



U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing
and submitting applications via Grants.gov to NIH and
other PHS agencies using the SF424 (R&R)

Forms Version C application packages

**An abridged and annotated Version, prepared for the School of Medicine,
September, 2013**

**Annotations in indicated by text in red
Emphasis points are indicated in blue**

(Note: While these instructions cover the majority of “R” or Research-Type awards, i.e. R01, they are not intended to replace the full instructions and do not cover non-standard applications.)

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Annotated for University of Virginia September 2013

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PART I

Instructions for Preparing and Submitting an Application

1. Foreword

Forms Version C Application Guide — Released July 25, 2013

This application includes changes to SF424 Research & Related (R&R) form instructions necessitated by the OMB renewal and Grants.gov's subsequent release of updated forms in June 2013. Changes have also been made to various PHS 398 forms and instructions approved by OMB in August 2012 and released by Grants.gov in June 2013. Parts II (Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan) and III (Policies, Assurance, Definitions, and Other Information) of the previous version of the application guide have been moved to a stand-alone document titled, "Supplemental Grant Application Instructions."

Modifications include the following:

SF424 (R&R) Forms

System for Award Management (SAM) Registration

- A change from the requirement to register with the Central Contractor Registry Database (CCR) to the System for Award Management (SAM).

SF424 (R&R) Cover Form

- A new field for the "Previous Grants.gov Tracking ID" is included. Form behavior will be adjusted so that applications with Submission Type of "Change/Corrected Application" require an entry in the "Previous Grants.gov Tracking ID" field rather than requiring an entry in the "Federal Identifier" field.
- The Person to be contacted section of the Applicant Information has expanded to include the additional contact information we have been including on the PHS 398 Cover Page Supplement form. The additional contact information has been removed from the PHS 398 Cover Page Supplement.
- The label for the "SFLL or other Explanatory Documentation" has been changed to "SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation."
- A new "Cover Letter Attachment" has been added and a separate PHS Cover Letter form will no longer be used. However, NIH will continue to keep the Cover Letter separate from the assembled application image and available only to authorized staff.

SF424 (R&R) Budget Form

- The cumulative Number of Participants/Trainees allowed on the SF424 (R&R) budget form and associated Subaward Budget forms has been expanded from 999 to 9999 to address a form bug. On previous form versions, maxing out the Number of Participants/Trainees on all budget periods caused an application to fail because the forms didn't allow a bigger number for the cumulative total.

SF 424 (R&R) Sr/Key Person Expanded Form

- The number of Sr/Key Persons that can be entered has been expanded from 40 to 100.

SF 424 (R&R) Project Performance Site Locations Form

- The number of Performance Sites that can be entered has been expanded from 30 to 300.

PHS 398 Forms

Planned Enrollment Report Form & PHS 398 Cumulative Inclusion Enrollment Report Form

- Added optional inclusion forms in application packages to allow for the collection as discrete data rather than .pdf attachments.
- Removed enrollment and inclusion attachment fields from PHS 398 Research Plan, PHS 398 Career Development Award Supplemental Forms.

PHS 398 Career Development Award Supplemental Form

- Removed “Application Type” section.
- Removed “Career Development Award Attachment” header.
- Removed Inclusion and Enrollment attachments (now separate forms in the application package).
- Added a new attachment for “Letters of Support from Collaborators, Contributors, and Consultants.”
- Renamed attachment from “Career Development/Training Activities During Award Period” to “Candidate’s Plan for Career Development/Training Activities During Award Period.”
- Renamed attachment from “Mentoring Plan” to “Candidate’s Plan to Provide Mentoring (as applicable).”
- Changed section header from “Statements of Support” to “Statements and Letters of Support.”
- Made adjustments to format and numbering.

PHS 398 Research Plan Form

- Removed “Application Type” section.
- Removed “Research Plan Attachment” header.
- Removed Inclusion and Enrollment attachments (now separate forms in the application package).
- Made adjustments to format and numbering.

PHS 398 Training Program Plan Form

- Removed “Application Type” section.
- Removed “Research Training Program Plan Attachment” header.
- Renamed attachment field from “Introduction to Application (for REVISION or RESUBMISSION applications only)” to “Introduction to Application (for RESUBMISSION or REVISION only).”
- Made adjustments to format and numbering.

PHS 398 Training Subaward Budget Attachment Form

- Limit of subaward budget attachments has increased from 10 to 30.

PHS 398 Cover Page Supplement Form

- Removed Applicant Organization Contact information that will be included on SF424 R&R Cover Form.
- Added fields from PHS 398 Checklist form. The separate PHS 398 Checklist Form will no longer be used.

- Limit of collection of human embryonic stem cell lines has increased from 20 to 200.
- Made adjustments to format and numbering.

Notes

This version of the Application Guide now also includes a separate instruction section for multi-component applications to accommodate their transition to electronic submission effective with submissions on/after September 25, 2013.

For additional details on all the form changes noted above, see NIH Guide Notice [NOT-OD-13-074](#).

This application guide contains instructions and other useful information for preparing grant applications to the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies for:

Public Health Service (PHS) Research Grants

Career Development (K) Awards

Institutional Training (T) Grants

Supplemental Instructions to the SF424 (R&R) for Preparing a Multi-Project Application

This application guide is used as a companion document to the SF424 Research and Related (R&R) application forms. In addition to the SF424 (R&R) forms, applications to NIH and other PHS agencies will include agency-specific forms, titled “PHS 398.” These PHS 398 forms were developed to continue the collection of agency-specific data required for a complete application. While these agency-specific forms are not identical to the PHS 398 application form pages, the PHS 398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) forms. A complete application to NIH and other PHS agencies will include SF424 (R&R) forms and PHS 398 forms. Instructions for all application forms, SF424 (R&R) and PHS 398, are found in this document.

The use of these forms also involves electronic submission of completed applications through Grants.gov. NIH and other PHS agencies continues to transition all activity codes to the new application forms and Grants.gov submission. NIH will continue to use Requests for Applications (RFAs) and Program Announcements (PAs) as categories of FOAs. See [Section 2.4.2](#) for definitions.

Applicants must carefully review FOAs for guidance on when to use the SF424 (R&R) forms, instructions, and electronic submission for a specific activity code (i.e., P01, P20, P50, etc.). This process will apply to all types of submissions for the announced activity code—new, resubmission, renewal, and revision grant applications. Each FOA will include a link to the most current version of these instructions. Applicants are encouraged to check the website frequently for the most current version.

For purposes of this document, any references to “NIH” may also mean “NIH and other PHS agencies” such as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

1.1 Application Guide Format

This application guide is organized into three distinct parts:

[Part I](#): Instructions for Preparing and Submitting the Application. Part I includes specific instructions for completing the application forms as well as information on electronically submitting applications through Grants.gov.

The following Parts are incorporated into this application guide by reference. They are in a separate document titled, “[Supplemental Instructions](#).”

[Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.](#) Part II is to be used if your proposed research will involve human subjects. These instructions assist in determining whether human subjects are involved and include scenarios and detailed instructions for completing the PHS 398 Research Plan form.

[Part III: Policies, Assurance, Definitions, and Other Information.](#) Part III includes information on policies, assurances, definitions, and other information relating to submission of applications to the PHS. Applicants should refer to this document as well as the instructional materials, Grants Information (GrantsInfo), and the relevant Grants Policy Statement for additional sources of information. The [NIH Grants Policy Statement](#) applies to all NIH awardees; other PHS agencies use the [HHS Grants Policy Statement](#).

1.2 NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (<http://grants.nih.gov/grants/oer.htm>) provides an array of helpful information. Applicants are encouraged to bookmark this site and visit it often.

The Division of Communications and Outreach (DCO) is the central source for general information about NIH extramural research and research training programs, funding activity codes, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DCO. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by e-mailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

1.3 Research Grant Activity Codes and Program Guidelines

A partial list of research grant activity codes and programs are provided below. As noted in the descriptions in Supplemental Instructions [Part III: Policies, Assurances, Definitions, and Other Information](#), not all awarding components use all activity codes or programs. For a complete listing of program guidelines, visit the OER Grants website http://grants.nih.gov/grants/funding/funding_program.htm.

Research Grants

- Basic Research Grant (R01)
- Small Research Grant (R03)
- Academic Research Enhancement Award (AREA) (R15)
- Exploratory/Developmental Grant (R21, R33, R21/R33)
- Small Business Innovation Research Grant (SBIR) (R43/R44)
- Small Business Technology Transfer Grant (STTR) (R41/R42)
- Program Project Grant (P01)
- Research Center Grant (P50)
- Scientific Meeting Support (R13, U13)

- Research Project Cooperative Agreement (U01)
- Research Grants to Foreign Institutions and International Organizations

Training, Fellowships and Career Development Programs

- NIH Institutional Ruth L. Kirschstein National Research Service Award (T32)
- Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA) (F30, F31, F32, F33, F34, etc.)
- Research Career Development Award (K Award)

Applications Available from Other Offices

- Health Services Project Application (5161-1)

1.4 Interactions with PHS Staff

The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process. Website addresses and staff phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below.

Table 1.4-1. PHS Agency Contact Table

PHS AGENCY (LINK TO WEBSITE)	AWARDING COMPONENT (LINK TO WEBSITE)	TELEPHONE NUMBER
National Institutes of Health (NIH)	Eunice Kennedy Shriver National Institute of Child Health and Human Development	301-496-0104
NIH	Fogarty International Center	301-496-1653
NIH	National Cancer Institute	301-496-3428
NIH	National Center for Complementary and Alternative Medicine	301-496-4792
NIH	National Center for Advancing Translational Sciences	301-496-6023
NIH	National Eye Institute	301-451-2020
NIH	National Heart, Lung, and Blood Institute	301-435-0260
NIH	National Human Genome Research Institute	301-496-7531
NIH	National Institute on Aging	301-496-9322
NIH	National Institute on Alcohol Abuse and Alcoholism	301-443-4375
NIH	National Institute of Allergy and Infectious Diseases	301-496-7291
NIH	National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
NIH	National Institute of Biomedical Imaging and Bioengineering	301-451-4792
NIH	National Institute on Deafness and Other Communication Disorders	301-496-1804
NIH	National Institute of Dental and Craniofacial Research	301-594-4800
NIH	National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
NIH	National Institute on Drug Abuse	301-443-2755

PHS AGENCY (LINK TO WEBSITE)	AWARDING COMPONENT (LINK TO WEBSITE)	TELEPHONE NUMBER
NIH	National Institute of Environmental Health Sciences	919-541-7723
NIH	National Institute of General Medical Sciences	301-594-4499
NIH	National Institute of Mental Health	301-443-3367
NIH	National Institute on Minority Health and Health Disparities	301-402-1366
NIH	National Institute of Neurological Disorders and Stroke	301-496-9248
NIH	National Institute of Nursing Research	301-594-6906
NIH	National Library of Medicine	301-496-4621
NIH	Center For Scientific Review	301-435-0715
Agency for Healthcare Research and Quality	Agency for Healthcare Research and Quality	301-427-1447
Centers for Disease Control and Prevention (CDC)	Coordinating Center for Health Information and Services	404-498-1186
CDC	Office of Infectious Disease	404-639-3770
CDC	National Center for Environmental Health	770-488-4668
CDC	National Center for Injury Prevention and Control	800-232-4636
CDC	National Center for Chronic Disease Prevention and Health Promotion	770-488-8390
CDC	National Institute for Occupational Safety and Health	404-498-2530
CDC	Procurement and Grants Office	770-488-2700
Food and Drug Administration	Food and Drug Administration	301-827-7185
Indian Health Service	Indian Health Service	301-443-0578
Agency for Toxic Substances and Disease Registry	Agency for Toxic Substances and Disease Registry	404-842-6630
Office of Public Health and Science	Office of Population Affairs	301-594-4004
Office of Public Health and Science	Office of Family Planning	301-594-4008

Before Submission

You may wish to contact NIH staff with a variety of questions before submitting an application.

Contact [GrantsInfo](#) and/or the [Division of Receipt and Referral, Center for Scientific Review \(CSR\)](#), [NIH](#):

- To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note requests for assignment to an Institute/Center and/or a SRG may be made in a [cover letter](#) at the time of application submission.

- To learn about grant programs.
- To receive advice on preparing and submitting an application (e.g., format, structure).

Contact program staff in the relevant awarding component:

- To determine whether your proposed application topic would fit into the NIH IC's or other non-NIH agency's programmatic area.
- To learn about programmatic areas of interest to the IC or other non-NIH agencies.
- To find out about requesting an assignment to an IC.
- To discuss whether you should respond to an RFA.

Contact Scientific Review Officers in the CSR to discuss requesting assignment to a CSR SRG.

After Submission

If the initial assignment to an IC or SRG seems inappropriate, the Program Director/Principal Investigator (PD/PI) may request reassignment. Such requests should be made in writing to:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 2030, MSC 7720
Bethesda, MD 20892-7720
Fax requests (301-480-1987) are also acceptable.

Although these requests will be carefully considered, the final determination will be made by the PHS agency.

Applicants must never contact reviewers regarding their applications because discussion of the scientific content of an application or an attempt to influence review outcomes will create serious breaches of confidentiality in the review process. Reviewers are required to notify the Scientific Review Officer if they are contacted by an applicant. Communication by the applicant to a reviewer may delay the review or result in the return of the application without review.

Communications from the Division of Receipt and Referral (DRR) are accessible to applicants and applicant organizations in the eRA Commons in a new "Correspondence" section of the Commons detailed status screen for the application. Applicants will be notified by email to check their Commons account. DRR will notify an applicant when: 1) additional information is required before her/his application can be assigned to a scientific review group (SRG) and NIH Institute or Center (IC) for funding consideration; 2) an applicant's request for an IC assignment cannot be honored; or 3) it has been determined that the application does not comply with NIH policy. For additional information, see NIH Guide Notice [NOT-OD-12-108](#).

After Assignment

Contact your Scientific Review Officer to discuss the review assignment, to request permission to send additional/corrective materials, and/or to discuss any review concerns (e.g., expertise needed on your SRG, conflicts, reviewers that may have bias).

After Peer Review

Feedback to applicants is very important. Once the PD/PI reviews the [Summary Statement](#) in the eRA Commons, the appropriate awarding component program official noted in the Summary Statement may be contacted:

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals in the Summary Statement.
- To find out the funding status of an application.

A paper copy of the Peer Review Outcome Letter and Summary Statement will not be mailed to the PI and may only be accessed through the eRA Commons.

1.5 Grants Policy Statements

- The [NIH Grants Policy Statement](#) serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards.
- The [HHS Grants Policy Statement](#) serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of grant awards from other PHS agencies, excluding NIH awards.

1.6 References

Applicants New to NIH: Getting Started

http://grants.nih.gov/grants/useful_links.htm

Award Information and Data

<http://report.nih.gov/index.aspx>

NIH Research Portfolio Online Reporting Tool (RePORT)

Contact Information for an NIH Staff Person

<http://ned.nih.gov>

NIH locator: (301) 496-4000

Applying Electronically

For additional information on the electronic submission process, including self-help resources, training material and answers to frequently asked questions, see:

<http://grants.nih.gov/grants/ElectronicReceipt/index.htm>

eRA Commons

<https://commons.era.nih.gov/commons/index.jsp>

Institutions and PD/PIs are required to register with the eRA Commons. Registered PD/PIs can check assignment/contact information, review outcome, and other important information. For more details on Commons registration, see [Section 2.2.2](#).

E-mail: commons@od.nih.gov.

Telephone: 1-866-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

Grant Writing Tips and Sample Applications

http://grants.nih.gov/grants/grant_tips.htm

Grants Information

<http://grants.nih.gov/grants/giwelcome.htm>

E-mail: GrantsInfo@nih.gov

Telephone: (301) 435-0714; (301) 451-5936 (TTY)

Grants.gov User Guide

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide at the following address:

<http://www.grants.gov/assets/ApplicantUserGuide.pdf>.

NIH Office of Extramural Research Human Subjects Website

<http://grants.nih.gov/grants/policy/hs/index.htm>

This site provides, in one place, DHHS and NIH requirements and resources for the extramural community involved in human subjects research.

Office for Human Research Protections (Department of Health and Human Services)

<http://www.hhs.gov/ohrp>

Information about human subject protections, Institutional Review Boards, and Federal Wide Assurances

Telephone: 1-866-447-4777 or (301) 496-7005

Office of Laboratory Animal Welfare (OLAW)

<http://olaw.nih.gov>

Information about animal welfare policy requirements, Institutional Animal Care and Use Committees (IACUC), and Animal Welfare Assurances

Telephone: (301) 496-7163

Receipt/Referral of an Application

<http://www.csr.nih.gov/EVENTS/AssignmentProcess.htm>

Division of Receipt and Referral

Center for Scientific Review

Telephone: (301) 435-0715

Fax: (301) 480-1987

Specific Application: Before Review

Telephone or e-mail the Scientific Review Officer identified for the application in the eRA Commons.

Specific Application: Post Review

Telephone or e-mail the NIH Program Official named in the Summary Statement for the application.

1.7 Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301(a) and 487 of the PHS Act, as amended (42 U.S.C. 241a and 42 U.S.C. 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

1.7.1 Collection of Personal Demographic Data

Federal agencies have a continuing commitment to monitor the operation of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. In addition, section 403 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on postdoctoral individuals supported on research grants, and section 489 of the PHS Act requires NIH to perform a continuing assessment of research personnel needs. Personal demographic data on PD/PIs and those with a postdoctoral role is vital to comply with these requirements.

NIH collects personal data through the eRA Commons Personal Profile. The data is provided one-time by the individual through a secure, electronic system, is confidential, and is maintained under the Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." When completing the data entry in the Commons Personal Profile, the individual is responsible for providing true, accurate, and complete data. All analyses conducted on date of birth, citizenship, gender, race, ethnicity, disability, and/or disadvantaged background data will report aggregate statistical findings only and will not identify individuals. Declining to provide information does not affect consideration of an application; however, for some programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data is required to determine eligibility.

The PHS also requests the last four digits of the Social Security Number (SSN) for accurate identification of individuals and for management of PHS grant programs. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this portion of the SSN. The PHS requests the last four digits of the SSN under Section 301(a) and 487 of the PHS act as amended (42 U.S.C. 241a and U.S.C. 288).

1.8 Paperwork Burden

The PHS estimates that it will take approximately 22 hours to complete this application for a regular research project grant. This estimate excludes time for development of the scientific plan. Other items such as human subjects are cleared and accounted for separately and therefore are not part of the time estimate. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). Do not send applications or any materials related to training or career award applications to this address.

2. Process for Application Submission via Grants.gov

Application submission through Grants.gov involves several steps. Some of the steps need only be done one time. Others are ongoing steps that will be necessary for each application submission. Before beginning the application process, you are encouraged to review [Grants.gov](#) and all the resources available there.

2.1 Overview

The following steps must be taken in order to submit a grant application through Grants.gov. Please be sure to complete all steps to ensure that NIH receives the application in a timely manner.

1. Register your organization at Grants.gov. (This is a one-time only registration process for all Federal agencies. However, an annual renewal of information provided to the System for Award Management ([SAM](#)) is necessary to retain active Grants.gov credentials. If your organization has already completed this step for any Federal agency submission, skip to step #2. If your organization has not completed this step, see Section 2.2 for more details.)
2. Register your organization and Program Director/Principal Investigator (PD/PI) in the eRA Commons. (This is a one-time only registration process. If your organization has already completed this step, skip to step #3. If your organization has not completed this step, see [Section 2.2](#) for more details.)
3. Find a Funding Opportunity Announcement (FOA) of interest using the NIH Guide for Grants and Contracts or [Grants.gov's "Find Grants"](#) feature. (See [Section 2.4](#) for more details.)
4. Download the associated Application Package from Grants.gov. (Adobe Reader required for download. See [Section 2.3](#) for more details.)
5. Complete the appropriate application forms, including all text and PDF attachments. Upload all attachments into the appropriate application form (See [Section 2.6](#) for more details on the requirements for text (PDF) attachments).
6. Review the completed application through your own organizational review process.
7. Coordinate with an Authorized Organization Representative (AOR) at the applicant organization to submit the application by the date and time specified in the FOA. **(Keep a copy locally at the Applicant Organization/Institution.)**
8. Receive the Grants.gov tracking number.
9. After successfully passing Grants.gov and agency validation, receive the agency tracking number (accession number). **Note:** Any errors encountered at Grants.gov or eRA Commons must be corrected in order to successfully complete your submission.
10. PD/PI and Signing Official (SO) must view the application in eRA Commons to ensure the assembled application correctly reflects their submission. (See [Section 2.11](#) for detailed information.)

The following sections explain each step in more detail.

2.2 Registration Processes

2.2.1 Grants.gov Registration

Grants.gov requires a **one-time** registration *by the applicant organization* in order to submit applications. Registration is not needed to download an application package or to prepare an application for submission. PD/PIs do not have to individually register in Grants.gov unless they also serve as the Authorized Organization Representative (AOR) for their institution/organization. If an applicant organization has already completed Grants.gov registration for another Federal agency, they can skip this section and focus on the eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at the Grants.gov Get Registered tab (http://grants.gov/applicants/get_registered.jsp). While Grants.gov registration is a one-time only registration process, it does involve several steps and will take some time. Applicant organizations needing to complete this process are encouraged to **start early** allowing at least six (6) weeks to complete all the steps before actually submitting an application through Grants.gov.

All registrations require that applicants be issued a [Dun and Bradstreet Universal Numbering System \(DUNS\)](#) number. After obtaining a DUNS number, applicants can begin both System for Award Management (SAM) (formerly CCR) and eRA Commons registrations. The same DUNS number must be used for all registrations and on the grant application itself.

Note that all applicant and grantee organizations must complete and maintain an active entity registration in SAM **which requires renewal at least annually**. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term. 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. Foreign organizations must obtain a NATO Commercial and Government Entity (NCAGE) code (in lieu of a CAGE code) in order to register in SAM. Use the SAM.gov "Manage Entity" function to manage your entity registrations. See the Grants Registrations User Guide at <http://www.sam.gov> for additional information.

For additional information regarding maintaining an active SAM registration, please see [NIH Guide Notice NOT-OD-11-004](#).

The AOR is an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. This individual has the authority to sign grant applications and required certifications and/or assurances that are necessary to fulfill the requirements of the application process. Once this individual is registered, the organization can then apply for any government funding opportunity listed in Grants.gov, including NIH and other PHS agencies grants.

Questions regarding Grants.gov registration should be directed to the Grants.gov Contact Center at telephone: 1-800-518-4726 or by e-mail at support@grants.gov. The Contact Center is available 24 hours a day, 7 days a week.

2.2.2 eRA Commons Registration

The applicant organization, all PD/PIs, and all individuals with a postdoctoral role (see definition of [postdoctoral scholar](#) in Supplemental Instructions Part III.3) and one month or more of measurable effort must also complete a **one-time** registration in the eRA Commons. Individuals with a postdoctoral role do not need an eRA Commons ID for application submission. However, individuals with a postdoctoral role must have an eRA Commons ID for reporting on awarded grants. Access to the Commons is vital for all

steps in the process after application submission. An organization and PD/PIs must be registered in the Commons before they can take advantage of electronic submission and retrieval of grant information, such as reviewing grant applications, institute/center assignments, review outcomes, and Summary Statements. Applicants must have an active DUNS number 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. Institutional/organizational officials are responsible for registering PD/PIs and individuals with a postdoctoral role in the eRA Commons. PD/PIs and individuals with a postdoctoral role should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least six (6) weeks prior to the submittal date of a Grants.gov submission. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field of the Senior/Key Person Profile Form will prevent the successful submission of an electronic application to NIH. Commons user name IDs for those with a postdoctoral role are not required at the time of application submission, but are required as part of the Non-Competing Continuation Progress Report (RPRR or PHS 2590).

2.2.2.1 Commons Registration for the Organization

Organizations may verify their current registration status by accessing the “List of Grantee Organizations Registered in eRA Commons” (http://era.nih.gov/commons/quick_queries/index.cfm#commons).

To register an Organization in the eRA Commons:

1. Complete the online Institution Registration Form at:
<https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp>
2. Print and fax the registration page
 - a. The Signing Official (SO) must sign, date and fax the registration to the number listed on the form
3. Signing Official must verify email address
 - a. Once the registration is submitted electronically, email verification is sent and the SO must click the link to verify email
 - b. The above steps must be completed before NIH can process the registration
 - c. The SO will receive an “Approval” email from NIH
 - d. The “Approval” email contains a link to information that you must verify as correct before the confirmation process is completed
4. Account Administrator (AA) receives user names and temporary passwords
 - a. After the completion of the confirmation, the SO and AA will receive two emails that contain the user names and temporary password for the SO and AA accounts created during the registration process
5. Log into Commons
 - a. The SO and AA log into Commons and administer additional accounts as needed
6. Affiliate your PIs
 - a. Your Principal Investigators must work with your organization to be registered in eRA Commons if they do not have an existing account. If they have an account, you

must affiliate it with your organization. Verify that you've selected the correct PI account!

For more information, see http://era.nih.gov/commons/faq_commons.cfm#II2.

This registration is independent of Grants.gov and may be done at any time.

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile for applications to be accepted. In addition, the DUNS number in the Institutional Profile must match that entered in the SF424 (R&R) Cover Form in Section 5, Applicant Information.**

Prior to submission, the AOR/SO should verify that their organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that your organization has a DUNS number or to find out if the DUNS number you have matches the one in Commons, access the List of Grantee Organizations Registered in eRA Commons (http://era.nih.gov/commons/quick_queries/index.cfm#commons). This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into Commons.

2.2.2.2 Commons Registration for the Program Directors/Principal Investigators (PD/PIs) and Individuals with a Postdoctoral Role

Once the organization is registered in the Commons, individuals can then be registered. **All PD(s)/PI(s) must have an eRA Commons account and the PI Role and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account.** If the PD/PI is also the organizational signing official, they must have two distinct eRA Commons accounts, one for each role. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** If submitting an application reflecting Multiple PD/PIs, the individual designated as the contact PI must be affiliated with the applicant organization. To register PD/PIs in the Commons, refer to the eRA Commons System Users Guide (http://era.nih.gov/commons/user_guide.cfm). For applications reflecting Multiple PD/PIs, all such individuals must be assigned the PI role, even those at organizations other than the applicant organization.

Once a PD/PI has received e-mail confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the PD/PI review and update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), e-mail, phone, fax, street address, city, state, country, zip and degrees earned. These data must contain the most recent information in order for the application to be processed accurately.

Both PD/PI and SO need separate accounts in Commons since each role enables different features within eRA Commons. For example, an SO can Reject a submitted application to prevent it from being sent on to agency staff. A PI has access to review outcome information (scores and summary statement). If you are the SO for your organization as well as a PD/PI of the grant, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

Individuals with a postdoctoral role and one month or more of effort must also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons system is accurate. The Commons user name ID for those with a postdoctoral role is not required at the time of application submission, but will be required as part of the Non-Competing Continuation Progress Report (RPRR or PHS 2590).

For additional information on how to prepare for electronic submission, see:
<http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm>.

2.3 Software Requirements

2.3.1 Adobe Reader

In order to access, complete and submit applications using Grants.gov's downloadable forms, applicants need to download and install the Adobe Reader, version 8.1.1 or later. For minimum system requirements and download instructions, please see the [Grants.gov User Guide](#) or visit http://grants.gov/help/download_software.jsp.

2.3.2 Creating PDFs for Text Attachments

NIH and other PHS agencies require all text attachments to the SF424 (R&R) application forms to be submitted as PDF files.

Applicants should prepare text attachments using any word processing program (following the format requirements in [Section 2.6](#)) and then convert those files to PDF before attaching the files to the appropriate form in the application package. (The PDF format is used to preserve document formatting.) Save all files with descriptive file names of 50 characters or less and be sure to only use standard characters in file names: A through Z, a through z, 0 through 9, underscore (_), hyphen (-), space (), and period (.). Do not use any other special characters (e.g., "&", "*", "%", "/", or "#") in the file name.

Some type of PDF-creation software is necessary to create the PDF. (The free Adobe Reader *will not* create a PDF.) To assist applicants searching for free PDF-creation software, Grants.gov has published a list of available tools and software, see Grants.gov's Download Software page at http://www.grants.gov/help/download_software.jsp.

Note that all PDF attachments must be submitted as individual files. Although some software packages allow bundling of multiple PDFs into a single file, eRA systems cannot support "Bundling" or "Portfolio" features at this time. Use of these features may result in delays in the review of an application or an application not being reviewed.

It is recommended that, as much as possible, applicants avoid scanning text documents to produce the required PDFs. Instead, NIH recommends producing the documents electronically using text or word-processing software and then converting documents to PDF. Scanning paper documents, without the proper Optical Character Recognition (OCR) process, will hamper automated processing of your application for NIH analysis and reporting.

DISCLAIMER: References to software packages or Internet services neither constitute nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the NIH or other PHS agencies, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

2.3.3 Special Instructions for Macintosh Users

With the conversion to Adobe Reader application submissions there are no longer special instructions for Macintosh users.

2.4. Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are **unsolicited** and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. Research project grants are awarded to organizations/institutions on behalf of PD/PIs to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding agency anticipates substantial program involvement during the conduct of the research, a cooperative agreement will be awarded rather than a grant. The NIH typically awards grants and cooperative agreements for terms ranging from one to five years. Organizational/institutional sponsorship assures that the awardee organization will provide the facilities and the financial stability necessary to conduct the research, and be accountable for the funds. For a list and brief description of grant activity codes, see Supplemental Instructions [Part III: Policies, Assurances, Definitions, and Other Information](#).

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts* (<http://grants.nih.gov/grants/guide>), a weekly electronic publication, contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs), including Parent Announcements, from NIH and other PHS agencies. The *NIH Guide* also contains vital information about policies and procedures. To subscribe to the *NIH Guide*, visit <http://grants.nih.gov/grants/guide/listserv.htm>.

2.4.2 Funding Opportunity Announcements

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an awarding component will encourage applications through the issuance of a PA to describe new, continuing, or expanded program interests, or issuance of an RFA inviting applications in a well-defined scientific area to accomplish a scientific purpose.

Definitions are as follows:

Parent Announcements: Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA). For applicants who wish to submit what were formerly termed “investigator-initiated” or “unsolicited” applications, NIH and other PHS agencies have developed Parent Announcements. Responding to such an omnibus or umbrella Parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. Additional information about, as well as links to published Parent Announcements, can be found at: http://grants.nih.gov/grants/guide/parent_announcements.htm.

Program Announcement (PA): A formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time. NIH may also make funds available through PARs (Program Announcements with special receipt, referral, and/or review considerations) and PASs (Program Announcements with set-aside funds).

Request for Applications (RFA): A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application submission date(s). Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

PAs (including Parent Announcements) and RFAs are published in the [NIH Guide for Grants and Contracts](#) (<http://grants.nih.gov/grants/guide>) and on Grants.gov under Find Grant Opportunities (http://www.grants.gov/applicants/find_grant_opportunities.jsp). Read the announcement carefully for special instructions. The instructions in the announcement may differ from these general instructions, and the instructions in the announcement **always** supersede these general instructions. Each announcement published in the [NIH Guide for Grants and Contracts](#), [Grants.gov Find](#), or other public document contains contact information under Inquiries in addition to information specific to the announcement.

While individual announcements will continue to carry an announcement number reference to “PA” or “RFA”, all announcements are “Funding Opportunity Announcements (FOAs).” This general term will be used to reference any type of funding announcement. NIH will continue to use the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

In reading any FOA in the *NIH Guide for Grants and Contracts*:

- A “Posted Date” refers to the date the FOA is posted on [Grants.gov](#). An applicant can download the application package on that date and begin filling it out. However, the applicant has to wait until the FOA’s “open date” to submit the application.
- An application can be submitted anytime between the “open date” and the “application due date(s)” noted for AIDS and non-AIDS applications. (Standard dates may apply; check <http://grants.nih.gov/grants/funding/submissionschedule.htm> for details.)
- When you download an application package from Grants.gov, the “expiration date” is pre-populated. Do not go strictly by this date since it may not apply to your particular situation; for instance, it may reflect the submission date for AIDS applications and you may be submitting a non-AIDS application that is due earlier. In this case, the pre-populated date has no bearing on your application and you should not be concerned by it.

All applications submitted to the NIH must be submitted in response to a FOA published in the NIH Guide for Grants and Contracts.

2.4.3 Finding a Funding Opportunity Announcement (FOA) for Grants.gov Submission

Implementation of the SF424 (R&R) application and electronic submission through Grants.gov will be announced through specific FOAs posted in the *NIH Guide for Grants and Contracts* and on Grants.gov under “Find Grants” (a.k.a. “Find”) and “Apply for Grants” (a.k.a. “Apply”). From the “For Applicants” section of the Grants.gov home page, select “Apply for Grants” and follow the steps provided. FOAs posted in Grants.gov Apply reflect those the agency is prepared to receive through electronic Grants.gov submission. Applicants are encouraged to read each FOA carefully for specific guidance on the use of Grants.gov submission.

There are several ways a prospective applicant can find a FOA on Grants.gov.

Using the *NIH Guide for Grants and Contracts*

FOAs in the *NIH Guide for Grants and Contracts* that reference electronic submission via Grants.gov include a link from the FOA directly to the Grants.gov site where you can download the specific application package. The **Apply for Grants Electronically** button is found in the *NIH Guide* FOA directly above the Table of Contents. This link is only provided in those announcements involving electronic submission through Grants.gov.

Using “Find Grants” (Find) Feature

Grants.gov Find provides general search capabilities. From the “Search Grants” page, you will find various options for: providing search criteria (e.g., keyword, Funding Opportunity Number, status, etc.) and identifying FOAs of interest.


Once you find an opportunity for which you wish to apply, you may initiate the application download process by selecting the “Application Package” tab.

Using “Apply for Grants” (Apply) Feature

If you know the specific funding opportunity number, a more direct route is to use the “Apply for Grants” feature. From the Grants.gov home page, select “Apply for Grants” and follow the steps provided. “Step 1” allows you to download an application package by inserting a specific Funding Opportunity Number (FOA). If you do not know the specific Funding Opportunity Number there is a link that will take you back to the Search Grants page.

The screenshot shows the Grants.gov website interface. At the top, the Grants.gov logo is on the left, and navigation links (Contact Us, SiteMap, Help, RSS, Home) are on the right. A left sidebar contains a menu with categories: 'FOR APPLICANTS' (with sub-links like Applicant Login, Find Grant Opportunities, Get Registered, Apply for Grants, Track My Application, Applicant Resources, Search FAQs, User Guides and Site Information), 'APPLICANT SYSTEM-TO-SYSTEM', 'FOR GRANTORS', 'ABOUT GRANTS.GOV', 'HELP', 'CONTACT US', and 'SITE MAP'. The main content area has a breadcrumb trail: Home > Applicants > Apply for Grants >. Below this is the heading 'DOWNLOAD APPLICATION PACKAGE'. A note states: 'Note: You will need to download and install [Adobe Reader](#) prior to downloading an Application Package.' The instructions read: 'To download an application package, enter the appropriate CFDA Number OR Funding Opportunity Number and click the "Download Package" button.' There are three input fields: 'CFDA Number:' with a placeholder '(#.###)', 'Funding Opportunity Number:' with a placeholder '(Can contain only letters, numbers and dashes)', and 'Funding Opportunity Competition ID:' with a placeholder '(Can contain only letters, numbers and dashes)'. A 'Download Package' button is located below these fields. At the bottom, a link is provided: 'If you do not remember the Funding Opportunity Number for the grant opportunity, return to the [Find Grant Opportunities](#) section to locate the grant opportunity and then return to this screen to enter the number.'

A Funding Opportunity Announcement (FOA) Number is referenced in every announcement. Enter this number in the Funding Opportunity Number field and click **Download Package**. This takes you to a “Selected Grant Applications for Download” screen.



[Contact Us](#) [SiteMap](#) [Help](#) [RSS](#) [Home](#)

[Home](#) > [Applicants](#) > [Apply for Grants](#) >

SELECTED GRANT APPLICATIONS FOR DOWNLOAD

Download the application and its instructions by selecting the corresponding download link. Save these files to your computer for future reference and use. You do not need Internet access to read the instructions or to complete the application once you save them to your computer.

READ BELOW BEFORE YOU APPLY FOR THIS GRANT!

Before you can view and complete an application package, you **MUST** have the Adobe Reader installed. Application packages are posted in Adobe Reader format. You may receive a validation error using incompatible versions of Adobe Reader. To prevent a validation error, it is now recommended you uninstall any earlier versions of Adobe Reader and install the latest compatible version of Adobe Reader .

If more than one person is working on the application package, ALL applicants must be using the same software version.

Click [here](#) to download the required Adobe Reader if you do not have it installed already.

Additional Resources:

- Sign-up for [Grants.gov Updates](#) for the latest issues and news.
- Download [Adobe Reader](#) for free.
- Visit [Help](#) for FAQs and more information on Applying for grants.

Below is a list of the application(s) currently available for the CFDA and/or Funding Opportunity Number that you entered.

To download the application instructions or package, click the corresponding download link. You will then be able to save the files on your computer for future reference and use.

CFDA	Opportunity Number	Competition ID	Competition Title	Agency	Instructions & Application
	PAR-13-215	ADOBE-FORMS-B2	Adobe-Forms-B2	National Institutes of Health	download
	PAR-13-215	FORMS-C	Use for due dates after 9/24/2013	National Institutes of Health	download

Click the corresponding **download** link to access the actual application form pages and instruction material. If more than one application package is listed, use the Competition ID and Competition Title to determine the appropriate package to download.

Download a fresh copy of the SF424 grant proposal every single time. The SF424 forms are not recyclable in the same way that the old PHS 398 forms were. It is OK to start a template and save different versions if you have multiple faculty who will be submitting the same proposal type at the same time.

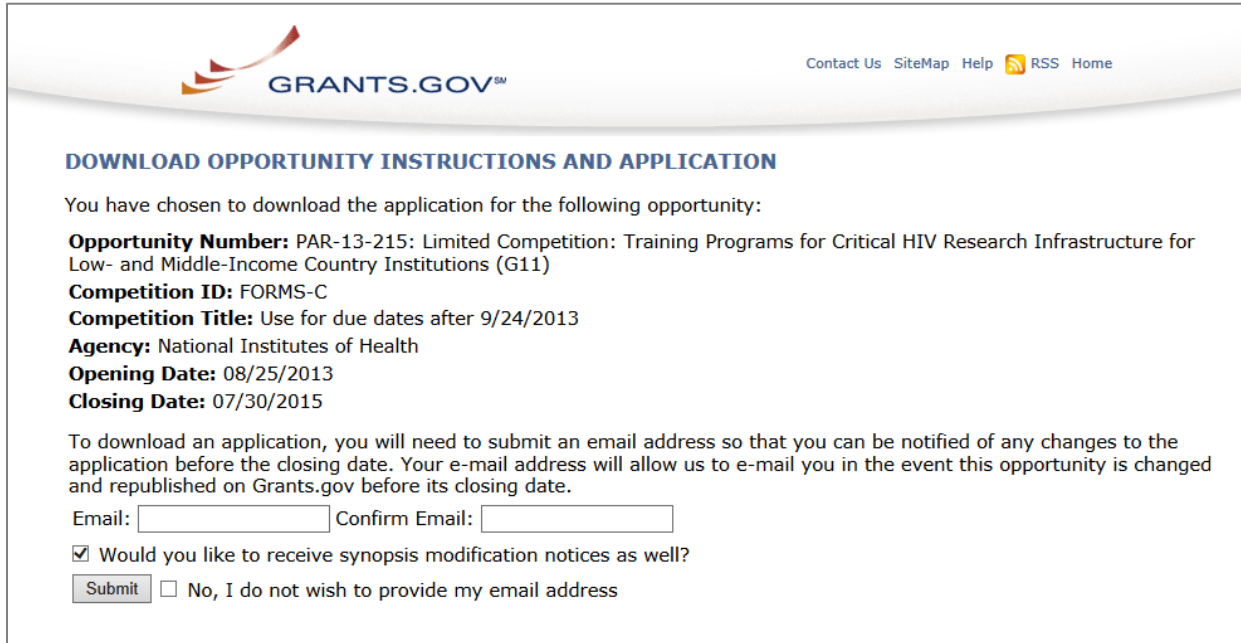
The link on the NIH website to parent (unsolicited) grant applications is:

http://grants1.nih.gov/grants/guide/parent_announcements.htm

The link to the School of Medicine Office of Grants and Contracts website:

<http://www.medicine.virginia.edu/research/offices/research>

The following screens appear:



The screenshot shows the Grants.gov website header with the logo and navigation links: Contact Us, SiteMap, Help, RSS, and Home. Below the header, the section is titled "DOWNLOAD OPPORTUNITY INSTRUCTIONS AND APPLICATION". The text states: "You have chosen to download the application for the following opportunity:". The opportunity details are listed: **Opportunity Number:** PAR-13-215: Limited Competition: Training Programs for Critical HIV Research Infrastructure for Low- and Middle-Income Country Institutions (G11); **Competition ID:** FORMS-C; **Competition Title:** Use for due dates after 9/24/2013; **Agency:** National Institutes of Health; **Opening Date:** 08/25/2013; **Closing Date:** 07/30/2015. A paragraph explains that an email address is required for notifications of changes. Below this, there are two input fields for "Email:" and "Confirm Email:". A checkbox is checked, labeled "Would you like to receive synopsis modification notices as well?". At the bottom, there is a "Submit" button and a radio button option: "No, I do not wish to provide my email address".

GRANTS.GOVSM

Contact Us SiteMap Help RSS Home

DOWNLOAD OPPORTUNITY INSTRUCTIONS AND APPLICATION

You have chosen to download the application for the following opportunity:

Opportunity Number: PAR-13-215: Limited Competition: Training Programs for Critical HIV Research Infrastructure for Low- and Middle-Income Country Institutions (G11)

Competition ID: FORMS-C

Competition Title: Use for due dates after 9/24/2013

Agency: National Institutes of Health

Opening Date: 08/25/2013

Closing Date: 07/30/2015

To download an application, you will need to submit an email address so that you can be notified of any changes to the application before the closing date. Your e-mail address will allow us to e-mail you in the event this opportunity is changed and republished on Grants.gov before its closing date.

Email: Confirm Email:

☒ Would you like to receive synopsis modification notices as well?

☐ No, I do not wish to provide my email address

Always enter your e-mail address to be notified of changes. There have been instances where the investigator was unaware of changes to the announcement and sent in an incorrect proposal that was rejected.



Contact Us SiteMap Help RSS Home

DOWNLOAD OPPORTUNITY INSTRUCTIONS AND APPLICATION

You have chosen to download the application for the following opportunity:

Opportunity Number: PAR-13-215: Limited Competition: Training Programs for Critical HIV Research Infrastructure for Low- and Middle-Income Country Institutions (G11)

Competition ID: FORMS-C

Competition Title: Use for due dates after 9/24/2013

Agency: National Institutes of Health

Opening Date: 08/25/2013

Closing Date: 07/30/2015

Since you did not subscribe, you will not be notified of any future changes to this opportunity. If you would like to receive notifications, [please click here](#).

Download the instructions and application by selecting the download links below. While the instructions or application files may open directly, you may save the files to your computer for future reference and use. You do not need Internet access to read the instructions or the application once you save them to your computer.

1. [Download Application Instructions](#)
2. [Download Application Package](#)

To access the instructions, click **Download Application Instructions**. For NIH opportunities and other PHS agencies using this Application Guide, this action will download a document containing a link to the NIH website where the most current set of application instructions is available (<http://grants.nih.gov/grants/funding/424/index.htm>). Applicants are encouraged to check this site regularly for the most current version.

To access the form pages, click **Download Application Package**. Section 2.5 provides specific information regarding the forms for an Application Package. [Section 3](#) provides additional instructions for properly using a package.

On the Download Opportunity Instructions and Applications screen you will be given an opportunity to provide an e-mail address if you would like to be notified of any changes to this particular opportunity. Applicants to NIH and other PHS agencies are strongly encouraged to complete this information. The agency can then use it to provide additional information to prospective applicants.

Note: The forms may or may not show a CFDA number and the CFDA field is not editable. Do not be concerned. The CFDA number is not used for assignment of the application. **Be assured the correct CFDA number will be assigned to the record once the appropriate IC assignment has been made.**

2.5 Forms for an Application to NIH or Other PHS Agencies

The SF424 (R&R) form set comprises a number of forms, each listed in the table below as a separate “document.” In addition to these forms, NIH and other PHS agencies applicants will also complete supplemental forms listed as “PHS 398” forms in the table below.

Table 2.5-1. Table 2.5-1. Forms for an NIH or Other PHS Agencies Application

DOCUMENT	REQUIRED	OPTIONAL	INSTRUCTIONS
SF424 (R&R) Cover	X		Section 4.2
SF424 (R&R) Project/Performance Site Locations	X		Section 4.3
SF424 (R&R) Other Project Information	X		Section 4.4
SF424 (R&R) Senior / Key Person Profile(s)	X		Section 4.5
SF424 (R&R) Budget (Use when required or allowed by the FOA)	*		Section 4.7
SF424 (R&R) Subaward Budget Attachment Form (Use when required or allowed by the FOA)		X	Section 4.8
PHS 398 Cover Page Supplement	X		Section 5.3
PHS 398 Modular Budget (Use when required or allowed by the FOA)	*		Section 5.4
PHS 398 Research Plan (Not required for Career Development Award (K) or Institutional Training Award (T) applications)	X		Section 5.5
Planned Enrollment Report		X	Section 5.8
PHS 398 Cumulative Inclusion Enrollment Report		X	Section 5.8
PHS 398 Career Development Award Supplemental Form (Required only for Career Development Award (K) applications)	X		Section 7.5
PHS 398 Research Training Program Plan (Required only for Institutional Training Award (T) applications)	X		Section 8.7
PHS 398 Training Budget (Use when required or allowed by the FOA)	*		Section 8.5
PHS 398 Training Subaward Budget Attachment (Use when required or allowed by the FOA)		*	Section 8.6

- * The application forms package associated with most NIH research grant funding opportunities includes two optional budget forms: (1) SF424 (R&R) Budget and (2) PHS 398 Modular Budget. NIH application submissions must include either the SF424 (R&R) Budget Form or the PHS 398 Modular Budget Form, but never both. (Note AHRQ does not accept modular budgets.) Unless otherwise stated in a funding announcement, an application must always be submitted with a budget form. For those programs where either form is a possibility, the budget forms will be considered “optional” by the Grants.gov package. Nonetheless, it is still required that you select and submit one of these budget forms for an application to be accepted by the NIH.

To determine which budget form to use for NIH applications, consult the modular budget guidelines found in [Section 5.4](#). Additional guidance may also be provided in the specific funding opportunity announcement.

Some funding opportunities will explicitly state the use of only one of the budget forms. In this case, the application package will only include the accepted budget form which will appear in the list of “mandatory” forms (not in the optional list).

For a small number of programs (e.g., S10, DP1, DP2, DP3, X01, X02), neither budget form is included and the only budget information required is the Estimated Project Funding section of the SF424 (R&R) cover.

All required and optional forms for electronic submission listed above are available through Grants.gov and should be downloaded from the FOA being applied to. Do not use any forms or format pages from other sources; these may include extraneous headers/footers or other information that could interfere with the electronic application process.

2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-enforced validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff.

NIH and other PHS agencies require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted below. Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process. (See [Section 2.3.2](#) for more information on creating PDFs.)

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for creating PDF files can be found at http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you **must** delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

File Name

Save all files with descriptive file names of **50 characters** or less and be sure **to only use standard characters in file names: A through Z, a through z, 0 through 9, underscore (_), hyphen (-), space (), and period (.).** **Do not use any other special characters (example: “&”, “*”, “%”, “/”, and “#”) or spacing in the file name.**

Font

Use **an Arial, Helvetica, Palatino Linotype, or Georgia** typeface, a black font color, and a font size of **11 points or larger**. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch.

Type may be no more than six lines per inch.

Paper Size and Page Margins

Use *standard paper size (8 ½" x 11)*.

Use at least **one-half inch margins** (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.

Page Formatting

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship

Use English and avoid jargon.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Page Limits

Although many of the sections of this application are separate text (PDF) attachments, page limits referenced in these instructions and/or funding opportunity announcement must still be followed. Agency validations will include many checks for page limits. Some accommodation will be made for sections that when combined must fit within a specified limitation. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they may not address all page limit requirements for a specific FOA and do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may lead to rejection of the application during agency validation or delay in the review process.

All applications for NIH and other PHS agency funding must be self-contained within specified page limits. Unless otherwise specified in an NIH solicitation, internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

Observe the page number limits given in [Table 2.6-1](#). Only when specifically allowed in a FOA will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See [Table 1.4-1. Agency Contact Table](#).) **The page number limitations may also be different for other specialized grant applications.** Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the

application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice [NOT-OD-11-080](#).

Page limits change depending on the PA, RFA, PAR. Please check this on each application and follow the guidance in the funding announcement. The limits listed below are for parent R01's and may not be true for a different funding mechanism.

Table 2.6-1. Page Limits

Please visit http://grants.nih.gov/grants/forms_page_limits.htm for a more detailed Table of Page Limits.

SECTION OF APPLICATION Also refer to the relevant section of the application instructions and the FOA.	PAGE LIMITS *
Introduction to Resubmission Application (3 pages for R25 on PHS 398 Research Plan and 3 pages for K12, T and D Training Grants on PHS 398 Training Program Plan)	1 page
Introduction to Revision Application	1 page
Specific Aims	1 page
Research Strategy (Item of Research Plan)	6 pages or 12 pages or Follow FOA instructions
Research Education Program Plan For R25 Research Education Grant Applications	25 pages
Plan for Instruction in the Responsible Conduct of Research Required for all Training Grant Activity Codes Required for all Individual Career Development Grant Activity Codes	3 pages 1 page
Biosketch (per person) (2 pages for DP1 and DP2 Activity Codes)	4 pages
Career Development Award (K) Application Upload to PHS 398 Career Development Award Supplemental Form: Combined Candidate Information (Candidate's Background, Career Goals and Candidate's Plan for Career Development/Training Activities During Award Period attachments) and Research Strategy attachment	12 pages
Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Application Research Training Program Plan: Combined Sections 8.7.2.2 – 8.7.2.4 (Background, Program Plan, and Recruitment and Retention Plan to Enhance Diversity)	25 pages

* FOA instructions always supersede these instructions.

2.7 “Resubmission” Applications

For all original new (i.e., never submitted) competing renewal applications submitted for the January 25, 2009 due date and beyond, NIH will accept only a single amendment (A1) to the original application (called a resubmission application). A lengthy hiatus after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no longer be relevant. Therefore, **a resubmission application must be submitted within 37 months after the date of receipt ("receipt date") of the initial New, Renewal, or Revision application** (see [NOT-OD-](#)

[10-140](#) and [NOT-OD-12-128](#)). After 37 months, you may submit a New application. Any second resubmission will be administratively withdrawn and not accepted for review.

NIH has established policies for application resubmissions of certain categories. See [Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code](#) in Supplemental Instructions Part III, 1.2.

There are five requirements for a Resubmission application:

- The Summary Statement must be available in the eRA Commons (<http://commons.era.nih.gov/commons>).
- The PD/PI(s) must make significant changes to the application.
- An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction is separate from the Cover Letter. Use “Introduction” of the PHS 398 Research Plan Form to provide this information. The page limit for the Introduction may not exceed one page unless indicated otherwise. Please refer to the relevant section of the application instructions and the FOA.
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted.
- For Mentored Career Development Award applications, new Letters of Reference must be submitted providing an up-to-date evaluation of the applicant’s potential to become an independent researcher, and the continued need for additional supervised research experience.

See [NOT-OD-11-057](#) for special conditions and due dates for new investigator resubmission applications submitted for consecutive review cycles. Note this applies only to new investigator R01s submitted for standard receipt dates and reviewed in recurring study sections in CSR.

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA keeps all versions (e.g., 01, A1) of a grant application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded, all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

Investigators who have submitted two versions of an application and have not been successful often ask NIH what constitutes a “new application.” It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests. However, a new application following two reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a Resubmission application. Simply rewording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Strategy should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all portions of the Specific Aims and Research Strategy. Requests for review by a different review committee or funding consideration by a different NIH IC are not sufficient reasons to consider an application as new.

In the referral process, NIH staff look at all aspects of the application, not just the title and Description (abstract). Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review. If identified after assignment or review, identical applications will be withdrawn.

2.8 “Revision” Application

A Revision application (formerly called a competing supplement) may be submitted to request support for a significant expansion of a project’s scope or research protocol.

Applications for revisions are **not appropriate** when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and must not extend beyond the term of the current award period.

Provide a one-page “Introduction” that describes the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Use Introduction to application, of the PHS 398 Research Plan form to provide this information. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application. Note that all revision applications must be submitted by the same PD/PI (or Contact PD/PI for multi-PI grants) as listed on the current award and applicants must use the same budget format (i.e. R&R Budget Form or PHS 398 Modular Budget Form) as the current award. Also, any budgetary changes for the remainder of the project period of the current grant should be discussed in the Budget Justification.

If the revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior Summary Statement, and substantial revisions must be clearly evident and summarized in the “Introduction.”

Administrative Supplements

An administrative supplement provides additional funding to meet increased costs that are within the scope of an approved application, but that were unforeseen when the new or competing renewal application was submitted. If considering administrative supplement funding, you must consult in advance with your designated Grants Management Officer and Program Official. It is important to submit a request before the grant expires. NIH now publishes all administrative supplement programs as FOAs, not Guide Notices as done previously. Administrative Supplement requests may now be submitted in response to an FOA through either the eRA Commons or Grants.gov, as described in [NOT-OD-12-024](#), or through the existing, paper-based process. If you submit a request in writing, you must submit to the IC (not to the Division of Receipt and Referral, Center for Scientific Review). For additional information, see NIH Guide Notice [NOT-OD-12-043](#). The request must be signed by the authorized Business Official and describe the need for additional funding and the categorical costs. In the letter, point out what will NOT be able to be accomplished if such a request is denied.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.

Submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that propose to develop a single

product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application; 3) submissions of applications previously submitted to an RFA that were not paid or resubmissions of investigator-initiated applications originally submitted to an RFA (see Grants Policy Statement section 2.3.7.3); and 4) resubmissions of applications with a changed grant activity code.

2.10 Submitting Your Application Via Grants.gov

The Authorized Organization Representatives (AORs) registered in Grants.gov are the only official with the authority to actually submit applications through Grants.gov. Therefore, PD/PIs will need to work closely with their AOR(s) to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the applicant organization.

Before starting the final submission step, **applicants are encouraged to save a copy of the final application locally**. Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all Grants.gov required data fields. If any of the required fields are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. Note that the Check Package for Errors button only checks a subset of Grants.gov application checks and does not guarantee that your application will pass subsequent Grants.gov and agency business rule checks done after submission. Only after the package has been saved with no errors will the **Save & Submit** button become active. Clicking the **Save & Submit** button will begin the application submission process. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Register with Grants.gov process (if not connected to the internet you will be instructed to do so).

Once logged in, the application package will be automatically uploaded to Grants.gov. A confirmation screen will appear once the upload is complete and a Grants.gov Tracking Number will be provided on this screen. Applicants should record this number so that they may refer to it should they need to contact Grants.gov Customer Support or the eRA Commons Help Desk.

For additional information, see http://www.grants.gov/applicants/apply_for_grants.jsp.

Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) before 5 p.m. on the receipt date, local time of the applicant organization. Applicants are encouraged to submit their applications to Grants.gov several days early to ensure enough time to correct any errors before the deadline.

2.11 After You Submit Your Application Via Grants.gov

Grants.gov's Track My Application feature for Applicants provides basic status information for a specified Grants.gov Tracking Number. The Authorized Organization Representative (AOR) can also login to Grants.gov with their username and password to obtain a more detailed status of an application by using the Check My Application Status feature.

Once an application has been submitted via Grants.gov, several e-mails are sent to the email address on file with Grants.gov for the AOR (known at NIH/in eRA Commons as the Signing Official [SO]) who submitted the application. Each email notification will reference a Grants.gov tracking number that is assigned to the submission:

- 1) **Submission Receipt:** An e-mail is sent indicating your application has been received by Grants.gov and is currently being validated.
- 2) **Submission Validation Receipt:** An e-mail is sent indicating your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.
- 3) **Grantor Agency Retrieval Receipt:** An e-mail is sent indicating your application has been retrieved by the Grantor agency.
- 4) **Agency Tracking Number Assignment for Application:** An e-mail is sent indicating your application has been assigned an Agency Tracking Number.

If the AOR/SO has not received a confirmation message from Grants.gov within 48 hours of submission, please contact:

Grants.gov Contact Center
Telephone: 1-800-518-4726
E-mail: support@grants.gov

At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the e-mail address provided for the PD/PI and for the AOR/SO on the SF424 (R&R) Cover form be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be e-mailed to the PD/PI, AOR/SO, and the Applicant Contact e-mail (if provided) named in the application.

This e-mail notification will inform the PD/PI, AOR/SO, and the Applicant Contact (if named) that the application has been received and processed by the agency and will indicate whether any errors or warnings resulted during the validation process. The PD/PI, AOR/SO, and the Applicant Contact will be invited to log on the [eRA Commons](#) to view the assembled application or review the list of warnings/errors that were encountered during the validation process. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

If there were no validation errors, this e-mail notification will also inform the PD/PI, AOR/SO, and the Applicant Contact of an agency accession number, which represents the "agency tracking number." This number replaces the Grants.gov tracking number that was assigned when the application was first submitted. The Grants.gov system will indicate that the agency tracking number has been assigned, and will reflect both numbers.

The eRA system will make every effort to send an e-mail to the PD/PI, AOR/SO, and the Applicant Contact summarizing download and validation results. However, since e-mail can be unreliable, applicants are responsible for checking on their application status in the Commons.

Once an application package has been successfully submitted through Grants.gov, any encountered errors have been corrected by the applicant, and an application image has been assembled by the eRA Commons, PD/PIs and AORs/SOs will have two business days (Monday – Friday, excluding Federal holidays) to check the assembled application before it automatically moves forward to NIH staff for further processing and consideration. Once the application has moved forward, no additional changes to the application will be accepted through Grants.gov or eRA Commons. This window is known as the application viewing window.

Within the viewing window, SOs have the authority to reject an application to stop it from completing the submission process. After an application is rejected, a changed/corrected application can be submitted to address warnings or other issues if it is still before the submission deadline. However, changed/corrected applications submitted after the submission deadline will be subject to the [NIH Late Policy](#) and may not be accepted.

Remember, warnings do not stop further application processing. If an application submission results in warnings (but not errors), the application will automatically move forward after the application viewing window if no action is taken. Some warnings may need to be addressed later in the process.

It is your responsibility to view the entire assembled application in eRA Commons and notify the [eRA Commons Help Desk](#) within this window if the assembled application does not correctly reflect the information submitted to Grants.gov (e.g., submitted information is missing in image, graph/chart appears upside-down). The eRA Commons Help Desk will provide guidance on appropriate corrective actions.

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](#).

Only the eRA Help Desk can confirm whether a system issue has taken place and provide instructions on how to resolve the issue. Applications affected by confirmed system issues will not be considered late as long as the applicant works diligently with the eRA Help Desk on a resolution. If the application needs to be Rejected and resubmitted, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications.

PIs should work with their AOR/SO to determine when the “Reject” feature is appropriate.

To view the assembled application the AOR/SO should:

1. Login to the eRA Commons (<https://commons.era.nih.gov/commons/>) with your Signing Official (SO) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** on the left-hand side of the screen.
4. Search for your application by date received, Grants.gov tracking number, or accession number, to view a hit list of available applications.
5. When you find the appropriate application, click the accession number in the **Application ID** column to view the Status Information screen.
6. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

Note: The SO can Reject the application by clicking on the **Reject eApplication** hypertext link from the Action column of the search hit list.

To view the assembled application the PD/PI should:

1. Login to the eRA Commons (<https://commons.era.nih.gov/commons/>) with your Principal Investigator (PI) account.
2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions** near the top of the screen to view a hit list of available applications.
4. When you find the appropriate application, click the accession number in the **Application ID** column to view the status information screen.
5. Click **e-Application** from the Other Relevant Documents section to view the assembled application.

2.12 Correcting Errors

Prior to a specified application due date, applicants may make corrections and resubmit an application through Grants.gov. If applicants make corrections and resubmit the application after the due date, the application will be considered late. In this case, applicants *must* include a cover letter explaining the reasons for the delay and acceptance will be considered on a case-by-case basis. Also see [Section 2.14](#) for additional information on submission dates.

If errors or warnings result from the validation process, the PD/PI, AOR/SO and Applicant Contact will be issued an e-mail instructing them to log on to the eRA Commons to review the list of warnings/errors that were encountered during the validation process. The eRA system will make every effort to send an e-mail to the PD/PI, AOR/SO and Applicant Contact indicating whether errors or warnings were detected. However, since e-mail can be unreliable, applicants are responsible for periodically checking on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible, before the deadline. SOs for the applicant organization, the PD/PI for the application and any Assistants that have been delegated in eRA Commons to view the PD/PIs status information will have access to the submission results in eRA Commons.

Please be aware of the distinction between *errors* and *warnings*. The word *error* is used to characterize any condition which causes the application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions, or incorrect formatting that have been identified in the body of the application. Conversely, the word *warning* characterizes any condition that is acceptable, at least for the time being, but worthy of bringing to the applicant's attention. It is at the applicant's discretion whether a warning condition requires any action, but some warnings may need to be addressed later in the process.

Failure to comply with stated NIH policies can also result in a submitted application being returned to the applicant without being reviewed. For this reason, applicants are strongly encouraged to review all warnings, to ensure that they require no further attention and that they are satisfied with the validation results. If desired, warnings can be corrected in the same manner as errors.

A Changed/Corrected application may also be submitted if the PDF image, as viewed in the eRA Commons, is incomplete or inaccurate from that submitted.

Submitting a Changed/Corrected application will overwrite the previous submission and the previous application cannot be reinstated.

Errors and warnings may be reviewed in the Commons by performing the following steps:

1. After the application has been downloaded from Grants.gov and validated by the system, login to the eRA Commons (<https://commons.era.nih.gov/commons/>) using your username and password.

2. Click the **Status** tab on the Commons menu bar.
3. Click **Recent/Pending eSubmissions**.
4. Search for your application by date received, Grants.gov tracking number, or accession number, if you are the SO. If you are the PI, clicking Recent/Pending eSubmissions will automatically display a hit list of your applications.
5. A hit list of applications is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hit list by its NIH accession number (e.g., “AN:2911064”). This is the same number that Grants.gov displays, and refers to as the “agency tracking number.”

If any *errors* were identified during validation, then the application still appears in the hit list, but in this case it is identified by its Grants.gov tracking number (e.g., “GRANT87654321”). This is the number that Grants.gov assigned to your application at the time of submission.

6. When you find the appropriate application in the hit list (Application Status will read “eSubmission Error” if errors were received), click its Application ID link to view the list of errors/warnings.
7. The error/warning page appears, and you are then able to review all conditions that were identified during validation. If only *warnings* were identified, you may elect to take action and resubmit; however you may also disregard the warnings and proceed to view the application, as described earlier.

To correct errors and resubmit the application:

1. Make whatever corrections are necessary, wherever appropriate, to your local copy of the application. Most often this means that you have to edit the data within the application forms to correct whatever problem or inconsistency that was noted. Be as careful as possible when correcting your application; NIH’s post-submission materials policy does not allow for applicants to correct oversights in their application after the due date.
2. Check the “Changed/Corrected Application” box in the Type of Submission field of the SF424 (R&R) Cover form.
 - If you are submitting this Changed/Corrected application after the due date, be sure to document the reason for the late submission in the form of a cover letter. NIH makes no guarantees that applications submitted after the due date will be accepted. See the NIH late policy for more information.
 - When you check the Changed/Corrected Application box, Previous Grants.gov Tracking ID field becomes required.
 - When you have made all of your corrections, save the Changed/Corrected application to your computer.
3. The AOR will have to submit the Changed/Corrected application package to Grants.gov. A new Grants.gov tracking number will be assigned and the applicant will have to follow the Changed/Corrected application through Grants.gov to the eRA Commons to view the application image or the list of errors/warnings received during the validation process. It is the applicant’s responsibility to track the application through to the eRA Commons. If you cannot view your application image in the Commons, NIH can’t review your application! Successful submission may take several rounds of Changed/Corrected applications, since correcting one error may reveal or create an additional error.

The same e-mail notifications will be issued once the agency has downloaded and validated the re-submitted application and the PD/PI, AOR/SO, and Applicant Contact will once again be required to log on to the Commons either to view the application or to review the errors that were encountered during validation.

The application will only be assigned for scientific review once errors are resolved.

In addition to the validations performed by the eRA system, further administrative review will be conducted by agency staff. The PD/PI and/or the applicant organization may be contacted for further corrections/clarifications.

2.13 Post-Submission Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from unforeseen administrative issues. Exceptions to this policy are indicated below. See [NOT-OD-10-091](#) and [NOT-OD-13-030](#) for additional information.

The materials should be sent as a PDF attachment to an e-mail. E-mail communication is preferred. If e-mail is not feasible, please send in a hard copy.

The original application is kept intact; any application material sent post-submission is sent separately to reviewers. Updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

Acceptable post-submission materials include:

- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PI moved to another university)
- News of an article accepted for publication
- News of a professional promotion or positive tenure decision for any Program Directors/Principal Investigators and Senior/Key Personnel also will be accepted as post-submission application material. The news must be received by the Scientific Review Officer one month (30 calendar days) prior to the peer review meeting, and demonstrate concurrence from the Authorized Organization Representative (AOR) of the applicant organization.
- If an application proposed to use a human embryonic cell line(s) that is approved by the NIH Stem Cell Registry at least 30 days prior to the peer review meeting, the SRO can include this update to the reviewers as part of the post-submission materials (see [NOT-OD-12-111](#)).
- Videos, within defined limits, (see, [NOT-OD-12-141](#)). Devices and other non-traditional materials will not be accepted after submission, unless the application is submitted for a Funding Opportunity Announcement that specifies other types of allowable post-submission materials.
- For institutional training and training-related grants [not fellowships (F series) or career (K series)] applications, the following types of information will be accepted:

- News of a trainee's or former trainee's graduation, employment, promotion, funding, publication or other professional achievement since the training grant was submitted;
- News of a faculty member's promotion, funding, publication, or other professional achievement since the training grant was submitted; and
- News of an additional faculty member who will be involved in the training activity.

Unacceptable post-submission materials [for all applications but those under Exceptions below] include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- Supplemental pages - information not contained in the existing application
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

Exceptions to this policy include:

- Applications submitted in response to Requests for Applications (RFAs) that have only one due date. Post-submission materials for these applications will be accepted as outlined in [NOT-OD-10-070](#)
- Applications submitted in response to Requests for Applications (RFAs) that have multiple due dates, the exception to this policy applies to applications submitted for the last due date of an RFA (see [NOT-OD-13-030](#))
- Applications for training grants (see [NOT-OD-10-104](#))
- Certain NIH Funding Opportunity Announcements (FOAs) may allow certain other types of post-submission materials to facilitate the goals of the program. Such stipulations must be explained in the FOA in the NIH Guide for Grants and Contracts

Page limits for post-submission materials under the new policy:

- All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in Part I.2.6 of the applicable application instructions
- NIH additional form pages such as budget, biographical sketches, and other required forms must follow NIH standards for required NIH form pages.
- If post-submission material is not required on a form page, each explanation or letter is limited to one page (see Acceptable post-submission materials above)
- If the application has subprojects or cores, each subproject or core is allowed explanations or letters (see Acceptable post-submission materials above), but each explanation or letter is limited to one page

The additional materials must be submitted to the NIH SRO with the concurrence of the applicant organization's designated AOR/SO. Although the content of post-submission materials may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting.

After the initial peer review phase is completed, the [NIH Chief Grants Management Officer](#) is the NIH official responsible for accepting additional materials. Most of the materials submitted after the initial peer review can be submitted as part of the [Just-In-Time](#) process (see Supplemental Instructions Part [III.1.7](#)).

2.14 Application Submission Dates

For submission of applications to NIH, each FOA includes an Opportunity Open Date and an Opportunity Close Date. Many announcements, including those using the “Standard Submission Dates, include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov and the NIH Guide to Grants and Contracts showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the Funding Opportunity Announcement carefully for specific submission/receipt dates. If specific dates are not referenced in the announcement, applicants should refer to the Standard Submission Dates for Competing Applications at this website: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Applications submitted for the Standard Submission Dates listed are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the appropriate date listed. Applications submitted to FOAs with a single submission date are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the appropriate date listed. Applications submitted for Special Receipt Dates are considered on time if they are submitted to Grants.gov on or before 5 p.m. local time on the specified Application Due Date(s). Requests for Applications (RFAs) and Program Announcements with Special Referral Considerations (PARs) with special receipt dates always must be received by Grants.gov on the dates designated in the announcement.

Weekend/Federal Holiday Submission Dates. When a postmark/submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day. If the submission deadline shifts beyond the expiration date of the FOA, applicants submitting electronically may receive a warning message from Grants.gov. This warning will **not** keep your application from processing through Grants.gov. As always, applicants must check the eRA Commons to view their application and to ensure they have addressed any errors (instances of non-compliance with NIH business rules) identified by NIH systems.

Modified Application Submission and Review Policy. A continuous submission process is available to appointed members of chartered standing NIH Study Sections, Boards of Scientific Counselors, Advisory Boards or Councils, Program Advisory Committees, and peer reviewers who have served as regular or temporary members of peer review committees six times in 18 months. This alternative submission and review process is limited to R01, R21, and R34 application that would normally be received on standard submission dates. See the [Peer Review Policies & Practices, Continuous Submission](#) web page for additional information on the continuous submission process and eligibility requirements.

Late Applications. Permission for a late submission is not granted in advance. In rare cases, late applications will be accepted but only when accompanied by a cover letter that details the compelling reasons for the delay. While the reasons are sometimes personal in nature, an objective evaluation of their merit requires that some details be provided. Late applications have been accepted for reasons such as: death of an immediate family member of the PD/PI, sudden acute severe illness of the PD/PI or immediate family member, or large scale natural disaster.

NIH will consider accepting late applications based on the acceptability of the explanation and the processing time required for two different kinds of submission/receipt dates.

- **Regular Standard Submission/Receipt Dates:** To be considered applications must be received at the NIH within two weeks of the standard submission date.
- **Expedited Standard Submission/Receipt Dates:** To be considered applications must be received at the NIH within one week of the standard submission date.
- NIH will not consider late applications for the Special Receipt Dates for RFAs and PARs. This includes the special receipt dates (March 20, July 20, and November 20) for resubmission applications that are part of the New Investigator Initiative (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html>).
- NIH does not expect to accept any applications received beyond the window of consideration.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications. In all cases, when the regular standard submission date or expedited submission date falls on a weekend or federal holiday and is extended to the next business day, the window of consideration for late applications will be calculated from that business day. Note that the late window always ends in a receipt (not submission) date.

If an application is submitted late, attach a Cover Letter to the SF424 (R&R) cover form using the Cover Letter Attachment field to provide specific information on the timing and nature of the cause of the delay. No other documentation is expected. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the [Division of Receipt and Referral, Center for Scientific Review \(CSR\), NIH](#) in advance will not influence the acceptance of a late application.

Related Guide Notices include:

- NOT-OD-12-001 Update of NIH Late Application Policy to Reflect Change in Due Dates for New Investigator R01 Resubmission Applications at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-001.html>;
- NOT-OD-11-035 NIH Policy on Late Submission of Grant Applications at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>; and
- NOT-OD-11-093 Change in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-093.html>.

2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided at this website: <http://grants.nih.gov/grants/dates.htm>. For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

The SF424 (R&R) should only be used for those activity codes where the Application Form is identified as the SF424 (R&R). Applicants should refer to the OER Applying Electronically website: <http://grants.nih.gov/grants/ElectronicReceipt/> for details on the transition to electronic submission.

Application Assignment Information

Competing grant applications that have been successfully submitted through Grants.gov (including correcting all errors and the grant application assembled by the eRA Commons system) will be processed through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. The application will be assigned to an appropriate Scientific Review Group and awarding component(s). Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by the system as well as NIH staff.

Standard Due Dates for Competing Applications

Application Due Dates

Activity Codes	Program Description	Application Form	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
P Series <i>All - new, renewal, resubmission, revision</i>	Program Project Grants and Center Grants NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	PHS 398* *NIH is transitioning to electronic submission using the SF424 (R&R). Please review the transition timeline .	January 25	May 25	September 25
R18/U18 R25 <i>All - new, renewal, resubmission, revision</i>	Research Demonstration Education Projects	SF424 (R&R)	January 25	May 25	September 25
T Series D Series <i>All - new, renewal, resubmission, revision</i>	Institutional National Research Service Awards Other Training Grants NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles. Applicants should refer to	SF424 (R&R)	January 25	May 25	September 25

	the IC Table of Contacts for information for each IC's scientific/research contact for the NRSA T32 program.				
C06/UC6 <i>All - new, renewal, resubmission, revision</i>	Construction Grants	SF424 (R&R)	January 25	May 25	September 25
G07, G08, G11, G13, G20, S11, S21, S22, SC1, SC2, SC3 <i>All - new, renewal, resubmission, revision</i>	Other Activity Codes	SF424 (R&R)	January 25	May 25	September 25
G12, M01, R10/U10, R24, R24/U24, S06, U19, U45, U54, U56 <i>All - new, renewal, resubmission, revision</i>	Other Activity Codes Transition to SF424 (R&R): On Hold	PHS 398	January 25	May 25	September 25
R01 <i>new</i>	Research Grants	SF424 (R&R)	February 5	June 5	October 5
U01 <i>new</i>	Research Grants - Cooperative Agreements	SF424 (R&R)	February 5	June 5	October 5
UM1 <i>new</i>	Research Grants - Multi-Component Cooperative Agreements	PHS 398	February 5	June 5	October 5
K series <i>new</i>	Research Career Development	SF424 (R&R)	February 12	June 12	October 12
R03, R21, R33, R21/R33, R34,	Other Research	SF424 (R&R)	February 16	June 16	October 16

R36 <i>new</i>	Grants				
R15 <i>All - new, renewal, resubmission, revision</i>	Academic Research Enhancement Award (AREA)	SF424 (R&R)	February 25	June 25	October 25
R01 <i>renewal, resubmission, revision</i>	Research Grants	SF424 (R&R)	March 5	July 5	November 5
U01 <i>renewal, resubmission, revision</i>	Research Grants - Cooperative Agreements	SF424 (R&R)	March 5	July 5	November 5
UM1 <i>renewal, resubmission, revision</i>	Research Grants - Multi-Component Cooperative Agreements	PHS 398	March 5	July 5	November 5
K series <i>renewal, resubmission, revision</i>	Research Career Development	SF424 (R&R)	March 12	July 12	November 12
R03, R21, R33, R21/R33, R34, R36 <i>renewal, resubmission, revision</i>	Other Research Grants	SF424 (R&R)	March 16	July 16	November 16
R41, R42 R43, R44, U43, U44, <i>All - new, renewal, resubmission,rev ision</i>	Small Business Technology Transfer (STTR) Small Business Innovation Research (SBIR)	SF424 (R&R)	April 5	August 5	December 5
F Series Fellowships <i>new, renewal, resubmission</i>	Individual Nation al Research Service Awards (Standard) (see NRSA Training Page)	SF424 (R&R)	April 8	August 8	December 8

R13, U13 <i>All - new, renewal, resubmission, revision</i>	Conference Grants and Conference Cooperative Agreements	SF424 (R&R)	April 12	August 12	December 12
F31 Diversity Fellowships <i>new, renewal, resubmission</i>	Individual Predoc toral Fellowships (F31) to Promote Diversity in Health-Related Research (see NR SA Training Page)	SF424 (R&R)	April 13	August 13	December 13
All Activity Codes Cited Above <i>new, renewal, resubmission, revision</i>	AIDS and AIDS-Related Applications	Based on Activity Code	May 7	September 7	January 7

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

NOTES:

The actual date of the Advisory Council may occur in the month before or after the month listed. For example, some ICs may actually hold the January Advisory Council meeting in February or the October Advisory Council meeting in September.

Awarding components may not always be able to honor the requested start date of an application. Before incurring any pre-award obligations or expenditures applicants should be aware of NIH policy governing pre-award costs prior to receiving a Notice of Award. See the NIH [Grants Policy Statement](#).

* Advisory Council Round for Cycle I applications may be August or October, and their earliest project start date may be September or December respectively.

Assignment to Review Group. The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as “SRGs” or “study sections”) that will perform the scientific/technical merit review. The CSR lists the recurring review panels (<http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/>), and you may suggest a specific group in the PHS Cover Letter form. See Part I, Section 5.2 of this Guide for a suggested format for requesting a specific SRG in the Cover Letter.

Assignment to Relevant Potential Awarding Component(s) (ICs). In addition, CSR will assign each application to the agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

After the submission date, usually within two (2) weeks, the PD/PI and the applicant organization will be able to access in the eRA Commons and view the following information regarding the grant application:

- Application assignment number;
- Name, address, and telephone number of the Scientific Review Officer (if the review takes place in CSR) of the Scientific Review Group to which the application has been assigned for peer review; and
- Assigned Institute/Center information.

Review outcome and other important information are also available in the Commons.

If assignment information is not available in the eRA Commons within two weeks of the submission date, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715; TTY (301) 451-5936. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons.

Applicant investigators must not communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality and conflicts of interest in the peer review process. From the time of assignment to the time the review of your application is complete, applicant investigators must direct all questions to the Scientific Review Officer. This individual is in charge of the review group and is identified in the eRA Commons.

2.16 Resources for Finding Help

2.16.1 Finding Help for Grants.gov Registration or Submissions

If help is needed with the Grants.gov registration process or with the technical aspects of submitting an application through the Grants.gov system, check first the resources available at Grants.gov (<http://grants.gov/>).

Grants.gov customer support is also provided by the following office:

Grants.gov Program Management Office
200 Independence Avenue, SW
HHH Building, Room 739F
Washington, DC 20201

Grants.gov Self-Service Web Portal: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Grants.gov Help Desk: support@grants.gov

Grants.gov Contact Center Phone Number: 800-518-4726 (Toll Free)
606-545-5035 (Local or International)

The Contact Center is available 24 hours a day, 7 days a week (except Federal holidays).

2.16.2 Finding Help for the eRA Commons Registration or eRA Commons Validation Processes

If help is needed with the eRA Commons registration process for the applicant organization and PD/PIs; with using ASSIST for the preparation and submission of multi-project applications; or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at the Applying Electronically website:

(<http://grants.nih.gov/grants/ElectronicReceipt/>).

eRA Commons customer support is also provided by the eRA Commons Help Desk:

eRA Website: <http://era.nih.gov>

eRA Commons Website: <https://commons.era.nih.gov/commons/index.jsp>

eRA Commons On-line Resources and Web Ticketing: <http://era.nih.gov/help/>

eRA Commons Help Desk E-mail: commons@od.nih.gov

eRA Commons Phone: 301-402-7469
866-504-9552 (Toll Free)
301-451-5939 (TTY)

The eRA Commons Help Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time (except Federal holidays).

NOTE: To help expedite your Help Desk request, we recommend that you have the following information readily available (NOTE: Additional details may be required depending upon the type of issue/request):

- Full Name of Affected User
- Full Name of Institution/Organization
- Grants.gov Tracking Number
- Submission Date
- Funding Opportunity Announcement (FOA)
- Principal Investigator's (PI) Username
- Signing Official's (SO) Username

2.16.3 Finding Help for Application Preparation

If after reviewing this application instruction guide, help is still needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-435-0714
301-451-5936 (TTY)

GrantsInfo E-mail: GrantsInfo@nih.gov


3. Using the Grant Application Package

This section describes the steps an applicant takes once the appropriate FOA (see [Section 2.4](#)) has been located and the corresponding grant application package has been successfully downloaded.

3.1 Verify Grant Information

When you select a funding opportunity in Grants.gov Apply, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply. Grants.gov auto-populates the following information:

- Opportunity Title
- Offering Agency
- CFDA Number
- CFDA Description
- Opportunity Number
- Competition ID
- Opportunity Open Date
- Opportunity Close Date
- Agency Contact

 Grant Application Package Print Cancel	
Opportunity Title:	Limited Competition: Training Programs for Critical HIV
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PAR-13-215
Competition ID:	FORMS-C
Opportunity Open Date:	08/25/2013
Opportunity Close Date:	07/30/2015
Agency Contact:	eRA Commons Help Desk Monday to Friday 7 am to 8 pm ET E-mail: helpdesk@od.nih.gov Phone: 1-866-504-9552

CFDA Number Field: Many FOAs include multiple CFDA (Catalog for Domestic Assistance) numbers. When this is the case, the CFDA Number and CFDA Description fields will appear blank in the Grants.gov Grant Application Package screen shown above. The appropriate CFDA number will be automatically assigned once the application is assigned to the appropriate agency awarding component.

Opportunity Open Date & Close Date Fields: Many FOAs posted by NIH and other PHS agencies include multiple submission/receipt dates and are active for several years. These announcements are posted in Grants.gov showing an Open/Close period that spans the entire active period of the announcement. Applicants should read the funding opportunity announcement carefully for specific submission/receipt dates. If specific dates are not referenced in the announcement, applicants should refer to the PHS submission, review, and award schedule at <http://grants.nih.gov/grants/dates.htm>. Applications submitted after a posted submission date will normally not be held over into the next review cycle. Instead, the PD/PI will be notified and will have to submit the application again. See [Part I, Section 2.14](#) of this Guide for more information on the late application policy.

3.2 Enter the Name for the Application

Enter a name for the application in the Application Filing Name field (this is a required field). This name is for use solely by the applicant for tracking the application through the Grants.gov submission process. It is not used by the receiving agency.

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name:

UVA naming convention:

PI Last Name.PI First Name. Agency. Funding Opportunity.Due Date.

Example. Grant.Ivan.NIH.PA13302.Oct012013

3.3 Open and Complete Mandatory Documents

Click the form name to navigate to the form in the application package and complete all of the Mandatory forms. **Complete the form titled SF424 (R&R) first.** Data entered in this form populates other mandatory and optional forms where applicable.

Select Forms to Complete		
Mandatory	<input type="button" value="Save"/>	<input type="button" value="Save & Submit"/>
<input type="button" value="Check Package for Errors"/>		
SF424 (R & R)		
PHS 398 Research Plan		
PHS 398 Cover Page Supplement		
Research & Related Budget		
Research and Related Senior/Key Person Profile (Expanded)		
Research And Related Other Project Information		
Project/Performance Site Location(s)		

3.4 Open and Complete Optional Documents

These documents can be used to provide additional information for the application or may be required for specific types of grant activities. Information on each of these documents is found later in these instructions. In some application packages applicants will see two budget options; e.g., Research & Related Budget and PHS 398 Modular Budget in the Optional Documents section. While both appear as Optional Documents, one or the other will always be required. See [Section 4.6 Selecting the Appropriate Budget Form](#) for additional details.

Click the check box next to the form name to add the form to the application package. To navigate to the form, click on the form name. To remove an optional form from the application package, uncheck the box next to the form name.

Optional	
<input type="checkbox"/>	Planned Enrollment Report
<input type="checkbox"/>	PHS 398 Cumulative Inclusion Enrollment Report
<input type="checkbox"/>	R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT

Consult the Program Announcement for a list of Mandatory Documents. Do not rely on the package to include them.

3.5 Submitting the Application via Grants.gov

Once you have properly completed all required documents and attached any required or optional documentation, click on the **Check Package for Errors** button to ensure that you have successfully completed all required data fields. If any of the fields required by Grants.gov are not completed you will receive an error notice which will indicate where revision is needed within your package. Correct any errors or if none are found, save the application package. The **Save & Submit** button will now become active and clicking this button will begin the application submission process. Only after the package has been saved with no errors will the **Save & Submit** button become active. The application package must then be saved once more before the submission process begins. Only an AOR will be able to perform the submit action, and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Grants.gov registration process (if not connected to the internet you will be instructed to do so).

NOTE: The check package for errors button only checks for completion of all data fields and does not check for agency guidelines.

The package is now ready to send to the Office of Grants & Contracts for review and submission. Please place the electronic copy on your department's folder on the Z drive.

4. Completing the SF424 Research and Related (R&R) Forms

4.1 Overview

This section contains all of the instructions you will need to complete the SF424 (R&R) forms.



Any agency-specific instructions on SF424 (R&R) forms used federal-wide are denoted by the DHHS logo displayed to the left of the paragraph, as illustrated here.

Conformance to all instructions is required and strictly enforced. Agencies may withdraw any applications from the review process that are not consistent with these instructions.

As you navigate through the Grants.gov forms, required fields are highlighted and outlined in red. Optional fields and completed fields are displayed in white. Data entered into a specific field is not accepted until you have navigated to the next field. If you enter invalid or incomplete information in a field, you will receive an error message.



Note the highlighted fields required for submissions, and the **Check Package for Errors** button, only refer to Grants.gov requirements and errors. They do not reflect all agency requirements or PHS business processes. Agency validations will be performed by the eRA Commons system after the application has been submitted.

For those forms that are more than one page, click the **Next** button at the top of the form or scroll down (using the scroll bar on the right hand side of the screen) to navigate to a subsequent page. Once all data have been entered scroll up using the scroll bar to return to the Grant Application Package Screen.

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. TYPE OF SUBMISSION <input type="checkbox"/> Pre-application <input type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application		3. DATE RECEIVED BY STATE <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		State Application Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
2. DATE SUBMITTED <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		Applicant Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		4. a. Federal Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
5. APPLICANT INFORMATION		b. Agency Routing Identifier <div style="border: 1px solid black; height: 40px; width: 100%;"></div>			
5. APPLICANT INFORMATION		c. Previous Grants.gov Tracking ID <div style="border: 1px solid black; height: 20px; width: 100%;"></div>			
5. APPLICANT INFORMATION					
Organizational DUNS: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Legal Name: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Department: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Division: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Street1: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Street2: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
City: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> County / Parish: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
State: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Province: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Country: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> ZIP / Postal Code: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Person to be contacted on matters involving this application					
Prefix: <div style="border: 1px solid black; height: 20px; width: 10%;"></div> First Name: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Middle Name: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Last Name: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Suffix: <div style="border: 1px solid black; height: 20px; width: 10%;"></div>					
Position/Title: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Street1: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Street2: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
City: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> County / Parish: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
State: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Province: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Country: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> ZIP / Postal Code: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Phone Number: <div style="border: 1px solid black; height: 20px; width: 30%;"></div> Fax Number: <div style="border: 1px solid black; height: 20px; width: 30%;"></div>					
Email: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
6. EMPLOYER IDENTIFICATION (EIN) or (TIN): <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
7. TYPE OF APPLICANT: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Other (Specify): <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Small Business Organization Type <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged					
8. TYPE OF APPLICATION:					
<input type="checkbox"/> New <input type="checkbox"/> Resubmission <input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision					
If Revision, mark appropriate box(es). <input type="checkbox"/> A. Increase Award <input type="checkbox"/> B. Decrease Award <input type="checkbox"/> C. Increase Duration <input type="checkbox"/> D. Decrease Duration <input type="checkbox"/> E. Other (specify): <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
Is this application being submitted to other agencies? Yes <input type="checkbox"/> No <input type="checkbox"/> What other Agencies? <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
9. NAME OF FEDERAL AGENCY: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
TITLE: <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: <div style="border: 1px solid black; height: 40px; width: 100%;"></div>					
12. PROPOSED PROJECT:					
Start Date Ending Date <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					
13. CONGRESSIONAL DISTRICT OF APPLICANT <div style="border: 1px solid black; height: 20px; width: 100%;"></div>					



Pre-Application: Unless specifically noted in a program announcement, the Pre-application option is not used by NIH and other PHS agencies.

Changed/Corrected Application: This box must be used if you need to submit the same application again to correct system validation errors, application assembly problems, or to incorporate other changes. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter Form.
- Submitting a Changed/Corrected application replaces the previous submission and removes the previous submission from consideration. Once an application has moved forward to agency staff following the [two-day application viewing window](#), subsequent Changed/Corrected applications will not be accepted unless the application is withdrawn. Note that if you are submitting additional grant application materials after the submission date some special guidelines may apply. See NIH Guide Notice NOT-OD-10-115 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html>) for the NIH Policy on Post-Submission Application Materials.
- When you check the Changed/Correct Application box the Previous Grants.gov Tracking ID becomes a required field.
- Do **not** use the Changed/Corrected Application box to denote a submission of a resubmission or amended application. That will be indicated in the Type of Application.

2. Date Submitted and Applicant Identifier

Enter the date the application is submitted to Federal agency (or State if applicable). In the applicant identifier field enter the applicant's control number (if applicable).

Leave blank



Note the Applicant Identifier field is a control number created by the applicant organization, not the Federal agency.

3. Date Received by State and State Application Identifier

Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable.



For submissions to NIH and other PHS agencies, leave these fields blank.

4.a. Federal Identifier

When a New Application is being submitted following a Pre-Application, enter the agency-assigned pre-application number, if applicable. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number)--even if submitting a Changed/Corrected application.



For submissions to NIH and other PHS agencies, include only the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1). The Federal Identifier is required for Resubmission, Renewal, and Revision applications.

USE: Type only the institute code and serial number: CA123456

Do not type in R01 or -01

Existing definitions for NIH and other PHS agencies applications are somewhat different:

- New is the same; i.e., an application that is submitted for the first time. See also the policy [Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code](#).
- Resubmission is equivalent to NIH and other PHS agencies Revision. Check this option when submitting a revised (altered or corrected) or amended application. See also the [NIH Policy on Resubmission Applications](#). Institutions submitting revision or renewal applications **that are also resubmissions** (A1 or A2 if allowed, see NIH Grant Notice NOT-OD-09-003, <http://grants.nih.gov/grants/guide/notice-files/not-od-09-003.html>) are instructed to select “Resubmission.” For additional information, see NIH Guide Notice [NOT-OD-10-052](#), <http://grants.nih.gov/grants/guide/notice-files/not-od-10-052.html>).
- Renewal is equivalent to NIH and other PHS agencies Competing Continuation.
- Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used and should **not** be checked.
- Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement, but proposes a change in 1) the Federal Government’s financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. In general, changes to the “terms and conditions of the existing award” would not require the submission of another application through Grants.gov. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a “New” application, this field should remain blank

Application Identification Numbers The application number identifies:

- type of application (1)
- activity code (R01)
- organization to which it is assigned (AI) this is short for the NIAID
- serial number assigned by the Center for Scientific Review (183723),
- suffix showing the support year for the grant (-01)
- other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number.

Sample Application Identification Number 1 R01 AI 183723 -01 A1 S1

Application Types

Type 1 New

Type 2 Competing continuation (a.k.a. renewal, re-competing)

Type 3 Application for additional (supplemental) support

Type 4 Competing extension for an R37 award or

first non competing year of a Fast Track SBIR/STTR award

Type 5 Non-competing continuation

Type 7 Change of grantee institution

Type 9 Change of NIH awarding Institute or Division (competing continuation)

4.b. Agency Routing Identifier


Enter the agency-assigned routing identifier per the agency-specific instructions. This is an optional field. Unless specifically noted in a program announcement, the Agency Routing Identifier is not used by NIH or other PHS agencies.


4.c. Previous Grants.gov Tracking ID

Enter the previous Grants.gov tracking number, if applicable.

5. Applicant Information

This information is for the Applicant Organization, not a specific individual.


Field Name	Instructions
Organizational DUNS	<p>Enter the DUNS or DUNS+4 number of the applicant organization. This field is required.</p> <p>Enter: 0653915260000</p>  <p>For submission to NIH and other PHS agencies, this DUNS must match the number entered in the eRA Commons Institutional Profile for the applicant organization. The applicant AOR is encouraged to confirm that a DUNS has been entered in the eRA Commons Institutional Profile (IPF) prior to submitting an application. If your organization does not already have a DUNS number, you will need to go to the Dun & Bradstreet website at http://fedgov.dnb.com/webform to obtain the number. The same DUNS should be used in the eRA Commons IPF, Grants.gov registration and in the DUNS field in the application.</p>
Legal Name	Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county/parish and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.
Division	Enter the name of the primary organizational division, office, or major subdivision which will undertake the assistance activity.
Street1	Enter the first line of the street address for the applicant in “Street1” field. This field is required.
Street2	Enter the second line of the street address for the applicant in “Street2” field. This field is optional.
City	Enter the city for address of applicant. This field is required.
County/Parish	Enter the county/parish for address of applicant.

Field Name	Instructions
State	Enter the State where the applicant is located. This field is required if the applicant is located in the United States.
Province	Enter the Province.  If "Country" is not Canada, please leave blank.
Country	Select the country for the applicant address. This field is required.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.

Person to be contacted on matters involving this application:

This information is for the Administrative or Business Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the AO profile information contained in the eRA Commons.

Field Name	Instructions
Prefix	The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Enter the first (given) name of the person to contact on matters related to this application. This field is required.
Middle Name	Enter the middle name of the person to contact on matters related to this application.
Last Name	Enter the last (family) name of the person to contact on matters related to this application. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters related to this application.
Position/Title	Enter the Position/Title for the person to contact on matters related to this application.
Street 1	Enter the first line of the street address for the applicant in "Street1" field. This field is required.

Field Name	Instructions
Street 2	Enter second line of the street address of the person to contact on matters related to this application. This field is optional.
City	Enter the city of the person to contact on matters related to this application. This field is required.
County/Parish	Enter the county/parish of the person to contact on matters related to this application.
State	Enter the State where the applicant is located. This field is required if the applicant is located in the United States.
Province	Enter the Province.  If "Country" is not Canada, please leave blank.
County	Select the country for the applicant address. This field is required.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.
Phone Number	Enter the daytime phone number for the person to contact on matters related to this application. This field is required
Fax	Enter the fax number for the person to contact on matters related to this application.
Email	Enter the e-mail address for the person to contact on matters related to this application

6. Employer Identification

Enter either TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the U.S., enter 44-4444444. This field is required. **UVA TIN: 546001796**




If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, **enter all 12 digits (e.g., 1123456789A1); this includes non-U.S. organizations.**

7. Type of Applicant




This information is for the Applicant Organization, not a specific individual AOR or PD/PI.



Field Name	Instructions
Type of Applicant	Select the appropriate applicant type code. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged. This field is required.

Field Name	Instructions
	 <p>For eligible Agencies of the Federal Government, select X: Other (specify), and then indicate the name of the appropriate Federal agency in the space below.</p>
Other (Specify)	Complete only if “Other” is selected as the Type of Applicant.
Woman Owned	Check if you are a woman-owned small business – a small business that is at least 51% owned by a woman or women, who also control and operate it.
Socially and Economically Disadvantaged	Check if you are a socially and economically disadvantaged small business, as determined by the U.S. Small Business Administration pursuant to Section 8(a) of the Small Business Act U.S.C. 637(a).

8. Type of Application

Field Name	Instructions
Type of Application	<p>Select the type from the following list. Check only one. This field is required.</p> <ul style="list-style-type: none"> • New: An application that is being submitted to an agency for the first time. • Resubmission: An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. • Renewal: An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time. • Continuation: A non-competing application for an additional funding/budget period within a previously approved project period. <p>NIH does not use the SF424 for Continuation proposals; those are done via the RPPR module in eRA Commons.</p> <ul style="list-style-type: none"> • Revision: An application that proposes a change in <ol style="list-style-type: none"> 1) the Federal Government’s financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. <p>  Existing definitions for NIH and other PHS agencies Type of Application are somewhat different: <ul style="list-style-type: none"> • New is the same. Check this option when submitting an application for the first time. See also the policy Resubmission of Unpaid RFA Applications and </p>

Field Name	Instructions
	<p>Resubmission of Applications with a Changed Grant Activity Code.</p> <ul style="list-style-type: none"> • Resubmission is equivalent to NIH and other PHS agencies Revision. Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH Policy on Resubmission Applications. Institutions submitting revision or renewal applications that are also resubmissions (A1 or A2 if allowed, see NIH Grant Notice NOT-OD-09-003, http://grants.nih.gov/grants/guide/notice-files/not-od-09-003.html) are instructed to select “Resubmission.” For additional information, see NIH Guide Notice NOT-OD-10-052, http://grants.nih.gov/grants/guide/notice-files/not-od-10-052.html). • Renewal is equivalent to NIH and other PHS agencies Competing Continuation. • Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will not be used and should not be checked. • Revision is somewhat equivalent to NIH and other PHS agencies Supplement, but would also include other changes as noted in the definition above. In general, changes to the “terms and conditions of the existing award” (as noted in example 2 above) would not require the submission of another application through Grants.gov. Applicants should contact the awarding agency for advice on submitting any revision/supplement application. <p>This field also affects how you complete the Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank unless otherwise specified in the funding opportunity announcement.</p> <p>If “Type of Application” is “Renewal,” “Revision,” or “Resubmission,” enter the IC and serial number of the previously assigned application/award number (e.g., use CA987654 from 1R01CA987654-01A1).</p>
If Revision, mark appropriate box(es)	<p>If Revision, mark appropriate box(es). May select more than one:</p> <ul style="list-style-type: none"> A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other

Field Name	Instructions
	<p>If “Other” is selected, please specify in the text box provided.</p>  <p>For the purposes of NIH and other PHS agencies, the boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA.</p>
Other	<p>If “Other” is selected for Revision, add text to explain.</p> <p>If Revision is chosen, the title must match <u>exactly</u>, the title of the funded grant as it appears in eRA Commons.</p>
Is this application being submitted to other agencies?	<p>Check box if applicable. One selection is required.</p>  <p>In the field “Is this application being submitted to other agencies?,” please check the box “yes” if one or more of the specific aims submitted in your application are also contained in a similar, identical, or essentially identical application submitted to another Federal agency. Indicate the agency or agencies to which the application has been submitted. For additional information, please see NIH Guide Notice NOT-OD-09-100, <i>Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code</i>, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html.</p>
What Other Agencies?	Enter Agency name.

9. Name of Federal Agency

Name the Federal agency from which assistance is being requested with this application. This field is pre-populated from the opportunity package.

10. Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)

This is the Catalog of Federal Domestic Assistance number of the program under which assistance is requested. This field is pre-populated from the opportunity package.



This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank; the field will not allow any data entry. The appropriate CFDA number will be automatically assigned by the agency once the application is assigned to the appropriate awarding component.

11. Descriptive Title of Applicant’s Project

Enter a brief descriptive title of the project. This field is required.



A “new” application must have a different title from any other PHS project with the same PD/PI. A “resubmission” or “renewal” application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A “revision” application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 81 characters, including the spaces between words and punctuation. Titles in excess of 81 characters will be truncated. Be sure to only use standard characters in the descriptive title: A through Z, a through z, 0 through 9, space (), and underscore (_).

12. Proposed Project

Start Date: Enter the proposed start date of the project. This field is required.

Ending Date: Enter the proposed end date of the project. This field is required.

13. Congressional District of Applicant

Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. **Examples:** CA-005 for California's 5th district, CA-012 for California's 12th district.

For UVA enter VA-005

If outside the U.S., enter 00-000.

To locate your congressional district, visit the Grants.gov website.



For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix:	<input type="text"/>	First Name:	<input type="text"/>	Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>			Suffix:	<input type="text"/>
Position/Title:	<input type="text"/>				
Organization Name:	<input type="text"/>				
Department:	<input type="text"/>	Division:	<input type="text"/>		
Street1:	<input type="text"/>				
Street2:	<input type="text"/>				
City:	<input type="text"/>	County / Parish:	<input type="text"/>		
State:	<input type="text"/>	Province:	<input type="text"/>		
Country:	<input type="text"/>	ZIP / Postal Code:	<input type="text"/>		
Phone Number:	<input type="text"/>	Fax Number:	<input type="text"/>		
Email:	<input type="text"/>				

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested	<input type="text"/>
b. Total Non-Federal Funds	<input type="text"/>
c. Total Federal & Non-Federal Funds	<input type="text"/>
d. Estimated Program Income	<input type="text"/>

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ I agree

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation**19. Authorized Representative**

Prefix:	<input type="text"/>	First Name:	<input type="text"/>	Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>			Suffix:	<input type="text"/>
Position/Title:	<input type="text"/>				
Organization:	<input type="text"/>				
Department:	<input type="text"/>	Division:	<input type="text"/>		
Street1:	<input type="text"/>				
Street2:	<input type="text"/>				
City:	<input type="text"/>	County / Parish:	<input type="text"/>		
State:	<input type="text"/>	Province:	<input type="text"/>		
Country:	<input type="text"/>	ZIP / Postal Code:	<input type="text"/>		
Phone Number:	<input type="text"/>	Fax Number:	<input type="text"/>		
Email:	<input type="text"/>				


Signature of Authorized Representative



Date Signed

20. Pre-application**21. Cover Letter Attachment**




14. Program Director/Principal Investigator (PD/PI) Contact Information

If submitting an application reflecting Multiple PD/PIs, the individual designated as the Contact PI must be affiliated in the Commons with the applicant organization and should be entered here. See [Section 4.5 Senior/Key Person Profile Forms](#) for additional instructions for Multiple PD/PIs. To avoid potential errors and delays in processing, please ensure that the information provided in this section is identical to the PD/PI profile information contained in the eRA Commons.

Field Name	Instructions
Prefix	The Project Director/Principal Investigator (PD/PI) is the individual responsible for the overall scientific and technical direction of the project. Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Enter the first name of the PD/PI. This field is required.
Middle Name	Enter the middle name of the PD/PI.
Last Name	Enter the last (family) name of the PD/PI. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D) of the PD/PI.  Do not use this field to record degrees. Degrees for the PD/PI are requested separately in the Senior/Key Person Profile.
Position/Title	Enter the position/title of the PD/PI.
Organization Name	Enter the name of organization for the PD/PI. This field is required. For UVA faculty enter: The Rector and Visitors of the University of Virginia
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Division	Enter the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Enter first line of the street address for the PD/PI in the “Street1” field. This field is required.
Street2	Enter the second line of the street address for the PD/PI in the “Street2” field. This field is optional.
City	Enter the City for address of the PD/PI. This field is required.
County/Parish	Enter the county/parish for address of the PD/PI.
State	Enter the State where the PD/PI is located. This field is required if the PD/PI is located in the United States.

Field Name	Instructions
Province	Enter the province for PD/PI.  If “Country” is not Canada, please leave blank.
Country	Select the country for the PD/PI address.
ZIP/Postal Code	Enter the Postal Code (e.g., ZIP code) of the PD/PI. This field is required if the PD/PI is located in the United States.  A nine-digit Zip code is required.
Phone Number	Enter the daytime phone number for the PD/PI. This field is required.
Fax Number	Enter the fax number for the PD/PI.
E-mail	Enter the e-mail address for the PD/PI. This field is required.

15. Estimated Project Funding

Field Name	Instructions
a. Total Federal Funds Requested	Enter total Federal funds requested for the entire project period. This field is required. This should match the total costs on the cumulative budget page.  Please ensure number(s) complies with application requirements.
b. Total Non-Federal Funds	Enter total non-Federal funds proposed for the entire project period. This field is required.  For NIH and other PHS agencies, enter “0” in this field unless cost sharing is a requirement for the specific announcement.
c. Total Federal & Non-Federal Funds	Enter total estimated funds for the entire project period, including both Federal and non-Federal funds. This field is required.  For NIH and other PHS agencies applicants, this field will be the same as Total Federal Funds Requested above unless the specific announcement indicates that cost sharing is a requirement.
d. Estimated Program Income	Identify any Program Income estimated for this project period if applicable. This field is required.

16. Is Application Subject to Review by State Executive Order 12372 Process?

If yes, check box. If the announcement indicates that the program is covered under Executive Order 12372, applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check appropriate box. One selection is required.

If block 16a is checked, insert date application was submitted to State.



For NIH and other PHS agencies submissions using the SF424 (R&R), applicants should check **“No, Program is not covered by E.O. 12372.”**

17. Certification

Check “I agree” to provide the required certifications and assurances. This field is required.



The list of NIH and other PHS agencies Assurances, Certifications, and other Policies is found in Supplemental Instructions [Part III, Policies, Assurances, Definitions, and Other Information](#).

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

18. SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation

If applicable, attach the SFLLL or other explanatory document per agency instructions.





If unable to certify compliance in with the Certification above attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents in this item. A fillable version of the SFLLL form is available at <http://www.whitehouse.gov/omb/assets/omb/grants/sflllin.pdf>.

19. Authorized Representative

This is equivalent to the individual with the organizational authority to sign for an application; otherwise known as the Authorized Organization Representative or the Signing Official.

Field Name	Instructions
Prefix	Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.
First Name	Enter the first (given) name of the Authorized Representative. This field is required.
Middle Name	Enter the middle name of the Authorized Representative.
Last Name	Enter the last (family) name of the Authorized Representative. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Authorized Representative.

Field Name	Instructions
	Representative.
Position/Title	Enter the title of the Authorized Representative. This field is required.
Organization	Enter the name of the organization for the Authorized Representative. This field is required.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.
Division	Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.
Street1	Enter the first line of the street address for the Authorized Representative in the “Street1” field. This field is required.
Street2	Enter the second line of the street address for the Authorized Representative in the “Street2” field. This field is optional.
City	City for address of the Authorized Representative. This field is required.
County/Parish	Enter the county/parish for address of the Authorized Representative.
State	Enter the state where the Authorized Representative is located. This field is required if the Authorized Representative is located in the United States.
Province	Enter the Province for the Authorized Representative.  If “Country” is not Canada, please leave blank.
Country	Select the country for the Authorized Representative address.
ZIP/Postal Code	Enter Postal Code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States.  A nine-digit Zip code is required.
Phone Number	Enter the daytime phone number for the Authorized Representative. This field is required.
Fax Number	Enter the fax number for the Authorized Representative.
E-mail	Enter the e-mail address for the Authorized Representative. This field is

Field Name	Instructions
	required.
Signature of Authorized Representative	It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave blank. If a hard copy is submitted, the AOR must sign this block.
Date Signed	If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.

20. Pre-Application

If submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions, and save the file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.



Unless specifically noted in a program announcement, NIH and other PHS agencies do not use *Pre-applications*.

21. Cover Letter Attachment

NOTE: New location for cover letter.

Attach the cover letter in accordance with the announcement and/or the agency specific instructions.



Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in Section 2.14) include specific information about the timing and nature of the cause of the delay.
7. When submitting a Changed/Corrected Application after the submission date, a cover letter is required explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
8. Explanation of any subaward budget components that are not active for all periods of the proposed grant.

9. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications \$500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc.

Suggested Cover Letter Format

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to Scientific Review Groups (SRGs). DRR will be utilizing knowledge management approaches as an adjunct to the work of referral experts as part of an overall plan to shorten the time from submission to review. Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter.

- List one request per line.
- Place Institute/Center (IC) and SRG review requests (if both are made) on separate lines.
- Place positive and negative requests (if both are made) on separate lines.
- Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].

Project/Performance Site Location(s)**Project/Performance Site Primary Location**☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.Organization Name: DUNS Number: * Street1: Street2: * City: County: * State: Province: * Country: * ZIP / Postal Code: * Project/ Performance Site Congressional District: **Project/Performance Site Location**☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.Organization Name: DUNS Number: * Street1: Street2: * City: County: * State: Province: * Country: * ZIP / Postal Code: * Project/ Performance Site Congressional District: **Additional Location(s)**




Project/Performance Site Primary Location




Generally, the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Cover Page Supplement Form of the application. If there is more than one performance site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them in the fields provided for Location 1 - # below. Applicants should also provide an explanation of resources available from each Project/Performance Site, the Facilities and Resources attachment of the Other Project Information form, and describe any consortium/contractual arrangements in the Consortium/Contractual Arrangements attachment of the PHS 398 Research Plan.

Unless otherwise instructed in a FOA, do not check the "I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization" box.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR part 46 and other NIH human subject related policies described in Supplemental Instructions Part II of this Application Guide and in the NIH Grants Policy Statement.



For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

Field Name	Instructions
Organization Name	Indicate the organization name of the primary site where the work will be performed. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed.  The DUNS Number is a required field for the Primary Performance Site.
Street1	Enter first line of the street address in "Street 1" field of the primary performance site location. This field is required.
Street2	Enter second line of the street address in "Street 2" field for the primary performance site location. This field is optional.
City	Enter the City for address of the primary performance site location. This field is required.
County	Enter the County of the primary performance site location.

Field Name	Instructions
State	Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States..
Province	Enter the province of the primary performance site location.  If “Country” is not Canada, please leave blank.
Country	Select the Country of the Primary Performance Site location. This field is required.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of the performance site location. This field is required if the performance site location is in the United States.  A nine-digit Zip code is required.
Project/Performance Site Congressional District	Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California’s 5th district, CA-012 for California’s 12th district. If all districts in a state are affected, enter “all” for the district number. Example MD-all for all congressional districts in Maryland. If nationwide (all districts in all states), enter US-all. If the program/project is outside the U.S., enter 00-000. To locate your congressional district, visit the Grants.gov website. Note it is likely this field will be identical to the “Congressional District of Applicant” field provided elsewhere in the application.  For States and U.S. territories with only a single congressional district enter “001” for the district code. For jurisdictions with no representative, enter “099”. For jurisdictions with a nonvoting delegate, enter “098” for the district number. Example: DC-098, PR-098.

Project/Performance Site Location 1

Field Name	Instructions
Organization Name	Indicate the organization name of the primary site where the work will be performed. If a portion of the project will be performed at any other sites(s), identify the site location(s) in the block(s) provided.
DUNS Number	Enter the DUNS number associated with the organization where the project will be performed. This field is optional.

Field Name	Instructions
Street1	Enter first line of the street address in "Street 1" field of the primary performance site location. This field is required.
Street2	Enter second line of the street address in "Street 2" field for the primary performance site location. This field is optional.
City	Enter the City of the performance site location. This field is required.
County	Enter the County of the performance site location.
State	Enter the State where the primary performance site location is located. This field is required if the Project Performance Site is located in the United States.
Province	Enter the Province where the primary performance site location is located.  If "Country" is not Canada, please leave blank.
Country	Select the name of the country for the primary project performance site.
ZIP Code	Enter the nine-digit Postal Code (e.g., ZIP code) of the primary performance site location. This field is required if the Project Performance Site is located in the United States.
Project/Performance Site Congressional District	<p>Enter the Congressional District in the format: 2 character State Abbreviation – 3 character District Number. Examples: CA-005 for California's 5th district, CA-012 for California's 12th district.</p> <p>If all districts in a state are affected, enter "all" for the district number. Example MD-all for all congressional districts in Maryland.</p> <p>If nationwide (all districts in all states), enter US-all.</p> <p>If the program/project is outside the U.S., enter 00-000.</p> <p>To locate your congressional district, visit the Grants.gov website. Note it is likely this field will be identical to the "Congressional District of Applicant" field provided elsewhere in the application.</p> <p> For States and U.S. territories with only a single congressional district enter "001" for the district code. For jurisdictions with no representative, enter "099". For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098, PR-098.</p>

For additional performance site locations, click **Next Site** to display the fields for Project/Performance Site Locations 2 through 300.

If you need to add more than 300 locations, enter the information in a separate file. In the Additional Locations section at the bottom of the form, click **Add Attachment**, select the file, and then click **Open**.

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number:

3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No

5.a. If yes, please explain:

6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments ☐

4.4 Other Project Information Form

1. Are Human Subjects Involved?

UVA's IRB advises that you must first determine whether your research is considered to have Human Subjects.

Here are two links to UVA's IRB website which help PI's determine this:

http://www.virginia.edu/vpr/irb/hsr/human_subject_research_definition.html

http://www.virginia.edu/vpr/irb/hsr/activities_examples.html

This link is a chart from OHRP which is helpful in determining human subject involvement:

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes.

Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If no, skip the rest. This field is required.

Mark YES to pending unless UVA's IRB has reviewed, approved and issued a "GIRB" approval, in addition to the protocol approval. If your application receives a score within the fundable range, UVA's IRB advises that the science be submitted for review at this time.

This link will guide you in that process:

http://www.virginia.edu/vpr/irb/hsr/submit_grant.html



Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with NIH and PHS policies covering human subjects research. Refer to [Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#).

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? Yes/No

NOTE: PI's cannot self-exempt. Any cited exemption requires prior IRB review and documentation.

Yes: If the project is exempt from Federal regulations, check Yes.

No: If the project is not exempt from Federal regulations, check No.

If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6

Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human

Subjects. These regulations can be found at

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.



OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (<http://answers.hhs.gov/ohrp/categories/1564>). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if all of the proposed research meets the criteria for one or more of the six exemptions.

If no, is the IRB review Pending? Yes/No

If IRB review is pending, check Yes. If IRB review is not pending, check No.

IRB Approval Date

Enter the latest Institutional Review Board (IRB) approval date (if available). Leave blank if Pending.

Enter the date for the GIRB; this is not the protocol approval, but rather the grant approval.



Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle as a [Just-In-Time](#) requirement.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) Number or Cooperative Project Assurance Number that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the FWA before the number.

UVA’s Human Subject Assurance Number: 00006183



Insert “None” if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in the Certification signature section on the SF424 (R&R) Cover form, is declaring that it will comply with 45 CFR part 46 and proceed to obtain a human subjects assurances (see <http://www.hhs.gov/ohrp>). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

2. Are Vertebrate Animals Used?

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2. This field is required.



Note that the generation of custom antibodies constitutes an activity involving vertebrate animals. If animal involvement is anticipated within the period of award but plans are indefinite, check “Yes” and add a Vertebrate Animals attachment to, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must provide all of the information required by adding a Vertebrate Animals attachment in the Research Plan and verifying of IACUC approval to the awarding component.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?

Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending.

Click Yes if an IACUC review is pending. Click **No**, if no review is pending.



Check “Yes” even if the IACUC review and approval process has not yet begun.

IACUC Approval Date

Enter the latest IACUC approval date (if available). Leave blank if Pending.

If YES, please supply the appropriate IACUC approval.



IACUC approval must have been granted within three years to be valid. Note that an IACUC Approval Date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under [Just-In-Time Policy](#).

Animal Welfare Assurance Number

Enter the Federally approved assurance number, if available.



Enter “None” if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. To determine if the applicant organization holds an Animal Welfare Assurance, see the lists of [Domestic](#) and [Foreign](#) Assured institutions. **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution.** When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative’s signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.

UVA’s Animal Assurance Number is A3245-01

3. Is proprietary/privileged information included in the application?

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation. " This field is required.



If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

4. Environmental Questions



Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer “No” to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked “Yes” should be checked and an explanation provided.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wastes, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does the project have an actual or perceived impact—positive or negative—on the environment?

Indicate if this project has an actual or perceived impact on the environment? Click **No** here if this is not the case. This field is required.

4.b. If yes, please explain

Explanation of the actual or perceived impact - positive or negative - on the environment.

4.c. If this project has an actual or perceived impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Check yes or no. This field is required.

4.d. If yes, please explain

Enter additional details about the EA or EIS.

5. Is the research performance site designated, or eligible to be designated, as a historic place? Yes/No

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes box and then provide an explanation in the box provided in 5.a. Otherwise, check the No box. This field is required.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

The Rotunda and certain parts of the Old Medical School building are designated as historic sites.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators?

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no. This field is required.



Applicants to NIH and other PHS agencies must check “Yes” if the applicant organization is a foreign institution or if the project includes a foreign component. For a definition of a [foreign component](#), see “Definitions” section of Supplemental Instructions Part III: Policies, Assurances, Definitions, and Other Information.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

6.b. Optional Explanation

Enter an explanation for involvement with outside entities (optional).



If you have checked “Yes” to 6, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file, attaching it on the Other Project Information form. In the body of the text, begin the section with a heading indicating “Foreign Justification.” When saving this file, please name it “Foreign Justification” as well.

7. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. Please click the **Add Attachment** button to the right of this field to complete this entry.



The **Project Summary** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. **This section must be no longer than 30 lines of text**, and follow the required [font and margin specifications](#). An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an

NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <http://report.nih.gov>) and will become public information.

The attachment must be in PDF format. (See [Section 2.6](#) for additional information on preparing attachments.)

8. Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the **Add Attachment** button to the right of this field to complete this entry.



For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

A separate Research Plan form is required for NIH and other PHS agencies applications. Refer to [Section 5.5, Research Plan Form](#), for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click **Add Attachment**.



Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan form (see [Section 5.5](#) for details on completing that form). **When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process."** A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

10. Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. **Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.** Please click the **Add Attachment** button to the right of this field to complete this entry.



No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. See, http://grants.nih.gov/grants/new_investigators/.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about select agents must be described in the Research Plan, Section 11 (Select Agent Research).

11. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the **Add Attachment** button to the right of this field to complete this entry.

12. Other Attachments

Attach a file only to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator		
Prefix:	* First Name:	Middle Name:
* Last Name:		Suffix:
Position/Title:		Department:
Organization Name:		Division:
* Street1:		
Street2:		
* City:		County/ Parish:
* State:		Province:
* Country:		* Zip / Postal Code:
* Phone Number:		Fax Number:
* E-Mail:		
Credential, e.g., agency login:		
* Project Role:		Other Project Role Category:
Degree Type:		
Degree Year:		
*Attach Biographical Sketch		
Attach Current & Pending Support		

PROFILE - Senior/Key Person		
Prefix:	* First Name:	Middle Name:
* Last Name:		Suffix:
Position/Title:		Department:
Organization Name:		Division:
* Street1:		
Street2:		
* City:		County/ Parish:
* State:		Province:
* Country:		* Zip / Postal Code:
* Phone Number:		Fax Number:
* E-Mail:		
Credential, e.g., agency login:		
* Project Role:		Other Project Role Category:
Degree Type:		
Degree Year:		
Attach Biographical Sketch		
Attach Current & Pending Support		

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

This form provides the ability to collect structured data for up to 100 senior/key persons. Data must be entered for the first 100 individuals (PD/PI + 99 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover form. See instructions in section 4.2 Cover Form if these fields are empty. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Further clarification of “Key Personnel”. Key personnel are individuals whose effort is absolutely essential to the success of the proposed activity, either because of their leadership position within the proposal (and consequently their intellectual guidance) or because of the uniqueness of the expertise they are contributing relative to the proposed scope of activity. Typically, replacement of any of these individuals requires approval from the sponsor. Graduate Students and Postdoctoral Research Associates usually do not meet the definition of **KEY**. A key person has **measurable effort** and will have a defined role with salary to match the committed effort.

Significant Contributor: A key person who does not have committed effort, but who is important to the success of the proposed activity, has the role of “Significant Contributor”. This person does not receive salary support from the grant.



Multiple PD/PIs

NIH is now accepting applications reflecting Multiple PD/PIs for all grant activity codes using the SF424 (R&R) application. When submitting an application involving Multiple PD/PIs, the Contact PD/PI must be affiliated in the Commons with the applicant organization and should be listed as the PD/PI in the SF424 R&R Cover Form (see [Section 4.2.14](#)). That information automatically prepopulates the first senior/key person profile record in this form. For the additional PD/PIs, complete all the requested information. **Each PD/PI must be assigned the PD/PI role, even those at subaward/consortium sites when applicable.** (Do **not** use the “Co-PD/PI” or Co-Investigator role.) For more information, please see [Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium](#).


Each PD/PI must also be registered in the eRA Commons and must be assigned the PI Role in that system (note other roles such as SO or IAR will not give PD/PIs the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the Credential field. For more information on NIH Implementation of Multiple PD/PIs, see: http://grants.nih.gov/grants/multi_pi/index.htm.




For multiple PI proposals, each PI must provide a goldenrod.



UVA Policy found here: <http://www.virginia.edu/finance/polproc/proc/8-10.html>

When completing the detailed budget form for either the prime organization or a subaward/consortium organization, the project roles listed in the budget form should be consistent with those used in the Senior/Key Person Form.

Profile – Program Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	Pre-populated from the SF 424 (R&R). The prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF 424 (R&R). The first (given) name of the PD/PI. This field is required.
Middle Name	Pre-populated from the SF 424 (R&R). The middle name of the PD/PI.
Last Name	Pre-populated from the SF 424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF 424 (R&R). The suffix (e.g., Jr, Sr, PhD) for the name of the PD/PI.
Position/Title	Pre-populated from the SF 424 (R&R). The title of the PD/PI.
Department	Pre-populated from the SF 424 (R&R). The name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	Pre-populated from the SF 424 (R&R). The name of organization of the PD/PI.
Division	Pre-populated from the SF 424 (R&R). The name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	Pre-populated from the SF 424 (R&R). The first line of the street address for the PD/PI in the "Street 1" field. This field is required.
Street2	Pre-populated from the SF 424 (R&R). The second line of the street address for the PD/PI in the "Street 2" field. This field is optional.
City	Pre-populated from the SF 424 (R&R). The city for address of PD/PI. This field is required.
County/Parish	Pre-populated from the SF 424 (R&R). The county/parish for address of PD/PI.
State	Pre-populated from the SF 424 (R&R). The state where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	Pre-populated from the SF 424 (R&R). The Province where the PD/PI is located.  If "Country" is not Canada, this will be blank.

Field Name	Instructions
Country	Pre-populated from the SF 424 (R&R). The country for the PD/PI address. This field is required.
ZIP Code	Pre-populated from the SF 424 (R&R). The postal Code (e.g., ZIP code) of PD/PI. This field is required if the PD/PI is located in the United States.  A nine-digit Zip code is required.
Phone Number	Pre-populated from the SF 424 (R&R). The daytime phone number for the PD/PI. This field is required.
Fax Number	Pre-populated from the SF 424 (R&R). The fax number for the PD/PI.
E-mail	Pre-populated from the SF 424 (R&R). The e-mail address for the PD/PI. This field is required for PD/PI.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank. eRA Commons User ID required for PD/PI.  For NIH and other PHS agencies, registration in the eRA Commons for all PD/PIs is required. The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.
Project Role	Select one. Use "Other" if a category is not listed in the pick list.  Select PD/PI for this person.
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	Enter the year the highest degree or other credential was obtained. This is optional information.

Field Name	Instructions
Attach Biographical Sketch NOTE: Use the link in these guidelines on p. I-80 to obtain biosketch format page.	<p>Provide a biographical sketch for the senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here. This is required information.</p> <p> Biographical sketches should follow the format described below.</p>
Attach Current & Pending Support	<p>Provide a list of all current and pending support for the PD/PI (even if they receive no salary support from the project(s)) for ongoing projects and pending applications. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of an application to other organizations for simultaneous consideration will not prejudice its review.</p> <p> Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, you will be instructed to refer to Other Support in Supplemental Instructions Part III, Policies, Assurances, Definitions and Other Information.</p>

Profile – Senior/Key Person [n]







The remaining senior/key person profiles should be listed in alphabetical order. While alphabetical order is preferred, it is not required. However, be aware that these profiles will appear in the application in the order provided by the applicant. Therefore, peer reviewers will see them in the order presented. Those with a postdoctoral role should be included if they meet the definition of senior/key personnel. Also use this section to list any Other Significant Contributors (OSCs). OSCs should be listed after all senior/key persons. OSCs are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project. These individuals are typically presented at “effort of zero person months” or “as needed” (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition.




A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the “investigator” review criterion. However, if an award is to be made, Other Support information will not be required or accepted since considerations of overlap do not apply to these individuals.


Should the level of involvement change for an individual listed as an OSC, the individual should be redesignated as “senior/key personnel.” This change should be made before any compensation is charged to the project.

After providing data for each individual senior/key person, click the **Next Person** button at the bottom of the form to enter data for the next senior/key person. Continue in this manner until data has been provided for up to 100 senior/key persons. To ensure proper performance of this form, after adding 20 additional senior/key persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 100 senior/key persons, the “Additional Senior/Key Person Profiles” fields will become available once data for the first 100 senior/key persons has been provided.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of the Senior/Key Person.
First Name	Enter the first (given) name of the Senior/Key Person. This field is required.
Middle Name	Enter the middle name of the Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of the Senior/Key Person. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Senior/Key Person.
Position/Title	Enter the title of the Senior/Key Person.
Department	Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization of the Senior/Key Person.
Organization Name	Enter the name of organization of the Senior/Key Person.  This is a required field for applications submitted to NIH and other PHS agencies.
Division	Enter the name of primary organizational division, office, or major subdivision of the Senior/Key Person.
Street1	Enter first line of the street address for the Senior/Key Person in the "Street 1" field. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person in the "Street 2" field. This field is optional.
City	City for address of Senior/Key Person. This field is required
County/Parish	County/ Parish for address of Senior/Key Person.
State	Enter the State where the Senior/Key Person is located. This field is required if the senior/key person is located in the United States.

Field Name	Instructions
Province	<p>Enter the Province where the Senior/Key Person is located.</p> <p> If “Country” is not Canada, please leave blank.</p>
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	<p>Enter the Postal Code (e.g., ZIP code) of Senior/Key Person. This field is required if the Senior/Key Person is located in the United States.</p> <p> A nine-digit Zip code is required.</p>
Phone Number	Enter the daytime telephone number for the Senior/Key Person. This field is required.
Fax Number	Enter the fax number for the Senior/Key Person.
E-mail	Enter the e-mail address for the Senior/Key Person. This field is required for the Senior/Key Person.
Credential, e.g., agency login	<p>If you are submitting to an agency (e.g., NIH) where you have an established personal profile, enter the agency ID. If not, leave blank.</p> <p> For NIH and other PHS agencies, registration in the eRA Commons for all PD/PIs is required. The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here and must have the PI role in eRA Commons. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.</p> <p>Note for applications reflecting Multiple PD/PIs, the Commons UserName must be provided for all individuals assigned the PD/PI Role on the application.</p>

Field Name	Instructions
Project Role	<p>Select one. Use "Other" if a category is not listed in the pick list.</p>  <p>For applications reflecting Multiple PD/PIs, all such individuals must be assigned the PD/PI role, even those at organizations other than the applicant organization. The role of "Co-PD/PI" is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of "Co-PD/PI" will not identify the application as a Multiple PD/PI application. If applicants wish to use a different role, select "Other" for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.</p> <p>If including individuals classified as "Other Significant Contributors (OSCs)," use the "Other" category and indicate "Other Significant Contributor" as the role in the "Other Project Role Category." OSCs should be listed last after all other senior/key persons have been listed.</p>
Other Project Role Category	Complete if you selected "Other Professional" or "Other" as a project role; e.g., Engineer, Chemist.
Degree Type	Enter the highest academic or professional degree or other credentials (e.g., R.N.). This is optional information.
Degree Year	<p>Enter the year the highest degree or other credential was obtained. This is optional information.</p>  <p>Applicants should ensure that their degree information is current in their Commons Profile.</p>
Attach Biographical Sketch	<p>Provide a biographical sketch for the Senior/Key Person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here. This field is required.</p>  <p>Biographical sketches should follow the format described below.</p>

Field Name	Instructions
Attach Current & Pending Support	<p>Provide a list of all current and pending support for the senior/key person (even if they receive no salary support from the project(s)) for ongoing projects and pending proposals. Show the total award amount for the entire award period (including indirect costs) as well as the number of person-months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.</p> <p> Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to Other Support in Supplemental Instructions Part III, Policies, Assurances, Definitions, and Other Information.</p>

Additional Senior/Key Person Profile(s)

If more than 99 senior/key person profiles are proposed, enter the information in a separate file and attach it here.



A sample Additional Senior/Key Person Profiles format page for greater than 100 profiles is found under “Additional Format Pages” at: <http://grants.nih.gov/grants/funding/424/index.htm>.

Additional Biographical Sketch(es) (Senior/Key Person)

Provide a biographical sketch for each senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here.



Biographical Sketches should follow the format described [below](#).

Additional Current and Pending Support(s)

Provide a list of all current and pending support for the PD/PI and each senior/key person (even if they receive no salary support from the project(s) for ongoing projects and pending proposals). Show the total award amount for the entire award period (including indirect costs) as well as the number of person months per year to be devoted to the project by the senior/key person, regardless of source of support. Concurrent submission of a proposal to other organizations will not prejudice its review.



Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions. This information is no longer required at the time of application submission. This information may be requested later in the pre-award cycle. When this occurs, refer to [Other Support](#) in Supplemental Instructions Part III, Policies, Assurances, Definitions, and Other Information.

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the [Biographical Sketch Format Page](#) to prepare this section for **all** (modular and other) grant applications. Include biographical sketches of all **senior/key personnel and Other Significant Contributors**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a [completed Biographical Sketch](#). If the individual is registered in the eRA Commons, include the Commons User Name. This data item is

required for the PD/PI but is currently optional for all other senior/key persons. In other federal forms this information is referred to as “Credential, e.g., agency login.” For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete sections A, B, C, and D as described below.

- A. **Personal Statement:** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application. Within this section you may, if you choose, briefly describe factors such as family care responsibilities, illness, disability, and active duty military service that may have affected your scientific advancement or productivity.
- B. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. **Selected Peer-reviewed Publication and Patent Citations.** NIH encourages applicants to limit the list of selected peer-reviewed publications, manuscripts in press, and patent citations to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material).
- D. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the senior/key person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*
- Don’t confuse “Research Support” with “Other Support.”** Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application. Within this section you may, if you choose, briefly describe factors such as family care responsibilities, illness, disability, and active duty military service that may have affected your scientific advancement or productivity.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Selected Peer-reviewed Publications

NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at:

http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hunt, Morgan Casey		POSITION TITLE Associate Professor of Psychology	
eRA COMMONS USER NAME (credential, e.g., agency login) huntmc			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have a demonstrated record of accomplished and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

B. Positions and Honors**Positions and Employment**

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-05	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11	NIH Risk, Adult Addictions Study Section, member

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004	Excellence in Teaching, Washington University, St. Louis, MO
2009	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Selected Peer-reviewed Publications (Selected from 42 peer-reviewed publications)

Most relevant to the current application

1. Merrylye, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merrylye, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMCID: PMC9162292
4. Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.
5. Hunt, M.C. & Sher, K.A. (2009). Successful intervention models for older drug-abusers: Research across the life-span. *American Psychologist*, in press. NIHMSID: NIHMS99135

Additional recent publications of importance to the field (in chronological order)

1. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
2. Shaft, B.M., Hunt, M.C., Merrylye, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
3. Hunt, M.C., Marks, A.E., Shaft, B.M., Merrylye, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2), 26-37.
4. Hunt, M.C., Merrylye, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *Journal of the American Geriatrics Society*, 57(4), 15-23.
5. Hunt, M.C., Pour, B., Marks, A.E., Merrylye, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
6. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMCID: PMC9000292
7. Merrylye, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMCID: PMC9002364
8. Hunt, M.C., Jensen, J.L. & Merrylye, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.
9. Hunt, M.C. (2009). Contrasting ethnicity with race in the older alcoholic. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, in press. PMCID: PMC Journal – In Process.
10. Hunt, M.C. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.

D. Research Support

Ongoing Research Support

R01 DA942367-03

Hunt (PI)

09/01/08-08/31/13

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI

4.6 Selecting the Appropriate Budget Form



The application forms package associated with most NIH funding opportunities includes two optional budget forms—(1) R&R Budget Form; and, (2) PHS 398 Modular Budget Form. NIH applications will include either the R&R Budget Form or the PHS 398 Modular Budget Form, but not both. (**Note AHRQ does not accept modular budgets.**)

To determine which budget form to use for NIH applications, consult the modular budget and foreign grantee guidelines below. Additional guidance may also be provided in the specific funding opportunity announcement.

Modular Budget Guidelines. Modular budgets are applicable to certain research grant applications requesting \$250,000 or less per year for direct costs. **Note, consortium/contractual F&A costs are not factored into the direct cost limit.**

Consortium F&A costs may be requested in addition to the \$250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application. The modular budget is applicable only to applications for R01, R03, R15, R21, and R34 **and their corresponding cooperative agreement activity codes.**

Instructions for completing a Modular Budget Form can be found in [Section 5.4](#). Instructions for completing the R&R Budget Form are provided in the next section.

Foreign Grantee Budget Guidelines. All competing (new, renewal, resubmission, and revision) grant applications from foreign (non-U.S.) institutions must include only detailed (non-modular) budgets. For additional information, see NIH Guide Notice NOT-OD-06-096, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-096.html>.

Applications from foreign (non-U.S.) institutions submitted via Grants.gov must follow the Research & Related Budget Form instructions and must complete and submit the Research & Related Budget forms. Applications from foreign organizations must request budgets in U.S. dollars.

4.7 R&R Budget Form

The R&R Budget form includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the **Previous** and **Next** buttons at the top of the form or use the scroll bar on the side of the screen. Complete the R&R Budget form following the instructions provided. You must complete a separate detailed budget for each year of support requested. The form will generate a cumulative budget for the total project period. **You must complete all the required information (i.e., those fields that are highlighted and outlined in red) before the Next Period button is activated.** If no funds are requested for a required field, enter “0.”

While the dollar fields allow cents to be entered, all dollar fields should be presented in whole numbers. **Please round to the nearest whole number.**

NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at: http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available.

If funds are being requested for more than one budget period, click the **Next Period** button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

Revision (Supplemental) Application. For a “Revision” (Supplemental) application, show only those items for which additional funds are requested. If the initial budget period of the supplementation application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

ORGANIZATIONAL DUNS:

Enter name of Organization:

Budget Type: ☐ Project ☐ Subaward/Consortium

Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Project Role:

Additional Senior Key Persons:

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Cal.	Months		Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
			Acad.	Sum.			
<input type="text"/>	Post Doctoral Associates	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Graduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Undergraduate Students	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	Secretarial/Clerical	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)

4.7.1 Section A and B

Organizational DUNS

Enter the DUNS or DUNS+4 number of the applicant organization. For project applicant, this field is pre-populated from the R&R SF424 Cover Page. For subaward applicants, this field is a required enterable field.

Enter name of Organization

Pre-populated from the R&R SF424. Enter the name of the organization.

Budget Type

Project, Subaward/Consortium: Check the appropriate block. This field is required.

Project: The budget requested for the primary applicant organization.

Subaward/Consortium: The budget requested for subawardee/consortium organization(s). Note, separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

If creating Subaward Budget, use the R&R Subaward Budget Attachment and attach as a separate file on the R&R Budget Attachment(s) form.



If you are preparing an application that includes a subaward/consortium, see [Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium](#).

Start Date

Pre-populated from the R&R SF424. Enter the requested/proposed start date of each budget period. This field is required.

Refer to the program announcement and/or the standard receipt dates for the Earliest Project Start Date:

End Date

Enter the requested/proposed end date of each budget period. This field is required.

The end date will be one day before the start date of the next budget year.

Example: For a 5 year project, Project Start Date of 7/1/2014, Budget End Date 6/30/2015.

The project end date of 6/30/2019 will be input in budget year 5.



Budget Period




Identify the specific budget period (for example, 1, 2, 3, 4, 5). If submitting through Grants.gov, the system will automatically generate a cumulative budget for the total project period. This is a required field.


(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the form.)

A. Senior/Key Person

This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions will be provided in the Subaward budget for each subaward/consortium organization. Personnel listed as Other Significant Contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services.

Field Name	Instructions
Prefix	Enter the prefix (e.g., Mr., Mrs., Rev.) for the name of each Senior/Key Person.
First Name	Enter the first (given) name of each senior/key person. Senior/Key Person.
Middle Name	Enter the middle name of each Senior/Key Person, if applicable.
Last Name	Enter the last (family) name of each Senior/Key Person. This field is required.
Suffix	Enter the suffix (e.g., Jr., Sr., PhD) of each Senior/Key Person.
Base Salary (\$)	<p>Enter the annual compensation paid by the employer for each Senior/Key Person. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank.</p>  <p>An applicant organization may choose to leave this blank; however, PHS staff will request this information prior to award.</p>
Cal. Months	<p>Identify the number of months devoted to the project for each senior/key person (i.e., calendar, academic, summer).</p>  <p>If effort does not change throughout the year, it is OK to use only the calendar months column. However, you may use both academic and summer months columns if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. Please use either calendar months OR a combination of academic and summer months. Some measurable effort is required for every Senior/Key Person entry.</p>

Field Name	Instructions
Sum. Months	<p>Identify the number of months devoted to the project for each senior/key person (for example, calendar, academic, summer).</p>  <p>If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification. Some measurable effort is required for every Senior/Key Person entry.</p>
Requested Salary (\$)	<p>Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each senior/key person. This field is required.</p>  <p>Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award; therefore requested salary should be based on institutional base salary at the time the application is submitted and not adjusted for any limitation. For guidance on current salary limitations, see the Salary Cap Summary on the NIH grants website or contact your office of sponsored programs.</p> <p>NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.</p>
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for each senior/key person.
Funds Requested (\$)	The requested salary and fringe benefits for each senior/key person. This field is auto-calculated.
Project Role	<p>Identify the project role of each senior/key person in this section. This section could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals. CoPD/PI not used by NIH</p>  <p>Roles should correspond to the roles included on the Senior/Key Person Profile (Expanded) Form.</p> <p>PD/PI <u>must</u> be used for each PI, or an error will be generated.</p>


Field Name	Instructions
Additional Senior/Key Persons	<p>If funds are requested for more than eight senior/key persons, include all pertinent budget information as identified in this section and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A. This attachment is required if funds are entered in line 9 of Section A.</p>  Use the same format as the budget form and include all required information.
Total Funds requested for all persons in the attached file	Enter the total funds requested for all senior/key persons. This is required information.
Total Senior/Key Persons	The total funds requested for all senior/key persons.







Special Instructions: Joint University and Department of Veterans Affairs (V.A.) Appointments

Individuals with joint university and V.A. appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the V.A.; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

B. Other Personnel

Field Name	Instructions
Number of Personnel	<p>For each project role category identify the number of personnel proposed.</p> <p>In most circumstances, the salaries of administrative or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs. Examples, however, of situations where direct charging of administrative or clerical staff salaries may be appropriate may be found at: http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html#exc. The circumstances for requiring direct charging of these services must be clearly described in the budget justification.</p>  For all Postdoctoral Associates and Graduate Students not already named in Section A. Senior/Key Person, individually list names, roles (e.g., PostDoc or Graduate Student), associated months, and salary & fringe benefits requested in the Budget Justification.

Field Name	Instructions
Project Role	<p>For each project role category identify the number of personnel proposed. List any additional project role(s) in the blank(s) provided, e.g., Engineer, IT Professionals, etc.</p> <p> Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.</p>
Cal. Months	Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer).
Acad. Months	<p>Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer).</p> <p> If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.</p>
Sum. Months	<p>Identify the number of months devoted to the project in the applicable box for each project role category (i.e., calendar, academic, summer).</p> <p> If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification.</p>
Requested Salary (\$)	<p>Regardless of the number of months being devoted to the project, indicate only the amount of salary/wages being requested for each project role.</p> <p> Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations, see the Salary Cap Summary on the NIH grants website or contact your office of sponsored programs.</p> <p>NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.</p>
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for this project role category.
Funds Requested	This field is auto-calculated.
Total Number of Other Personnel	This total will auto-calculate. Total Number of Personnel.
Total Other Personnel	Total Funds requested for all other Personnel.

Field Name	Instructions
Total Salary, Wages and Fringe Benefits (A+B)	Total Funds requested for all Senior/Key persons and all Other Personnel. This total will auto-calculate.

To navigate to the next page (Sections C through E), click the **Next** button at the top of the form or use the scroll bar on the left-hand side of the screen.

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item	Funds Requested (\$)
<input type="text"/>	<input type="text"/>
Additional Equipment: <input type="text"/>	
Total funds requested for all equipment listed in the attached file	<input type="text"/>
Total Equipment	<input type="text"/>

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	<input type="text"/>
2. Foreign Travel Costs	<input type="text"/>
Total Travel Cost	<input type="text"/>

E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	<input type="text"/>
2. Stipends	<input type="text"/>
3. Travel	<input type="text"/>
4. Subsistence	<input type="text"/>
5. Other <input type="text"/>	<input type="text"/>
<input type="text"/> Number of Participants/Trainees	<input type="text"/>
Total Participant/Trainee Support Costs	<input type="text"/>

4.7.2 Sections C through E

C. Equipment Description	
List items and dollar amount for each item exceeding \$5,000	
Equipment item	Funds Requested (\$)
<input type="text"/>	<input type="text"/>
Additional Equipment: <input type="text"/>	<input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
Total funds requested for all equipment listed in the attached file <input type="text"/>	
Total Equipment <input type="text"/>	
D. Travel	
	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	<input type="text"/>
2. Foreign Travel Costs	<input type="text"/>
Total Travel Cost	<input type="text"/>
E. Participant/Trainee Support Costs	
	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	<input type="text"/>
2. Stipends	<input type="text"/>
3. Travel	<input type="text"/>
4. Subsistence	<input type="text"/>
5. Other <input type="text"/>	<input type="text"/>
<input type="text"/> Number of Participants/Trainees	Total Participant/Trainee Support Costs <input type="text"/>

The information for Organizational DUNS, Budget Type, Name of Organization, and Start and End Dates is automatically filled in based on the information entered on the first budget screen. To edit this information, return to the initial budget screen (Sections A and B) by clicking the **Previous** button.

C. Equipment Description

List of items and dollar amount for each item exceeding \$5,000.

Field Name	Instructions
Equipment Item	Equipment is defined as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.
Funds Requested	List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.
Additional Equipment	If this section cannot accommodate all the equipment proposed, attach a file in the block provided. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested in the following field
Total funds requested for all equipment listed in the attached file	Total funds requested for all equipment listed in the attached file. Dollar amount for each item should exceed \$5000.
Total Equipment	Total Funds requested for all equipment.

D. Travel

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	Identify the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known), and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Foreign Travel Costs	Identify the total funds requested for foreign travel. Foreign travel includes any travel outside of North America and/or U.S. possessions. In the budget justification section, include the purpose, destination, dates of travel (if known) and number of individuals for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Total Travel Cost	Total Funds requested for all travel.

E. Participant/Trainee Support Costs

Unless specifically stated otherwise in an announcement, NIH and other PHS agencies applicants should leave blank Section E. Note: Tuition remission for graduate students should continue to be included in Section F. Other Direct Costs when applicable.

Field Name	Instructions
Tuition/Fees/Health Insurance	List total funds requested for Participant/Trainee Tuition / Fees / Health insurance.
Stipends	List total funds requested for Participant/Trainee stipends.
Travel	List total funds requested for Participant/Trainee travel.
Subsistence	List total funds requested for Participant/Trainee subsistence.
Other	Describe any other participant trainee funds requested. List total funds requested for any other Participant/Trainee costs described.
Number of Participants/Trainees	List total number of proposed Participants/Trainees. Value cannot be greater than 999.
Total Participant/Trainee Support Costs	Total Funds requested for all trainee costs. This field is required if any data has been entered in section E.

F. Other Direct Costs

		Funds Requested (\$)
1.	Materials and Supplies	60,000.00
2.	Publication Costs	2,000.00
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	324,120.00
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
Total Other Direct Costs		386,120.00

G. Direct Costs

		Funds Requested (\$)
Total Direct Costs (A thru F)		445,778.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
MTDC	58.00	146,658.00	85,062.00
Total Indirect Costs			85,062.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)	Arif Karim - Acting Director, Division of Cost Allocation 7700 Wisconsin Ave, Suite #2300 Bethesda, MD 20857 Tel: 301.492.4855 Fax: 301.492.5091
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I. Total Direct and Indirect Costs

		Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)		530,840.00


J. Fee



		Funds Requested (\$)


K. Budget Justification

(Only attach one file.)	BudgetJustificaton.pdf	Add Attachment	Delete Attachment	View Attachment
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F. Other Direct Costs

Field Name	Instructions
1. Materials and Supplies	List total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than \$1,000 are not required to be itemized.
2. Publication Costs	List the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.
3. Consultant Services	<p>List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs.</p> <p>This is a PAID service having no sponsored research activity and occurring in the consultant's institution's facilities and must be consistent with that institution's policies. Consultants cannot be employed by UVA or any other Virginia state agency.</p>  <p>In the budget justification also provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.</p>
4. ADP/Computer Services	List total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.

Field Name	Instructions
5. Subawards/Consortium/ Contractual Costs	<p>List total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project.</p>  <p>This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.</p> <p>NIH policy provides for exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. Please see the Supplemental Instructions, Part III, Section 1.1 for additional information regarding this exclusion Policy</p>
6. Equipment or Facility Rental/User Fees Rarely used at UVA	<p>List total funds requested for equipment or facility Rental/Use fees. In the budget justification, identify each rental user fee and justify.</p>
7. Alterations and Renovations Rarely used at UVA	<p>List total funds requested for alterations and renovations. In the budget justification, itemize by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.</p>  <p>Under certain circumstances the public policy requirements that apply to construction activities may also apply to A&R activities. Please refer to the NIH Grants Policy Statement section on “Construction Grants – Public Policy Requirements and Objectives” for more information.</p> <p>Note, costs for any Alterations and Renovations (A&R) were previously unallowable on applications from foreign institutions, international organizations and domestic applications with foreign subawards. However, an HHS policy change now allows for minor A&R (≤\$500,000) on these applications.</p> <p>When requesting minor A&R costs under this policy, please provide detailed information on the planned A&R in the budget justification.</p>

Field Name	Instructions
8-10 Other	<p>Add text to describe any “other” direct costs not requested above. Use the budget justification to further itemize and justify.</p> <p>List total funds requested for items 8-10 “Other.”</p>  <p>Use lines 8-10 for such costs as patient care and tuition remission. If requesting patient care costs, request inpatient and outpatient costs separately using lines 8 and 9.</p>
Total Other Direct Costs	Total Funds requested for all other direct costs.



Special Instructions for Patient Care Costs

If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each in the budget justification.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.


Provide specific information regarding anticipated sources of Other Support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers.

G. Total Direct Costs (A through F)

Total Funds requested for all direct costs.

H. Indirect Costs

Field Name	Instructions
Indirect Cost Type MTDC	<p>Indicate the type of cost e.g.; Salary & Wages, Modified Total Direct Costs, or Other explain. Also indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, “None—will negotiate” and include information for a proposed rate. Use the budget justification if additional space is needed.</p>

Field Name	Instructions
Indirect Cost Rate (%) Effective 12/13/12 58% On Grounds (labs) 26% Off Grounds (medical center, clinics)	Indicate the most recent indirect cost rate(s) (also known as Facilities & Administrative Costs [F&A]) established with the cognizant Federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency.  If this field does not allow a figure greater than 100% to be entered, use two lines to show the entire calculation. This field should be entered using a rate such as “55.5.”
Indirect Cost Base (\$)	Enter the amount of the base for each indirect cost type.
Funds Requested	Enter funds requested for each indirect cost type.
Total Indirect Costs	Total Funds requested for indirect costs.
Cognizant Federal Agency DHHS is UVA’s cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name and phone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter “None.” Department of Health and Human Services (DHHS) Arif Karim, Acting Director Division of Cost Allocation Tel: 301-492-5081

I. Total Direct and Indirect Institutional Costs (G + H)

Total Funds requested for direct and indirect costs.

J. Fee

Generally, a fee is not allowed on a grant or cooperative agreement. Do not include a fee in your budget, unless the program announcement specifically allows the inclusion of a “fee” (e.g., SBIR/STTR). If a fee is allowable, enter the requested fee.

K. Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories. Only one file may be attached. The attachment is required.



Use this section to list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included in Budget Section B. Other Personnel.

Include a justification for any significant increases or decreases from the initial year budget. Justify budgets with more than a standard escalation from the initial to the future year(s) of support. Also use this section to explain any exclusions applied to the F&A base calculation.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See [Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium](#).

Completing Budget Periods 2-5

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the **Next Period** button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and outlined in red) before the **Next Period** button is activated. If no funds are requested for a required field, enter “0.” Note the Budget Justification is also a required item and must be attached before the **Next Period** button is activated.



Supplemental/Revision Application

For a supplemental/revision application, show only those items for which additional funds are requested. If the initial budget period of the supplemental/revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

Submitting Budgets With More Than 5 Budget Periods

When authorized or requested by the appropriate NIH IC, applicants may submit applications with more than 5 budget periods. In these situations complete the detailed budget for periods 1-5 as usual. However, include the same level of detail for Period 6 in the Budget Justification along with an explanation of the situation. Also, be sure to include a cover letter that addresses these extra budget periods, and include the IC Program Official’s preapproval as part of the Cover Letter PDF.

4.7.4 Cumulative Budget

All values on this form are calculated automatically. They present the summations of the amounts that you have entered previously, under Sections A through K, for each of the individual budget periods. Therefore, no data entry is allowed or required, in order to complete this “Cumulative Budget” section.

If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

NOTE: The total costs that appear in Section I. Total Direct and Indirect Institutional Costs (G +H), should match Box 15 a. and 15 c. on page 2 of the SF424. 15 b and 15 d. should be \$0.00 unless there is program income or non-Federal Funds.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals (\$)
Section A, Senior/Key Person	<input type="text"/>
Section B, Other Personnel	<input type="text"/>
Total Number Other Personnel	<input type="text"/>
Total Salary, Wages and Fringe Benefits (A+B)	<input type="text"/>
Section C, Equipment	<input type="text"/>
Section D, Travel	<input type="text"/>
1. Domestic	<input type="text"/>
2. Foreign	<input type="text"/>
Section E, Participant/Trainee Support Costs	<input type="text"/>
1. Tuition/Fees/Health Insurance	<input type="text"/>
2. Stipends	<input type="text"/>
3. Travel	<input type="text"/>
4. Subsistence	<input type="text"/>
5. Other	<input type="text"/>
6. Number of Participants/Trainees	<input type="text"/>
Section F, Other Direct Costs	<input type="text"/>
1. Materials and Supplies	<input type="text"/>
2. Publication Costs	<input type="text"/>
3. Consultant Services	<input type="text"/>
4. ADP/Computer Services	<input type="text"/>
5. Subawards/Consortium/Contractual Costs	<input type="text"/>
6. Equipment or Facility Rental/User Fees	<input type="text"/>
7. Alterations and Renovations	<input type="text"/>
8. Other 1	<input type="text"/>
9. Other 2	<input type="text"/>
10. Other 3	<input type="text"/>
Section G, Direct Costs (A thru F)	<input type="text"/>
Section H, Indirect Costs	<input type="text"/>
Section I, Total Direct and Indirect Costs (G + H)	<input type="text"/>
Section J, Fee	<input type="text"/>

4.8 Special Instructions for Preparing Applications with a Subaward/Consortium

A complete subaward/consortium budget form (including the budget justification section) should be completed by each consortium grantee organization. Separate budgets are required only for subawardee/consortium organizations that perform a substantive portion of the project.

Note, a complete subaward/consortium budget form is only required when the prime grantee is submitting a detailed budget using the R&R Budget Form. Do not use this subaward/consortium budget form for applications using the PHS 398 Modular Budget Form. Applicants using the Modular Budget Form should see Section 5.4 for instructions concerning information on consortium budgets.

For any subaward or consortium sites, it is appropriate and expected that someone may be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at that site. However, when completing the Project Role for the consortium lead investigator, the project role of “PD/PI” should only be used if the entire application is being submitted under the Multiple PI policy. Otherwise, this individual should be assigned some other project role in the senior/key personnel section of the application. Also, the role of Co-PD/PI is not currently used by NIH and other PHS agencies. Assigning an individual(s) the role of “Co-PD/PI” will not identify the application as a Multiple PD/PI application. Although NIH now recognizes the role of “Co-Investigator,” if applicants wish to use the role of “Consortium PI” or some other similar role, select “Other” for the Project Role field and then insert the appropriate role descriptor in the Other Project Role Category field.

NIH continues to support the policy established in April 2004, (revised in November 2004) regarding applications that involve consortium/contractual F&A costs (See [NOT-OD-05-004](#)). This policy allows applicants to exclude consortium/contractual F&A costs when determining compliance for any application where a direct cost limit applies. The use of the SF424 (R&R) application with separately submitted subaward/consortium budgets allows NIH to take advantage of a system validation for this policy. When an application is submitted in response to a program with a direct cost limit, the eRA system will perform the calculation by taking the total direct costs requested by the prime/parent organization in their detailed budget, and subtracting all subaward/consortium F&A from each and every subaward budget attached. When the validation calculation equals or exceeds the respective direct cost limit, the application will receive a warning. There are circumstances, when the system does not have sufficient information to exclude all allowable F&A costs. Applicants should document in their budget justification, how their budget falls below the direct cost limit.

This form accommodates a set number of separate subaward budgets (30). If you are submitting an application with more subaward budgets than the form allows, the remaining budgets should be converted to PDF and included as part of Section K. Budget Justification of the parent budget. Reminder, the sum of all subaward budgets; e.g., those attached separately and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the parent budget.

To start the process, the applicant organization should:

- Select the Subaward Budget Attachment Form from the Optional Documents in the Grant Application Package.
- Open the form, and click the **Click here to extract the R&R Subaward Budget Attachment** button in the middle of the form. A “SAVE” dialog box appears.
- Save the file locally using the first ten letters of the consortium organization’s name and use “.pdf” as the file extension. (The extracted file is an Adobe PDF file.) Once you have saved the

file there is no need to extract another budget attachment. Doing so may cause you to lose any data already stored in the saved file.

- E-mail the extracted, saved form to the consortium grantee. Note: consortium grantees must have installed a compatible version of Adobe Reader before they can complete the form. The consortium grantee should complete all the budget information as instructed in the R&R Budget form instructions in [Section 4.7](#). The Budget Type should be set to Subaward/Consortium. Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.
- The consortium grantee must complete the budget form and e-mail it back to the applicant organization.
- Return to the Subaward Budget Attachment Form and attach the consortium grantee's budget to one of the blocks provided on the form.

Submitting Subaward Budgets that are not Active for all Periods of the Prime Grant

When submitting subaward budgets that are not active for all periods of the prime grant, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period should reflect the corresponding prime budget period start/end dates. This approach is the most workable solution to the limitations in existing forms that do not allow an “empty” budget period and do not allow submission of a subaward budget with zero effort to skip a budget period.

For example, suppose the prime has filled out a budget form with the following periods:

- period 1 Jan 1, 2013 – Dec 31, 2013
- period 2 Jan 1, 2014 – Dec 31, 2014
- period 3 Jan 1, 2015 – Dec 31, 2015
- period 4 Jan 1, 2016 – Dec 31, 2016
- period 5 Jan 1, 2017 – Dec 31, 2017

Now, suppose there is a subaward that performs in support year 1 and does not become active again until support year 4. The subaward can fill out the first two periods of their budget form as follows:

- period 1 Jan 1, 2013 – Dec 31, 2013 (dates correspond to prime period 1)
- period 2 Jan 1, 2016 – Dec 31, 2016 (dates correspond to prime period 4)

It is not necessary that the budget period numbers between the prime and subaward match; the correlation is reflected in the dates. Do be careful, however, that the dates exactly match what is listed for the period in the prime budget.

Note this approach may cause a validation warning regarding the NIH \$500,000 per year limit on direct costs, therefore you should document in both the cover letter and the subaward budget justification that the subaward is only active for specific periods of the prime. Appropriate NIH staff has access to the cover letter and reviewers have access to the budget justification. This documentation will make the date correlation immediately apparent and will help avoid any confusion.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a form from your application, uncheck the box next to the form name in the Optional document section.

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1	
2) Please attach Attachment 2	
3) Please attach Attachment 3	
4) Please attach Attachment 4	
5) Please attach Attachment 5	
6) Please attach Attachment 6	
7) Please attach Attachment 7	
8) Please attach Attachment 8	
9) Please attach Attachment 9	
10) Please attach Attachment 10	
11) Please attach Attachment 11	
12) Please attach Attachment 12	
13) Please attach Attachment 13	
14) Please attach Attachment 14	
15) Please attach Attachment 15	
16) Please attach Attachment 16	
17) Please attach Attachment 17	
18) Please attach Attachment 18	
19) Please attach Attachment 19	
20) Please attach Attachment 20	
21) Please attach Attachment 21	
22) Please attach Attachment 22	
23) Please attach Attachment 23	
24) Please attach Attachment 24	
25) Please attach Attachment 25	
26) Please attach Attachment 26	
27) Please attach Attachment 27	
28) Please attach Attachment 28	
29) Please attach Attachment 29	
30) Please attach Attachment 30	

5. Completing PHS 398 Form

5.1 Overview

In conjunction with the SF424 (R&R) forms, NIH and other PHS agencies grants applicants should also complete and submit additional forms titled “PHS 398.” Note the PHS 398 forms include additional data required by the agency for a complete application. While these are not identical to the PHS 398 application form pages, the PHS 398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) forms. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS 398 forms. The PHS 398 forms include:

- PHS 398 Cover Page Supplement (this supplements the data requirements in the R&R Cover form)
- PHS 398 Modular Budget Form (use only when a modular budget is submitted instead of a detailed budget)
- PHS 398 Research Plan Form
- Planned Enrollment Report
- PHS 398 Cumulative Inclusion Enrollment Report

Complete each form using the instructions provided below.

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

2. Human Subjects

Clinical Trial? ☐ No ☐ Yes

*Agency-Defined Phase III Clinical Trial? ☐ No ☐ Yes

3. *Disclosure Permission Statement

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

☐ Yes ☐ No

4. *Program Income

*Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount (\$)	*Source(s)
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

1. Program Director/Principal Investigator (PD/PI)

Field Name	Instructions
Prefix	Pre-populated from the SF424 (R&R). The prefix (for example, Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	Pre-populated from the SF424 (R&R). The first (given) name of the PD/PI. This field is required.
Middle Name	Pre-populated from the SF424 (R&R). The middle name of the PD/PI.
Last Name	Pre-populated from the SF424 (R&R). The last (family) name of the PD/PI. This field is required.
Suffix	Pre-populated from the SF424 (R&R). The suffix (for example, Jr., Sr., PhD) for the name of the PD/PI.

2. Human Subjects

Field Name	Instructions
Clinical Trial?	Check "yes" or "no" to indicate whether the project includes a clinical trial. See Supplemental Grant Application Instructions, Part III.3. for the specific definition.
Agency-Defined Phase III Clinical Trial	<p>Check “Yes” or “No” to indicate whether the project is an NIH-defined Phase III clinical trial.</p> <p>An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.</p>

3. *Disclosure Permission Statement

Field Name	Instructions
------------	--------------

Field Name	Instructions
If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?	Select "yes" or "no" to indicate whether disclosure permission is granted. This field is required. Your response will not affect any peer review or funding decisions.

4. Program Income

Field Name	Instructions
Is program income anticipated during the periods for which the grant support is requested?	If program income is anticipated during the periods for which the grant support is requested, check "Yes," and then complete the section below. If no program income is anticipated, check "No" and leave the following section blank.
Budget Period	If program income is anticipated, enter the budget periods in this column. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.
Anticipated Amount (\$)	If program income is anticipated, enter the amount anticipated for each budget period listed.
Source(s)	If program income is anticipated, enter the source for each budget period listed.

PHS 398 Cover Page Supplement

5. Human Embryonic Stem Cells

*Does the proposed project involve human embryonic stem cells? ☐ No ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <http://stemcells.nih.gov/research/registry/>. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): ☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

*Inventions and Patents: Yes ☐ No ☐

If the answer is "Yes" then please answer the following:

*Previously Reported: Yes ☐ No ☐

7. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

5. Human Embryonic Stem Cells

Field Name	Instructions
Does the proposed project involve human embryonic stem cells?	If the proposed project involves human embryonic stem cells, check Yes and complete the section below. If the proposed project does not involve human embryonic stem cells, check No.
Specific stem cell line cannot be referenced at this time. One from the registry will be used.	If a specific line cannot be referenced at the time of application submission, check this box. Additionally, provide a strong justification for why an appropriate cell line is not available from the Registry at this time. The justification should be included as part of the Research Strategy or Program Plan as appropriate..
Cell Line(s)	List in this section the registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry

6. Inventions and Patents (For renewal applications only)

Field Name	Instructions
Inventions and Patents	<p>This block need only be completed if submitting an R&R “Renewal” application or a Resubmission of a Renewal application. If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable. If any inventions were conceived or reduced to practice during the previous period of support, check “Yes.”</p> <p>Note: NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at http://www.iedison.gov. The grantee is encouraged to submit reports electronically using Interagency Edison (http://www.iedison.gov).</p>
Previously Reported	If the item above is checked "Yes", indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

7. Change of Investigator/Change of Institution Questions

NOTE: NIH is now requiring a Type 7 electronic application for grant transfers. The link to the current PA is:

<http://grants.nih.gov/grants/guide/pa-files/PA-12-270.html>

At this time (August 2013), the parent application is no longer accepted for grant transfers.

Field Name	Instructions
Change of Program Director/Principal Investigator	Check here, if this application reflects a change in principal investigator/program director from that indicated on a previous application. This is not generally applicable to a "New" application
Prefix	If this application reflects a change in PD/PI, enter the name prefix (for example, Mr., Mrs., Rev.) of the former PD/PI.
First Name	If this application reflects a change in PD/PI, enter the first name of the former PD/PI.
Middle Name	If this application reflects a change in PD/PI, enter the middle name of the former PD/PI.
Last Name	If this application reflects a change in PD/PI, enter the last name of the former PD/PI.
Suffix	If this application reflects a change in PD/PI, provide the suffix (for example, Jr., Sr., PhD) of the former PD/PI.
Change of Grantee Institution	Check here, if this application reflects a change in grantee institution from that indicated on a previous application. This is not generally applicable to a "New" application.
Name of Former Institution	If this application reflects a change in grantee institution, insert the name of the former institution here.

5.4 Modular Budget Form

Selecting the Appropriate Budget Form

The application forms package associated with most NIH funding opportunities includes two optional budget forms—(1) R&R Budget Form; and, (2) PHS 398 Modular Budget Form. NIH applications will include either the R&R Budget Form or the PHS 398 Modular Budget Form but not both. (**Note AHRQ does not accept modular budgets.**)

To determine which budget form to use for NIH applications, consult the modular budget guidelines below. Additional guidance may also be provided in the specific funding opportunity announcement.

Modular Budget Guidelines

Modular budgets are applicable to certain research grant applications from domestic organizations requesting \$250,000 or less per year for direct costs. International organizations and others that do not fall under this definition should use the detailed budget forms described in Section 4.7. Note, consortium/contractual F&A costs are not factored into the direct cost limit. They may be requested in addition to the \$250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

For all modular budgets, request total direct costs (in **modules of \$25,000**), reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.

NIH may request (prior to award) additional budget justification in exceptional circumstances. For further information, see <http://grants.nih.gov/grants/funding/modular/modular.htm> and http://grants.nih.gov/grants/funding/modular/modular_review.htm.

Using the Modular Budget Form

The Modular Budget Form provides budget fields for up to 5 years of support (e.g., budget periods 1 - 5). If requesting less than 5 years of support, complete only those years requested and leave the others blank.

PHS 398 Modular Budget

OMB Number: 0925-0001

Budget Period: 1			
Start Date:		07/01/2014	End Date:
End Date:		06/30/2015	
A. Direct Costs			Funds Requested (\$)
Direct Cost less Consortium F&A			250,000.00
Consortium F&A			14,000.00
Total Direct Costs			264,000.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC	58.00	225,000.00
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Arif Karim, DHHS Acting Director of the Division of Cost Allocation 7700 Wisconsin Avenue, Suite 2300 Bethesda, MD 20857 301-492-4855	
Indirect Cost Rate Agreement Date			12/13/2012
Total Indirect Costs			130,500.00
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			394,500.00

Budget Period: 2			
Start Date:		07/01/2015	End Date:
End Date:		06/30/2016	
A. Direct Costs			Funds Requested (\$)
Direct Cost less Consortium F&A			250,000.00
Consortium F&A			14,000.00
Total Direct Costs			264,000.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC	58.00	200,000.00
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Arif Karim, DHHS Acting Director of the Division of Cost Allocation 7700 Wisconsin Avenue, Suite 2300 Bethesda, MD 20857 301-492-4855	
Indirect Cost Rate Agreement Date			12/13/2012
Total Indirect Costs			116,000.00
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			380,000.00

PHS 398 Modular Budget

Budget Period: 3			
Start Date:		07/01/2016	End Date:
End Date:		06/30/2017	
A. Direct Costs			Funds Requested (\$)
Direct Cost less Consortium F&A			250,000.00
Consortium F&A			14,000.00
Total Direct Costs			264,000.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC	58.00	200,000.00
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Arif Karim, DHHS Acting Director of the Division of Cost Allocation 7700 Wisconsin Avenue, Suite 2300 Bethesda, MD 20857 301-492-4855	
Indirect Cost Rate Agreement Date		12/13/2012	Total Indirect Costs
			116,000.00
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			380,000.00

Budget Period: 4			
Start Date:		07/01/2017	End Date:
End Date:		06/30/2018	
A. Direct Costs			Funds Requested (\$)
Direct Cost less Consortium F&A			250,000.00
Consortium F&A			14,000.00
Total Direct Costs			264,000.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC	58.00	200,000.00
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Arif Karim, DHHS Acting Director of the Division of Cost Allocation 7700 Wisconsin Avenue, Suite 2300 Bethesda, MD 20857 301-492-4855	
Indirect Cost Rate Agreement Date		12/13/2012	Total Indirect Costs
			116,000.00
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			380,000.00

PHS 398 Modular Budget

Budget Period: 5																							
Start Date: <input style="width: 100px;" type="text" value="07/01/2018"/>		End Date: <input style="width: 100px;" type="text" value="06/30/2019"/>																					
A. Direct Costs			Funds Requested (\$) <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Direct Cost less Consortium F&A 250,000.00</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Consortium F&A 14,000.00</div> <div style="border: 1px solid black; padding: 2px;">Total Direct Costs 264,000.00</div>																				
B. Indirect Costs			<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;"></th> <th style="width: 15%;">Indirect Cost Rate (%)</th> <th style="width: 15%;">Indirect Cost Base (\$)</th> <th style="width: 20%;">Funds Requested (\$)</th> </tr> </thead> <tbody> <tr> <td>1. <input style="width: 90%;" type="text" value="MTDC"/></td> <td style="text-align: center;">58.00</td> <td style="text-align: center;">200,000.00</td> <td style="text-align: center;">116,000.00</td> </tr> <tr> <td>2. <input style="width: 90%;" type="text"/></td> <td style="text-align: center;"><input style="width: 40px;" type="text"/></td> <td style="text-align: center;"><input style="width: 100px;" type="text"/></td> <td style="text-align: center;"><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>3. <input style="width: 90%;" type="text"/></td> <td style="text-align: center;"><input style="width: 40px;" type="text"/></td> <td style="text-align: center;"><input style="width: 100px;" type="text"/></td> <td style="text-align: center;"><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>4. <input style="width: 90%;" type="text"/></td> <td style="text-align: center;"><input style="width: 40px;" type="text"/></td> <td style="text-align: center;"><input style="width: 100px;" type="text"/></td> <td style="text-align: center;"><input style="width: 80px;" type="text"/></td> </tr> </tbody> </table> <div style="margin-top: 10px;"> Cognizant Agency (Agency Name, POC Name and Phone Number) <div style="border: 1px solid black; padding: 5px; display: inline-block;"> Arif Karim, DHHS Acting Director of the Division of Cost Allocation 7700 Wisconsin Avenue, Suite 2300 Bethesda, MD 20857 301-492-4855 </div> </div> <div style="margin-top: 10px;"> Indirect Cost Rate Agreement Date <input style="width: 100px;" type="text" value="12/13/2012"/> <div style="float: right;"> Total Indirect Costs <input style="width: 100px;" type="text" value="116,000.00"/> </div> </div>		Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)	1. <input style="width: 90%;" type="text" value="MTDC"/>	58.00	200,000.00	116,000.00	2. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>	3. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>	4. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>
	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)																				
1. <input style="width: 90%;" type="text" value="MTDC"/>	58.00	200,000.00	116,000.00																				
2. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>																				
3. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>																				
4. <input style="width: 90%;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 80px;" type="text"/>																				
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$) <input style="width: 100px;" type="text" value="380,000.00"/>																				

Cumulative Budget Information	
1. Total Costs, Entire Project Period	
Section A, Total Direct Cost less Consortium F&A for Entire Project Period	\$ <input style="width: 150px;" type="text" value="1,250,000.00"/>
Section A, Total Consortium F&A for Entire Project Period	\$ <input style="width: 150px;" type="text" value="70,000.00"/>
Section A, Total Direct Costs for Entire Project Period	\$ <input style="width: 150px;" type="text" value="1,320,000.00"/>
Section B, Total Indirect Costs for Entire Project Period	\$ <input style="width: 150px;" type="text" value="594,500.00"/>
Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period	\$ <input style="width: 150px;" type="text" value="1,914,500.00"/>
2. Budget Justifications	
Personnel Justification	<input style="width: 200px;" type="text" value="BudgetJust.pdf"/> <div style="display: flex; gap: 5px;"> <div style="border: 1px solid black; padding: 2px 5px;">Add Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">Delete Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">View Attachment</div> </div>
Consortium Justification	<input style="width: 200px;" type="text"/> <div style="display: flex; gap: 5px;"> <div style="border: 1px solid black; padding: 2px 5px;">Add Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">Delete Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">View Attachment</div> </div>
Additional Narrative Justification	<input style="width: 200px;" type="text"/> <div style="display: flex; gap: 5px;"> <div style="border: 1px solid black; padding: 2px 5px;">Add Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">Delete Attachment</div> <div style="border: 1px solid black; padding: 2px 5px;">View Attachment</div> </div>

NOTE: The form allows for up to five budget periods followed by a cumulative budget for all budget periods. The fields are the same for all budget periods. The following instructions can be used for each.

Budget Period

Field Name	Instructions
Start Date	Enter the requested/proposed start date of the budget period. Use the following format: MM/DD/YYYY.
End Date	Enter the requested/proposed end date of the budget period. Use the following format: MM/DD/YYYY.

A. Direct Costs

Field Name	Instructions
Direct Cost less Consortium F&A	Enter the amount of Direct Costs, less actual consortium F&A costs for this budget period. This figure must be in \$25,000 increments, and it may not exceed \$250,000. Any consortium F&A costs are excluded from this figure. This field is required.
Consortium F&A	If this project involves a consortium, enter the actual consortium F&A costs for this budget period. If this project does not involve a consortium, leave blank.
Total Direct Costs	This field auto-calculates.

B. Indirect Costs

Field Name	Instructions
Indirect Cost Type MTDC	Indicate the type of base (for example, Salary & Wages, Modified Total Direct Costs, Other [explain]), and indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, “None—will negotiate” and include information for a proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%) 58% On Grounds (labs) 26% Off Grounds (medical center, clinics)	Indicate the most recent Indirect Cost rate(s) (also known as Facilities & Administrative Costs [F&A]) established with the cognizant Federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency.
Indirect Cost Base (\$)	Enter the amount of the base for each indirect cost type.

Field Name	Instructions
Funds Requested (\$)	Enter funds requested for each indirect cost type.
Cognizant Agency (Agency Name, POC Name and Phone Number) DHHS is UVA's cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name, and phone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter "None." Department of Health and Human Services (DHHS) Arif Karim, Acting Director Division of Cost Allocation Tel: 301-492-5081
Indirect Cost Rate Agreement Date	If you have a negotiated rate agreement, enter the agreement date. Agreement Effective 12/13/12
Total Indirect Costs	This field auto-calculates.

C. Total Direct and Indirect Costs (A+B) Funds Requested (\$)

The total funds requested for direct and indirect costs. This field is required.

Once you have entered all required information for budget period 1, press the **Next Period** button to enter information for the subsequent budget period.

5.4.2 Cumulative Budget Information**Cumulative Budget Information**

All values for the Cumulative Budget Information are calculated automatically. They equal the summations of the amounts that you have entered previously for each of the individual budget periods. Therefore, no data entry is allowed or required, in order to complete this "Cumulative Budget" section.

NOTE: The total costs that appear in Section C. Total Direct and Indirect Institutional Costs (G +H), should match Box 15 a. and 15 c. on page 2 of the SF424. 15 b and 15 d. should be \$0.00 unless there is program income or non-Federal Funds.

If any of the amounts displayed on this form appears to be incorrect, you may correct it by adjusting one or more of the values that contribute to that total. To make any such adjustments, you will need to revisit the appropriate budget period form(s), to enter corrected values.

Modular Budget Justifications

Field Name	Instructions
Personnel Justification	<p>List all personnel, including names, percent of effort and roles on the project. No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations contact your office of sponsored programs.</p> <p>NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. This limit should also be used when estimating the number of modules. See: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</p> <p>Save the information in a single file and click the add attachment button to complete this entry.</p>
Consortium Justification	<p>Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest \$1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic.</p> <p>While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the total consortium/contractual costs must be included in the overall requested modular direct cost amount.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
Additional Narrative Justification	<p>If the requested budget requires any additional justification; e.g, variations in the number of modules requested, save the information in a single file and click the add attachment button to complete this entry.</p>

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a form from your application, uncheck the box next to the form name in the Optional document section.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application
(for RESUBMISSION or REVISION only)

2. Specific Aims

3. *Research Strategy

4. Progress Report Publication List

Human Subjects Sections

5. Protection of Human Subjects

6. Inclusion of Women and Minorities

7. Inclusion of Children

Other Research Plan Sections

8. Vertebrate Animals

9. Select Agent Research

10. Multiple PD/PI Leadership Plan

11. Consortium/Contractual Arrangements

12. Letters of Support

13. Resource Sharing Plan(s)

Appendix (if applicable)

14. Appendix

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

Research Plan Attachments (See also [Section 2.3.2 Creating PDFs for Text Attachments](#))

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. In addition, be sure to save files with descriptive file names.

Note: Short file names with no special characters are best in order to avoid errors.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Full-sized glossy photographs of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.

Investigators must use image compression such as JPEG or PNG. Do not include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.

Separate Attachments

Separate attachments have been designed for the Research Plan sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the Research Plan sections will be concatenated in the appropriate order so that reviewers and agency staff will see a single cohesive Research Plan.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you **must** delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

Page Limits

Applicants must follow the page limits described in table 2.6.1 unless the FOA specifies otherwise.

All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede these instructions.

All applications and proposals for NIH funding must be self-contained within specified page limits. Agency validations will include many checks for page limits. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they may not address all page limit requirements for a specific FOA and do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may be delayed in the review process. Unless otherwise specified in an NIH solicitation, internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are not obligated to view the internet sites. Moreover, reviewers are cautioned that they should not directly access an website (except to review

publications cited in the Biographical Sketch or Progress Report publication list) as it could compromise their anonymity.

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, make sure you have checked “Yes” for the proprietary/privileged information question in the Other Project Information form.

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. However, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government’s right to use the information if it is obtained without restriction from another source.

Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see [45 CFR Part 5](#)). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc).

Field Name	Instructions
1. Introduction to Application (for Resubmission or Revision only)	<p>Use only if Type of Application is Resubmission or Revision. See specific instructions in Part I Section 2.7, Resubmission Applications and Part I Section 2.8, Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction.</p> <p>The Introduction is a required attachment for Resubmissions and Revisions. Follow the page limits for the Research Strategy in the table of page limits (Table 2.6-1), unless specified otherwise in the FOA.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
2. Specific Aims Limited to 1 page.	<p>State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p>

Field Name	Instructions
	<p>List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>The Specific Aims attachment is required unless otherwise specified in the FOA. Follow the page limits for the Research Strategy in the table of page limits (Table 2.6-1), unless specified otherwise in the FOA.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
<p>3. Research Strategy</p> <p>See FOA for page limits as they vary for different funding mechanisms.</p>	<p>Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9).</p> <p>Follow the page limits for the Research Strategy in the table of page limits (Table 2.6-1), unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.</p> <p>(a) <i>Significance</i></p> <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. <p>(b) <i>Innovation</i></p> <ul style="list-style-type: none"> • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. <p>(c) <i>Approach</i></p> <ul style="list-style-type: none"> • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless

Field Name	Instructions
	<p>addressed separately the Resource Sharing Plan, attachment include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</p> <ul style="list-style-type: none"> • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. • Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment, below. • If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time. <p>If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.</p> <p>As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.</p> <p>Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in application from Early Stage Investigators than on the preliminary data in applications from more established investigators).</p> <p>Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant</p>

Field Name	Instructions
	<p>budget reductions. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
4. Progress Report Publication List (Renewal Applications Only)	<p>List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.</p> <p>Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Part I Section 5.5.15 for more information).</p>

Human Subjects Sections

Field Name	Instructions
<p>5. Protection of Human Subjects</p> <p>NOTE: If you answered YES to Human Subjects on the Other Project Information page, you must attach a PDF for numbers 5, 6, and 7.</p>	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.</p> <p>Complete this section if you answered “yes” to the question “are human subjects involved?” on the R&R Other Project Information Form. If you answered “no” to the question but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section or your claim that no human subjects are involved. Follow the instructions provided in the Application Guide and the FOA regarding the Protection of Human Subject attachment.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
6. Inclusion of Women and Minorities	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Complete this section if you</p>

Field Name	Instructions
	<p>answered “yes” to the question “are human subjects involved?” on the R&R Other Project Information Form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
7. Inclusion of Children	<p>Refer to Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Sections 4.4 and 5.7 Complete this section if you answered “yes” to the question “are human subjects involved?” on the R&R Other Project Information Form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>

Other Research Plan Sections

Field Name	Instructions
<p>8. Vertebrate Animals</p> <p>NOTE: If you answered YES to Vertebrate Animals on the Other Project Information page, you must attach a PDF for number 8.</p>	<p>Complete this section if you answered “yes” to the question “are Vertebrate Animals Used?” on the R&R Other Project Information Form.</p> <p>If Vertebrate Animals are involved in the project, address each of the five points below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application’s impact/priority score may be negatively affected.</p> <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 below and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance, then an applicable Animal Welfare Assurance will be required (see Part III Section 2.2 Vertebrate Animals for more information).</p> <p>The five points are as follows:</p> <ol style="list-style-type: none"> 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species,

Field Name	Instructions
	<p>strains, ages, sex, and numbers of animals to be used in the proposed work.</p> <ol style="list-style-type: none"> Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. Provide information on the veterinary care of the animals involved. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. <p>For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf.</p> <p>Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
9. Select Agent Research	<p>Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See http://www.selectagents.gov/.</p> <p>If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The list of exclusions is available at http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html.</p> <p>If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific</p>

Field Name	Instructions
	<p>page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> 1. Identify the select agent(s) to be used in the proposed research. 2. Provide the registration status of all entities* where select agent(s) will be used. <ul style="list-style-type: none"> • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed. <p>*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”</p> 3. Provide a description of all facilities where the select agent(s) will be used. <ul style="list-style-type: none"> • Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s). • Describe the biocontainment resources available at all performance sites. <p>If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.</p> <p>Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.</p> <p>Save this file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
10. Multiple PD/PI Leadership Plan	<p>For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.</p> <p>If budget allocation is planned, the distribution of resources to specific parts of the project or the individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.</p>

Field Name	Instructions
	Save this file in a location you remember. Click Add Attachment , browse to where you saved the file, select the file, and then click Open .
11. Consortium/Contractual Arrangements	<p>Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&R) cover form signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p style="padding-left: 40px;">The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
12. Letters of Support (e.g., Consultants) Note: Remove all active hyperlinks from letters of support as these generate an error on the Commons.	<p>Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
13. Resource Sharing Plan(s)	<p>NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions Part III, 1.5 Sharing Research Resources.</p> <p>1. <i>Data Sharing Plan</i>: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why</p>

Field Name	Instructions
	<p>data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.</p> <p>2. <i>Sharing Model Organisms</i>: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.</p> <p>3. <i>Genome Wide Association Studies (GWAS)</i>: Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and http://gwas.nih.gov/.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
15. Appendix	<p>Only one copy of appendix material is necessary. Use the Add Attachments button to the right of this field to complete this entry.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details and check the FOA for any specific instructions), though not all grant activity codes allow publications to be included in the appendix.</p> <p>Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.</p> <p>Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the</p>

Field Name	Instructions
	<p>appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications may include the following materials in the Appendix (note, however, that some FOAs do not permit publications):</p> <ul style="list-style-type: none"> • Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications: <ul style="list-style-type: none"> ○ Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment. ○ Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment. ○ Patents directly relevant to the project: The entire document should be submitted as a PDF attachment. <p>(Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)</p> <ul style="list-style-type: none"> • Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary. • For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application. <p>Items that must not be included in the appendix:</p> <ul style="list-style-type: none"> • Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed. • Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a form from your application, uncheck the box next to the form name in the Optional document section.

5.6 (Reserved)

5.7 (Reserved)

5.8 Planned Enrollment Report and Cumulative Inclusion Enrollment Report

NOTE: These report formats should NOT be used for collecting data from study participants. To ensure proper performance, please save frequently.

Planned Enrollment Report

OMB Number: 0925-0002

This report format should NOT be used for collecting data from study participants.

Study Title:

IVAN'S Study

Domestic/Foreign:

Domestic

Comments:

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	25	25	0	0	50
White	15	15	10	10	50
More than One Race	0	0	0	0	0
Total	40	40	10	10	100

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Domestic/Foreign	Select whether the participants described in the planned enrollment report are domestic or foreign. At a minimum, domestic and foreign participants must be reported separately even if for the same study. This is a required field.
Comments	Enter information you wish to provide about this planned enrollment report. This includes but is not limited to addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset. Maximum 500 characters.
American Indian/Alaska Native	Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. These are required fields.
Asian	Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. These are required fields.
Black or African American	Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. These are required fields.
White	Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are White and Hispanic or Latino. These are required fields.

Field Name	Instructions
More than One Race	Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females and males who are Not Hispanic or Latino and all racial categories for females and males who are Hispanic or Latino. The total fields at the right are auto-calculated to total all males and females of both Not Hispanic or Latino and Hispanic or Latino ethnicity in each racial category.

Cumulative Inclusion Enrollment Report

OMB Number: 0925-0002

This report format should NOT be used for collecting data from study participants.

Study Title:

IVAN's Cumulative Study

Comments:

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	25	25	0	0	0	0	0	0	0	50
White	15	15	0	10	10	0	0	0	0	50
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	40	40	0	10	10	0	0	0	0	100

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. The title should be the same as submitted on the original Planned Enrollment form for this study. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Comments	Enter information you wish to provide about this Cumulative Inclusion Enrollment Report. This includes but is not limited to information if distinctive subpopulations are relevant to the scientific hypotheses being studied. Maximum 500 characters.
American Indian/Alaska Native	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and of unknown/not reported ethnicity. These are required fields.
Asian	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and of unknown/not reported ethnicity. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and of unknown/not reported ethnicity. These are required fields.

Black or African American	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and of unknown/not reported ethnicity. These are required fields.
White	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and of unknown/not reported ethnicity. These are required fields.
More than One Race	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and of unknown/not reported ethnicity. These are required fields.
Unknown or Not Reported	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino; all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino, and all racial categories for females, males, and individuals of unknown/not reported sex/gender who are of unknown/not reported ethnicity. The total fields at the right are auto-calculated to total all individuals in a given racial category.

6. Peer Review Process

Overview

NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects" ([42 CFR part 52h](#)).

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils composed of both scientific and lay members are chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council (or the IC in the case of fellowships) are considered for funding. Only the NIH Institute or Center may make funding decisions.

NIH has implemented Special Council Review procedures for the additional review of grant and cooperative agreement applications from Program Director(s)/Principal Investigator(s) [PD(s)/PI(s)] who already receive in excess of \$1 million per year in total costs to determine if additional funds should be provided to already well-supported investigators. It is important to note that the Special Council Review does not represent a cap on total NIH funding for any one investigator. For additional information, please see [NOT-OD-12-110](#) and [NOT-OD-12-140](#).

A detailed description of what happens to a research project grant application at NIH after it is received for peer review can be found at the following location:
http://grants.nih.gov/grants/peer_review_process.htm.

Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate Institute, Center, or Office. Information on CDC review procedures is located at http://www.cdc.gov/phpr/science/erp_policies.htm.

Streamlining

The initial scientific peer review of most applications will also include a process in which only those applications deemed by the reviewers to have the highest scientific and technical merit, generally the better half of the applications under review, will be discussed at the SRG meeting, assigned an impact score, and receive a second level review. Applications in the lower half are reviewed by SRG members but they are not discussed or assigned overall impact scores at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

Before the review meeting, each reviewer and discussant assigned to an application will give a separate score for each of (at least) five review criteria and a preliminary impact score for that application (see below). The preliminary impact scores help the SRG to determine which applications will be discussed.

Scoring

Each FOA specifies all of the review criteria and considerations that will be used in the evaluation of applications submitted for that FOA; RFAs and other types of funding opportunities (e.g., for construction or fellowship applications) may include different and/or additional review criteria and considerations. SRG members are instructed to evaluate research applications by addressing the scored review criteria (see below) and additional review criteria as applicable for the application.

For each application that is discussed, a final overall impact/priority score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the potential overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

As part of the initial merit review, and regardless of whether an application is discussed or not discussed (streamlined), all applicants will receive a written critique, called a Summary Statement. Unless stated otherwise in the FOA, the Summary Statement represents a combination of the reviewers' written comments and scores for individual criteria. The Summary Statement for discussed applications includes the Scientific Review Officer's summary of the members' discussion during the SRG meeting; the final impact score; the recommendations of the SRG, including budget recommendations; and administrative notes of special considerations. For applications that are not discussed by the full committee, the scores of the assigned reviewers and discussants for the five scored criteria will be reported individually on the Summary Statement. Final, numerical impact scores are not given for applications that are not discussed.

Research Project Evaluation Criteria

Overall Impact. Reviewers will provide an overall impact/priority 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 scored review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical 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? 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/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or 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? 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?

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 consider the following additional items in the determination of scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Appropriate Representation (for Conference Grant Applications): How well do the plans for inclusion of women, racial/ethnic minorities, persons with disabilities, and other individuals who traditionally have been underrepresented in science provide for their appropriate representation in the planning, organization, and execution of the proposed conference/scientific meeting? For more information, visit Inclusion of Women, Minorities and Persons with Disabilities in NIH-Supported Conference Grants

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 [Human Subjects Protection and Inclusion Guidelines](#).

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 see the [Human Subjects Protection and Inclusion Guidelines](#).

Vertebrate animals: The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

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.

Resubmission Applications: When reviewing a Resubmission application the committee will evaluate the application as now presented, taking into consideration the response to comments from the previous scientific review group and changes made to the project.

Renewal Applications: When reviewing a Renewal application, the committee will consider the progress made in the last funding period.

Revision Applications: When reviewing a Revision application, 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 address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Provision of Family Care Facilities (for Conference Grant Applications). Are the plans to inform attendees about family care resources adequate?

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 (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

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

Dual-Level Peer Review

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute/Center's mission, programs and priorities.

NIH has implemented Special Council Review procedures for the additional review of grant and cooperative agreement applications from Program Director(s)/Principal Investigator(s) [PD(s)/PI(s)] who already receive in excess of \$1 million per year in total costs to determine if additional funds should be provided to already well-supported investigators. It is important to note that the Special Council Review does not represent a cap on total NIH funding for any one investigator. For additional information, please see [NOT-OD-12-110](#) and [NOT-OD-12-140](#).