should be used for budgeting purposes on sponsored project proposals with deadline dates falling on or after February 15, 2018.

Employee Classification	Rate
<b>CU Denver Faculty</b>	
Full-time (≥ 50% FTE)	29.52%
Part-time (< 50% FTE)	21.61%
<b>CU Anschutz Faculty</b>	
Full-time (≥ 50% FTE)	25.04%
Part-time (< 50% FTE)	16.59%
<b>CU Denver   Anschutz</b>	
University Staff (≥ 50% FTE)	34.60%
University Staff (<50% FTE)	26.08%
Classified Permanent	44.29%
Classified Temporary	21.86%
Post Doc Fellow	25.43%
Professional Research Assistant	37.49%
Student Faculty / Student Hourly	0.53%
Residents / Pre Doc Fellows	Contact GME

### Calculating Fringe Benefit Amounts

To calculate an employee's fringe benefits, multiply the fringe benefit rate by the proposed salary.

For example, a PI proposing 20% effort at the salary cap level would be requesting \$37,920 in salary and \$9,495 in fringe benefits.

*Calculation:*

$$\$189,600 \text{ (salary cap)} * 20\% \text{ (effort)} = \$37,920 * 25.04\% = \$9,495 \text{ (fringe benefits)}.$$

#### 4.4 Exercise – Calculating Salary

Background: Dr. Sirleaf has provided you the following information regarding the personnel on her project. Dr. Richards is a faculty member at the Denver Campus.

Role	Name	Effort	Base Salary	Notes
PI	Sirleaf	20%	\$210,575	
Co-Investigator	Kumaratunga	15%	\$130,100	
PostDoc Fellow	Cortez	10%	\$54,715	
PRA	Ojeda	20%	\$38,560	
Grad. Student	Conway	4%	\$47,300	
Statistician	Richards	3%	\$97,783	9 month appointment – effort only committed during the academic year

Directions: Complete the salary calculations using the following template from InfoEd. For the salaries for Year/Period 2, calculate an inflation factor of 3%.

	YEAR / PERIOD 1						
	Base Salary	Calendar	Academic	Summer	Salary	Fringe Benefits	Total
Sirleaf	\$				\$	\$	\$
Kumaratunga	\$				\$	\$	\$
Cortez	\$				\$	\$	\$
Ojeda	\$				\$	\$	\$
Conway	\$				\$	\$	\$
Richards	\$				\$	\$	\$

	YEAR / PERIOD 2						
	Base Salary	Calendar	Academic	Summer	Salary	Fringe Benefits	Total
Sirleaf	\$				\$	\$	\$
Kumaratunga	\$				\$	\$	\$
Cortez	\$				\$	\$	\$
Ojeda	\$				\$	\$	\$
Conway	\$				\$	\$	\$
Richards	\$				\$	\$	\$

	Salary	Fringe Benefits	Total
<b>Total</b>	\$	\$	\$

## *Travel*

The travel category refers to the travel costs for project personnel that are necessary and reasonable to effectively manage and carryout project activities, provide oversight, present results from sponsored research, or measure program effectiveness. Domestic and foreign travel associated with the proposed project should be specified. If foreign travel is not specified in the budget, the university generally must request prior approval for such travel from the sponsor during the post award phase.

All budgeted travel costs must be directly associated with the project.

Considerations for the travel include:

- Some sponsors define Mexico and/or Canada as domestic travel
- Typical travel costs supported by sponsors include airfare, lodging, incidental expenses (per diem), conference registration costs, and local travel costs such as car rental
- Travel costs budgeted in the proposal must adhere to the university's travel policy
- The Fly America Act regulates international travel



### **Resources**

The university's travel policies and travel-related resources are located at:

<https://www.cu.edu/psc/travel>

## *Equipment*

The university, in accordance with 2 CFR 200, classifies non-expendable tangible personal property that has a useful life of more than one year and a per-unit acquisition cost of \$5,000 or more as equipment.

For budgeting equipment:

- General-purpose equipment, such as office equipment, should not be directly charged, unless the equipment will be used primarily or exclusively for the project
- Equipment costs included in the budget should be analyzed to ensure the request is reasonable
- Ensure that the sponsor allows for equipment purchases
- Freight charges, installation costs, subcomponents, or peripherals needed to make the equipment operational are included in the cost
- Use vendor quotations when possible
- Trying to circumvent the \$5,000 threshold by parceling out the purchase is not allowable
- Equipment costs are exempt from indirect (F&A) costs when using modified total direct cost (MTDC)

### *Materials and Supplies*

Tangible Personal property that is not classified as equipment is considered a supply. All supplies included in the budget must be directly related to the project. Many sponsors require itemization of proposed supply purchases. Estimates for supplies should be supported by a complete description of the supplies and the basis for computing the estimates.

#### **Example – Supply Budget**

<b>Purchases</b>	<b>Total</b>
30 rats @ \$35 each plus \$500 shipping	\$1550
5 Fluoprodige Assay Kits @ \$225 each	\$1125
2 Inverted Trinocular Metallurgical Microscope @ \$3600 each	\$7200

### *Contractual (Consultants)*

A consultant is an individual who will provide professional services or advice for the project, and whose services are not available at the university. Conflict of interest policies apply to hiring consultants and steps must be taken to prevent a real or apparent conflict of interest.

Personnel employed by any university unit, regardless of campus, may not serve as consultants on a project. University of Colorado Denver | Anschutz personnel should be included under the personnel category, and other University of Colorado personnel should be included in the subawards (outgoing subcontracts) category.

Considerations for budgeting consultants include:

- Compensation should be based on the consultant's salary/rate history for comparable services
- Consultants do not receive fringe benefits
- Consultants can receive reimbursement for project-related travel expenses

### *Subawards (Outgoing Subcontracts)*

Subawards are made to other organizations that will be responsible for carrying out a portion of the project's scope of work. 2 CFR 200.330 provides guidance for subrecipient determination.

A subaward represents any portion of the project that is performed by another organization. All associated subaward costs must be identified in the budget proposal. Subrecipient organizations must submit a budget, which is included in the university's proposal. The budget must include the subrecipient's indirect (F&A) costs.

For indirect (F&A) costs, only the first \$25,000 of each subaward is included in the MDTC cost base.

### *Trainee Costs*

The allowability of trainee costs varies by sponsor and program. Some sponsors will require trainee costs to be included in the Other Direct Cost category. Trainee expenses may include:

- Stipends
- Tuition and fees

- Dependency allowances
- Travel allowances

Stipends are generally only budgeted for training grants and fellowships. Per university policy, stipends may only be budgeted when required by the sponsor. Most students involved as research assistants on sponsored programs are paid salary and fringe benefits; therefore, there is no need for stipends. Stipends also carry tax implications for recipients.

#### *Other Direct Costs*

This is a budget category for costs that do not fit in any of the other categories. Costs that may be in this category include:

- Publication costs
- Communication charges
- Rental fees
- Participant support costs
- Patient care costs
- Animal maintenance and care

#### *Indirect (F&A) Costs<sup>8</sup>*

Budgets for sponsored projects indicate the total for direct costs and indirect (F&A) costs. The indirect cost total is a percentage of the direct cost base. This percentage is known as the **indirect cost rate**. The indirect (F&A) costs paid by sponsors to the university are referred to as indirect cost recovery, as the university is recovering incurred costs to provide operational support for the project.

The university negotiates an indirect (F&A) cost rate with the federal government. The federally negotiated rate, sometimes referred to as the **Negotiated Indirect Cost Rate Agreement (NICRA)**, must be, with limited exceptions, accepted for all federally sponsored projects. Any deviation from the

#### **University Indirect (F&A) Waiver Process**

When a deviation from the normal indirect (F&A) administrative rate is deemed desirable, the PI must request approval using the Facilities and Administrative Cost Variance Request. A committee will review the request and determine if the request will be granted. The waiver process may take up to 4 weeks. A waiver should be submitted as soon as possible.

The university **HIGHLY DISCOURAGES** this practice, and any waiver must provide an extremely compelling reasoning.

Under university policy, for-profit sponsors must accept the university's full indirect (F&A) cost rate regardless of the entity's established policy. If a for-profit sponsor does not accept the university's full rate, an indirect (F&A) waiver must be submitted.

If a waiver is denied, then the PI's department is responsible for the difference.

<sup>8</sup> Financial Services' Cost Principles for Sponsored Projects course provides a detailed explanation of indirect (F&A) costs.

negotiated rate requires a waiver from OGC, which will be granted in very limited situations. For non-federal awards, the university follows the sponsor’s published and consistently applied policy.

The following table identifies the university’s indirect (F&A) cost rate.

<b>CU Denver   Anschutz Medical Campus Indirect (F&amp;A) Costs July 1, 2016 - June 30, 2020</b>			
<b>Project Type</b>	<b>On-Campus</b>	<b>Off-Campus</b>	<b>Cost Base</b>
Organized Research	55.5%	26%	MTDC
Instruction	42%	26%	MTDC
Other Sponsored Projects	26%	26%	MTDC
Industry/Non-federal Clinical Trials	28%	28%	TDC
Proof of Concepts Awards (POCg) Tech Transfer	8%	8%	MTDC
Non-profit Associations and Foundations	Sponsor consistently applied published policy <u>OR</u> 10% if no sponsor policy		TDC

The Modified Total Direct Cost (MTDC) represents all direct salaries, applicable fringe benefits, materials and supplies, services, travel, and the first \$25,000 for each subaward. MTDC does not include:

- Equipment
- Capital expenditures
- Charges for patient care
- Building rental costs
- Tuition remission
- Scholarships
- Fellowships
- Participant support costs
- The portion of each subaward in excess of \$25,000.

**Indirect (F&A) Cost Formula**

A sponsor may limit the total award amount. In this situation, use the following formula to determine the **approximate** total direct costs and indirect (F&A) costs for the award.

1. Divide total budget amount by 1.00 + indirect (F&A) cost rate. This gives you the total direct costs for the project.
2. Subtract the results from Step 1 from the total budget amount. This gives you the total indirect (F&A) costs for the project.
3. To verify your calculation, add the amounts from step 1 and step 2. If your calculations are correct, this total will equal the award amount.

**Practice Activity** – A sponsor limits an award to \$100,000. What is the approximate total direct cost that may be charged to this project when applying the university’s 55.5% indirect (F&A) cost rate?

### Step 3: Ensuring consistency between the project narrative and the budget

The budget should be compared against the project narrative to ensure consistency. The PI may have made changes to the project which could affect the budget. The costs in the budget must support the activities described in the narrative. Any item or activity identified in the project narrative should be accounted for in the budget, and vice versa. In addition, elements such as the amount of effort described in the narrative must correspond to the funding requested to support that effort.

### Step 4: Writing the budget narrative / justification

The budget narrative, also referred to as the budget justification, serves to explain the project's proposed costs. Generally, the PI is responsible for writing the budget narrative, though the research administrator should verify that the proposed budget is aligned with the budget narrative.

The budget justification should:

- Follow the sponsor's proposal instructions as closely as possible, providing as much detail and justification as necessary
- Give details about significant items, which would include:
  - Specific information regarding travel costs, such as:
    - The destination
    - Number of people traveling
    - Dates or duration of all anticipated travel
    - Justification of how the travel is directly related to the project
  - Detailed equipment lists and supplies
  - Justification for consultants and subawards
- Explain why each of the items included in the budget is necessary in order to accomplish the project
- Make it clear that all budget requests are reasonable and consistent with sponsor and university policies.

#### **Example – Budget Narrative**

The budget narrative should explain why each of the requested items is necessary to accomplish the project.

An example of a poorly written budget justification would be:

*Dr. Uwilingiyimana will serve as the Co-Investigator on the project.*

An example of an improved budget justification would be:

*Dr. Uwilingiyimana will serve as the Co-Investigator on the project. She will be responsible for the design and creation of DNA constructs in support of specific aims (i) and (ii). She will train and supervise one or more undergraduate students to assist her in executing these experiments. She will communicate regularly with the PI to provide research updates, analyze data, and plan future work in order to meet the goals and objects of the project. She will devote 2.4 calendar months effort to the project.*

### Step 5: Verify that the Budget Adheres to Sponsor and University Requirements

A final review of the budget should be completed to ensure compliance with both university and sponsor policies. During this review, a research administrator should:

- Verify that all costs included in the budget are allowable, and remove all unallowable costs from the budget
- Ensure that each cost is consistently treated as either a direct or indirect (F&A) cost
- Confirm that the budget adheres to any program-specific limitations, such as a salary-cap
- Evaluate that the budget is realistic and that the budget is not inflated or underfunded
- Determine if the budget conforms to university policies; as sponsored funds must be treated exactly as university funds, if the university prohibits a specific cost, then sponsored funding cannot be used for that activity
- Make sure the budget calculations are correct
- Verify the correct indirect (F&A) cost rate is used and applied correctly

### Step 6: Upload the Budget Into InfoEd

Once the budget has been finalized, the research administrator is responsible for uploading the budget into InfoEd, along with all other required proposal documents.

### 4.5 Cost Sharing or Matching

Some sponsors require recipients to provide a percentage of the overall project cost. **Cost sharing or matching** represents the portion of project costs provided by the university. For example, a sponsor may award \$250,000 for research and the university may commit to contribute \$15,000 to buy a piece of equipment needed for the research.

Many sponsors providing funding for research do not require cost sharing. Typically, it is not necessary nor desirable to engage in cost-sharing except when mandated by the sponsor or needed to accurately reflect the level of effort required for the project.

Sponsors define and acknowledge various types of cost sharing or matching funds, including:

- **Mandatory cost sharing.** Sponsors may require cost sharing as a condition for making an award.
- **Voluntary committed cost sharing.** Applicants may provide support for a project when the sponsor does not require cost sharing. Some applicants believe that providing voluntary cost sharing will improve their chances for funding. Under 2 CFR 200.306, voluntary committed cost share is not expected on federal research awards, nor can it be used by a federal awarding agency as a factor in the review process unless specifically authorized by federal regulations and included in the funding announcement. Any voluntary committed cost sharing incorporated into an award agreement is legally binding, and is subject to all compliance, reporting, and audit requirements.
- **Voluntary uncommitted cost sharing.** A recipient may contribute time or resource to a project that are not included in the project budget. For example, if a PI proposes and charges 25% effort, but actually devotes 35%, the additional effort is voluntary uncommitted cost sharing. The university highly discourages the use of voluntary cost sharing.

### Calculating Cost Share – Practice CRA Question

*Question:* An agency requires 20% cost sharing of the total project costs. The federal agency is providing \$200,000 for the project. What amount must the university provide as cost share?

*Answer:* \$50,000.

$\$200,000$  (Federal Share) / 80% (Federal Percentage) =  $\$250,000$  (Total Cost)

$\$250,000$  (Total Cost) -  $\$200,000$  (Federal Share) =  $\$50,000$  (University Cost Share)

The university's Fiscal Policy for Cost Sharing outlines responsibilities and procedures for cost sharing. Under the university's policy, providing resources for cost sharing is the responsibility of the PI and their department. The department providing the cost sharing must provide signature approval on the routing form at the time the proposal is submitted to OGC for review.

Under university policy, if a cost sharing commitment exists, the expenses used must be:

- Verifiable from university records
- Used as cost sharing for only one sponsored project
- Allowable and allocable to the project
- Necessary and directly related to the project's objectives
- Provided for in the approved budget when required by the sponsor
- Not paid for by federal funds under another award, except where authorized by federal statute to be used for cost sharing
- Incurred during the applicable award period of the sponsored project
- Recorded in a separate project (speedtype) if there is a specific mandatory dollar amount of cost sharing or non-payroll cost sharing
- Recorded in a separate project (speedtype) if there is a cost overrun of \$50,000 or more of non-faculty/professional salary/benefit expense or cost overrun of non-personnel expense.

Under the university policy, the following expenditures may be used for cost sharing:

- Faculty, staff, or student salaries and related fringe benefits
- Laboratory supplies
- Travel
- Waivers of indirect (F&A) costs with university approval

The university prohibits the following expenditures for cost sharing:

- Expenditures that are normally charged as indirect costs, such as administrative salaries or office supplies
- Unallowable costs, such as alcoholic beverages, entertainment, or any costs disallowed by the sponsor
- Equipment, unless required by the sponsor
- Service Center expenses

### **NIH Salary Cap and Cost Sharing**

An individual's salary above the NIH salary cap cannot be used for cost sharing or matching purposes.

For example, assume a PI's institutional base salary is \$200,000 and the PI is spending 10% of their effort on the NIH award. The maximum that can be charged to the award is \$18,900. The remainder of the PI's salary for the related time and effort, \$1,100, cannot be used as cost share.

### **4.6 Program Income**

Sponsored projects may generate income. **Program income** is the gross income directly generated by a sponsored activity or earned as a result of an award during the period of performance.

Program income includes:

- Income from fees for services performed
- The sale of commodities or items fabricated under an award
- License fees
- Royalties on patents and copyrights
- Registration fees

Some sponsors may require a projection of program income and the intended use of the income. Calculation of program income should be based on historical information and prior projects.

For most research awards, program income is generally added to the project's budget. This is known as the **additive method**. Some sponsors may use the **deductive method**, which reduces the sponsor's contribution to the project by the amount of program income generated.

Sponsor guidelines will generally identify how program income should be treated.

### **4.7 Payment Types**

The payment type for the proposed project needs to be considered during budget development. Most payments for sponsored awards are through one of following three methods:

- **Advanced Payment.** Sponsors may provide funding for allowable project costs before the university incurs costs for the project.
- **Cost-Reimbursable.** Sponsors will reimburse the university for allowable project costs incurred during either: the period of performance of the project or during specific budget periods.
- **Fixed Amount.** Sponsors may provide a specific level of funding without regard to actual costs incurred. The funding level is definitive and is not subject to further adjustment. Incremental funding may be provided when the project meets specific milestones, such as when the PI provides deliverables to the sponsor. Because an absolute limit is imposed on spending, special consideration needs to be taken when preparing the budget to ensure that the university is in the best possible position to fulfill its proposed obligations. Any project cost overruns are the responsibility of the PI and their department.

#### **4.8 Foreign Currency Conversion**

Sponsors have differing requirements for addressing foreign currency. The following list indicates some considerations for budget development:

- **Federal awards.** All costs must be in U.S. dollars, therefore, all cost estimates in a foreign currency must be converted.
- **Non-federal awards.** Sponsor requirements will vary. If the sponsor is based in a foreign country, it is likely the sponsor will require the budget in that country's currency; however, OGC will require the budget also be presented using U.S. dollars.

Exchange rates fluctuate, and sometimes the fluctuation can be dramatic. The PI and their department are responsible for any fund shortages due to conversion deviations.



#### **Resource**

The Treasury Department provides daily and historical exchange rates at:

<https://www.fiscal.treasury.gov/fsreports/rpt/treasRptRateExch/currentRates.htm>

#### **4.9 – Exercise: Developing a Budget**

**Background:** Based on Dr. Sirleaf’s proposed research, you have developed the following non-personnel budget:

- Travel to Thailand, costing approximately \$16,000 for Year 1 and approximately \$7750 in Year 2.
- Laboratory supplies, costing approximately \$7,000, will be purchased in Year 1.
- Laboratory analysis, costing approximately \$20,000, will be conducted in Year 2.
- A piece of equipment, costing approximately \$10,000, will be purchased in Year 1.

NIH does not require a detailed budget for R21 proposals; however, you will need to submit a detailed budget to OGC for their review.

The following tables provide details for non-personnel costs. The tables are shown here to demonstrate a best practice in estimating budget costs. For the purpose of this exercise, assume the science is correct.

#### **Travel Expenses**

**YEAR 1**  
November 2019 - 3 people X 15 nights

	People	Units	\$ Per Unit	Total
Airfare	3	1	\$1,100	\$3,300
Hotel	3	15	\$38	\$1,710
Per Diem	3	17	\$58	\$2,958
Transportation	1	1	\$350	\$350

March 2020 - 3 people X 13 nights

Airfare	3	1	\$1,100	\$3,300
Hotel	3	13	\$38	\$1,482
Per Diem	3	15	\$58	\$2,610
Transportation	1	1	\$350	\$350

**Year 1                      \$16,060**

#### **YEAR 2**

October 2020 - 3 people X 13 nights

Airfare	3	1	\$1,100	\$3,300
Hotel	3	13	\$38	\$1,482
Per Diem	3	15	\$58	\$2,610
Transportation	1	1	\$350	\$350

**Year 2                      \$7,742**

**TOTAL                      \$23,802**

## SUPPLIES

### YEAR 1

Supplies	Participants	Number	Cost/unit	Total
Creatinine Strips	75 strips x 1 day x 1 time per day	75	\$315, box 50 strips	\$472.50
Creatinine Strips	100 strips x 3 days x 1 times per day	450	\$315, box 50 strips	\$2,835.00
Urine Tubes for Lab Analysis	75 tubes x 1 day x 1 time per day x 2 per participant	150	\$250, box 1000	\$37.50
Urine Tubes for Lab Analysis	75 tubes x 1 day x 1 time per day x 6 per participant	450	\$250, box 1000	\$112.50
Urine Tubes for Lab Analysis	100 tubes x 3 days x 1 times per day x 2 per participant	600	\$250, box 1000	\$150.00
Urine Tubes for Lab Analysis	100 tubes x 3 days x 1 times per day x 6 per participant	3,600	\$250, box 1000	\$900.00
Blood sample tubes (EDTA tubes)	100 tubes x 3 days x 1 times per day	300	\$35, 100	\$105.00
Blood sample tubes (EDTA tubes)	101 tubes x 3 days x 1 times per day	300	\$35, 100	\$105.00
Blood tube rack	2	2	\$10	\$20.00
Needles	100 needles x 3 days x 1 time per day	300	\$15, box 100	\$45.00
Materials	100	4	\$2	\$800.00
Compensation for participants	100	3	\$3	\$900.00
Compensation for participants	175	1	\$3	\$525.00

**Year 1 - Total \$7,007.50**

**Lab Analysis**

**YEAR 2**

<b>Abnormal Livers</b>		<b>Number</b>	<b>Cost/test</b>	<b>Total</b>
NSAID	75 x 1 days x 1 times per day	75	70	\$ 5,250
NGAL	75 x 1 days x 1 times per day	75	12	\$ 900
Cotinine	75 x 1 days x 1 times per day	75	9	\$ 675
Uranium	75 x 1 days x 1 times per day	75	14	\$ 1,050
Arsenic	75 x 1 days x 1 times per day	75	14	\$ 1,050
Cadmium	75 x 1 days x 1 times per day	75	14	\$ 1,050
2,4 D	75 x 1 days x 1 times per day	75	25	\$ 1,875
Glyphosate	75 x 1 days x 1 times per day	75	25	\$ 1,875
Creatinine	75 x 1 days x 1 times per day	75	5	\$ 375
Copeptin	75 x 1 days x 1 times per day	75	62	\$ 4,650
<b>Koi Pla</b>				
Uranium		10	2	\$ 280
Lead		10	2	\$ 280
Arsenic		10	2	\$ 280
Cadmium		10	2	\$ 280
2,4-D		10	2	\$ 280
Glyphosate		10	2	\$ 280

**Year 2 - Total      \$      20,430**

**EQUIPMENT**

	<b>Number</b>	<b>Cost</b>	<b>Total</b>
Hand-held Ultrasound machine	1	10,000	10,000

**Year 1 - Total      \$10,000.00**

Directions: Assume the cost analysis for the laboratory analysis, laboratory supplies, and travel and are accurate. Answer the following questions.

1. InfoEd provides the following categories in the Budget Module:

- Animal Costs
- Computer Automated Data Processing Services
- Consultant Services
- Equipment Maintenance
- Equipment or Facility Rental/User Fees
- Human Subject Costs
- Inpatient Costs
- Tuition Remission
- Non-MTDC
- Other Costs
- Outpatient Costs
- Participant Other
- Participant Stipends
- Participant Tuition and Fees
- Publication Costs
- Purchases Equipment
- Subsistence
- Supplies
- Travel-Domestic
- Travel-Foreign
- Other Direct Costs

Using the category list above, complete the following chart as you would in InfoEd for the non-personnel costs associated with this project.

<b>Personnel Category</b>	<b>Period 1</b>	<b>Period 2</b>	<b>Direct Costs</b>
Subtotal Personnel	\$94,430	\$95,841	\$190,271

<b>Non-Personnel Category</b>	<b>Period 1</b>	<b>Period 2</b>	<b>Direct Costs</b>
	\$	\$	\$
<b>Subtotal</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

2. Calculate the indirect (F&A) costs associated with this project.

3. What is the total cost for this project?

## **5. Application Routing and Submission Process**

### **5.1 Routing a Proposal to OGC<sup>9</sup>**

After the proposal documents have been uploaded into InfoEd, the proposal is sent to OGC for review in a process known as routing. **Routing** is the process for completing and submitting all required forms and documents for review and approval by designated university officials. Routing allows for OGC to review a proposal and provide institutional support. Some administrative units also have intra-departmental routing procedures.

Proposals must be accompanied by an Approval of Application for Grant or Contract (Routing) form that is prepared electronically in InfoEd. Routing is completed and electronically approved by the PI, the Department Chair or Director, and, if applicable, an appropriate Dean or Administrator prior to the proposal being submitted to Grants and Contracts. Upon satisfactory review of a proposal, OGC will provide institutional endorsement, and the proposal is returned electronically.

Formal routing is required for:

- New monetary awards, including competing continuation awards and noncompeting continuation awards
- Non-monetary awards including:
  - Sponsored Research Agreement (SRA) and Clinical Trial Agreement (CTA)
  - Master Agreement
- Pre-applications requiring a full detailed budget and institutional endorsement
- When the proposal requires university agreement with specific terms and conditions before the award is made

Be sure to highlight any special sponsor deadlines or instructions when routing a proposal to OGC.

The following actions do not require routing through InfoEd, though OGC assistance may still be necessary or required:

- Award notices for proposals that have been already routed
- Requests or authorizations for additional time (no-cost extensions)
- Carry-forward requests
- Just-in-time Requests
- Request for authorizations for rebudgeting
- Amendments to contracts which do not add funds
- Confidentiality agreements

The following items need to be included in the routing process:

- Completed routing form with signatures from the PI, department chairperson, and applicable dean or administrator
- Clinical Trial Supplemental Budget and Certification Form for industry-sponsored contracts only
- Sponsor's instructions or funding announcement, except for the NIH

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<sup>9</sup> See Appendix F on page 76 for an example of the routing form and associated directions.

- All forms and attachments required by the sponsor
- Proposed budget for the entire period of performance
- Salary increase verification if the PI's salary in the proposal is above the university's allowable inflationary increase of 5%
- Current Veterans Affairs (VA) Memorandum of Understanding for any person who is listed in the proposal budget that has a dual appointment with the VA
- For known subrecipient awards, the following information is required:
  - All forms the sponsor requires for subrecipients, which must include institutional endorsement from the subrecipient organization
  - Budget proposal
  - Budget justification
  - Scope of work
  - All other documents the subrecipient submitted

Please note, that OGC does not require the projective narrative or scientific-related aspects of the proposal; however, research administrators are encouraged to include a copy of the final format of the project narrative when routing to OGC. If the final format is included, OGC will verify that the format adheres to sponsor requirements.

### **Discussion Question**

A pre-award research administrator routed a proposal to OGC for review. The final format of the project narrative was not included, therefore the formatting of the narrative was never reviewed. The proposal was submitted to NIH on-time; however, the proposal was rejected and not reviewed because the project narrative used the wrong font size.

Question: If you were the pre-award administrator in this scenario, how would you explain the proposal rejection to your PI?

### **No-Cost Extensions**

Sponsors may approve a no-cost extension to a project. A **no-cost extension** extends the project period without any additional funding from the sponsor.

OGC must be notified when a sponsor has approved a no-cost extension. Sponsor notification and method of providing a no-cost extension varies. Internal departmental procedures to process sponsor approval and notification of OGC will also vary. In some university departments, the pre-award research administrator is responsible for processing no-cost extensions.

## **5.2 Purpose of Routing**

The purpose of routing is to:

- Establish the eligibility of an individual to be a PI
- Define the appropriate administrative unit to receive recognition for the proposal and award
- Ensure the appropriate indirect (F&A) cost rate is applied
- Identify the correct human and/or animal protocols associated with the project

- Identify radiation and biosafety approvals
- Review any cost sharing requirements
- Verify that appropriate conflict of interest disclosures have been filed
- Provide departmental endorsement of the project
- Ensure compliance with federal, state, and university requirements
- Make sure that the university can agree to the sponsor's terms and conditions

The Routing form is also used by OGC in the Award Setup phase when a sponsor awards funding. Delays in the award setup will likely occur if the routing form is incomplete or inaccurate.

### **5.3 Xenia Email**

[Xenia@ucdenver.edu](mailto:Xenia@ucdenver.edu) is the email account OGC uses to process pre-award actions.

[Xenia@ucdenver.edu](mailto:Xenia@ucdenver.edu) is also used for:

- General departmental inquiries
- Notifying OGC of pre-application submissions
- Requesting indirect (F&A) cost waivers
- Forwarding grant award notices from sponsors to OGC for award set-up
- Requesting no-cost extensions

Research administrators must use [eapp.xenia@ucdenver.edu](mailto:eapp.xenia@ucdenver.edu) when notifying OGC that a proposal is ready for submission to the sponsor.

### **5.4 OGC Review**

When a proposal is routed, OGC reviews the proposal for compliance with sponsor requirements. Some items that will be reviewed include:

- Page limits, margins, and fonts
- Document formats
- Verifying required documents are attached
- The budget
- Ensuring the appropriate indirect (F&A) cost rate has been used in the proposal
- Cost share proposals
- Special sponsor requirements

The OGC PreAward team will provide supporting documentation from sponsors to explain edits and corrections.

The following images show examples of OGC reviews of university proposals.



<http://www.ncbi.nlm.nih.gov/sites/myncbi/1ZA1R85viyKk3/bibliographahy/47389913/public/?sort=date&direction=ascending>

**D. Research Support**  
**Ongoing Research**

*DoD requires Previous, Current, and Pending Support categories (if none ~~possible~~ enter "none")*

The Safety of Oral Apixaban (Eliquis) versus Subcutaneous Enoxaparin (Lovenox) for Thromboprophylaxis in Women with Suspected Pelvic Malignancy; a Prospective Randomized Open Blinded End-point Design.

**Principal Investigator:** Responsible for protocol development, study initiation, oversight of study, medical monitoring, data analysis and presentation of results at two study sites.

**Objective:** Phase III trial comparing Apixaban, an oral anti-coagulant agent, to Enoxaparin, an injectable medication, for thromboprophylaxis following pelvic surgery. Currently women with pelvic surgery for gynecologic malignancies have a 23% rate of a VTE event following surgery; this may be due to inconsistencies in prescribing thromboprophylaxis or patient non-compliance.

**Completed Research**

Sexual Dysfunction in Women with Gynecologic Cancer

**Principal Investigator:** Oversaw the trial and analysis of data at all 4 sites. Responsible for recruitment and study initiation of all sites, and recruitment/enrollment at the lead site. Took the lead on presentation of study results.

**Objective:** To identify sexual dysfunction as a significant risk following gynecologic cancer and having a negative impact on survivorship quality of life and partner relationships.

**Sponsor:** Patty Brisben Foundation; January 2014-March 2015

A Prospective Study of COXEN Chemotherapy Prediction in Recurrent Ovarian, Fallopian Tube, and Peritoneal Carcinomas

*Support should be listed in a separate attachment named "Support - LastName.PDF"*

Research Asst: TBH: ██████████ - 50% Yrs 1-3, 40% Yr 4	\$28,643	\$29,502	\$30,387	\$25,039	\$113,570
Student Data Collector - 10 hrs/week at \$15/hr, Yrs 1-4 (9 mos/yr)	\$5,850	\$5,850	\$5,850	\$5,840	\$23,390
<b>Personnel Sub-Total</b>	<b>\$134,610</b>	<b>\$138,473</b>	<b>\$142,452</b>	<b>\$147,559</b>	<b>\$563,094</b>
<b>FRINGE BENEFITS</b>					
27% of Faculty	\$18,648	\$19,207	\$19,783	\$22,342	\$79,980
28% of Professional Staff salaries	\$16,715	\$17,216	\$17,732	\$16,512	\$68,175
1% of Student	\$59	\$59	\$59	\$58	\$234

*\$10 short if working the exact same hours as the other years  
Looks like this was done to keep under \$1.4 million cap*



Administrative Offices  
The Education Center  
Human Resources  
Psychological Services  
Respite Programs  
301 Camp Meeting Road  
Sewickley, PA 15143  
(412) 741-1800

Friendship Academy  
255 South Negley Avenue  
Pittsburgh, PA 15206  
(412) 365-3800

LEAP Preschool  
Training and Consultation  
WISCA  
200 Linden Avenue  
Pittsburgh, PA 15215  
(412) 781-1708

June 8, 2016

[REDACTED]  
CU Denver School of Education &  
Human Development  
1380 Lawrence Street  
Denver, Colorado 80204  
[REDACTED]

*Incomplete Routing*  
- Should include a signed commitment form with both the subawardee and the PI  
Should also have the correct budget figures for year 1 and the totals

I am writing on behalf of The Watson Institute to affirm our collaboration with the University of Colorado-Denver in its IES grant application 'LEAP Sustainability: Exploring Malleable Factors that Predict Long-Term Fidelity.'  
We are prepared to fulfill our subcontract obligations over the 4-year grant period and have assigned two very experienced staff, [REDACTED], M.Ed. and [REDACTED], M.Ed. to lend this effort, possibly a third person, [REDACTED], M.Ed.

As you know, we have been involved in replicating LEAP for nearly 30 years and have contacts with some 50 sites that have used our coaching services. We are well aware that sites vary widely in their long-term use of LEAP practices and understanding who maintains and under what conditions is of enormous importance.

We look forward to continuing our long-term collaborations and hope the proposal is favorably viewed.

After OGC has completed the review, the proposal will be returned to the department for corrections.

Research administrators should ensure that deadlines to route proposals to OGC are met. If a proposal is routed past the deadline, OGC may not be able to complete a full review. Instead, OGC will complete a truncated review, which, depending on time constraints, may only include reviewing the budget. All proposal errors on late routings are the responsibility of the PI and the department.

### **5.5 Submitting the Proposal to the Sponsor**

The responsible party for submitting the final application depends on the type of sponsor.

- For most federal awards, OGC is responsible for submitting the proposal.
- For non-federal awards, either OGC or the department will submit the proposal.
  - If the funding opportunity announcement requires AOR submission, then OGC must submit the proposal
  - If the funding opportunity announcement does not require AOR submission, then the department or PI may submit the proposal.

If you are unsure if OGC is required to submit the proposal, you should email [Xenia@ucdenver.edu](mailto:Xenia@ucdenver.edu) as soon as possible in the proposal development stage.

### **Common Routing Form Problems**

Mistakes on the routing form can cause delays with the award set-up process and potentially award management problems. The following list provides best practices to mitigate these problems:

- For subrecipients, indicate the number of Speedtypes needed in the routing form comment section
- Verify employee ID numbers are correct
- Ensure the employees listed as fiscal staff are still working on the award
- Update the budget as soon as possible after receiving the notice of award to reflect any sponsored approved budgetary changes
- Verify the correct org code has been used
- Verify the location of the project on the routing form is correct and is appropriately classified as either “on campus” or “off campus”
- For clinical trial budgets, do not put in zero for the budget in InfoEd. Instead, use a budget estimate based on the per patient rate

## **6. Sponsor Review and Award Process**

### **6.1 Sponsor Review and Evaluation**

The process in which sponsors review proposals will vary. Generally, sponsors will explain the review process and identify anticipated dates for funding decisions in the funding announcement or sponsor website.

For federal awards, 2 CFR 200 identifies a governmentwide review framework, while providing each agency the flexibility to develop an agency- or program-specific process. In general, the federal review and evaluation is as follows:

- **Compliance review.** Federal awarding agencies will typically complete an initial compliance review to evaluate an applicant's eligibility and adherence to program and application requirements. Proposals that did not follow directions, or are not eligible, are generally removed from the competition and not reviewed.
- **Merit Review.** Proposals are next evaluated for the programmatic or technical aspects of the project. Depending on the agency and program, this review may be conducted by a panel of leading experts or by agency personnel. The review panels will score each proposal based on the evaluation criteria established in the funding announcement.
- **Business Evaluation.** Agency personnel will review the proposal's budget and may complete a cost analysis.
- **Applicant Evaluation.** Before making an award, each federal agency is required to evaluate the university's ability to administer federal awards. This process includes:
  - Determining the university and PI's eligibility through the System for Award Management (SAM) and the Do Not Pay List
  - Evaluating the university's qualifications through the Federal Awardee Performance and Integrity Information System (FAPIIS)
  - Conducting a pre-award risk assessment
- **Selecting Recipients.** Based on the reviews, high-level agency personnel will select the proposals that will receive funding. Under 2 CFR 200, agencies are allowed to select recipients out of rank order of the merit review scores only if the selection criteria has been included in the funding announcement.

For non-federal awards, the review and evaluation process will vary.



#### **Resource**

The NIH produced a 15-minute video depicting the peer review process.

The video is located at:

<https://www.youtube.com/watch?v=fBDxI6I4dOA>

## Common Proposal Mistakes

The following list identifies some of the common proposal mistakes that will likely result in a low or unqualified score:

- Submitting a proposal similar to an already funded project
- Missing or incorrect documents
- Unclear or unfocused specific aims or objectives
- Project has a lack of significance
- Lack of innovation
- Weak or missing hypothesis
- Overly ambitious
- PI's productivity has been recently low
- Insufficient expertise
- Insufficient institutional support
- Insufficient preliminary data
- Lack of necessary controls
- Weak statistical plan or lack of power analysis
- Little to no discussion of how data will be interpreted
- Little or no discussion of next steps
- Little or no discussion of potential problems or strategies to address them
- Poorly written or poorly organized

## 6.2 Just-In-Time Requests

Some sponsors may request information from the university or PI prior to making an award. Sponsors may use this process either to reduce the burden on applicants during the submission process or to clarify information in the application. Receiving a sponsor request does not constitute an award. The NIH calls this process a **just-in-time** request (JIT).

Information that may be requested includes:

- List of active and pending financial awards
- Certifications for human or animal subjects
- Revised budgets

For JITs, the research administrator must coordinate with the PI to compile all requested information. The research administrator then submits the documents and the JIT request to OGC for an initial

### NIH eRA Commons and NSF Research.gov

The NIH and the National Science Foundation (NSF) each use their own online grants management system which provides, among other activities, and an ability to receive information regarding proposal status.

The NIH uses the electronic Research Administration (eRA) Commons system and the NSF uses Research.gov.

review. OGC will return the documents to the research administrator to make any corrections. The research administrator returns the corrected documents to OGC, which then submits the information to the sponsor.

### **6.3 Award Process**

Following the review process, sponsors may provide the proposal's evaluation scores and/or reviewer comments to the applicant. For proposals that were not successful, PIs should review the scores to identify areas of weakness in order to improve the possibility of receiving funding in the future. If a sponsor does not automatically provide the evaluations, PIs should try to obtain them from the sponsor. PIs may be able to even discuss the evaluation with the sponsor in some situations.

The options for PIs when an application is not successfully funded varies by sponsor. Some possible actions include:

- Revising the proposal and resubmitting during a future competition
- Applying through another sponsor
- Creating a new application to pursue a similar idea
- Appealing the decision

For proposals that were successfully funded, the sponsor will provide a notice of award to the university. In some situations, the university may need to negotiate with the sponsor before the award is accepted. Some items that might be negotiated include:

- Award specific terms and conditions
- Scope of work
- Budget

#### **NIH Guidance on Resubmission**

The NIH provided the following question and answer regarding resubmissions.

Question: When should I resubmit?

NIH Answer: You should consider the resubmission application when you can address the weaknesses described in the summary statement. Often, additional preliminary data are needed to address the criticisms. Therefore, you may need to skip a due date or two and plan on including the results from additional experiments. Note that the [standard due dates](#) for resubmission applications are often later than those for new applications. An application can be resubmitted up to 37 months after the original application's due date; after that, it must be submitted as a new application and not refer to the previous review. However, as the time increases between the original application and the resubmission, reviewers may expect more preliminary data, as evidence that the investigator is productive and committed to the project. Alternatively, you may discuss with your Program Officer the possibility of submitting a new application rather than a Resubmission application.

## **Appendix A – Acronyms**

<b>Acronym</b>	<b>Term</b>
AA	Animal Assurance
AAALAC	American Association of Animal Laboratory Accreditation Council
ACM\$	Award Cash Management Service
ADA	Americans with Disabilities Act of 1990
AOR	Authorized Organization Representative
BAA	Broad Agency Announcement
CAS	Cost Accounting Standards
CDER	Common Data Element Repository
CFDA	Catalog of Federal Domestic Assistance (now known as the Assistance Listings)
CFR	Code of Federal Regulations
CO	Contracting Officer
COGR	Council on Government Relations
COI	Conflict of Interest
COMBIR	Colorado Multiple Institutional Review Board
Co-PI	Co-Principal Investigator
CRADA	Cooperative Research and Development Agreement
DARPA	Defense Advanced Research Projects Agency
DOD	Department of Defense
DUNS	Data Universal Numbering System
ED	U.S. Department of Education
EIN	Entity Identification Number
EPA	Environmental Protection Agency
F&A	Facilities and Administration
FAIN	Federal Award Identification Number
FAPIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDP	Federal Demonstration Partnership
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report
FOIA	Freedom of Information Act
FR	Federal Register
FTE	Full-time Equivalent
FY	Fiscal Year
GAAP	Generally Accepted Accounting Principles
GAO	Government Accountability Office
GMO	Grants Management Office
GPRA	Government Performance and Results Act
HBCU	Historically Black Colleges and Universities
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development

IACUC	Institutional Animal Care and Use Committee
IBS	Institutional Base Salary
IHE	Institute of Higher Education
IP	Intellectual Property
IPA	Intergovernmental Personnel Act
IRB	Institutional Review Board
ITAR	Institutional Traffic in Arms Regulations
JIT	Just-in-Time
LOI	Letter of Intent
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
MTDC	Modified Total Direct Costs
NGA	Notice of Grant Award
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NICRA	Negotiated Indirect Cost Rate Agreement
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute on Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NIST	National Institutes of Standards and Technology
NOAA	National Oceanic and Atmospheric Administration
NOFA	Notice of Funding Availability
NOFO	Notice of Funding Opportunity
NPS	National Park Service
NSF	National Science Foundation
OGC	Office of Grants and Contracts
OIG	Office of Inspector General
OMB	Office of Management and Budget
ONR	Office of Naval Research
ORDE	Office of Research Development Education

PA	Program Announcement
PAPPG	Proposal & Award Policies & Procedures Guide (NSF)
PHI	Protected Health Information
PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
PMS	Payment Management System
PO	Program Official / Officer
PTE	Pass-through Entity
R&D	Research and Development
R&R	Research and Related
RFA	Request for Applications
RFP	Request for Proposal
RPPR	Research Performance Progress Report
RTC	Research Terms and Conditions
S&W	Salaries and Wages
S2S	System to System
SAM	System for Award Management
SAMHSA	Substance Abuse and Mental Health Administration
SBIR	Small Business Innovation Research
SF-424	Standard Form 424
SF-424 (R&R)	Standard Form 424 (Research and Related)
SNAP	Streamline Non-Competing Application Process
SO	Signing Official
SOW	Statement of Work
SRO	Scientific Review Officer
STTR	Small Business Technology Transfer Program
TDC	Total Direct Costs
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
VA	U.S. Department of Veterans Affairs

## **Appendix B – Glossary**

### **Appropriation**

Congressional action that provides funding for federal government activities.

### **Appropriation Mandates**

A rider inserted into an appropriations bill which directs a federal agency to take a specific action. For example, Congress includes a salary cap for PIs working on NIH grants.

### **Assistance Listings**

Formerly known as the Catalog of Federal Domestic Assistance (CFDA), it is the official government database providing a description each federal financial assistance program and associated compliance requirements. It is located at [beta.sam.gov](https://beta.sam.gov).

### **Authorized Organization Representative (AOR)**

The officials approved to sign and submit proposals, and other award-related documents, on behalf of the university.

### **Authorizing Statutes**

A law that provides the authority for a federal awarding agency to establish a financial assistance program and that establishes programmatic requirements.

### **Budget**

An estimate of the expenditures needed to conduct a project.

### **Career Development Grants**

Sponsored funding to new researchers to foster their research opportunities.

### **Clinical Trials**

A type of sponsored project to evaluate medications and medical devices on a population.

### **Competing Continuation Proposals**

*See Renewal Proposal.*

### **Conference Grants**

Sponsored funding to support individuals to attend conferences.

### **Continuation Proposal**

An extension or renewal of an existing award for one or more additional budget period(s). Receipt of a continuation grant is usually based on availability of funds, project performance, and compliance with sponsor requirements.

### **Construction Grants**

Sponsored funding to support the construction, modernization, or major alterations and renovations of facilities.

**Equipment Grants**

Sponsored funding to assist researchers in obtaining necessary equipment for their studies.

**Fellowship Grants**

Sponsored funding to support students and researchers at various stages of their careers.

**Funding Opportunity Announcement (FOA).**

A formal notification by a sponsor announcing a funding opportunity. Sponsors may call formal announcements by a variety of names, including: Notice of Funding Opportunity (NOFO), Request for Funding Application (RFA), Request for Proposal (RFP), Notice of Funding Availability (NOFA), and Solicitations.

**Grants.gov**

The federal government database that lists open and future federal award competitions.

**InfoEd eRA Portal**

The official electronic research administration system adopted by the University of Colorado to manage the research lifecycle from start to finish.

**Just-in-Time Request (JIT)**

A request from a sponsor for specific proposal elements to be submitted later in the application process. A JIT does not constitute an award.

**Limited Solicitation**

A funding announcement that restricts the number of proposals that the university may submit.

**No-Cost Extension**

A formal extension of the project period to allow additional time to complete a project at no additional cost to the sponsor.

**Non-Competing Continuation Proposal**

*See Continuation Proposal*

**Non-research Project Grants**

Sponsored funding to support a specific project that is not research related.

**Pre-Application**

A preliminary submission providing summary-level information concerning an applicant's intent to submit a proposal. Sponsors typically use pre-applications to determine the applicant's eligibility and evaluate the proposed project's merit.

**Pre-Award Phase**

The phase of the project lifecycle encompassing all activities leading to a sponsor making an award and university acceptance.

**Program Guidelines**

Guidance issued by a federal awarding agency describing the requirements of a federal financial assistance program. Program guidelines are not binding, unless incorporated into the terms and conditions of an award.

**Public Policy Requirements**

Non-financial compliance requirements relating to social, economic, other policy objectives attached to federal financial awards. Some federal agencies may call these requirements national policy requirements.

**Renewal Proposal**

A request for additional funding after the project period has ended. The request reflects an expansion or continuation of the scope of the previously approved project.

**Research Grants**

Sponsored funding to expand the body of scientific knowledge and to develop new technologies.

**Regulations**

A rule or order issued by a federal agency, which carries the force of law. Federal agencies must post proposed and final rules in the Federal Register.

**Specific Conditions**

Award-specific terms and conditions imposed by a sponsor. Specific conditions, sometimes called special conditions, are typically more restrictive than a sponsor's general award terms and conditions.

**Training Grants**

Sponsored funding to develop or enhance research training opportunities, usually for pre- or post-doctoral work.

**Travel Grants**

Sponsored funding to support individuals to travel for research and training.

**Unsolicited Proposals**

A submitted application to a sponsor that is not in direct response to an official funding announcement.

**[Xenia@UCDenver.Edu](mailto:Xenia@UCDenver.Edu)**

An email account used by OGC to process pre-award actions and to answer general departmental inquires.

## **Appendix C – Elements of a Federal Funding Opportunity Announcement**

Federal awarding agencies are required to publicly announce competitions for grants and cooperative agreements using a standard, governmentwide form. Once you know the elements of the template, reading any federal government opportunity becomes easier.

2 CFR 200 (Uniform Guidance) uses the term **notice of funding opportunity** (NOFO) to refer to funding opportunities. Federal agencies may use other names, such as:

- Notice of Funding Availability (NOFA)
- Request for Application (RFA)
- Request for Proposal (RFP)
- Federal Funding Opportunity (FFO)
- Funding Opportunity Announcement (FOA)

Regardless of what an agency calls the notification, each agency must use the same format. Every funding announcement must contain two parts:

- Synopsis of the Funding Announcement
- Full Text of the Funding Announcement

### **Synopsis**

The synopsis of the funding announcement contains six elements to provide potential applications with the essential information about the opportunity:

- Federal awarding agency
- Funding opportunity title
- Announcement type to indicate if it is a new notice or a modification
- Funding opportunity number
- Catalog of Federal Domestic Assistance (CFDA) number
- Key dates including the due date for application submission

Federal agencies must post the synopsis on Grants.gov, though many agencies also post funding announcement on agency websites and other resources. Federal regulations require agencies to post funding announcements at least 30 days before the application deadline unless exigent circumstances exist.

### **Full Text of the Funding Announcement**

The funding announcement is organized in eight sections.

- Funding Opportunity Description
- Federal Award Information
- Eligibility Information
- Application and Submission Information
- Application Review Information
- Award Administration Information
- Agency Contacts
- Other Information

## **Section 1 - Funding Opportunity Description**

Federal agencies use the first section of the funding announcement to provide a detailed description of the financial assistance program. This section describes the funding priorities of the program and the purpose. This section must also provide citations for authorizing statutes and regulations governing the grant program.

Federal agencies may include additional information in this section, including:

- A history of the program
- Examples of previously funded projects or possible projects
- Indicators of successful projects

## **Section 2 - Federal Award Information**

Federal agencies must use this section to provide sufficient information to help an applicant make an informed decision about whether to submit a proposal. Federal agencies must identify the award type, such as a grant or cooperative agreement. Additional information in this section can include:

- Total amount of funding expected to be awarded
- The anticipated number of awards
- The amount of funding per award, which may include an estimated range and the maximum award amount
- The estimated number of awards
- Anticipated start date and period of performance
- Whether renewal applications are eligible for the competition

## **Section 3 – Eligibility Information**

This section of the funding announcement has three subsections addressing applicant eligibility:

- **Eligible Applicants.** The federal agency must identify what entities are eligible to apply, any factors affecting the eligibility of the principal investigator, and any criteria that makes particular applicants or projects ineligible for funding.
- **Cost Sharing or Matching.** The federal agency must identify if the grant program requires cost sharing, matching, or cost participation.
- **Other Information.** This portion of the funding announcement is reserved for additional eligibility information, such as go/no-go criteria. The federal agency may also indicate if the university may submit multiple applications or if the competition is limited to one application. This section may additionally indicate any statutory limitations on either the applicant or beneficiaries.

## **Section 4 – Application and Submission Information**

This section has seven subsections that detail the application format, submission deadlines, and any other application requirement.

- **Address to Request Application Package.** Federal agencies must indicate how the applicant can access the application package.
- **Content and Form of Application Submission.** This section identifies the required content of an application and the forms or formats that an applicant must use for the proposal. For example, this section indicates:
  - If a pre-application of letter of intent is required

- Page limitations, font size, margins indentations, and any other formatting requirements for the application
- The components of the application, such as: research strategy or project narrative; budget information and narrative; attachment requirements; evaluation strategy; logic models; and, dissemination plans.
- Unique Entity Identifier and System for Award Management. The university is responsible for maintaining an active DUNS number and SAM registration. PIs and research administrators only need to ensure that the correct DUNS number is used on the application.
- Submission Dates and Times. The federal agency must identify the due dates and times for all submissions, if late applications will be accepted, submission process, and how the agency will notify of receipt of application.
- Intergovernmental Review. The state of Colorado does not participate in the intergovernmental review process, therefore this section is not applicable to the university.
- Funding restrictions. The funding announcement will identify any funding restrictions. This section is critical to review when developing the project's budget. For example, the federal agency may indicate limitations on foreign travel, equipment purchases, and indirect (F&A) costs. This section also indicates if pre-award costs are allowable.
- Other Submission Requirements. This section details any other information about the application process. For example, this section may discuss post submission materials.

### **Section 5 – Application Review Information**

The federal agency must detail the evaluation and selection process for the competition. Federal regulations prohibit agencies from deviating from their stated review policies. Reviewing this information is essential in preparing a competitive proposal as this section identifies review criteria and any statutory or regulatory preferences provided to applicants. This section has four subsections:

- Criteria. The federal agency must explain the scoring criteria used in evaluating proposals.
- Review and Selection Process. This subsection identifies additional criteria, other than merit criteria, that may be used by the federal agency to select award recipients. The federal agency may also describe the composition of the review panel, how reviewers are selected, and how conflicts of interest are avoided. This section may also identify the official(s) ultimately responsible for award selection.
- FAPIIS Review Requirements. The information provided in this subsection explains the responsibilities for federal agencies to review the Federal Awardee Performance and Integrity Information System (FAPIIS) before making an award.
- Anticipated Announcement and Federal Award Dates. This is an optional section for the funding announcement and federal agencies may indicate when the awards might be announced.

### **Section 6 – Federal Award Administration Information**

This section explains post-award requirements for successful applicants. There are three subsections:

- Federal Award Notices. This subsection explains how the federal agency will notify successful applicants.
- Administrative and National Policy Requirements. Federal agencies must identify applicable administrative and national policy compliance requirements.

- Reporting. This section explains the financial and progress reporting requirements. Any additional reporting requirements should be listed.

### **Section 7 – Federal Awarding Agency Contacts**

The funding announcement must identify the agency personnel that are available to address questions from applicants. Federal agency employees may not assist in the application process, but may answer technical questions or provide clarifications on the program.

### **Section 8 – Other Information**

The final section of the funding announcement is optional for federal agencies. This section may include:

- Whether the program is one-time initiative or ongoing funding opportunity
- Definitions
- Routine or standard disclaimers regarding the competition

## Appendix D – Institutional Information

This appendix identifies commonly requested information for proposals.

<b>INSTITUTIONAL INFORMATION</b>	
Legal Name of Institution	Regents of the University of Colorado
Doing Business As	University of Colorado Denver
Type of Institution	Public/State Controlled Institution of Higher Education
Institutional Address	Grants and Contracts, Mail Stop F428 Anschutz Medical Campus, Bldg 500 13001 E 17th Pl, Room W1124 Aurora, CO 80045-2571
Email	<a href="mailto:xenia@ucdenver.edu">xenia@ucdenver.edu</a>
County	Adams
Congressional District of Applicant	CO-06
Project / Performance Site Congressional District	<ul style="list-style-type: none"> <li>• Anschutz Medical Campus - CO-06</li> <li>• Denver Campus - CO-01</li> </ul>

<b>IDENTIFICATION NUMBERS</b>	
DUNS Number / Unique Entity Identifier DUNS +4	041096314 0410963140000
Commercial and Government Entity (CAGE) No	<ul style="list-style-type: none"> <li>• Anschutz Medical Campus - 0P6C1</li> <li>• Denver Campus - 1F6M9</li> </ul>
IRS EIN	84-6000555
NAICS Code	631130
FICE Code	006740
Drug Enforcement Act Number	AU3361071

<b>TAX INFORMATION</b>	
Tax Exempt Status	<ul style="list-style-type: none"> <li>• Internal Revenue Code Section 501(c)(3) Exemption issued October 1939</li> <li>• Not a private foundation within the meaning of Section 509(a)</li> </ul>
State of Colorado Tax Exempt Number	98-02565-0000

<b>ANIMAL SUBJECTS AND HUMAN SUBJECTS TESTING</b>	
PHS Animal Assurance of Compliance Number	<ul style="list-style-type: none"> <li>• D16-00171 (expires 07-31-2019)</li> <li>• USDA License 84-R-0059 (expires 11-07-2019)</li> <li>• AAALAC Accreditation File Number - 00235 (Approved 6-30-2015)</li> </ul>
Human Subjects Federal Approval Number	FWA00005070

<b>AGENCY SPECIFIC INFORMATION</b>	
NSF Organization Number	0001271000 0001289000
HHS Entity Identification	1846000555A7
NIH Institutional Profile File	1199905

<b>SYSTEM FOR AWARD MANAGEMENT (SAM.GOV) INFORMATION</b>	
SAM Registry Expiration	10/23/2018

<b>ASSURANCES</b>	
Assurances and Agreements	<ul style="list-style-type: none"> <li>• Affirmative Action Policy - 06/05/1998</li> <li>• AAALAC - 10/23/2009</li> <li>• Civil Rights Assurances - 06/05/1998</li> <li>• Debarment and Suspension - Organization / Institutional</li> <li>• Delinquent Federal Debt</li> <li>• Drug Free Workplace</li> <li>• Federal Awardee Performance and Integrity System (FAPIIS)</li> <li>• Federal Financial Conflict of Interest - University of Colorado Denver</li> <li>• Lobbying</li> <li>• Misconduct in Science - 02/06/03</li> <li>• Nuclear Regulatory Commission (Radioactive Materials License through Colorado Department of Health) - 11/30/11</li> <li>• Rehabilitation Assurance (Section 504) - 06/05/98</li> <li>• Sex Discrimination (Section 901, Title IX) - 06/05/98</li> </ul>
Institution covered by EO. 12372 - Intergovernmental Review?	No

<b>AUDIT INFORMATION</b>	
Single Audit (A-133 Audit/ 2 CFR 200 Audit)	Audit Report Period Ending: 6/30/2018 Link: <a href="https://leg.colorado.gov/sites/default/files/documents/audits/radacted_1801f_statewide_single_audit_fiscal_year_ended_june_30_2018.pdf">https://leg.colorado.gov/sites/default/files/documents/audits/radacted_1801f_statewide_single_audit_fiscal_year_ended_june_30_2018.pdf</a>
Cognizant Audit Agency	Federal: Ms. Barbara Bennett Regional Inspector General for Audit HHS/OIG Office of Audit Services, Room 284A 601 East 12th Street Kansas City, MO 64106 Telephone: 816-426-3591  State: State Auditor (General Assembly) 200 East 14th Avenue Denver, Colorado 80203 Telephone: 303-866-2051

<b>SIGNATURE AUTHORITY</b>	
Authorized Organization Representative (AOR) - Grant Applications and Grant Awards	<ul style="list-style-type: none"> <li>• David White: Sr. PreAward Specialist</li> <li>• Ryan Holland: Director - PreAward and Contracting Services</li> <li>• Amy Gannon: Associate Vice Chancellor for Financial Services &amp; Controller</li> </ul>
Authorized Organization Representative (AOR) - Contract Proposals, Contract Awards, and Subcontracts	<ul style="list-style-type: none"> <li>• Denise Queen: Contracts Manager</li> <li>• Ryan Holland: Director - PreAward and Contracting Services</li> <li>• Amy Gannon: Associate Vice Chancellor for Financial Services &amp; Controller</li> </ul>

<b>MISCELLANEOUS INFORMATION</b>	
Controlled by Parent Entity?	No
Maturity of Financial System	Over five years
FDP Expanded Clearinghouse Participation?	No

**PAYMENTS**

Award Payments - Electronic and Wire Payments	<a href="mailto:ogc.4payments@ucdenver.edu">ogc.4payments@ucdenver.edu</a>
Award Payments	Payable to: University of Colorado Denver Grants and Contracts [grant # – PI's initials] PO Box 910238 Denver CO 80291-0238
State Transfers	When payments are made by transfer within the State accounting system, University of Colorado Denver is identified as:  Department: #GFE Fund: #310 Balance Sheet: #1370 Report Code: #9001

# Appendix E – Overview of InfoEd ERA

OGC produced the following document to provide an overview of InfoEd.

## OVERVIEW OF INFOED ERA

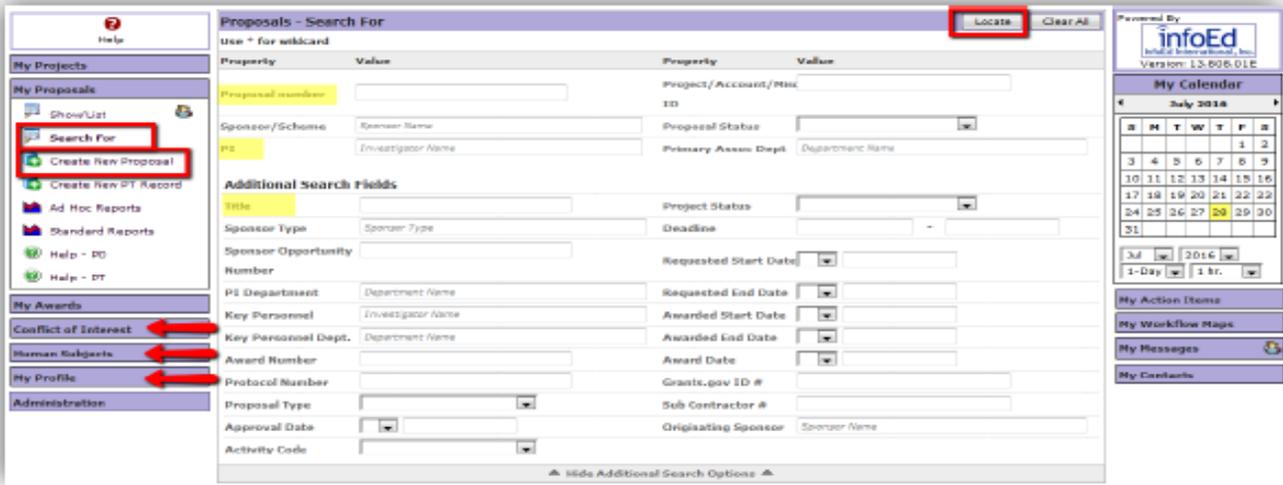
### Items to remember

Final applications submitted by OGC must be received in OGC for review 12 business days before the deadline.

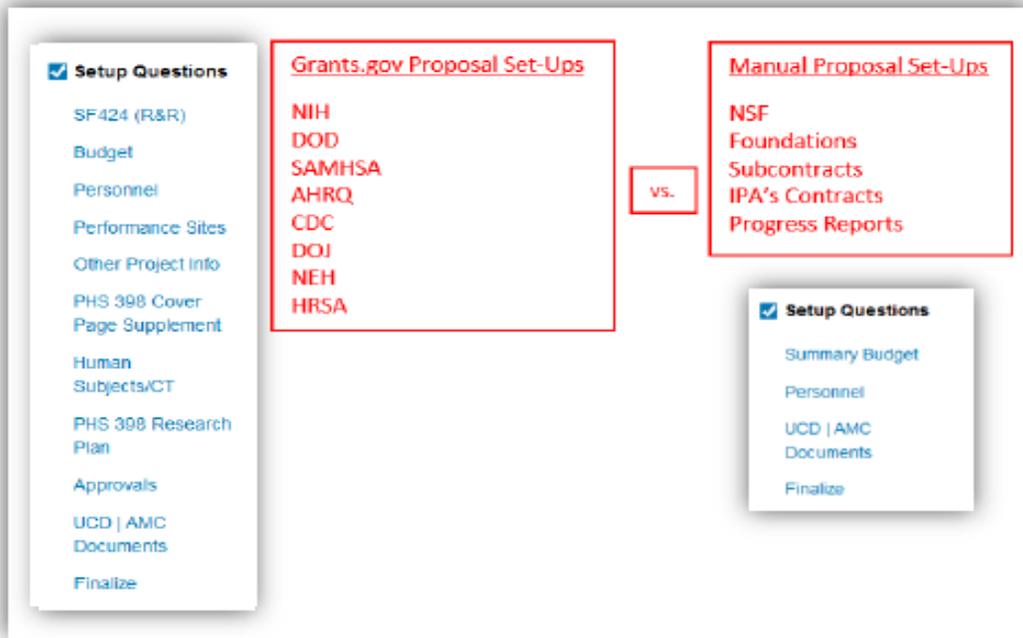
Final applications submitted by the dept/PI must be received in OGC for review 5 business days before the deadline.

Route under the Sponsored Programs/Gifts Org. Code

Initial Screen – InfoEd (<https://era.cu.edu>) – use \* as a wildcard to search



### Required tabs for Routings



## OVERVIEW OF INFOED ERA

### Key Items to Attach to Routing

NIH Items to Route (S2S)	Additional Items (Non-S2S/Manual)
Detailed Budget Spreadsheet	Sponsor Instructions
Budget Justification (Detailed)/Personnel Justification (Modular)	Screenshots of proposal in Sponsor Portal
Biosketches for Key Personnel	<b>Completed/Signed</b> Sponsor forms for AOR signature
Subcontract Budget, LOI, Justification, etc.	

Upload all necessary documents for efficient review. Don't upload docs twice!

### Finalizing and Routing

Finalize

**BUILD PDF / FORM PAGES**

**ASSEMBLE APPLICATION**

**SUBMIT FOR INTERNAL REVIEW**

Once your proposal has been completed, it can be electronically routed internally for necessary approvals. This page will display in two modes: Un-submitted and Submitted.

The screen is in Un-submitted mode when your proposal has not yet been routed. You can determine this by visually identifying a "thumbs up" on the screen. If it is there, then the proposal has not yet been submitted.

The screen is in Submitted mode when your proposal has been submitted and you can see the approval path it is on. Your Administrators have configured the approval path that they feel is appropriate for your proposal. If you have any questions regarding this process, please contact them.

Components for Initial Application

Form/Document Name	Sub	Status	Upload	Remove
Proposal Routing Form (Proposal Routing)		Completed		
Assembled Doc		Completed		

[Add Institution Form/Supporting Documents](#)

Submit Final Review

Proposal 170428 - Grant Garceau "Testing Title" (In Development)

Route Path - **Office of Grants and Contracts**

Step	Action	Reviewer	Status
Step 1	<b>P1 Review</b>	Grant Garceau	
Inserted Step	<b>Inserted Step</b>	Miss Dung Pham	
Step 2	<b>Administrative Approval</b>	Elizabeth A. Collins	

Add New Person to Review Path

Submit

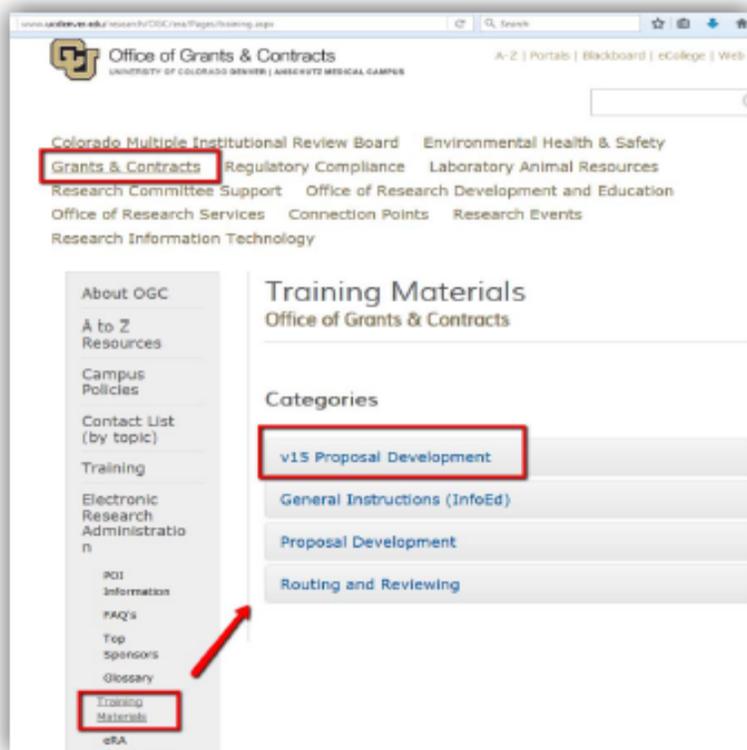
Proposal is locked during routing.

Obtain reviewed proposal on the PT side (attachments folder) → incorporate edits → follow instructions on face page to have proposal submitted.

## OVERVIEW OF INFOED ERA

### UCD InfoEd Resources

PreAward & General Inquiries <a href="mailto:xenia@ucdenver.edu">xenia@ucdenver.edu</a>	Do you have general inquiries? Please contact xenia for requests including: Grant award notices from sponsors No-cost extensions for grants Just-in-Time requests
Contracts <a href="mailto:OGC.Contracts@ucdenver.edu">OGC.Contracts@ucdenver.edu</a>	Questions regarding the contracting process? Requests and questions can include: E-copies of contracts & amendments for incoming contracts No-cost extension requests for contracts Other general contract inquiries
Award Status <a href="mailto:OGC.4Status@ucdenver.edu">OGC.4Status@ucdenver.edu</a>	Have you received your award? If so, and you want an update regarding the status of your account set up, please contact OGC 4 Status.
Subcontracts <a href="mailto:OGC.Subcontracts@ucdenver.edu">OGC.Subcontracts@ucdenver.edu</a>	Questions regarding the subcontracting process? Requests/questions can include: Subcontract requests with other entities using UC Denver prime awards Subcontract-specific inquiries
Payments <a href="mailto:OGC.4Payments@ucdenver.edu">OGC.4Payments@ucdenver.edu</a>	Looking to check on the status of your payments? Please contact OGC 4 Payments.



### Useful Items

Helpdesk E-mail: [erasupport@ucdenver.edu](mailto:erasupport@ucdenver.edu)

Helpdesk Phone: 303-724-9568

<https://grants.nih.gov/grants/how-to-apply-application-guide.htm> (NIH Instructions)

<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm> (NIH Standard Due Dates for Competing Apps)

[http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596) (FDP FCOI)

## Appendix F – Routing Form

The following is the routing form for monetary awards.

Updated By: @
<b>Grant or Contract Routing Form - Monetary</b>
<b>Page 1</b>
<b>PROPOSAL/ROUTING NUMBER</b> Proposal/Routing Number from InfoEd _____
<b>PRINCIPAL INVESTIGATOR INFORMATION</b> PI *Sponsored Programs/Gifts Org Code *Rank *Does this Funding Opportunity Require a Mentor (e.g Fellowship or Training Grant)? <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>CONTRACT/PROPOSAL ROUTING</b> *Routing Type _____ *Is this industry-sponsored human subjects research? <input type="checkbox"/> Yes <input type="checkbox"/> No How would you categorize the type of research activity (check all that apply): Basic Science <input type="checkbox"/> Clinical Research <input type="checkbox"/>  Please attach all of the following documents to the UCD AMC Documents tab prior to submitting the routing 1. Protocol                      2. Budget                      3. Contract (with editable Word version)                      4. All Attachments                      5. Prime Agreement (if an incoming subcontract)  <b>(If these items are not provided there may be delays in the review process)</b>
<b>SPONSORING/FUNDING AGENCY INFORMATION</b> *Name of Sponsoring Agency Sponsor Contact Email *Is this a flow-through proposal (does funding originate from a source other than the agency listed above)? <input type="checkbox"/> Yes <input type="checkbox"/> No Funding Opportunity Number from PD <small>(Automatically populated when using a Grants.gov S2S template only)</small> List additional funding sources (other than the agencies listed above)
<b>PROJECT INFORMATION</b> *Project Title *Project Type
<b>PROPOSAL INFORMATION</b> <i>Budget Period</i> *Begin Date: _____ *End Date: _____ *Project Status: Current Project #: _____  <i>Project Period</i> *Begin Date: _____ *End Date: _____ Previous Proposal Routing #: Current Agency Award #:
<b>DEADLINE INFORMATION</b> <i>Sponsor/Funding Agency</i> *Deadline Type: _____                      *Deadline Date: _____                      *Deadline Time:  <i>Requested Return</i> *Date: _____
<b>ADMINISTRATIVE UNIT CONTACT INFORMATION</b> *Contact Name *Contact Phone                      Contact Fax                      Campus Box *E-mail *Fiscal Manager Name *Fiscal Manager Position Number                      *Role _____ *Add Fiscal Staff? <input type="checkbox"/> Yes <input type="checkbox"/> No

**FACILITIES**

- \*Is adequate space available to conduct the project?  Yes  No
- \*Will work for this project be performed at Children's Hospital Colorado?  Yes  No
- \*Performance site is:

**HUMAN SUBJECTS**

- \*Will human subjects be included as part of the project?  Yes  No

**LAB ANIMALS**

- \*Will animals be used as part of the project?  Yes  No

**RADIATION SAFETY**

- \*Will radioactive materials be used as part of this project?  Yes  No

**BIOSAFETY**

- \*Will biohazards be used as part of this project?  Yes  No

**CHEMICAL SAFETY**

- \*Will chemical or mineral hazardous materials be used as part of this project?  Yes  No

**DUAL USE RESEARCH OF CONCERN**

- \*Does the research project use any agent or toxin that is considered Dual Use Research of Concern (DURC)? Click [here](#) for additional information.  Yes  No

**CONFLICT OF INTEREST**

The PI is responsible for ensuring that all individuals performing work that directly impacts the proposed project scope of work have a current Conflict of Interest Disclosure on file with the UCD COI office

- \*Agreed

**CLINICAL TRIAL**

- \*Is this project a clinical trial?  Yes  No

**EXPORT CONTROL**

- \*a. Will the project require any export controlled information to be received by CU Denver, or is the Program Announcement or Request for Proposals designated as "Export Controlled"?  Yes  No
- \*b. Is project participation (faculty, student, other) restricted based on country of origin or citizenship?  Yes  No
- \*c. Will the sponsor have the right to approve or restrict the publications or other disclosure of the research results?  Yes  No
- \*d. Will the project include collaboration with a foreign organization or be conducted outside of the United States?  Yes  No
- \*e. Will the project involve the shipment of equipment, software, data, or biological materials to a foreign country?  Yes  No
- \*f. Will the project require the use of another party's proprietary information or materials?  Yes  No

**NOTES**

Add any additional information here

**SUBCONTRACTOR INFORMATION**

- \*Are there any subcontractors on this contract or award?  Yes  No

**COST SHARING**

- \*Does this proposal contribute any UCD resources (i.e. costs that will not be paid or reimbursed by the sponsor)?  Yes  No

**SUMMARY OF PROPOSED BUDGET**

Budget Summary

Start Date	End Date	Direct Costs	Subawards	Indirect Costs	Total Project
-	-	\$0.00	\$0.00	\$0.00	\$0.00

- \*What is the F&A Rate on the Budget Period for this routing?
- \*Have UCD's standard F&A costs been calculated into the budget?  Yes  No

**FOR OFFICE USE ONLY**

Grants and Contracts  
Date

## Routing Form Fields

The following information applies when the routing form is completed after all relevant and required documents have been uploaded into InfoEd.

### Proposal / Routing Number

- The proposal/routing number will autopopulate.

### PI Information

- The PI's contact information will autopopulate.
- The Sponsored Programs/Gifts Org Code will autopopulate.
- Rank – Enter the PI's title (e.g. Professor, Assistant Professor, etc.).
- Mentor Question - Check the appropriate Yes/No box, if yes:
  - Mentor Name and Title – Enter the appropriate information.

### Contract/Proposal Routing

- Routing Type -
  - Select "Proposal" if it is a grant proposal the PreAward team needs to review/approve.
  - Select "Agreement Ready for Negotiation/Execution" if it is a contract that either OGC Contracts or CRAO need to review and approve. This is most common for Industry Sponsored projects.
- Human Subjects Question – Check the appropriate Yes/No box, if yes:
  - PreAward Request Attachment - Check the appropriate Yes/No box.
- Research Activity Category –
  - Basic Science – Check this box if the proposal is considered a research project.
  - Clinical Research – Check this box if human subjects will be involved in the project.
  - If neither of the above apply to the proposal, leave this section blank.
- Attached Documents – The identified documents should be uploaded into InfoEd before completing the routing form.
  - Protocol – Attach the IRB and/or IACUC protocol.
  - Budget – The budget must be in InfoEd before you begin the routing form.
  - Contract – If the routing type is "Agreement Ready for Negotiation/Execution," then you must attach the contract.
  - All Attachments – All other required documents must be uploaded into InfoEd.
  - Prime Agreement – Attach this document when the university is a subrecipient.

### Sponsoring/Funding Agency Information

- Sponsoring Agency will autopopulate.
- Sponsor Contact Email – Enter the relevant sponsor contact if known
- Flow-Through Proposal Question – Check the appropriate Yes/No box, if yes:
  - Name of Primary Agency – If the university is a subrecipient, identify the original source of funding. The pass-through entity should provide this information on their documents to the university.
- Is the Primary Agency a Federal Entity Question - Check the appropriate Yes/No box, if yes:
  - CFDA Number – Enter the CFDA number for federal funds.
  - Funding Opportunity Number – Enter the number from the funding announcement.

- Funding Opportunity Number from PD – This number will autopopulate, if applicable.
- List Additional funding sources – If applicable, enter the appropriate information.

### **Project Information**

- Project Title – This will autopopulate from InfoEd.
- Project Type – This will autopopulate from InfoEd. This field is important to ensure the appropriate indirect (F&A) cost rate is applied. If you select “other,” this may cause delays during the Award Setup phase.

### **Proposal Information**

- Budget Period – This information will autopopulate from InfoEd.
- Project Period - This information will autopopulate from InfoEd.
- Current Project # - If the proposal is for continuation funding or any award amendments, enter the current project number. Failure to do so may cause delays during the Award Setup phase.
- Current Agency Award # - If the proposal is for continuation funding or any award amendments, enter the current project number. Failure to do so may cause delays during the Award Setup phase.

### **Deadline Information**

- Sponsor/Funding Agency Deadline Information – This information will autopopulate from InfoEd.
- Requested Return – Enter the date you need OGC to complete the review.

### **Administrative Unit Contact Information**

- Contact Information – Enter your contact information.
- Fiscal Manager Information – Enter the contact information for your administrative unit’s fiscal manager.
- Fiscal Staff – Check Yes and enter the contact information for the individual(s) in your administrative unit who helps manage accounts.

### **Facilities**

- Adequate Space Question – Check the appropriate Yes/No box, if yes:
  - Site/Location/Building Question - Enter the building name where 50% or more of the project will be completed. Entering the specific location will assist during the Award Setup process.
  - Identify Room – Enter the room number where the majority of the project will be performed. The buildings and room should match locations listed on the on/off campus list on the OGC website.
- Project Performed at Children’s Hospital Colorado Question - Check the appropriate Yes/No box.
- Performance Site – Select the appropriate choice based on where the majority (50% or more) of the project will be performed.

## **Compliance Questions - Human Subjects, Lab Animals, Radiation Safety, Biosafety, Chemical Safety, and Dual Use Research of Concern**

- Check the appropriate Yes/No box for each question. If you answer yes to any question, additional questions will appear.

## **Conflict of Interest**

- Certification – Check the Agreed box after discussing this information with the PI.

## **Export Control**

- Questions A-F – Check the appropriate Yes/No box for each question.

## **Notes**

- Enter any additional comments about the proposal or award that can assist OGC in reviewing and setting up the award, such as:
  - The need for fixed speed types or multiple speed types
  - If an indirect (F&A) cost waiver has been approved
  - Any other item that may be out of the ordinary for the project

## **Subcontractor Information**

- Subcontractors Question – Check the appropriate Yes/No box.
- Number of Subcontractors Question – Indicate the number of confirmed subcontractors, if applicable.

## **Cost Sharing**

- Cost Sharing Question - Check the appropriate Yes/No box.
- Additional Cost Sharing Questions A-D - Check the appropriate Yes/No box.
- Amount of Cost Sharing – Identify the amount of cost sharing in the proposal.

## **Summary of Proposed Budget**

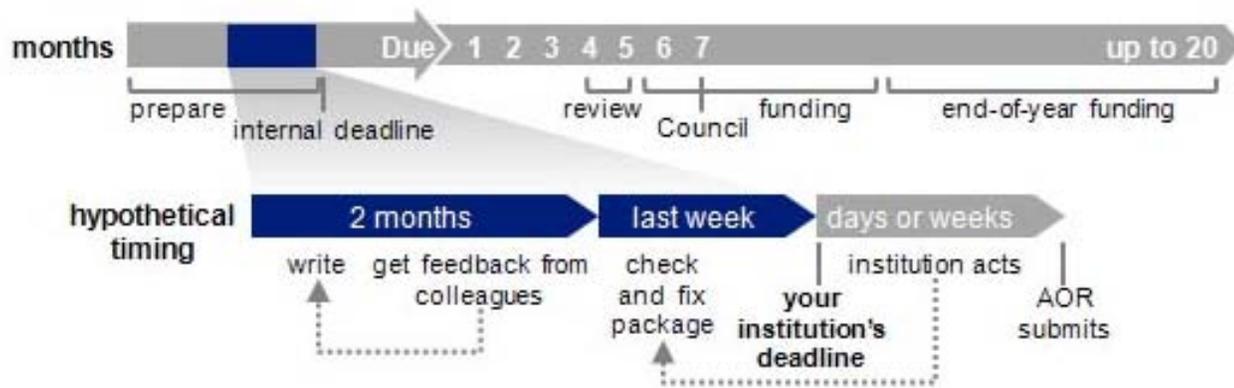
- Budget Summary – This information will autopopulate from InfoEd.
- F&A Rate – Enter the indirect (F&A) cost rate used for the budget.
- UCD F&A Rate Question - Check the appropriate Yes/No box, if no:
  - Sponsor Consistently Applied F&A Rate Question - Check the appropriate Yes/No box
  - Submission of F&A Waiver - Check the appropriate Yes/No box

## Appendix G – NIH Information

The following graphic shows an overview of the NIH grants process.



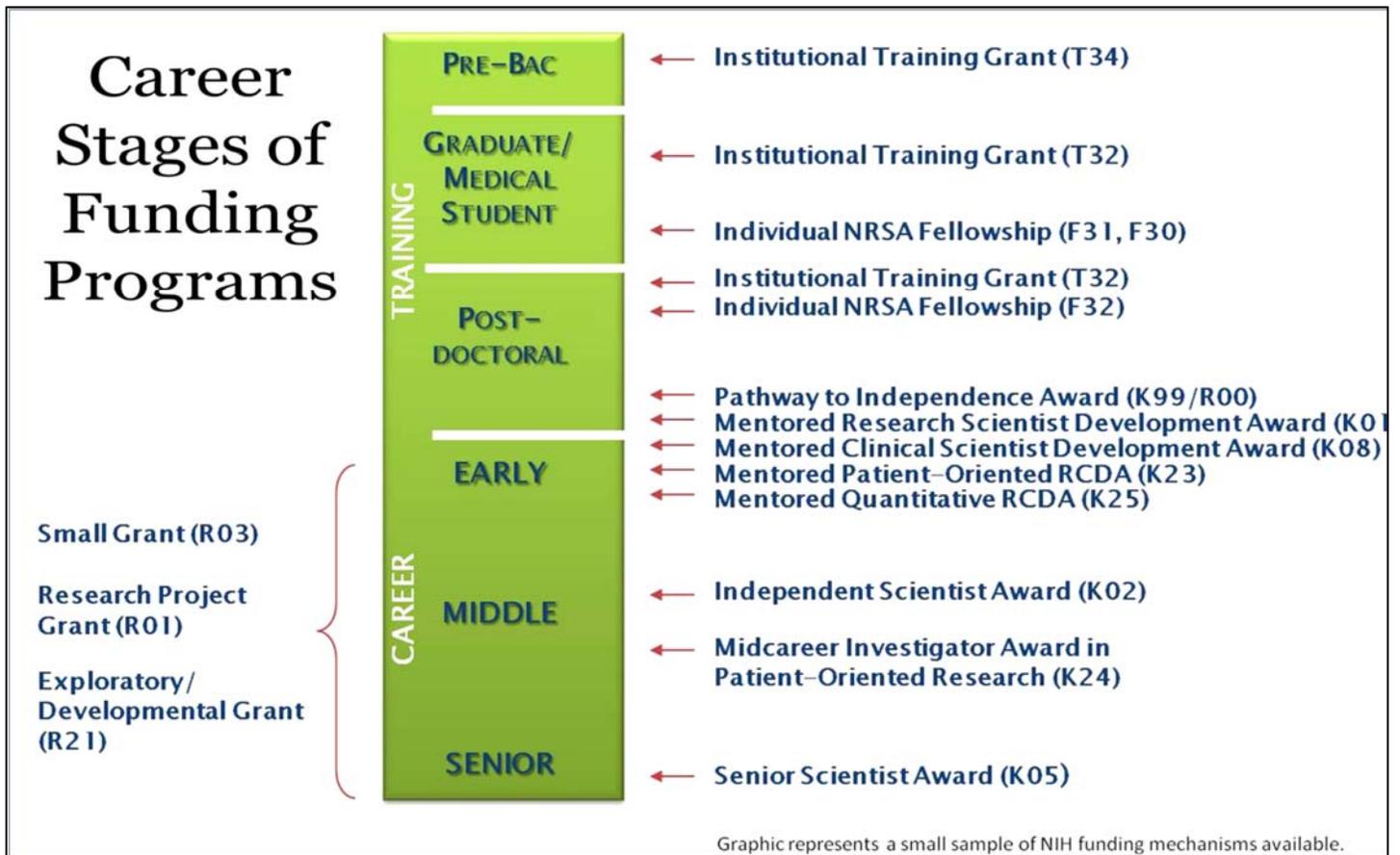
The NIH developed the following suggested timeline for proposal preparation.



The following table identifies the research project success rates by NIH Institute for 2017

NIH Institute/Center	Number of Applications Reviewed	Number of Applications Awarded	Award Amount	Success Rate	Fiscal Year
FIC	195	21	\$4,238,514	10.80%	2017
NCATS	119	26	\$17,992,074	21.80%	2017
NCCIH	251	42	\$20,557,680	16.70%	2017
NCI	9,702	1,139	\$535,521,305	11.70%	2017
NEI	1,222	304	\$121,075,093	24.90%	2017
NHGRI	389	93	\$78,280,829	23.90%	2017
NHLBI	4,074	958	\$551,169,239	23.50%	2017
NIA	3,055	812	\$759,672,789	26.60%	2017
NIAAA	914	201	\$74,103,396	22%	2017
NIAID	6,363	1,216	\$584,149,579	19.10%	2017
NIAMS	1,597	272	\$97,655,299	17%	2017
NIBIB	1,570	204	\$72,692,236	13%	2017
NICHD	3,290	530	\$198,607,461	16.10%	2017
NIDA	2,053	404	\$191,332,349	19.70%	2017
NIDCD	795	194	\$73,795,785	24.40%	2017
NIDCR	870	155	\$61,407,566	17.80%	2017
NIDDK	3,421	608	\$411,610,302	17.80%	2017
NIEHS	1,116	167	\$61,696,768	15%	2017
NIGMS	3,770	1,155	\$463,342,730	30.60%	2017
NIMH	2,735	571	\$314,339,663	20.90%	2017
NIMHD	432	93	\$50,085,599	21.50%	2017
NINDS	4,211	745	\$355,035,934	17.70%	2017
NINR	570	51	\$22,110,648	8.90%	2017
NLM	161	24	\$8,514,388	14.90%	2017
OD Common Fund	1,033	122	\$150,506,496	11.80%	2017
OD ORIP-SEPA	97	16	\$4,216,910	16.50%	2017
<b>FY Totals</b>	<b>54,005</b>	<b>10,123</b>	<b>\$5,283,710,632</b>	<b>18.70%</b>	<b>2017</b>

The following graphic shows an overview of award opportunities for PIs at each stage of their career.



The final graphic shows the NIH proposal scoring matrix.

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact  
Moderate Weakness: A weakness that lessens impact  
Major Weakness: A weakness that severely limits impact

## Appendix H – Sample Assistances Listing (CFDA) Program Description

This appendix contains a sample of an Assistance Listing Program Description. This Assistance Listing is for the R21 program used for this course's exercises.

### ASSISTANCE LISTINGS

## Environmental Health



Note: This Assistance Listing was not updated by the issuing agency in 2018. Please contact the issuing agency listed under "Contact Information" for more information.

#### Assistance Listing

##### Popular Name

National Institute of Environmental Health Sciences

##### Sub-tier

NATIONAL INSTITUTES OF HEALTH

##### CFDA Number

93.113

##### Related Federal Assistance

Not Applicable.

[View available opportunities on Grants.gov related to this Assistance Listing](#)

### Overview

#### Objectives

To foster understanding of human health effects of exposure to environmental agents in the hope that these studies will lead to: the identification of agents that pose a hazard and threat of disease, disorders and defects in humans; the development of effective public health or disease prevention strategies; the overall improvement of human health effects due to environmental agents; the development of products and technologies designed to better study or ameliorate the effects of environmental agents; and the successful training of research scientists in all areas of environmental health research. Supported grant programs focus on the following areas: (1) Understanding biological responses to environmental agents by determining how chemical and physical agents cause pathological changes in molecules, cells, tissues, and organs, and become manifested as respiratory disease, neurological, behavioral and developmental abnormalities, cancer, and other disorders; (2) Determining the mechanisms of toxicity of ubiquitous agents like metals, natural and synthetic chemicals, pesticides, and materials such as nanoparticles, and natural toxic substances, and their effects of on various human organ systems, on metabolism, on the endocrine and immune systems, and on other biological functions; (3) Developing and integrating scientific knowledge about potentially toxic and hazardous chemicals by concentrating on toxicological research, testing, test development, validation and risk estimation; (4) Identifying interactions between environmental stressors and genetic susceptibility and understanding biologic mechanisms underlying these interactions, including the study of environmental influences on epigenetics and transcriptional regulation; (5) Conducting environmental public health research, including in areas of environmental justice and health disparities, that requires communities as active participants in all stages of research, dissemination,

and evaluation to advance both the science and the development of practical materials for use in communities, with a focus on translating research findings into tools, materials, and resources that can be used to prevent, reduce, or eliminate adverse health outcomes caused by environmental exposures; (6) Expanding and improving the SBIR program; to increase private sector commercialization of innovations derived from Federal research and development; to increase small business participation in Federal research and development; and to foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in technological innovation; (7) Expanding and improving the STTR program to stimulate and foster scientific and technological innovation through cooperative research and development carried out between small business concerns and research institutions; to foster technology transfer between small business concerns and research institutions; to increase private sector commercialization of innovations derived from Federal research and development; and to foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in technological innovation; (8) Providing support for broadly based multi-disciplinary research and training programs in environmental health .These programs include the Environmental Health Sciences Core Centers , which serve as national focal points and resources for research and manpower development. The Centers for Neurodegenerative Science addresses the need for integrated research efforts involving basic and clinical scientists in a quest to discover the causes of and possible treatments for neurodegenerative diseases. The Breast Cancer and the Environment Research Program (co-funded with NCI) studies the impact of prenatal–to-adult environmental exposures that may predispose a woman to breast cancer. A special emphasis is on the impact of environmental factors on a girl’s pubertal development, a known risk fact for breast cancer. Through these programs, NIEHS expects to achieve the long range goal of developing new clinical and public health applications to improve disease prevention, diagnosis, and therapy. Additional Centers programs developed in recent years, include the Centers for Oceans and Human Health (co-funded with NSF), Children’s Environmental Health Centers (co-funded with US EPA) and the Autism Centers of Excellence (co-funded with other NIH Institutes) and the ; (9) Supporting research training programs which serve to increase the pool of trained research manpower with needed expertise in the Environmental Health Sciences through support of Individual and Institutional National Research Service Awards (NRSAs); (10) The Outstanding New Environmental Scientist Program which provides first time research grant funding to outstanding junior scientists in the formative stages of their career who are proposing to make a long term commitment to environmental health sciences research and to address the adverse effects on environmental exposures on human biology, human pathophysiology and human disease.

### **Examples of Funded Projects**

**Fiscal Year 2017:** A detailed listing and description of NIEHS funded projects can be found at <http://www.niehs.nih.gov/research/supported/whowefund/index.cfm>.

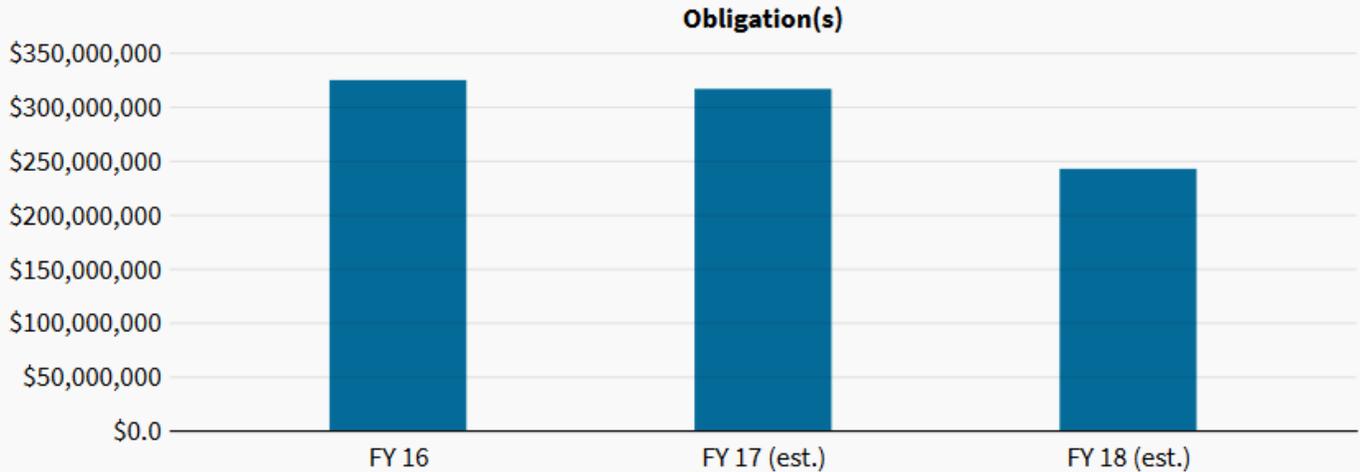
**Fiscal Year 2018:** A detailed listing and description of NIEHS funded projects can be found at <http://www.niehs.nih.gov/research/supported/whowefund/index.cfm>.

### **Authorizations**

Public Health Service Act, Sections 301, 401, 437, 463 and 487, Public Laws 78-410 and 99-158, as amended, 42 U.S.C. 241, and 42 U.S.C. 288, as amended, SBIR and STTR Reauthorization Act of 2011, Public Law 113-6

## Financial Information

These funding amounts do not reflect the award amounts that are displayed on USASpending.gov



Obligation(s)	FY 16	FY 17 (est.)	FY 18 (est.)
■ Project Grants Total	\$324,460,107	\$316,349,000	\$242,315,000
Totals	\$324,460,107	\$316,349,000	\$242,315,000

### Range and Average of Financial Assistance

Range: \$2,000 to \$1,749,000 Average: \$339,863

### Accomplishments

**Fiscal Year 2017:** Fiscal Year 2017: In FY 2017 NIEHS anticipates issuing 578 RPG awards (including SBIR and STTR Awards), 28 Research Center awards, 35 Individual and 44 Institutional training awards. Information about NIEHS present and past FOAs can be found at <https://www.niehs.nih.gov/funding/grants/index.cfm>.

**Fiscal Year 2018:** In FY 2018 NIEHS anticipates issuing 480 RPG awards (including SBIR and STTR Awards), 25 Research Center awards, 29 Individual and 34 Institutional training awards. Information about NIEHS present and past FOAs can be found at <https://www.niehs.nih.gov/funding/grants/index.cfm>.

### Account Identification

75-0862-0-1-552

### Criteria for Applying

#### Types of Assistance

B - Project Grants

#### Credentials and Documentation

Applications must be signed by appropriate officials of the submitting institution. The cost principles for awards under this program are set forth in HHS regulations at 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75. Commercial organizations are subject to the cost principles located at 48 CFR 31.2 Federal Acquisition Regulation. See the NIH Grants Policy Statement (NIH GPS) for further guidance on the applicability of cost principals

(<http://grants.nih.gov/grants/policy/nihgps/index.htm>).

2 CFR 200, Subpart E - Cost Principles applies to this program.

## Applicant Eligibility

### Designations

#### Designations

Federal, State (includes District of Columbia, public institutions of higher education and hospitals), Local (includes State-designated Indian Tribes, excludes institutions of higher education and hospitals), Public nonprofit institution/organization (includes institutions of higher education and hospitals), Other public institution/organization, U.S. Territories and possessions, U.S. Territories and possessions (includes institutions of higher education and hospitals), Non-Government - General, Specialized group (e.g. health professionals, students, veterans), Small business (less than 500 employees), Profit organization, Private nonprofit institution/organization (includes institutions of higher education and hospitals), Other private institutions/organizations, Native American Organizations (includes Indian groups, cooperatives, corporations, partnerships, associations)

Research Grants, Cooperative Agreements, Science Education Grants, SBIR Grants, Independent Scientist Awards, Mentored Research Scientist Development Award, Mentored Clinical Scientist Development Award, and the Academic Career Awards: A university, college, hospital, State, local or tribal governments, nonprofit research institution, or for-profit organization may submit an application and receive a grant for support of research by a named principal investigator. Candidates for Academic Career Awards Awards and Midcareer Investigator Awards in Patient Oriented Research must have a doctoral degree and peer-reviewed, independent, research support at the time the award is made. Candidates for Mentored Clinical Scientist Development Awards and Mentored Patient Oriented Research Career Development Awards must have a clinical degree or its equivalent and must have initiated post graduate clinical training. Candidates holding a Ph.D. degree are ineligible. Candidates who have served as principal investigators on PHS-supported research projects are ineligible. A candidate for Academic Career Awards must have a clinical or research doctorate degree. Those eligible for the Development Award must be able to devote at least 75 percent effort. SBIR grants can be awarded only to domestic small businesses (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed, and have no more than 500 employees). Primary employment (more than one-half time) of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. STTR grants can be awarded only to domestic small business concerns (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed and have no more than 500 employees) which "partner" with a research institution in cooperative research and development. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent by the research institution. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council. Centers: A university-based, nonprofit research institution, or for-profit organization proposing an integrated research program established to accomplish a stated mission, covering activities ranging from very basic research to the actual application of research results in the prevention and control of environmental health problems, may submit an application under the direction of a named Center Director. National Research Service Awards: (1) Nonprofit domestic organizations may apply for the Institutional NRSA; (2) Individual NRSA awardees must be nominated and sponsored by a public for-profit or nonprofit private institution having staff and facilities appropriate to the proposed research training program; (3) all awardees must be citizens or have been admitted to the United States for permanent residence; (4) to be eligible, predoctoral awardees must have completed the baccalaureate degree and

postdoctoral awardees must have a professional or scientific degree (M.D., Ph.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree).

## **Beneficiary Eligibility**

### **Designations**

#### **Designations**

Federal, U.S. Territories, Specialized group (e.g. health professionals, students, veterans), Small business, Profit organization, Private nonprofit institution/organization, Other private institution/organization, Native American Organizations, Education Professional, Student/Trainee, Graduate Student, Scientist/Researchers, State, Local, Sponsored organization, Public nonprofit institution/organization, Other public institution/organization, Federally Recognized Indian Tribal Governments

For Research Grants: Any nonprofit or for-profit organization, company, or institution engaged in biomedical research. For Centers and Training Grants: University-based nonprofit institutions; for-profit organizations conducting research; and individuals nominated by a private institution conducting research.

### **Length and Time Phasing of Assistance**

Research Grants, Cooperative Agreements, Center Grants, and NRSA Institutional grants may be awarded for up to 5 years, generally in 12-month budget periods and may be extended through a competitive renewal. Science Education Grants may be awarded for up to 5 years, in 12-month budget periods, and are not renewable. Independent Scientist Awards are awarded for 5 years in 12-month budget periods, and are non-renewable. Mentored Research Scientist Awards are for up to 5 years, 12-month budget periods, and are non-renewable. Mentored Clinical Scientist Development Awards and Academic Career Awards are for up to 5 years and are renewable. SBIR: Normally, Phase I awards are for 6 months; normally, Phase II awards are for 2 years. STTR: Normally, Phase I awards are for 1 year; normally, Phase II awards are for 2 years. National Research Service Awards: Individual awards are non-renewable and may be for 1, 2, or 3 years, but no individual may receive NRSA support at the predoctoral level for more than 5 years and at the postdoctoral level for more than 3 years. Method of awarding/releasing assistance: Funds are released via an Electronic Transfer System.

### **Use of Assistance**

#### **Designations**

Environment (water, air, solid waste, pesticides, radiation), Health/Medical, Science and Technology

### **Designations**

Environment (water, air, solid waste, pesticides, radiation), Health/Medical, Science and Technology

Research Grants and Cooperative Agreements are intended to support the direct costs of a project, in accordance with an approved budget, plus an appropriate amount for indirect costs. SBIR Phase I grants (of approximately 6-months' duration) are to establish the technical merit and feasibility of a proposed research effort that may lead to a commercial product or process. Phase II grants are for the continuation of the research initiated in Phase I and that are likely to result in commercial products or processes. Only Phase I awardees are eligible to receive Phase II support. STTR Phase I

grants (normally of 1-year duration) are to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort that has potential for commercial application. Phase II funding is based on results of research initiated in Phase I, scientific and technical merit, and commercial potential of the Phase II application. A number of Career Development awards are supported. The Independent Scientist Award provides up to five years of salary support for newly independent scientists who have recently obtained independent research funding, generally an R01 research grant from NIEHS. The award is intended to allow the candidate protected time to focus on the further development of the independent research career and does not include additional research support. The Mentored Clinical Research Career Development Award provides three to five years of salary support for investigators with clinical degrees (e.g., M.D., D.V.M.). The Transition to Independent Environmental Health Research (TIEHR) Career Development Award provides three years of support for candidates who are within three years of their first independent faculty appointment and who have not yet obtained significant research grant funding (an R01 or equivalent). The award includes salary support and pilot funding. The Mentored Patient-Oriented Research Career Development Award provides up to five years of support for clinically trained investigators who make a commitment to focus on patient-oriented research. The Mid Career Investigator Award in Patient-Oriented Research provides up to five years of support to outstanding clinical scientists who are actively engaged in patient-oriented research and who are within 15 years of their specialty training. The Mentored Quantitative Research Development Award provides up to five years of support for junior faculty with quantitative scientific and engineering backgrounds outside of biology or medicine that are transitioning to behavioral or biomedical research. The NIH Pathway to Independence Award is divided into two phases. The initial award (K99) provides up to two years of mentored, postdoctoral support. The second phase (R00) provides up to three years of independent research support, when the awardee accepts a full-time tenure track, or equivalent, faculty position. All these Career Development awards provide salary consistent with the level of effort devoted to the research career development activities, plus fringe benefits, an allowance for career development activities and 8 percent fiscal and administrative costs. All Career Development Awards, except for the NIH Pathway to Independence Award, have a US citizenship requirement. Details of specific restrictions for the Career Development Awards can be found at <http://www.niehs.nih.gov/careers/research/trainingfrom/career/index.cfmt>. NIEHS Core Center grants (P30) are primarily intended to provide infrastructure support and the support of core research facilities. In addition, an appropriate facilities and administrative cost is provided as determined by negotiated agreement with the grantee's cognizant government organization. National Research Service Awards (NRSAs): Individual predoctoral and postdoctoral training awards are made for the support of fellows who engage in research training in environmental toxicology, environmental pathology, environmental mutagenesis, or environmental epidemiology/biostatistics. In addition to individual training awards, institutional training grants (T32) are made to institutions to enable institutions to make awards to individuals selected by them, for both predoctoral and postdoctoral research training in the aforementioned areas. Each individual who receives a postdoctoral NRSA, either through an institutional or individual training award mechanism, is obligated upon termination of the award to comply with certain service and payback provisions.

## **Applying for Assistance**

### **Deadlines**

Contact the headquarters or regional location, as appropriate for application deadlines

### **Preapplication Coordination**

Preapplication coordination is not applicable. Environmental impact information is not required for this program. This program is excluded from coverage under E.O. 12372.

### **Application Procedures**

2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards applies to this program.

Awards made under this program are subject to 2 CFR 200, as implemented by 45 CFR 75 “Public Welfare, Uniform Administrative Requirements, Cost Principles and Audit Requirements for HHS Awards”. The policies and procedures generally applicable to NIH grants are set forth in the NIH GPS (<http://grants.nih.gov/grants/policy/nihgps/index.htm>). Application forms and instructions for their submission are available at <http://grants.nih.gov/grants/forms.htm>. Applicants are encouraged and in some cases required to consult with NIEHS Program Officials prior to submission of an application. Detailed information about NIEHS grant programs and staff contacts can be found at <http://www.niehs.nih.gov/research/supported/index.cfm>.

### **Criteria for Selecting Proposals**

The major elements in evaluating proposals include assessments of: (1) The scientific merit and general significance of the proposed study and its objectives; (2) the technical adequacy of the experimental design and approach; (3) the competency of the proposed investigator or group to successfully pursue the project; (4) the adequacy of the available and proposed facilities and resources; (5) the necessity of the budget components requested in relation to the proposed project; and (6) the relevance and importance to stated program objectives. The following criteria will be used in considering the scientific and technical merit of SBIR/STTR Phase I grant applications: (1) The soundness and technical merit of the proposed approach; (2) the qualifications of the proposed principal investigator, supporting staff, and consultants; (3) the technological innovation of the proposed research; (4) the potential of the proposed research for commercial application; (5) the appropriateness of the budget requested; (6) the adequacy and suitability of the facilities and research environment; and (7) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment. Phase II grant applications will be reviewed based upon the following criteria: (1) The degree to which the Phase I objectives were met and feasibility demonstrated; (2) the scientific and technical merit of the proposed approach for achieving the Phase II objectives; (3) the qualifications of the proposed principal investigator, supporting staff, and consultants; (4) the technological innovation, originality, or societal importance of the proposed research; (5) the potential of the proposed research for commercial application; (6) the reasonableness of the budget requested for the work proposed; (7) the adequacy and suitability of the facilities and research environment; and (8) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment.

### **Award Procedure**

Made on the basis of dual review by peer groups of all applications. The first level of reviews is by a study section for scientific merit. In addition, a national advisory council provides a secondary level of review for all applications. As required by P.L. 109-482, the NIH Health Reform Act of 2006, all research grant and cooperative agreements must undergo Advisory Council/Board review and approval prior to funding. Review of Individual NRSA applications by an Advisory Council/Board is not required. Final approval of these recommendations and decisions concerning funding are made by the Director, NIEHS.

### **Date Range for Approval/Disapproval**

> 180 Days. Receipt, review and approval processes range in length from six to nine months.

### **Renewals**

Research Grants, Cooperative Agreements, Center Grants, and Institutional Training Grants: Renewal applications are subject to same criteria as new applications. Independent Scientist Awards, Mentored Research Scientist Development Awards, Mentored Clinical Scientist Development Award, Academic Career Awards, and Individual Training grants are non-renewable.

## **Appeals**

A principal investigator (P.I.) may question the substantive or procedural aspects of the review of his/her application by communicating with the staff of the Institute. A description of the NIH Peer Review Appeal procedures is available on the NIH home page <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html>.

## **Compliance Requirements**

### **Policy Requirements**

The following 2CFR policy requirements apply to this assistance listing:

Subpart B, General provisions

Subpart C, Pre-Federal Award Requirements and Contents of Federal Awards

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

The following 2CFR policy requirements are excluded from coverage under this assistance listing:

*Not Applicable*

Additional Information:

## **Reports**

Annual and final progress reports are required for all Grant Awards. Annual financial reports are due for a subset of grant awards. Final financial reports are due for all grant awards. Additional reports are required after termination of National Research Service Awards to ascertain compliance with the service and payback provisions. Annual and final progress reports are required for all Grant Awards. Annual financial reports are due for a subset of grant awards. Final financial reports are due for all grant awards. Additional reports are required after termination of National Research Service Awards to ascertain compliance with the service and payback provisions. Review of annual performance reports is conducted by appropriate agency staff prior to issuance of additional funding.

## **Audits**

In accordance with the provisions of 2 CFR 200, Subpart F - Audit Requirements, nonfederal entities that expend financial assistance of \$750,000 or more in Federal awards will have a single or a program-specific audit conducted for that year. Non-Federal entities that expend less than \$750,000 a year in Federal awards are exempt from Federal audit requirements for that year, except as noted in 2 CFR 200.503 Awards made under this program are subject to the audit requirements of OMB 2 CFR 200, as implemented by 45 CFR 75, Subpart F, and in the NIH GPS (<http://grants.nih.gov/grants/policy/nihgps/index.htm>).

## **Records**

In accordance with the provisions of 45 CFR 75, Subpart D – Post Federal Award Requirements, Record Retention and Access, §75.361, expenditures and other financial records must be retained for 3 years from the day on which the grantee submit the last expenditure report for the report period.

## **Regulations, Guidelines, and Literature**

42 CFR 52; 45 CFR 75; 45 CFR 92; NIH Guide to Grants and Contracts; various other publications and application kits, the Division of Extramural Outreach and Information Resources, Office of Extramural Research, NIH, Room 6207, 6701 Rockledge Drive, Bethesda, MD 20892. Grants will be available under the authority of and administered in accordance with the NIH GPS and Federal regulations at 42 CFR 52 and 42 USC 241; Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant and Cooperative Agreement Applications. Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer (STTR) Grant Applications.

## Formula and Matching Requirements

Statutory formula is not applicable to this assistance listing.

Matching requirements are not applicable to this assistance listing.

MOE requirements are not applicable to this assistance listing.

## Contact Information

### Regional or Local Locations:

None. Program Contacts: Research Grants: Dr. William A Suk, Chief, Hazardous Substances Research Branch, DERT, NIEHS, E-mail: suk@niehs.nih.gov. Telephone: (919) 541-0797; or Dr. Cindy Lawler, Chief, Genes, Environment, and Health Branch, E-mail lawler@niehs.nih.gov. Telephone: (919)316-4671; or Dr. Claudia Thompson, Chief, Population Health Branch, E-mail: thomps14@niehs.nih.gov; Telephone: (919) 541-4638; or Dr. David Balshaw, Chief, Exposure, Response, and Technology Branch, Email: balshaw@niehs.nih.gov. Telephone: (919) 541-2448. NRSA Institutional Training Grants, Independent Scientist Awards, Mentored Research Scientist Development Awards, Mentored Clinical Research Scientist Development Awards, Academic Career Awards: Dr. Carol Shreffler, Program Administrator, Exposure, Response, and Technology Branch, E-mail: shreffl1@niehs.nih.gov. Telephone:(919)541-1445. SBIR and STTR Grant Programs: Dr. Daniel Shaughnessy, Program Administrator, Exposure, Response, and Technology Branch, E-mail: shaughn1@niehs.nih.gov. Telephone: (919)541-2506. P30 Core Centers Program Contact: Dr. Claudia Thompson, Chief, Population Health Branch, E-mail: thomps14@niehs.nih.gov; Telephone: (919) 541-4638; AREA grants: Dr. Lisa Chadwick, Email: lisa.chadwick@nih.gov, Telephone: (919) 491-4702; and NRSA Individual Fellowships: Dr. Michael Humble, Program Administrator, Genes, Environment, and Health Branch, E-mail: humble@niehs.nih.gov. Telephone: (919) 316-4621. Grants Management Contact: Mr. George Tucker, Chief, Grants Management Officer, Grants Management Branch, E-mail: george.tucker@nih.gov. Telephone: (919) 541-2749. For each program contact, the rest of the mailing address is: Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233, Research Triangle Park, NC 27709.

### Headquarters Office:

Benny Encarnacion  
111 TW Alexander Drive,  
Research Triangle Park, NC 27709  
[encarna1@niehs.nih.gov](mailto:encarna1@niehs.nih.gov)  
(919) 541-5147.

**Website:** <http://www.niehs.nih.gov>

### History

- **2006** Title Changed

*Environmental Health*

- **1990** Number Changed

*Number changed from 13.113*

- - Published

*Biological Response to Environmental Health Hazards*

## Appendix I – Federal Funding Opportunity Announcement

This appendix contains a sample federal funding opportunity announcement for the R21 program used in the exercises for this course.



**Grants & Funding**  
NIH's Central Resource for Grants and Funding Information

Use this page to learn about application cycles and their relationship to due dates, review and council dates, and earliest possible start dates.

### General Information

- Grant applications and associated documents (e.g., reference letters) are due by 5:00 PM local time of application organization on the specified due date.
- Check the funding opportunity announcement (FOA) for due date information.
- If the FOA says "standard dates apply", refer to the table below using the [activity code](#) specified in the title of the FOA.
- Note that [renewal/resubmission/revision](#) applications may have different due dates than [new applications](#). Read the table carefully.
- The [AIDS and AIDS-related dates](#) apply to all activity codes.

### ***Application Due Dates***

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3 <i>new</i>	<b>Other Research Grants and Cooperative Agreements</b>	February 16	June 16	October 16

# Department of Health and Human Services

## Part 1. Overview Information

### Participating Organization(s)

National Institutes of Health ([NIH](#))

### Components of Participating Organizations

National Eye Institute ([NEI](#))

National Human Genome Research Institute ([NHGRI](#))

National Institute on Aging ([NIA](#))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))

National Institute of Allergy and Infectious Diseases ([NIAID](#))

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](#))

National Institute on Drug Abuse ([NIDA](#))

National Institute on Deafness and Other Communication Disorders ([NIDCD](#))

National Institute of Dental and Craniofacial Research ([NIDCR](#))

National Institute of Environmental Health Sciences ([NIEHS](#))

National Institute on Minority Health and Health Disparities ([NIMHD](#))

National Institute of Nursing Research ([NINR](#))

National Library of Medicine ([NLM](#))

National Center for Complementary and Integrative Health ([NCCIH](#))

Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the [R21 IC-Specific Scientific Interests and Contact](#) website. ICs that do not participate in this announcement will not consider applications for funding.

### Funding Opportunity Title

**NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)**

### Activity Code

[R21](#) Exploratory/Developmental Research Grant

### Announcement Type

Reissue of [PA-16-161](#) for due dates on or after January 25, 2018

### Related Notices

- [May 18, 2018](#) - Notice of Information: NIMH Council Workgroup on Genomics' Recommendations for Basic and Clinical Research. See Notice [NOT-MH-18-035](#).

### Funding Opportunity Announcement (FOA) Number

PA-18-489

## Companion Funding Opportunity

[PA-18-344](#) - Parent R21 Clinical Trial Required

Check Components of Participating Organizations and Related Notices for restrictions.

## Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

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

93.273, 93.866, 93.855, 93.846, 93.213, 93.279, 93.173, 93.121, 93.113, 93.867, 93.172, 93.879, 93.307, 93.361

## Funding Opportunity Purpose

The NIH Exploratory/Developmental Grant supports exploratory and developmental research projects by providing support for the early and conceptual stages of these projects. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.

Key Dates

Posted Date

December 6, 2017

Open Date (Earliest Submission Date)

January 16, 2018

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

[Standard dates](#) apply 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.

The first standard application due date for this FOA is February 16, 2018.

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)

[Standard AIDS dates](#) apply by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on these dates.

The first AIDS application due date for this FOA is May 7, 2018. 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.

Scientific Merit Review

[Standard dates](#) apply

Advisory Council Review

[Standard dates](#) apply

Earliest Start Date

[Standard dates](#) apply or Month(s) Year(s)

Expiration Date

January 8, 2021

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](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). 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](#) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov](#) Workspace to prepare and submit your application and [eRA Commons](#) to track your application.

Table of Contents

[Part 1. Overview Information](#)

[Part 2. Full Text of the Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)  
[Section IV. Application and Submission Information](#)  
[Section V. Application Review Information](#)  
[Section VI. Award Administration Information](#)  
[Section VII. Agency Contacts](#)  
[Section VIII. Other Information](#)

## **Part 2. Full Text of Announcement**

### **Section I. Funding Opportunity Description**

The evolution and vitality of the biomedical, behavioral, and clinical sciences require a constant infusion of new ideas, techniques, and points of view. These may differ substantially from current thinking or practice and may not yet be supported by substantial preliminary data. Through the NIH Exploratory/Developmental Research Grant Program, the NIH seeks to foster the introduction of novel scientific ideas, model systems, tools, agents, targets, and technologies that have the potential to substantially advance biomedical, behavioral, and clinical research.

This program is intended to encourage new exploratory and developmental research projects. For example, such projects could assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research. Another example could include the unique and innovative use of an existing methodology to explore a new scientific area. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.

Applications for Exploratory/Developmental Research Grant awards should include projects distinct from those supported through the traditional R01 activity code. For example, long-term projects, or projects designed to increase knowledge in a well-established area, are not appropriate for this FOA. Applications submitted to this FOA should be exploratory and novel. These studies should break new ground or extend previous discoveries toward new directions or applications. Projects of limited cost or scope that use widely accepted approaches and methods within well-established fields are better suited for the [NIH Small Research Grant Program](#).

This Funding Opportunity Announcement does not accept applications proposing clinical trial(s)

Applications are assigned to participating Institutes and Centers (ICs) based on receipt and referral guidelines and many applications are assigned to multiple participating ICs with related research interests. Applicants are encouraged to identify a participating IC that supports their area of research via the [R21 IC-Specific Scientific Interests and Contact](#) website and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

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  
Revision

The [OER Glossary](#) and the SF424 (R&R) Application Guide provide details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

[Need help determining whether you are doing a clinical trial?](#)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

The combined budget for direct costs for the two-year project period may not exceed \$275,000. No more than \$200,000 may be requested in any single year.

Award Project Period

The total project period may not exceed 2 years.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made from 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)

## For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

## Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

## Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

## Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement](#), **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](#) 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 \(DUNS\)](#) - 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 \(SAM\)](#) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- [NATO Commercial and Government Entity \(NCAGE\) Code](#) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.

- [eRA Commons](#) - 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](#) – 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.

### **2. Cost Sharing**

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).

### **3. Additional Information on Eligibility**

#### **Number of Applications**

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

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](#)).

## **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](#), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications](#).

### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) 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.

#### SF424(R&R) Senior/Key Person Profile

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

#### R&R or Modular Budget

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

#### 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:** Since the goal of this program is to support exploratory and developmental research projects, extensive background material and preliminary data are not required. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data.

**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:**

Only limited Appendix materials are allowed. 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 (and when applicable, clinical trials research experience) 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 **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.

#### Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement](#), and procedures for foreign institutions.

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

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

#### 4. Submission Dates and Times

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

Organizations must submit applications to [Grants.gov](https://www.grants.gov) (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](#), 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](#).

#### 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](#).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#).

#### 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](#). 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](#). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

#### **Important reminders:**

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

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

See [more tips](#) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

#### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](#). Any instructions provided here are in addition to the instructions in the policy.

## **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](#), 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.

For this particular announcement, note the following:

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

#### 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?

#### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? 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?

## 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?

## 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?

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?

## 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.

## 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](#).

## 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](#).

#### 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](#).

#### 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

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

#### 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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

#### 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](#); (2) [Sharing Model Organisms](#); and (3) [Genomic Data Sharing Plan \(GDS\)](#).

### 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) in accordance with [NIH peer review policy and procedures](#), 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.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. 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.
- Relevance of the proposed project to program priorities.

## 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](#). 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](#).

## **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](#).

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](#) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

### 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](#) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#). More information is provided at [Award Conditions and Information for NIH Grants](#).

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>; and <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>. 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> 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>.

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 \(RPPR\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](#).

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](http://www.fsrs.gov) on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) for additional information on this reporting requirement.

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

## **Section VII. Agency Contacts**

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

## Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)  
Finding Help Online: <http://grants.nih.gov/support/> (preferred method of contact)  
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)  
Contact Center Telephone: 800-518-4726  
Email: [support@grants.gov](mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)  
Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (preferred method of contact)  
Telephone: 301-945-7573

## Scientific/Research Contact(s)

Participating NIH Institutes and Centers are listed in “Components of Participating Organizations” in [Part 1. Overview](#). Scientific/Research Contact information is listed on the [R21 IC-Specific Scientific Interests and Contact](#) website.

## Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

## Financial/Grants Management Contact(s)

Participating NIH Institutes and Centers are listed in “Components of Participating Organizations” in [Part 1. Overview](#). Financial/Grants Management Contact information is listed on the [R21 IC-Specific Scientific Interests and Contact](#) website.

## **Section VIII. Other Information**

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

## 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.

## **Appendix J – Sample Non-Federal Funding Opportunity Announcement**

This appendix contains a sample non-federal funding opportunity announcement.

# Research Grants | American Parkinson Disease Assoc.

**Deadline: 03/12/2019**

[Apply for a research Grant](#)

## Award details

One year grants up to a maximum of \$75,000 will be awarded to research scientists (MD, MD/PhD, or PhD). The same investigator can reapply the following year to be considered for a second consecutive year of funding. When submitting applications for a grant on the same subject for the second consecutive year, the applicant will also submit a report of the results obtained during the prior APDA funding years.

The applicants will receive notification of the decision in July 2019. The APDA grant year runs from September 1st to August 31st.

## Goal

APDA Research Grants are intended to support basic or applied research aimed at reducing the burden of Parkinson's disease. The APDA seeks to promote the entry of new investigators in to the field of Parkinson research, as well as to support important new ideas in the field worthy of investigation.

## Eligibility

All research scientists in the field of Parkinson's research can apply, but the selection committee will more favorably consider researchers who are new to the field of Parkinson's disease.

## Application Process and Proposal

Complete application form. Upload as one PDF document. Description of the research proposal should not exceed three (3) pages to include background rationale, research plan/methods, and significance. The proposal should include a description of where the research will be done, the resources available and a statement of how the proposal relates to Parkinson's disease. The applicant's NIH biosketch, as well as two letters of reference should be included. The applicant should list all current and pending support, including sponsoring agency, amount and dates for awards. The application should indicate how other sponsored research complements or supplements the present proposal.

The three page limit only applies to the length of the proposal, not the entire application.

After the submit button is clicked, applicants can print the complete application.

## Funding

Funding is not to be used for:

- Indirect costs.
- Institutional overhead.
- Salary for the principal investigator higher than \$50,000.
- Travel expenses.
- Publication costs higher than \$1,000.
- Equipment costs higher than \$8,000.

## Grant Disbursement

Funds will be awarded as follows:

- 50% on or about September 2019.
- 25% on receipt of an acceptable six (6) month scientific report.
- 25% on receipt of acceptable twelve (12) month scientific and financial reports.

[Apply for a research Grant](#)

**Strength in optimism. Hope in progress.**

Every day, we provide the support, education, and research that will help everyone impacted by Parkinson's disease live life to the fullest. We depend on the generosity of donors like you. **Join our cause and donate today.**

## **Appendix K – OGC Organizational Chart**

This appendix contains the OGC Organizational Chart.

# Financial Services - Office of Grants and Contracts D R A F T

