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

# Grants.gov Application Guide SF424 (R&R)

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A guide for preparing and submitting applications via  
Grants.gov

Version 2 (To be used with **PureEdge** application packages  
indicating Version 2 and Version 2a)

April 19, 2007

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## **PART I**

# **Instructions for Preparing and Submitting an Application**

# 1. Foreword

## Version 2 — Released July 5, 2006

Version 2 of this application guide includes changes to instructions necessitated by the recent upgrade of the SF424-R&R form set, from version 1.0 to version 2.0. Grants.gov recently performed this upgrade in order to make the SF424-R&R data items consistent wherever possible, with identical items that are also collected on the base SF424 forms (discretionary, mandatory, individual, and short). These changes include the addition of a few new fields, updates to the help text, and several modifications to the lists of values that are presented in drop-down lists.

Many of the Grants.gov changes affect all components with detailed address fields. Address changes include the addition of a separate field for Province, and a modification to all State fields to now include US Possessions, territories and Military Codes.

Other changes of note to specific components include:

### SF424 (R&R) Cover

5. Type of Applicant: An expanded list of values has been incorporated.
6. Employer Identification: The agency-specific instruction has been modified to instruct applicants to use the entire 12-digit EIN if one has been established.
14. Congressional District: Instructions have been modified to provide more specific details including a specific format; e.g., CA-012.
21. Additional Project Congressional Districts: This is a new data field and is an attachment option for those projects needing to provide more information than can be entered in Item 14.

### PHS398 Research Plan Component

Four sections have been added to the Research Plan: Inclusion Enrollment Report and Progress Report Publication List are now separate attachments. These were previously part of section 4. Preliminary Studies/Progress Report. They have been separated out to avoid being counted in the page limit validations. In addition, new distinct sections have been added for Select Agent Research and Multiple PI Leadership Plan. Some of the previous sections have been renumbered.

Another change to the Research Plan Component eliminates the separate section for Data and Safety Monitoring. This is now incorporated as a subtopic within section 8. Protection of Human Subjects.

### PHS398 Checklist Component

This component has been modified to remove the itemized list of policies, assurances, and certifications that appeared on the form. Instead, applicants are instructed to consult a specific website.

### General Text Edits

Throughout Version 2 text has also been edited to provide additional clarity and guidance.

- All references to the eRA Commons verification steps for the PD/PI and AOR have been changed to now reflect the 2-day period to view an application.
- Additional agency-specific instructions have been included in 4.7 R&R Budget Component for Person Months, Requested Salary, Consultants, Subawards/Consortium, Patient Care Costs, Joint University/VA Appointments, Budget Justification and Supplemental/Revision Applications.

- Instruction text throughout *Part II. Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan* has been revised to reflect the revised sections of the PHS398 Research Plan component.
- A number of text edits have been made to the instruction text of specific R&R data elements so that it reflects revised text used by Grants.gov in the actual forms.

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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*

This application guide is used as a companion document to a new set of application forms, the SF424 Research and Related (R&R). In addition to the SF424 (R&R) form components, applications to NIH and other PHS agencies will include agency-specific form components, titled “PHS398.” These PHS398 components were developed to continue the collection of agency-specific data required for a complete application. While these agency-specific components are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to NIH and other PHS agencies will include SF424 (R&R) components and PHS398 components. Instructions for all application components, SF424 (R&R) and PHS398, are found in this document.

The use of these new forms also involves electronic submission of completed applications through Grants.gov. NIH and other PHS agencies will gradually transition all mechanisms to the new application forms and Grants.gov submission. Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. 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 424 (R&R) forms, instructions, and electronic submission for a specific mechanism (i.e., R13, R15, etc.). This new process will apply to all types of submissions for the announced mechanism—new, resubmission (formerly “revised/amended”), renewal (formerly “competing continuation”), and revision (formerly “competing supplemental”) grant applications. Each FOA will include a link to the most current version of these instructions. Applicants are encouraged to check the Web site 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 form components as well as information on electronically submitting applications through Grants.gov.

**[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 Items 8 – 11 of the PHS 398 Research Plan component.

**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 [NIH Grants Policy Statement](#) sections for additional sources of information.

## 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 Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DEOIR. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by emailing your request to: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) or by calling (301) 435-0714.

## 1.3 Research Grant Mechanisms and Program Guidelines

A partial list of research grant mechanisms is provided below. As noted in the descriptions in [Part III: Policies, Assurances, Definitions, and Other Information](#), not all awarding components use all programs. For a complete listing of program guidelines, visit the OER Grants website [http://grants.nih.gov/grants/funding/funding\\_program.htm](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 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 \(NRSA\) \(F31, F32, F33, F34, etc.\)](#)
- [Research Career Development Award \(K Award\)](#)

## Applications Available from Other Offices

- [International Research Fellowship Award Application \(NIH 1541-1\)](#)
- [Nonresearch Training Grant Application \(PHS 6025\)](#)
- [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. Web site 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 Contact Table	
<b>NATIONAL INSTITUTES OF HEALTH</b>	
<a href="#">Fogarty International Center</a>	301-496-1653
<a href="#">National Cancer Institute</a>	301-496-3428
<a href="#">National Center for Complementary and Alternative Medicine</a>	301-496-4792
<a href="#">National Center on Minority Health and Health Disparities</a>	301-402-1366
<a href="#">National Center for Research Resources</a>	301-496-6023
<a href="#">National Eye Institute</a>	301-451-2020
<a href="#">National Heart, Lung, and Blood Institute</a>	301-435-0260
<a href="#">National Human Genome Research Institute</a>	301-496-7531
<a href="#">National Institute on Aging</a>	301-496-9322
<a href="#">National Institute on Alcohol Abuse and Alcoholism</a>	301-443-4375
<a href="#">National Institute of Allergy and Infectious Diseases</a>	301-496-7291
<a href="#">National Institute of Arthritis and Musculoskeletal and Skin Diseases</a>	301-594-2463
<a href="#">National Institute of Biomedical Imaging and Bioengineering</a>	301-451-4792
<a href="#">National Institute of Child Health and Human Development</a>	301-496-0104
<a href="#">National Institute on Deafness and Other Communication Disorders</a>	301-496-1804
<a href="#">National Institute of Dental and Craniofacial Research</a>	301-594-4800
<a href="#">National Institute of Diabetes and Digestive and Kidney Diseases</a>	301-594-8834
<a href="#">National Institute on Drug Abuse</a>	301-443-2755
<a href="#">National Institute of Environmental Health Sciences</a>	919-541-7723

<b>PHS Agency Contact Table</b>	
<a href="#">National Institute of General Medical Sciences</a>	301-594-4499
<a href="#">National Institute of Mental Health</a>	301-443-3367
<a href="#">National Institute of Neurological Disorders and Stroke</a>	301-496-9248
<a href="#">National Institute of Nursing Research</a>	301-594-6906
<a href="#">National Library of Medicine</a>	301-496-4621
<b><a href="#">CENTER FOR SCIENTIFIC REVIEW</a></b>	301-435-0715
<b>OTHER PHS AGENCIES WITHIN DHHS</b>	
<b><a href="#">AGENCY FOR HEALTHCARE RESEARCH AND QUALITY</a></b>	301-427-1457
<b><a href="#">CENTERS FOR DISEASE CONTROL AND PREVENTION</a></b>	
<a href="#">National Institute for Occupational Safety and Health</a>	404-498-2530
Procurement and Grants Office	770-488-2700
<b><a href="#">FOOD AND DRUG ADMINISTRATION</a></b>	301-827-7185
<b>OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH</b>	
<a href="#">Office of Adolescent Pregnancy Programs</a>	301-594-4004
<a href="#">Office of Family Planning</a>	301-594-4008
<a href="#">Agency for Toxic Substances and Disease Registry</a>	404-842-6630
<a href="#">Indian Health Service</a>	301-443-0578

### 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 mechanisms](#).
- **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 Administrators in the CSR to discuss requesting assignment to a SRG.

### After Submission

If the initial assignment to an IC or SRG seems inappropriate, the Project 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 outcome will constitute a conflict of interest in the review process. Reviewers are required to notify the Scientific Review Administrator 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.

### After Assignment

Contact your Scientific Review Administrator 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 study section, 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](http://grants.nih.gov/grants/useful_links.htm)

### Award Data

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

([CRISP](#), [extramural research grants](#), [award trends](#), [training and career awards](#))

### Contact Information for an NIH Staff Person

<http://directory.nih.gov>

NIH locator: (301) 496-4000

### eRA Commons

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

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

Email: [commons@od.nih.gov](mailto: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](http://grants.nih.gov/grants/grant_tips.htm)

### Grants Information

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

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)

Telephone: (301) 435-0714

### Grants.gov User Guide

The Grants.gov User Guide is a comprehensive reference to information about Grants.gov. Applicants can download the User Guide as a Microsoft Word document or as a PDF document. The user guide can be accessed at the following address: <http://www.grants.gov/Customersupport>.

### NIH Office of Extramural Research Human Subjects Website

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

This site provides, in one place, HHS 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://grants.nih.gov/grants/olaw/olaw.htm>

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 email the Scientific Review Administrator identified for the application in the eRA Commons.

## Specific Application: Post Review

Telephone or email 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 USC 241a and 42 USC 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.

## 1.8 Paperwork Burden

The PHS estimates that it will take approximately 40 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. Access the “Get Started” tab on the Grants.gov Web site (<http://grants.gov>). 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](http://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:

1. Register your organization at Grants.gov. (This is a one-time only registration process for all Federal agencies. 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 Project 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) using the [Grants.gov “Apply”](#) feature that reflects use of the SF424 (R&R) forms and electronic submission through Grants.gov. (See [Section 2.4](#) for more details.)
4. Download the associated Application Package from Grants.gov. (PureEdge Viewer required before download. See [Section 2.3](#) for more details.)
5. Complete the appropriate application components, including all text (PDF) and PureEdge attachments. Upload all attachments into the appropriate application component. (See [Section 2.6](#) for more details on the requirements for text (PDF) attachments.)
6. The completed application should be reviewed through your own organizational review process.
7. Coordinate with a Authorized Organizational Representative (AOR) at the applicant organization to submit the application by the date specified in the FOA. (**Keep a copy locally at the Applicant Organization/Institution.**)
8. Receive the Grants.gov tracking number.
9. After agency validation, receive the agency tracking number (accession number).
10. PD/PI and Signing Official (SO) complete a verification process in the eRA Commons. (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*. PDs/Pis do not have to individually register in Grants.gov unless they also serve as the Authorized Organizational 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 NIH eRA Commons registration steps noted below. For those applicant organizations still needing to register with Grants.gov, registration information can be found at Grants.gov/GetStarted (<http://www.grants.gov/GetStarted>). 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 several weeks to complete all the steps before actually submitting an application through Grants.gov.

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. Contact Center hours of operation are Monday–Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

## 2.2.2 eRA Commons Registration

The applicant organization and the PD/PI must also complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. An organization and PDs/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. Institutional/organizational officials are responsible for registering PDs/Pis in the eRA Commons. PDs/Pis 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 **two (2) 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 Profile Component will prevent the successful submission of an electronic application to NIH.

### 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 NIH eRA Commons” ([http://era.nih.gov/userreports/ipf\\_com\\_org\\_list.cfm](http://era.nih.gov/userreports/ipf_com_org_list.cfm)).

To register an Organization in the eRA Commons:

1. Open the eRA Commons homepage (<https://commons.era.nih.gov/commons/>).
2. Click Grantee Organization Registration (found in “About the Commons” links on the right side of the screen).
3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click Submit. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

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., 5555555555A5) 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 Component in Section 5, Applicant Information.** This information will be used to generate the electronic grant application image that the Signing Official and the PD/PI will be asked to verify within the eRA Commons. See [Section 2.11](#) for details on the Commons application verification process.

Since eRA has not required a DUNS number during eRA Commons registration, there are many accounts that do not contain valid information in this field. 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 NIH eRA Commons ([http://era.nih.gov/userreports/ipf\\_com\\_org\\_list.cfm](http://era.nih.gov/userreports/ipf_com_org_list.cfm)). 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 Project Director/Principal Investigator (PD/PI)**

The individual designated as the PD/PI on the application must also be registered in the Commons. The PD/PI must hold a PI account **and** be affiliated with the applicant organization. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register PDs/Pis in the Commons, refer to the NIH eRA Commons System Users Guide ([http://era.nih.gov/Docs/COM\\_UGV2630.pdf](http://era.nih.gov/Docs/COM_UGV2630.pdf)).

Once the PD/PI has received email 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), email, 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 both need to verify the application. If you are the SO for your organization as well as a 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.

It is important to note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

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

## **2.3 Software Requirements**

### **2.3.1 PureEdge**

In order to access, complete and submit applications, applicants need to download and install the [PureEdge Viewer](#). For minimum system requirements and download instructions, please see the [Grants.gov User Guide](#).

## 2.3.2 Creating PDFs for Text Attachments

NIH and other PHS agencies *require* all text attachments to the PureEdge forms to be submitted as Portable Document Format (PDF) files.

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Attachments generated from PureEdge forms, such as the R&R SubAward Budget Attachment Form, should *not* be converted to PDF.

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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 component in the application package. (The PDF format is used to preserve document formatting.)

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 PDF-creation software, Grants.gov has published the following list of available tools and software: <http://www.grants.gov/assets/PDFConversion.pdf>. Additionally, applicants may find Planet PDF's "Find PDF Software" feature ([http://www.planetpdf.com/find\\_software.asp](http://www.planetpdf.com/find_software.asp)) useful to browse or search a comprehensive database of free, shareware, or commercial PDF products. Applicants should choose the PDF-creation software that best suits their needs.

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.

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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.

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## 2.3.3 Special Instructions for Macintosh Users

Mac users can use any of the following options to view, complete and submit Grants.gov PureEdge-based applications:

- **IBM Workplace Forms (PureEdge) Viewer for Macintosh:** IBM has provided Special Edition Mac Viewers for PPC and Intel that are now available for download. See [http://www.grants.gov/resources/download\\_software.jsp](http://www.grants.gov/resources/download_software.jsp) for more information.
- **NIH-hosted Citrix® servers:** For non-Windows users, a free Citrix server is available to remotely launch a Windows session and submit completed grant applications. See [http://www.grants.gov/resources/download\\_software.jsp](http://www.grants.gov/resources/download_software.jsp) for more information.
- **Commercial Service Providers** offer a wide range of platform independent services - from low-cost, single transaction options through full scale, end-to-end grants management solutions.

You should coordinate with your institutions' grants office to explore these options further. See <http://era.nih.gov/ElectronicReceipt/sp.htm> for more information.

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If you have problems setting-up the software, you may not have security permissions to install new programs on your organization's computer system. If that is the case, contact your organization's system administrator.

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## 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 PDs/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 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 mechanisms, see [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) (<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 Grant and Cooperative Agreement 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](http://grants.nih.gov/grants/guide/parent_announcements.htm).

**Program Announcement (PA):** A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, 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.

**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) (<http://grants.nih.gov/grants/guide>), the [Federal Register](#)

(<http://www.gpoaccess.gov/nara/index.html>), and on Grants.gov under Find Grant Opportunities (<http://www.grants.gov/Find>). 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*, the *Federal Register*, [Grants.gov Find](http://www.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 “release/posted date” refers to the date the FOA is posted on [Grants.gov/Apply](http://www.grants.gov/Apply). 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 “opening date” to submit the application.
- An application can be submitted anytime between the “opening date” and the “application submission 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 prepopulated. 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 prepopulated date has no bearing on your application and you should not be concerned by it.

### 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 Grant Opportunities” (a.k.a. “Find”) and “Apply for Grants” (a.k.a. “Apply”). While all FOAs are posted in Grants.gov Find, not all reference electronic submission via Grants.gov at this time. 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 now 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 under the announcement number. This link is only provided in those announcements involving electronic submission through Grants.gov.

## Using “Find Grant Opportunities” (Find) Feature

Grants.gov Find provides general search capabilities. From the “Find Grant Opportunities” page, you may search by clicking on the “Search Grant Opportunities” link. This takes you to a screen providing options for: 1) Basic Search; 2) Browse by Category; 3) Browse by Agency; and 4) Advanced Search. To perform a **basic search** for a grant, complete the “Keyword Search”; the “Search by Funding Opportunity Number”; **OR** the “Search by CFDA Number” field; and then click the “Search” button below.

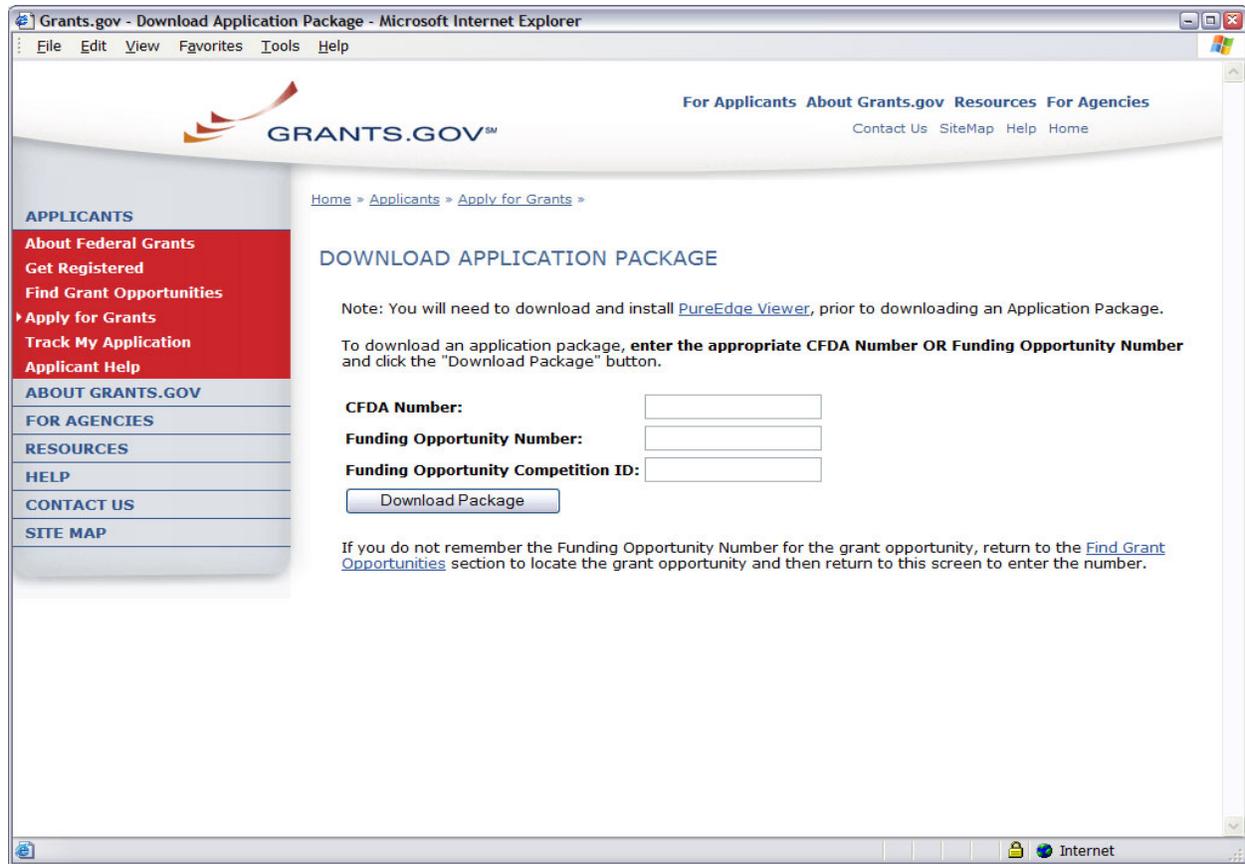
Note that NIH has made it easier for applicants by adding a button (“Apply for Grant Electronically”) to the *NIH Guide for Grants and Contracts* announcements that allows applicants to access the Grants.gov application package directly from the *NIH Guide*. See the preceding paragraph “Using the *NIH Guide for Grants and Contracts*” for more details.

Access Search Tips for helpful search strategies, or click the Help button in the upper right corner of Grants.gov to get help with the Search screen.

Once you find an opportunity for which you wish to apply, you may initiate the application download process immediately by selecting the “How to Apply” link that appears on the FOA synopsis page. Or you may elect to initiate the application download at a later time. In this case, you should record the Funding Opportunity number or CFDA number and enter it manually later on the [Download Application Packages](#) screen in the [Grants.gov/Apply](#) section of this site.

## 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 Find Grant Opportunities page.**



A Funding Opportunity Number is referenced in every announcement. It may be called a Program Announcement (PA) Number or a Request for Application (RFA) Number. Enter this number in the Funding Opportunity Number field and click “Download Package.” This takes you to a “Selected Grant Applications for Download” screen. If you searched only on a specific opportunity number, only one announcement is provided in the chart. Click the corresponding “download” link to access the actual application form pages and instruction material. The following screen appears:



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 Web site 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 components of 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: if multiple CFDA numbers are cited in the FOA, the Download Opportunity Instructions and Applications screen may prefill a CFDA number and description that may not correspond to the Institute/Center of interest to you; or the CFDA information may not appear at all. In either case, do not be concerned since the Center for Scientific Review, NIH does not use the CFDA number 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 Components of an Application to NIH or Other PHS Agencies

The SF424 (R&R) form set is comprised of a number of components, each listed in the table below as a separate “document.” In addition to these components, NIH and other PHS agencies applicants will also complete supplemental components listed as “PHS398” components in the table below.

**Table 2.5-1. Components of an NIH or Other PHS Agencies Application**

Document	Required	Optional	Instructions
SF424 (R&R) Cover	✓		<a href="#">Section 4.2</a>
SF424 (R&R) Project/Performance Site Locations	✓		<a href="#">Section 4.3</a>
SF424 (R&R) Other Project Information	✓		<a href="#">Section 4.4</a>
SF424 (R&R) Senior / Key Person Profile(s)	✓		<a href="#">Section 4.5</a>
SF424 (R&R) Budget (If NOT using PHS398 Modular Budget.)	*		<a href="#">Section 4.7</a>
SF424 (R&R) Subaward Budget Attachment Form		✓	<a href="#">Section 4.8</a>
PHS398 Cover Letter		✓	<a href="#">Section 5.2</a>
PHS398 Cover Page Supplement	✓		<a href="#">Section 5.3</a>
PHS398 Modular Budget (If NOT using SF424 (R&R) Budget)	*		<a href="#">Section 5.4</a>
PHS398 Research Plan	✓		<a href="#">Section 5.5</a>
PHS398 Checklist	✓		<a href="#">Section 5.6</a>

\* The application forms package associated with most NIH funding opportunities includes two optional budget components: (1) SF424 (R&R) Budget and (2) PHS398 Modular Budget. NIH application submissions must include either the SF424 (R&R) Budget Component or the PHS398 Modular Budget Component, but never both. (Note AHRQ does not accept modular budgets.) Unless other stated in a funding announcement, an application must always be submitted with a budget component. 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 component 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 components. 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).

## 2.6 Format Specifications for Text (PDF) Attachments

Designed to maximize system-conducted 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 concatenated into a single document that is used by peer reviewers and agency staff.

NIH and other PHS agencies require all text attachments be submitted as PDFs and 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://era.nih.gov/ElectronicReceipt/pdf\\_guidelines.htm](http://era.nih.gov/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.

### **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.

### **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.

### **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.

While each section of the Research Plan needs to eventually be uploaded separately, applicants are encouraged to construct the Research Plan as a single document, separating sections into distinct PDF attachments just before uploading the files. In this way the applicant can better monitor formatting requirements such as page limits. When validating for page limits, the eRA Commons will not count the white space created by breaking the text into separate files for uploading.

**Page Limits**

Although many of the sections of this application are separate text (PDF) or PureEdge attachments, page limitations referenced in these instructions and/or funding opportunity announcement must still be followed. Agency validations will include 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 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 and proposals for NIH and other PHS agency funding must be self-contained within specified page limitations. 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 limitations given in Table 2.6-1. Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) 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 (e.g., R03 and R21 applications). Consult and follow the additional instructions for those applications.**

**Table 2.6-1. Page Limitations and Content Requirements**

Section	Page Limit	Content
<a href="#">Introduction</a> - New applications - Resubmission applications - Revision applications	Not required/Not to be submitted 1-3 (check announcement for specific guidance) 1	See Instructions
<a href="#">Research Plan</a> Sections 2-5 Sections 6 - 17	25* * Some exclusions for renewal applications none	Text including all figures, charts, tables, and diagrams.
<a href="#">Biographical Sketches</a>	4	No more than four pages for each person listed as Senior/Key Persons.

Section	Page Limit	Content
<a href="#">Appendix</a>	none	<b>New requirements effective 1/3/2007.</b> See Instructions for specifics. Generally limited publications are allowed now only in certain situations. Only questionnaires and other materials are allowed.
<a href="#">PAs and RFAs</a>	Page limitations specified in the PA and RFA announcement in the <i>NIH Guide</i> take precedence.	See specific instructions in PAs and RFAs published in the <i>NIH Guide</i> .

## 2.7 “Resubmission” (Revised) Applications

NIH allows the submission of up to two revised applications (now known as “Resubmission” applications) and no longer restricts those submissions to a two-year timeframe. See [NIH Policy on Submission of a Revised \(amended\) Application](#) in Part III.

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

Before a resubmission application can be submitted, the Project Director/Principal Investigator (PD/PI) must have received the Summary Statement from the previous review.

Acceptance of a resubmission application automatically withdraws the prior version, since two versions of the same application cannot be pending simultaneously.

**Introduction to Resubmission Application.** The resubmission must include a brief Introduction (1-3 pages depending on the mechanism) that *summarizes* the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the Summary Statement. **Use Item 2.1, Introduction to Application, of the PHS 398 Research Plan component to provide this information.** Page limits for the Introduction vary for specialized mechanisms (e.g., R03 and R21 applications). Applicants **must** follow the page limits that are outlined in the specific announcement.

**Research Plan of Resubmission Application.** A resubmission application must include substantial changes. Identify the changes in each section of the Research Plan clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. **Do not underline or shade changes.** The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted.

Application processing may be delayed or the application may be returned if it does not comply with all of these requirements.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted needs to be, as it will be considered 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 three 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 Plan should produce a

significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Project Summary/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.

## 2.8 “Revision” (Competing Supplemental) Application

A competing supplemental application (now known as a “Revision” application) 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 **may 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 Item 2.1, Introduction to Application, of the PHS 398 Research Plan component to provide this information. Any budgetary changes for the remainder of the project period of the current grant should be discussed in section K, Budget Justification, of the Research & Related Budget component. 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.

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 “Revisions” (a.k.a. Supplements)

An administrative supplement provides additional funding to meet increased costs that are within the scope of your approved application, but that were unforeseen when the new or competing renewal (formerly “competing continuation”) application was submitted. If you are contemplating supplemental funding, you must consult in advance with your designated Grants Management Officer and Program Official. It is important for you to submit a request before your grant expires. To be considered for an administrative supplement, you must submit a request in writing to the IC (not to CSR), signed by the authorized Business Official, describing the need for additional funding and the categorical costs. In your letter, also be sure to point out what you will NOT be able to accomplish if such a request is denied. At this time, administrative revisions/supplements will not be submitted through Grants.gov.

## 2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.
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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 be returned to the applicant without review.

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; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

## 2.10 Submitting Your Application Via Grants.gov

The Applicant Organizational Representative (AOR) registered in Grants.gov is the only official with the authority to actually submit applications through Grants.gov. Therefore, PDs/PIs will need to work closely with their AOR 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 all required documents are properly completed and the application has been saved, the “Submit” button will become active. Click the “Submit” button to submit the application to Grants.gov. A confirmation page will appear asking for verification that this is the funding opportunity and Agency to which you want to submit an application. Applicants should review the provided application summary to confirm that the application will be submitted to the intended program. Click the “Yes” button if this information is correct and you are ready to submit the application. If not already connected to the Internet, applicants will be directed to do so. Log in to Grants.gov using the username and password that was established in the Register with Grants.gov process.

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.

For additional information, access Grants.gov/Submit Application Package (<http://grants.gov/SubmitApplication>).

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**Note, on-time submission of an application is currently a 2-step process: 1) accepted by Grants.gov on or before 5 p.m. Local Time (of the applicant organization) on the submission date; and 2) verified within two business days of the image being available in Commons. Note, the image is available only once all errors are corrected. For this initial transition period, NIH provides a one week window for correction of any validation errors after initial submission.**

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## 2.11 After You Submit Your Application Via Grants.gov

The Authorized Organizational Representative (AOR) can use Grants.gov to check the status of an application at any time. Note that Grants.gov requires a user login and password. To check the status of an application, go to <https://apply.grants.gov/ApplicantLoginGetID>.

Once an application has been submitted via Grants.gov, several emails are generated by Grants.gov and sent to the AOR (also known as the Signing Official [SO]) named in the grant application indicating a Grants.gov tracking number that is assigned to the submission:

- 1) Submission Receipt: An email is sent indicating your application has been received by Grants.gov and is currently being validated.

- 2) Submission Validation Receipt: An email 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 email is sent indicating your application has been retrieved by the Grantor agency.
- 4) Agency Tracking Number Assignment for Application: An email is sent indicating your application has been assigned an Agency Tracking Number.

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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  
Email: [support@grants.gov](mailto:support@grants.gov)

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At that point, the application will be scheduled for download into the eRA system for agency validation. It is imperative that the email address provided in blocks 15 for the PD/PI and 19 for the AOR/SO on the SF424 (R&R) Cover component be current and accurate. Once agency validation is completed, an agency notification (not Grants.gov) will be emailed to the PD/PI and AOR/SO named in the application.

This email notification will inform the PD/PI and AOR/SO 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 and AOR/SO 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.

If there were no validation errors, this email notification will also inform the PD/PI and AOR/SO 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. In subsequent interaction with the eRA Commons, however, it is the agency accession number that will be used to refer to the application, not the Grants.gov tracking number.

The eRA system will make every effort to send an email to the PD/PI and AOR/SO summarizing download and validation results. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the Commons.

Once an application package has been successfully submitted through Grants.gov, all errors are corrected and an application has been assembled by the eRA Commons, PDs/PIs and AORs/SOs will have two **weekdays (Monday – Friday, including holidays)** to view the application. If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two **weekdays**. (Note, the previous PI & SO Verification steps have been eliminated effective with submissions made on/after May 10, 2006.)

If, however, it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application.

The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken. Some warnings may need to be addressed later in the process.

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 **eApplications** from the Status list to the right of the search screen.
4. From the **eApplication Status** header, select the All or Pending Verification option from the dropdown list and click **Search** to get a hit list of applications.
5. When you find the appropriate application, select the **Application number** hypertext link from the Application ID column on the left-hand side.
6. Click e-Application from the Other Relevant Documents section to view the assembled application.

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

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**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. When you find the appropriate application, select the **Application number** hypertext link from the Application ID column on the left-hand side.
4. Click e-Application from the Other Relevant Documents section to view the assembled application.

## 2.12 Correcting Errors

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

If validation errors or warnings result from the validation process, the PD/PI and AOR/SO will be issued an email 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 email to the PD/PI and AOR/SO indicating whether errors or warnings were detected. However, since email can be unreliable, applicants are strongly encouraged to periodically check on their application status in the eRA Commons, so that any errors or warnings can be resolved in the timeliest manner possible.

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, but worthy of bringing to the applicant's attention. It is at the applicant's discretion, whether a warning condition requires any action.

Error conditions must be corrected, and then the application may be submitted as a changed/corrected application (as outlined below) in order for the application to be accepted. Please note that if validation has identified *warnings only*, then the PD/PI and SO will be allowed to view the application. Warnings do not

require any action or submission of a changed/corrected application at this time. However, please be aware that some warnings may need to be addressed later in the process or review stages. Failure to comply with stated NIH policies can also result in a submitted application being returned to the applicant without review. 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.

**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, access the eRA Commons (<https://commons.era.nih.gov/commons/>).
2. Click the **Status** tab on the Commons menu bar.
3. A hitlist of application numbers is displayed. If the application was validated with warnings only, or without encountering any problems whatsoever, then it is identified in the hitlist 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 hitlist, but in this case it is identified by its Grants.gov tracking number (e.g., “**GRANT12345678**”). This is the number that Grants.gov assigned to your application at the time of submission.

4. When you find the appropriate application in the hitlist, click its application link.
5. 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 accept 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. Most often this means that you have to edit **the data within** the application forms to correct whatever problem or inconsistency that was noted.
2. Check the “Changed/Corrected Application” box in block 1 of the SF424 (R&R) Cover component.
  - If submitting after the submission date, include an explanation in the Cover Letter Component.
  - When you check the Changed/Corrected Application box, Item 4. Federal Identifier becomes a required field.
  - When submitting a Changed/Corrected Application for a “New” Type of Application (Item 8 = New), in the Federal Identifier field (Item 4) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter “N/A.”
  - When submitting a Changed/Corrected Application for a “Resubmission,” “Renewal,” or “Revision” Type of Application (Item 8 = Resubmission, Renewal, or Revision), in the Federal Identifier field (Item 4) enter the previously assigned grant number (e.g., CA123456).
  - Do not use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8, Type of Application.
3. Have the AOR/SO submit the revised **application package** to Grants.gov again.

The same email notifications will be issued once the agency has downloaded and validated the re-submitted application and the PD/PI and AOR/SO 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 Submission of Supplementary or Corrective Information

Unless specifically required by these instructions (e.g., vertebrate animals verification), do not send supplementary or corrective material after the submission date unless the Scientific Review Administrator (SRA) of the Scientific Review Group solicits or agrees to accept this information. Such additional information will be sent directly to the SRA and will not be submitted through Grants.gov.

## 2.14 Application Submission Dates

For electronic submission through Grants.gov, each FOA posted in Grants.gov Apply includes an Opportunity Open Date and an Opportunity Close Date. Many announcements, including those using the “Standard Submission Dates” noted in Table 2.15-1 below, 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 Standard Submission Dates for Competing Applications noted in Table 2.15-1.

Applications submitted for the Standard Submission Dates listed in Table 2.15-1 are considered on time if they are submitted to Grants.gov on or before the appropriate date listed. When multiple submission dates are included in a specific FOA, applications submitted for Special Receipt Dates listed in a FOA are considered on time if they are submitted to Grants.gov on or before the appropriate date listed. When only a single submission date is referenced in the FOA, the Closing Date noted in Grants.gov Apply will be that submission date. In this case, applications are considered on time if they are submitted to Grants.gov on or before the Grants.gov posted Closing Date.

**Weekend/holiday Submission Dates.** If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a holiday, the submission date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

**Late Applications.** Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, use the optional PHS 398 Cover Letter component to explain the reasons for the delay and include this component with the completed application. 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. For additional information on late applications, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-086.html>.

## 2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided in Table 2.15-1. For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

Note, Table 2.15-1 references all funding mechanisms, regardless of which application is currently used. Some of the mechanisms listed continue to use applications other than the SF424 (R&R). Applicants should refer to the OER Electronic Submission of Grant Applications website:

<http://era.nih.gov/ElectronicReceipt/> for details on mechanisms that have transitioned to electronic submission using the SF424 (R&R) application.

**Table 2.15-1. Submission Dates, Review, and Award Cycles**

<b>New Schedule effective January 3, 2007</b>	<b>RECEIPT CYCLE I</b>	<b>RECEIPT CYCLE II</b>	<b>RECEIPT CYCLE III</b>
<b>Program Project Grants and Center Grants – all P Series***</b> <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb. 1)	May 25 (old date June 1)	September 25 (old date Oct. 1)
<b>Research Grants –R10, R18, R24, R25</b> <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb. 1, March 1)	May 25 (old date June 1, July 1)	September 25 (old date Oct. 1, Nov. 1)
<b>Research-Related and Other Programs – all S and G Series, C06, M01</b> <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb. 1)	May 25 (old date June 1)	September 25 (old date Oct. 1)
<b>Institutional Ruth L. Kirschstein National Research Service – T Series (Training)**</b> <i>new, renewal, resubmission, revision*</i>	January 25 (old date Jan. 10)	May 25 (old date May 10)	September 25 (old date Sept. 10)
<b>Research Grants –R01</b> <i>new</i>	February 5 (old date Feb. 1)	June 5 (old date June 1)	October 5 (old date Oct. 1)
<b>Research Career Development –all K Series</b> <i>new</i>	Feb. 12 (old date Feb. 1)	June 12 (old date June 1)	October 12 (old date Oct. 1)
<b>Research Grants –R03, R21, R33, R21/R33, R34, R36</b> <i>new</i>	February 16 (old date Feb. 1)	June 16 (old date June 1)	October 16 (old date Oct. 1)
<b>Academic Research Enhancement Award (AREA) – R15</b> <i>new, renewal, resubmission, revision*</i>	February 25 (no change)	June 25 (no change)	October 25 (no change)
<b>Research Grants –R01</b> <i>renewal, resubmission, revision*</i>	March 5 (old date March 1)	July 5 (old date July 1)	November 5 (old date Nov. 1)
<b>Research Career Development –all K Series</b> <i>renewal, resubmission, revision*</i>	March 12 (old date March 1)	July 12 (old date July 1)	November 12 (old date Nov. 1)
<b>Research Grants –R03, R21, R33, R21/R33, R34, R36</b> <i>renewal, resubmission, revision*</i>	March 16 (old date March 1)	July 16 (old date July 1)	November 16 (old date Nov. 1)

<b>New Schedule effective January 3, 2007</b>	<b>RECEIPT CYCLE I</b>	<b>RECEIPT CYCLE II</b>	<b>RECEIPT CYCLE III</b>
<b>New Investigator –R01</b> <i>resubmission* for those applications involved in pilot ONLY (<a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html</a>)</i>	March 20 (no change)	July 20 (no change)	November 20 (no change)
<b>Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants</b> – R41, R42, R43 and R44 <i>new, renewal, resubmission, revision*</i>	April 5 (old date April 1)	August 5 (old date Aug. 1)	December 5 (old date Dec. 1)
<b>Individual Ruth L. Kirschstein National Research Service Awards (Standard) – all F Series Fellowships****</b> <i>new, renewal, resubmission*</i>	April 8 (old date April 5)	August 8 (old date August 5)	December 8 (old date December 5)
<b>Conference Grants and Conference Cooperative Agreements – R13, U13</b> <i>new, renewal, resubmission, revision*</i>	April 12 (old date April 15)	August 12 (old date Aug. 15)	December 12 (old date Dec. 15)
<b>AIDS and AIDS-Related Grants</b> All of the mechanisms cited above <i>new, renewal, resubmission, revision*</i>	May 1 (no change)	September 1 (no change)	January 2 (no change)
<p>NOTE for all applications:</p> <ul style="list-style-type: none"> <li>• <b>RFAs and some PARs</b> have special receipt dates indicated in the specific NIH Guide Announcement.</li> <li>• <b>* Change in Terminology:</b> The move to electronic applications has brought a change in terminology. The new Grants.gov terminology (included in the table above) corresponds to the traditional NIH terms as follows: <ul style="list-style-type: none"> <li><b>New</b> = New</li> <li><b>Resubmission</b> = A Revised or Amended application</li> <li><b>Renewal</b> = Competing Continuation</li> <li><b>Continuation</b> = Noncompeting Progress Report</li> <li><b>Revision</b> = Competing Supplement</li> </ul> </li> <li>• <b>**Institutional Research Training Grants (T32)</b> are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates.</li> <li>• <b>***Program Project and Center Grants</b> – Applicants should check with individual ICs since some ICs do not accept P series applications three times a year.</li> <li>• <b>****Individual Pre-Doctoral Fellowships (F31)</b> for <a href="#">Minority Students</a> and <a href="#">Students with Disabilities</a> has special receipt dates.</li> <li>• All <b>AIDS and AIDS-related</b> applications (no matter the type) are submitted on the AIDS and AIDS-related dates.</li> </ul>			

Review and Award Cycles:	Cycle I	Cycle II	Cycle III
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Review	September - October	January - February	May - June
Earliest Project Start Date	December	April	July
Note: Awarding components may not always be able to honor the requested start date of an application; therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.			

### 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.

**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 398 Cover Letter component.

**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 **three (3)** weeks, the PD/PI and the applicant organization will be able to access in the eRA Commons the application’s assignment number; the name, address, and telephone number of the Scientific Review Administrator of the Scientific Review Group to which the application has been assigned; and the assigned Institute contact and phone number. Review outcome and other important information is also available in the Commons.

If assignment information is not available in the eRA Commons within **three** 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) 451-0088. If there is a change in assignment, you will receive a notification.

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 Administrator. This individual is in charge of the review group and is identified in the assignment notice that is mailed to you.

## 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 Helpdesk: [support@grants.gov](mailto:support@grants.gov)

Grants.gov Contact Center Phone Number: 1-800-518-4726

The Contact Center's hours of operation are Monday-Friday from 7:00 a.m. to 9:00 p.m. Eastern Time.

### 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 PDs/PIs or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at Electronic Submission of Grant Applications (<http://era.nih.gov/ElectronicReceipt/>).

**eRA Commons customer support is also provided by the eRA Commons Helpdesk:**

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

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

eRA Commons Helpdesk Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

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

The eRA Commons Helpdesk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time.

### 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  
301-451-0088 (TTY)

GrantsInfo Email: [GrantsInfo@nih.gov](mailto: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. Note when you “Save” the package locally for the first time, you will receive an error message indicating “One or more of the items in this form contains an invalid value. Do you want to proceed anyway?” Applicants should always answer “Yes.” This error message shows because no data has been entered yet. In fact, applicants will get this or a similar message every time the package is saved until all data entry is completed. Applicants can ignore this error message until the final save before the application is submitted. When an application is ready to be submitted, if this error message is still shown, applicants are encouraged to use the “Check Package for Errors” button to determine what needs to be corrected. When errors are found, a message box will appear indicating the total number of errors found and the details about the first one. Unfortunately there is no way to get a comprehensive list at this time. For instance, if five errors are found, the first one will need to be corrected, and then repeat the “check package for errors” process until all are corrected.

Note the “Check Package for Errors” button only checks errors in the actual PureEdge forms. It does not check the forms for data errors against NIH business processes. Those validations will be performed by the eRA Commons system after the application has been submitted.

#### 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

**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 Standard Postmark/Submission Dates for Competing Applications found in [Table 2.15-1. Submission Dates, Review, and Award Cycles](#). Applications submitted after a posted submission date will be held over into the next review cycle. See also [Section 2.14](#) above for 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:

### 3.3 Open and Complete Mandatory Documents

Open and complete all of the documents listed in the Mandatory Documents box. **Complete the component titled SF424 (R&R) first.** Data entered in this component populates other mandatory and optional forms where applicable.

Mandatory Documents		Mandatory Completed Documents for Submission
SF424 (R&R)	Move Form to Submission List	
PHS 398 Research Plan	=>	
PHS 398 Cover Page Supplement		
PHS 398 Checklist	Move Form to Documents List	
Research & Related Other Project Information	<=	
Research & Related Senior/Key Person		
<input type="button" value="Open Form"/>		<input type="button" value="Open Form"/>

To open an item:

1. Click the document name in the Mandatory Documents box.
2. Click **Open Form**.
3. When a form or document has been completed, click the document name to select it, and then click the => button. This moves the form/document to the Completed Documents box. To remove a document from the Completed Documents box, click the document name to select it, and then click the <= button. This returns the document to the Mandatory Documents or Optional Documents box.

### 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.

Optional Documents		Optional Completed Documents for Submission
Research & Related Budget	Move Form to Submission List	
PHS 398 Modular Budget	=>	
PHS 398 Cover Letter File		
R&R Subaward Budget Attachment Form	Move Form to Documents List	
	<=	
<input type="button" value="Open Form"/>		<input type="button" value="Open Form"/>

Once all documents have been completed and saved locally, click **Submit** to submit the application to Grants.gov. Only an AOR will be able to perform the submit action, and will be prompted to enter username and password to verify his/her identity. The Submit button does not become active until all

required documents have been properly completed and the application has been saved. If an edit has been made somewhere in the application package, the file must be resaved before attempting to submit. If the Submit button is grayed out, resave the file. Reminder, the system will not consider a component form document to be complete until it has been moved to the Completed Documents box. Once you click the Submit button, a confirmation page appears asking you to verify the desired funding opportunity and Agency to which the application is being submitted.

## 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 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 forms, required fields are highlighted in yellow and noted with an asterisk (\*). 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.

For those form components that are more than one page, click the “Next” button at the top of the form to navigate to a subsequent page. Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.



## 1. Type of Submission

Select Type of Submission. If this submission is to change or correct a previously submitted application, click Changed/Corrected Application box and enter the Grants.gov tracking number in the Federal Identifier field. **Unless requested by the agency, applicants may not use this to submit changes after the closing date. This field is required.**



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 because of corrections for system validation errors or if a portion of the application was lost or distorted during the submission process. This option is for correcting system validation errors only and may not be used to include last minute changes to any of the PDF attachments. When submitting a Changed/Corrected Application:

- If submitting after the submission date, include an explanation in the Cover Letter Component.
- When you check the Changed/Correct Application box, Item 4. Federal Identifier becomes a required field.
- When submitting a Changed/Corrected Application for a “New” Type of Application (Item 8 = New), in the Federal Identifier field (Item 4)) enter the Grants.gov tracking number for the previous application that you are correcting. If you are unable to recall the Grants.gov tracking number, enter “N/A.”
- When submitting a Changed/Corrected Application for a “Resubmission,” “Renewal,” or “Revision” Type of Application (Item 8 = Resubmission, Renewal, or Revision), in the Federal Identifier field (Item 4) enter the previously assigned grant number (e.g., **only** CA123456).
- Do **not** use the Changed/Corrected Application box to denote a submission of a revised or amended application. That will be indicated in item 8. Type of Application.

## 2. Date Submitted and Applicant Identifier

In the Date Submitted field, enter the date the application is submitted to the Federal agency (or state, if applicable). In the Applicant Identifier field, enter the applicant’s control number (if applicable).



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. Federal Identifier

New project applications should leave this field blank, unless you are submitting a Changed/Corrected application. When submitting a changed/corrected “new” application, enter the Grants.gov tracking number. 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, an example of **a grant number need only be** CA123456.

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 Mechanism](#).
- Resubmission is equivalent to NIH and other PHS agencies Revision; i.e., a revised or amended application. See also the [Revised NIH Policy on Submission of a Revised \(Amended\) Application](#).
- 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.
- Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement. 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 unless you are submitting a Changed/Corrected Application. In this case, where Item 1 = Changed/Corrected Application and Item 8 = New, the Federal Identifier field becomes a required field. Therefore you must enter the Grants.gov tracking number assigned to the application that you are correcting. If you are unable to recall the tracking number, enter “N/A.”

## 5. Applicant Information



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

Field Name	Instructions
Organizational DUNS <i>099114287000</i>	Enter your organization’s DUNS or DUNS+4 number.  For submission to NIH and other PHS agencies, this DUNS <b>must</b> 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 prior to submitting an application.
Legal Name <i>Oak Ridge National Laboratory/UT-Battelle, LLC</i>	Enter the legal name of the applicant which will undertake the assistance activity, enter the complete address of the applicant (including county and country), and name, telephone number, e-mail, and fax of the person to contact on matters related to this application.
Department <i>N/A</i>	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization that will undertake the assistance activity.
Division <i>N/A</i>	Enter the name of the primary organizational division, office, or major subdivision that will undertake the assistance activity.
Street1	Enter the first line of the street address for the applicant in “Street1”

Field Name	Instructions
<i>P. O. Box 2008</i>	field.
Street2 <i>One Bethel Valley Road</i>	Enter the second line of the street address for the applicant in “Street2” field. This field is optional.
City <i>Oak Ridge</i>	Enter the city for address of applicant.
County <i>Anderson</i>	Enter the county for address of applicant.
State <i>TN</i>	Select the state where the applicant is located. This field is required if the applicant is located in the United States.
Province	Enter the province where the applicant is located.
Country <i>USA</i>	Select the country for the applicant address.
ZIP Code <i>37831</i>	Enter the 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.

Field Name	Instructions
Prefix <i>Dr.</i>	Enter the prefix (e.g., Mr., Mrs., Rev.) for the person to contact on matters related to this application.   See also the <a href="#">PHS398 Cover Page Supplement</a> for additional required contact information.
First Name <i>Kristina</i>	Enter the first (given) name of the person to contact on matters relating to this application.
Middle Name <i>D.</i>	Enter the middle name of the person to contact on matters relating to this application.
Last Name <i>Thiagarajan</i>	Enter the last (family) name of the person to contact on matters relating to this application.
Suffix <i>PhD</i>	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the person to contact on matters relating to this application.
Phone Number <i>865-241-5214</i>	Enter the daytime phone number for the person to contact on matters relating to this application.
Fax Number	Enter the fax number for the person to contact on matters relating to this

Field Name	Instructions
	application.
Email <i>thiagarajakd@ornl.gov</i>	Enter the email address for the person to contact on matters relating to this application.  This is a required field for applications submitted to NIH and other PHS agencies.

**6. Employer Identification**

**ORNL's EIN: 62-1788235**

Enter the TIN or EIN as assigned by the Internal Revenue Service. If your organization is not in the US, type 44-4444444.



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

**7. Type of Applicant**



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

Field Name	Instructions
Type of Applicant	Select from the menu or enter the appropriate letter in the space provided. If Small Business is selected as Type of Applicant, then note if the organization is Woman-owned and/or Socially and Economically Disadvantaged.  For eligible Agencies of the Federal Government, select X: Other ( <i>specify</i> ), and then indicate the name of the appropriate Federal agency in the space below.
Other (Specify) <i>DOE National Laboratory</i>	Complete only if X: Other was selected as the Type of Applicant.
Woman Owned	Check the box 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 the box if you are a socially and economically disadvantaged small business, as determined by the US 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:</p> <ul style="list-style-type: none"> <li>• <b>New:</b> An application that is being submitted to an agency for the first time.</li> <li>• <b>Resubmission:</b> An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration.</li> <li>• <b>Renewal:</b> 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.</li> <li>• <b>Continuation:</b> A non-competing application for an additional funding/budget period within a previously approved project period.</li> <li>• <b>Revision:</b> An application that proposes a change in             <ol style="list-style-type: none"> <li>1) the Federal Government’s financial obligations or contingent liability from an existing obligation, or</li> <li>2) any other change in the terms and conditions of the existing award.</li> </ol> </li> </ul> <p> Existing definitions for NIH and other PHS agencies Type of Application are somewhat different:</p> <ul style="list-style-type: none"> <li>• New is the same. Check this option when submitting an application for the first time. See also the policy <a href="#">Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism</a>.</li> <li>• Resubmission is equivalent to NIH and other PHS agencies Revision. Check this option when submitting a revised or amended application. See also the <a href="#">Revised NIH Policy on Submission of a Revised (Amended) Application</a>.</li> <li>• Renewal is equivalent to NIH and other PHS agencies Competing Continuation.</li> <li>• 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 <b>not</b> be used and should <b>not</b> be checked.</li> <li>• 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</li> </ul>

Field Name	Instructions
	<p>contact the awarding agency for advice on submitting any revision/supplement application.</p> <p>This field also affects how you complete Item 4. Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected “New” application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT12345678). If you are unable to find the tracking number, enter “N/A”.</p> <p>If “Type of Application” is “Renewal”, “Revision” or “Resubmission”, enter the IC and serial number of the prior application/award number (e.g. CA123456). For these types of applications, do not change the Federal Identifier field when submitting Changed/Corrected applications.</p>
<p>If Revision, Enter Appropriate Letter(s) in Box(es)</p>	<p>If application is a revision, check the appropriate box(es):</p> <ul style="list-style-type: none"> <li>A. Increase Award</li> <li>B. Decrease Award</li> <li>C. Increase Duration</li> <li>D. Decrease Duration</li> <li>E. Other</li> </ul> <p>May select more than one.</p>
<p>Other (Specify)</p>	<p>If <i>E. Other</i> was selected as the Revision, enter text to explain.</p>
<p>Is this application being submitted to other agencies?</p>	<p>Check the box, if applicable.</p>
<p>What Other Agencies?</p>	<p>Enter Agency name.</p>

**9. Name of Federal Agency**

Name the Federal agency from which assistance is being requested with this application. This information is pre-populated by [Grants.gov](https://www.grants.gov).

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

Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested. This information is pre-populated by [Grants.gov](https://www.grants.gov).



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.



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.

### 12. Areas Affected by Project (Cities, Counties, States, Etc.)

List only the largest political entities affected by the project (for example, state, counties, cities).



Enter “N/A” for not applicable.

### 13. Start Date and Ending Date

Enter the proposed start date of the project in the Start Date field. Enter the proposed end date in the Ending Date field. Use the following format: MM/DD/YYYY.

### 14. Congressional District Applicant and Congressional District Project

**Congressional District – 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. *ORNL congressional district: TN:003*

If outside the U.S., enter 00-0000.

To locate your congressional district, visit the Grants.gov web site.

**Congressional District – Project:** 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 00-0000.

To locate your congressional district, visit the Grants.gov web site.

Attach an additional list of Project Congressional Districts on page 2 (Item 21), if needed.

### 15. Project Director/Principal Investigator (PD/PI) Contact Information

If submitting an application reflecting Multiple PDs/Pis, the individual designated as the Contact PI should be entered here. See [Section 4.5 Senior/Key Person Profile Components](#) for additional instructions for Multiple PDs/Pis.

Field Name	Instructions
Prefix	Enter the prefix (Mr., Mrs., Rev.) for the name of the PD/PI.  See also the <a href="#">PHS398 Cover Page Supplement</a> for additional PD/PI required data.

Field Name	Instructions
First Name	Enter the first (given) name of the PD/PI.
Middle Name	Enter the middle name of the PD/PI.
Last Name	Enter the last (family) name of the PD/PI.
Suffix	Enter the suffix (e.g., Jr., Sr., Ph.D.,) for the name of the PD/PI.  Do not use this field to record degrees. Degrees for the PD/PI are requested separately in the PHS398 Cover Page Supplement.
Position/Title	Enter the title of the PD/PI.
Organization Name <i>Oak Ridge National Laboratory, LLC</i>	Enter the name of the organization for the PD/PI.
Department	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Division	Enter the name of the primary organizational division, office, or major subdivision of the PD/PI.
Street1 <i>P. O. Box 2008 MS-(PI's)</i>	Enter the first line of the street address for the PD/PI. This field is required.
Street2	Enter the second line of the street address for the PD/PI, if applicable.
City <i>Oak Ridge</i>	Enter the city for the address of the PD/PI. This field is required.
County <i>Anderson</i>	Enter the county for the address of the PD/PI.
State <i>TN</i>	Select the state where the PD/PI is located in the United States.
Province	Enter the province for PD/PI.
Country <i>USA</i>	Select the country for the PD/PI address.
ZIP Code <i>37831</i>	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.
Phone Number	Enter the daytime telephone number for the PD/PI. This field is required.
Fax Number	Enter the fax number for the PD/PI.
Email	Enter the email address for the PD/PI. This field is required.

**SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE**

<p><b>16. ESTIMATED PROJECT FUNDING</b></p> <p>a. * Total Estimated Project Funding <input style="width: 100%;" type="text"/></p> <p>b. * Total Federal &amp; Non-Federal Funds <input style="width: 100%;" type="text"/></p> <p>c. * Estimated Program Income <input style="width: 100%;" type="text"/></p>	<p><b>17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b></p> <p>a. YES <input type="radio"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: _____</p> <p>b. NO <input type="radio"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR <input type="radio"/> PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</p>
<p><b>18. 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)</b></p> <p style="text-align: center;"><input type="checkbox"/> * I agree</p> <p style="text-align: center; font-size: small;">* 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.</p>	
<p><b>19. Authorized Representative</b></p> <p>Prefix: <input style="width: 50px;" type="text"/> * First Name: <input style="width: 200px;" type="text"/> Middle Name: <input style="width: 150px;" type="text"/> * Last Name: <input style="width: 150px;" type="text"/> Suffix: <input style="width: 50px;" type="text"/></p> <p>* Position/Title: <input style="width: 200px;" type="text"/> * Organization: <input style="width: 350px;" type="text"/></p> <p>Department: <input style="width: 200px;" type="text"/> Division: <input style="width: 200px;" type="text"/></p> <p>* Street1: <input style="width: 200px;" type="text"/> Street2: <input style="width: 200px;" type="text"/></p> <p>* City: <input style="width: 100px;" type="text"/> County: <input style="width: 150px;" type="text"/> * State: <input style="width: 50px;" type="text"/></p> <p>Province: <input style="width: 100px;" type="text"/> * Country: <input style="width: 50px;" type="text"/> * ZIP / Postal Code: <input style="width: 100px;" type="text"/></p> <p>* Phone Number: <input style="width: 100px;" type="text"/> Fax Number: <input style="width: 100px;" type="text"/> * Email: <input style="width: 200px;" type="text"/></p> <p style="text-align: center;"><b>* Signature of Authorized Representative</b> <span style="float: right;"><b>* Date Signed</b></span></p> <p style="text-align: center;">_____ Completed on submission to Grants.gov <span style="float: right;">Completed on submission to Grants.gov</span></p>	
<p><b>20. Pre-application</b> <input style="width: 300px;" type="text"/> <span style="float: right;"> <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/> </span></p>	
<p><b>21. Attach an additional list of Project Congressional Districts if needed.</b></p> <p style="text-align: right;"><input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/></p>	

OMB Number: 4040-0001  
Expiration Date: 04/30/2008

### 16. Estimated Project Funding

Field Name	Instructions
Total Estimated Project Funding	Enter the total Federal funds requested for the entire project period.
Total Federal & Non-Federal Funds	Enter the total estimated funds for the entire project period, including both Federal and non-Federal funds.   For NIH and other PHS agencies applicants, this field will be the same as item 16a unless the specific announcement indicates that cost sharing is a requirement.
Estimated Program Income	Identify any Program Income estimated for this project period, if applicable.

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

If yes, check the “Yes” box. If the announcement indicates that the program is covered under Executive Order 12372, you should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check the appropriate box. This field is required.

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

### 18. Complete Certification

Check the “I agree” box 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 [Part III, Policies, Assurances, Definitions, and Other Information](#).

### 19. Authorized Representative

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

Field Name	Instructions
Prefix <i>Dr.</i>	Enter the prefix (Mr., Mrs., Rev.) for the name of the Authorized Representative.
First Name <i>Reinhold</i>	Enter the first (given) name of the Authorized Representative.
Middle Name <i>C.</i>	Enter the middle name of the Authorized Representative.
Last Name <i>Mann</i>	Enter the last (family) name of the Authorized Representative.
Suffix <i>PhD</i>	Enter the suffix (e.g., Jr., Sr., Ph.D.) for the name of the Authorized Representative.
Position/Title <i>Associate Laboratory Director</i>	Enter the title of the Authorized Representative.

Field Name	Instructions
Organization <i>Oak Ridge National Laboratory/UT-Battelle, LLC</i>	Enter the name of the organization for the Authorized Representative.
Department <i>B&amp;ES Directorate</i>	Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization of the Authorized Representative.
Division <i>N/A</i>	Enter the name of the primary organizational division, office, or major subdivision of the Authorized Representative.
Street1 <i>P. O. Box 2008, MS-6253</i>	Enter the first line of the street address for the Authorized Representative. This field is required.
Street2 <i>One Bethel Valley Road</i>	Enter the second line of the street address for the Authorized Representative, if applicable.
City <i>Oak Ridge</i>	Enter the city for the address of the Authorized Representative. This field is required.
County <i>Anderson</i>	Enter the county for the address of the Authorized Representative.
State <i>TN</i>	Select 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.
Country <i>USA</i>	Select the country for the Authorized Representative address.
ZIP Code <i>37831-6253</i>	Enter the postal code (e.g., ZIP code) of the Authorized Representative. This field is required if the Authorized Representative is located in the United States.
Phone Number <i>865-574-4333</i>	Enter the daytime telephone number for the Authorized Representative. This field is required.
Fax Number <i>865-574-9869</i>	Enter the fax number for the Authorized Representative.
Email <i>mannrc@ornl.gov</i>	Enter the email address for the Authorized Representative. This field is 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

Field Name	Instructions
	Grants.gov, leave this field blank. If a hard copy is submitted, the AOR must sign here.
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 you are 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. Additional Project Congressional Districts

If additional Congressional Districts are affected, attach a file using the appropriate buttons.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 4.3 Project/Performance Site Locations Component

**RESEARCH & RELATED Project/Performance Site Location(s)**

**Project/Performance Site Primary Location**

Organization Name:

\* Street1:  Street2:

\* City:  County:  \* State:

Province:  \* Country:  \* ZIP / Postal Code:

---

**Project/Performance Site Location 1**

Organization Name:

\* Street1:  Street2:

\* City:  County:  \* State:

Province:  \* Country:  \* ZIP / Postal Code:

---

**Additional Location(s)**

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Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided. If more than eight project/performance site locations are proposed, provide the information in a separate file, and then attach.



**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. If there is more than one performance site, list all additional sites in the fields provided for Location 1 - # below.

Field Name	Instructions
Organization Name	Indicate the primary site where the work will be performed.
Street1	Enter first line of the street address of the primary performance site location. This field is required.
Street2	Enter second line of the street address of the primary performance site location, if applicable.
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.
State	Select the state of the primary performance site location. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province of the primary performance site location.
Country	Select the country of the primary performance site location. This field is required.
ZIP Code	Enter the 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 Location 1**

Field Name	Instructions
Organization Name	Enter the name of organization of the performance site location.
Street1	Enter first line of the street address of the performance site location. This field is required.
Street2	Enter second line of the street address of the performance site location, if applicable.
City	Enter the city of the performance site location. This field is required.

Field Name	Instructions
County	Enter the county of the performance site location.
State	Select the state where the performance site is located. This field is not active until USA has been selected for the country. This field is required if the performance site location is in the United States.
Province	Enter the province of the performance site location.
Country	Select the country for the performance site location. This field is required.
ZIP Code	Enter the 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.

For additional performance site locations, click Next Site to display the fields for Project/Performance Site Locations 3 through 8.

If you need to add more than eight locations, enter the information in a separate file. On the form, click Add Attachment, select the file, and then click Open. A sample Additional Performance Sites format page for greater than 8 locations is found under “Additional Format Pages” at:

<http://grants.nih.gov/grants/funding/424/index.htm>.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 4.4 Other Project Information Component

**RESEARCH & RELATED Other Project Information**

1. \* Are Human Subjects Involved?  Yes  No

1.a. If YES to Human Subjects

Is the IRB review Pending?  Yes  No

IRB Approval Date:

Exemption Number:  1  2  3  4  5  6

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 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.a. \* Does this project involve activities outside the U.S. or partnership with International Collaborators?  Yes  No

5.b. If yes, identify countries:

5.c. Optional Explanation:

6. \* Project Summary/Abstract

7. \* Project Narrative

8. Bibliography & References Cited

9. Facilities & Other Resources

10. Equipment

11. Other Attachments

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### 1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check the Yes box. Check Yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If no activities involving human subjects are planned, check the No box, and skip the rest of block 1. This field is required.



Refer to [Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#).

#### 1.a. Is the IRB review Pending?

If the Institutional Review Board (IRB) review is pending, check the Yes box. Otherwise, check the No box. In the IRB Approval Date field, enter the latest IRB approval date, if available. Leave blank if Pending.



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.

For Exemption Number, 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.htm>.

For Human Subject Assurance Number, enter the approved Federal Wide Assurance (FWA) Number that the applicant has on file with the Office for Human Research Protections, if available. Enter only the 8-digit number; do not enter the “FWA” before the number.



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 item 19 on the SF424 (R&R) Cover component, is declaring that it will comply with 45CFR 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 the Yes box. Otherwise, check the No box, and skip the rest of block 2. This field is required.



Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

### 2.a. If YES to Vertebrate Animals

For the “Is the IACUC review Pending” field, if an Institutional Animal Care and Use Committee (IACUC) review is pending, check the Yes box. Otherwise check the No box. For IACUC Approval Date, enter the IACUC approval date, if available. Leave blank if Pending.

For Animal Welfare Assurance Number, enter the Federally approved assurance number, if available. (To determine if your organization holds an Animal Welfare Assurance, see <http://grants.nih.gov/grants/olaw/olaw.htm#assur>.)



Applicants should check “Yes” to the question “Is the IACUC review Pending?” even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle as a Just-In-Time requirement. If the applicant organization does not have an approved Animal Welfare Assurance on file with the [Office of Laboratory Animal Welfare \(OLAW\), NIH](#), enter : “None” in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting “None” at the time of submission, the applicant organization is essentially declaring that it will comply with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW.

## 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 the “Yes” box 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.”

#### 4. Environmental Questions



Unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies, applicants should check “No.”

##### 4.a. Does this project have an actual or potential impact on the environment?

If your project will have an actual or potential impact on the environment, check the Yes box, and then explain in the box provided in 4.b. Otherwise, check the No box.

##### 4.b. If yes, please explain

If you checked the Yes box indicating an actual or potential impact on the environment, enter the explanation of the actual or potential impact on the environment here.

##### 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 an Environmental Impact Statement (EIS) been performed?

If an exemption has been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed, check the Yes box, and then explain in the box provided in 4.d. Otherwise, check the No box.

##### 4.d. If yes, please explain

If you checked the Yes box indicating an exemption has been authorized or an EA or EIS has been performed, enter the explanation here. If desired, you can provide the information in a separate file, and attach by clicking Add Attachments located to the right of Step 11 - Other Attachments.

#### 5. Activities Outside US or with International Collaborators Questions

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

If your project involves activities outside the United States or partnerships with international collaborators, check the Yes box, and then explain in the box provided in 5.b. Otherwise, check the No box.



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 [substantial foreign component](#), see “Definitions” section of Part III: Policies, Assurances, Definitions, and Other Information.

##### 5.b. If yes, identify countries

If you checked the Yes box indicating your project involves activities outside the US, enter the countries with which international cooperative activities are involved.

##### 5.c. Optional Explanation

Use this block to provide any supplemental information, if necessary. If desired, you can provide the information in a separate file, and attach by clicking “Add Attachments” located to the right of Item 11, Other Attachments.



If you have checked “Yes” to 5.a, 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 as Item 11, Other Attachments. 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.

## 6. 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.

To attach a project summary/abstract file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.



The first and major component of the Project Summary/Abstract (i. e., “Description”) is a **Project Summary**. It 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.

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

## 7. Project Narrative



**For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary.** The second component of the Project Summary/Abstract (i.e., “Description”) is **Relevance**. 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 component is required for NIH and other PHS agencies applications. Refer to [Section 5.5, Research Plan Component](#), for separate file uploads and instructions.

## 8. 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. 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 bibliography, click “Add Attachment,” browse to where you saved the file, select the file, and then click “Open.”



**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 component(see [Section 5.5](#) for details on completing that component). The reference 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. **For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material.**

## 9. 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.

To attach a facilities and other resources file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.



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. If there are multiple performance sites, then resources available at each site should be described. 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 employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described.

## 10. Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. To attach an equipment file, click Add Attachment, browse to where you saved the file, select the file, and then click Open.

## 11. Other Attachments

Attach a file to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction by clicking Add Attachment, browsing to where you saved the file, selecting the file, and then clicking Open.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 4.5 Senior/Key Person Profile(s) Component(s)

Two components are now available to collect information on Senior/Key persons. The original component continues to be called “Research & Related Senior/Key Person.” The new component is titled: “Research & Related Senior/Key Person Expanded.” Application packages will include one or the other, but never both. Eventually, only the expanded version will be used in application packages. Until that transition is complete, instructions are provided in this section for both components.

### Multiple PDs/PIs

NIH is now accepting applications reflecting Multiple PDs/PIs for all grant mechanisms using the SF424 (R&R) application. When submitting an application involving Multiple PDs/PIs, the Contact PI should be listed as the PD/PI in the SF424 R&R Cover Component (see [Section 4.2.15](#)). That information automatically prepopulates the first Senior/Key Person Profile record in this component. For the additional

PDs/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-PI” role.)

**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 PDs/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 PDs/PIs, see: [http://grants.nih.gov/grants/multi\\_pi/index.htm](http://grants.nih.gov/grants/multi_pi/index.htm).

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

### 4.5.1 Senior/Key Person Profile Component

**RESEARCH & RELATED Senior/Key Person Profile**

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PROFILE - Project Director/Principal Investigator

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

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Credential, e.g., agency login: <input type="text"/>				
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* Project Role:	<input type="text"/>	PD/PI	Other Project Role Category:	<input type="text"/>
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*Attach Biographical Sketch	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Attach Current & Pending Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

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PROFILE - Senior/Key Person 1

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

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Credential, e.g., agency login: <input type="text"/>				
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* Project Role:	<input type="text"/>	Other Project Role Category:	<input type="text"/>
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*Attach Biographical Sketch	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Attach Current & Pending Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

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ADDITIONAL SENIOR/KEY PERSON PROFILE(S)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Biographical Sketch(es) (Senior/Key Person)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Current and Pending Support(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

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Part I: Instructions for Preparing and Submitting an Application

Version 2 - I-56

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, measurable 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.

**Profile – Project Director/Principal Investigator (PD/PI)**

Field Name	Instructions
Prefix	This field is automatically populated from the SF424 (R&R). It is the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	This field is automatically populated from the SF424 (R&R). It is the first (given) name of the PD/PI. This field is required.
Middle Name	This field is automatically populated from the SF424 (R&R). It is the middle name of the PD/PI.
Last Name	This field is automatically populated from the SF424 (R&R). It is the last (family) name of the PD/PI. This field is required.
Suffix	This field is automatically populated from the SF424 (R&R). It is the suffix (e.g., Jr., Sr., PhD) for the name of the PD/PI.
Position/Title	This field is automatically populated from the SF424 (R&R). It is the title of the PD/PI.
Department	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	This field is automatically populated from the SF424 (R&R). It is the name of the organization of the PD/PI.
Division	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	This field is automatically populated from the SF424 (R&R). It is the first line of the street address of the PD/PI.
Street2	This field is automatically populated from the SF424 (R&R). It is the second line of the street address of the PD/PI, if applicable.
City	This field is automatically populated from the SF424 (R&R). It is the city for the address of the PD/PI.
County	This field is automatically populated from the SF424 (R&R). It is the county for the address of the PD/PI.

Field Name	Instructions
State	This field is automatically populated from the SF424 (R&R). It is the state where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	This field is automatically populated from the SF424 (R&R). It is the province where the PD/PI is located.
Country	This field is automatically populated from the SF424 (R&R). It is the country for the PD/PI address.
ZIP Code	This field is automatically populated from the SF424 (R&R). It is 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.
Phone Number	This field is automatically populated from the SF424 (R&R). It is the daytime phone number for the PD/PI.
Fax Number	This field is automatically populated from the SF424 (R&R). It is the fax number for the PD/PI.
Email	This field is automatically populated from the SF424 (R&R). It is the email address for the PD/PI.
Credential, e.g., agency login	<p>If you are submitting to an agency (e.g., NIH and other PHS agencies) 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 PDs/Pis is required. <b>The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.</b></p>
Project Role	Select a project role from the list. Select “Other” if an appropriate project role is not listed.
Other Project Role Category	Complete if you selected “Other Professional” or “Other” as a project role. For example, Engineer, Chemist.
Attach Biographical Sketch	<p>Provide a biographical sketch for the PD/PI. 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 by clicking Add Attachment.</p> <p> Biographical sketches should follow the format described <a href="#">below</a>.</p>

Field Name	Instructions
Attach Current & Pending Support	 <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 <a href="#">Other Support</a> in 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.** Also use this section to list any Other Significant Contributors (OSCs). OSCs should be listed after all 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. This would also be an appropriate designation for mentors on Career awards.

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, they should be redesignated as “key personnel.” This change should be made before any compensation is charged to the project.

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,

Field Name	Instructions
	or equivalent level within the organization of the Senior/Key Person.
Organization Name	Enter the name of organization of the Senior/Key Person.  <b>This is a required field for applications submitted to NIH and other PHS agencies.</b>
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. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person, if applicable.
City	Enter the city for the address of the Senior/Key Person. This field is required.
County	Enter the county for the address of the 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.
Province	Enter the Province of Senior/Key Person.
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the Postal Code (e.g., ZIP Code) of the Senior/Key Person address. This field is required if the Senior/Key Person is located in the United States.
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.
Email	Enter the email address for the Senior/Key Person. This field is required for the Senior/Key Person.
Credential, e.g., agency login	If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank.  For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. <b>The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other</b>

Field Name	Instructions
	<p><b>PHS agencies. Applications will not pass agency validation requirements without this field.</b></p> <p>Note for applications reflecting Multiple PDs/PIs, the Commons UserName must be provided for all individuals assigned the PD/PI Role.</p>
Project Role	<p>Select a project role from the list. Select “Other” if an appropriate project role is not listed.</p>  <p>If you are submitting an application reflecting Multiple PDs/PIs, all such individuals <b>must</b> 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. Do not assign any individual this role. If applicants wish to use the role of “Co-Investigator” 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.</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	<p>Complete if you selected “Other Professional” or “Other” as a project role. For example, Engineer, Chemist.</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 by clicking Add Attachment.</p>  <p>Biographical sketches should follow the format described <a href="#">below</a>.</p>
Attach Current & Pending Support	 <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 <a href="#">Other Support</a> in Part III, Policies, Assurances, Definitions, and Other Information.</p>

Note: After completing Profile – Senior/Key Person 1, click the Next Person button to display the fields for Profile – Senior/Key Person 2.

**Additional Senior/Key Person Profile(s)**

If more than eight Senior/Key Person profiles are proposed, enter the information in a separate file. On the form, click Add Attachment, select the file, and then click Open.



A sample Additional Senior/Key Person Profiles format page for greater than 8 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 by clicking Add Attachment.



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 Part III, Policies, Assurances, Definitions, and Other Information.

## **4.5.2 Senior/Key Person Profile (Expanded) Component**

This component provides the ability to collect structured data for up to 40 Senior/Key Persons. Data must be entered for the first 8 individuals (PD/PI + seven 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 component. See instructions in section 4.2 Cover Component if these fields are empty.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)				
<b>PROFILE - Project Director/Principal Investigator</b>				
Prefix	* First Name	Middle Name	* Last Name	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position/Title: <input type="text"/>		Department: <input type="text"/>		
Organization Name: <input type="text"/>		Division: <input type="text"/>		
* Street1: <input type="text"/>		Street2: <input type="text"/>		
* City: <input type="text"/>	County: <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"/>		* E-Mail <input type="text"/>
Credential, e.g., agency login: <input type="text"/>				
* Project Role: <input type="text"/>		PD/PI	Other Project Role Category: <input type="text"/>	
*Attach Biographical Sketch <input type="text"/>		<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Attach Current & Pending Support <input type="text"/>		<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
<b>PROFILE - Senior/Key Person 1</b>				
Prefix	* First Name	Middle Name	* Last Name	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position/Title: <input type="text"/>		Department: <input type="text"/>		
Organization Name: <input type="text"/>		Division: <input type="text"/>		
* Street1: <input type="text"/>		Street2: <input type="text"/>		
* City: <input type="text"/>	County: <input type="text"/>	* State: <input type="text"/>	Province: <input type="text"/>	
* Country: <input type="text" value="UNITED ST"/>	* Zip / Postal Code: <input type="text"/>			
* Phone Number <input type="text"/>		Fax Number <input type="text"/>		* E-Mail <input type="text"/>
Credential, e.g., agency login: <input type="text"/>				
* Project Role: <input type="text"/>		Other Project Role Category: <input type="text"/>		
*Attach Biographical Sketch <input type="text"/>		<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Attach Current & Pending Support <input type="text"/>		<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
<input type="button" value="Reset Entry"/>		<input type="button" value="Select to attach additional Senior/Key Person Forms"/>		<input type="button" value="Next Person"/>
OMB Number: 4040-0001 Expiration Date: 04/30/2008				

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, measurable 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.

**Profile – Project Director/Principal Investigator (PD/PI)**

Field Name	Instructions
Prefix	This field is automatically populated from the SF424 (R&R). It is the prefix (e.g., Mr., Mrs., Rev.) for the name of the PD/PI.
First Name	This field is automatically populated from the SF424 (R&R). It is the first (given) name of the PD/PI. This field is required.
Middle Name	This field is automatically populated from the SF424 (R&R). It is the middle name of the PD/PI.
Last Name	This field is automatically populated from the SF424 (R&R). It is the last (family) name of the PD/PI. This field is required.
Suffix	This field is automatically populated from the SF424 (R&R). It is the suffix (e.g., Jr., Sr., PhD) for the name of the PD/PI.
Position/Title	This field is automatically populated from the SF424 (R&R). It is the title of the PD/PI.
Department	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational department, service, laboratory, or equivalent level within the organization of the PD/PI.
Organization Name	This field is automatically populated from the SF424 (R&R). It is the name of the organization of the PD/PI.
Division	This field is automatically populated from the SF424 (R&R). It is the name of primary organizational division, office, or major subdivision of the PD/PI.
Street1	This field is automatically populated from the SF424 (R&R). It is the first line of the street address of the PD/PI.
Street2	This field is automatically populated from the SF424 (R&R). It is the second line of the street address of the PD/PI, if applicable.
City	This field is automatically populated from the SF424 (R&R). It is the city for the address of the PD/PI.
County	This field is automatically populated from the SF424 (R&R). It is the county for the address of the PD/PI.
State	This field is automatically populated from the SF424 (R&R). It is the state where the PD/PI is located. This field is required if the PD/PI is located in the United States.
Province	This field is automatically populated from the SF424 (R&R). It is the province where the PD/PI is located.

Field Name	Instructions
Country	This field is automatically populated from the SF424 (R&R). It is the country for the PD/PI address.
ZIP Code	This field is automatically populated from the SF424 (R&R). It is 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.
Phone Number	This field is automatically populated from the SF424 (R&R). It is the daytime phone number for the PD/PI.
Fax Number	This field is automatically populated from the SF424 (R&R). It is the fax number for the PD/PI.
Email	This field is automatically populated from the SF424 (R&R). It is the email address for the PD/PI.
Credential, e.g., agency login	<p>If you are submitting to an agency (e.g., NIH and other PHS agencies) 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 PDs/PIs is required. <b>The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.</b></p>
Project Role	Select a project role from the list. Select “Other” if an appropriate project role is not listed.
Other Project Role Category	Complete if you selected “Other Professional” or “Other” as a project role. For example, Engineer, Chemist.
Attach Biographical Sketch	<p>Provide a biographical sketch for the PD/PI. 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 by clicking Add Attachment.</p>  <p>Biographical sketches should follow the format described <a href="#">below</a>.</p>
Attach Current & Pending Support	 <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 <a href="#">Other Support</a> in Part III, Policies, Assurances, Definitions and</p>

Field Name	Instructions
	Other Information.

**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. Also use this section to list any Other Significant Contributors (OSCs). OSCs should be listed after all 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. This would also be an appropriate designation for mentors on Career awards.

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, they should be redesignated as “key personnel.” This change should be made before any compensation is charged to the project.

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

Field Name	Instructions
	subdivision of the Senior/Key Person.
Street1	Enter first line of the street address for the Senior/Key Person. This field is required.
Street2	Enter second line of the street address for the Senior/Key Person, if applicable.
City	Enter the city for the address of the Senior/Key Person. This field is required.
County	Enter the county for the address of the 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.
Province	Enter the Province of Senior/Key Person.
Country	Select the country for the Senior/Key Person address. This field is required.
ZIP Code	Enter the Postal Code (e.g., ZIP Code) of the Senior/Key Person address. This field is required if the Senior/Key Person is located in the United States.
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.
Email	Enter the email 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 and other PHS agencies) 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 PDs/PIs is required. <b>The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. Applications will not pass agency validation requirements without this field.</b></p> <p>Note for applications reflecting Multiple PDs/PIs, the Commons UserName must be provided for all individuals assigned the PD/PI Role.</p>
Project Role	Select a project role from the list. Select “Other” if an appropriate project role is not listed.

Field Name	Instructions
	 <p>If you are submitting an application reflecting Multiple PDs/PIs, all such individuals <b>must</b> 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. Do not assign any individual this role. If applicants wish to use the role of “Co-Investigator” 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.</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. For example, Engineer, Chemist.
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 by clicking Add Attachment.</p>  <p>Biographical sketches should follow the format described <a href="#">below</a>.*</p>
Attach Current & Pending Support	 <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 <a href="#">Other Support</a> in Part III, Policies, Assurances, Definitions, and Other Information.</p>

Note: After completing Profile – Senior/Key Person 1, click the Next Person button to display the fields for Profile – Senior/Key Person 2.

Once you have completed the data entry in all required fields for the first 8 individuals (PD/PI + seven others), the “Select to attach additional Senior/Key Person Forms” button at the bottom of the form becomes active.

Clicking this button engages a new page that allows up to four additional Senior/Key Person (PureEdge) components to be attached (each containing another 8 individuals).

\*See Resources at <http://www.ornl.gov/adm/nih/package.shtml>.

## RESEARCH & RELATED Senior/Key Person Profile (Expanded)

### Additional Senior/Key Person Form Attachments

When submitting senior/key persons in excess of 8 individuals, please attach additional senior/key person forms here. Each additional form attached here, will provide you with the ability to identify another 8 individuals, up to a maximum of 4 attachments (32 people).

The means to obtain a supplementary form is provided here on this form, by the button below. In order to extract, fill, and attach each additional form, simply follow these steps:

- Select the "Select to Extract the R&R Additional Senior/Key Person Form" button, which appears below.
- Save the file using a descriptive name, that will help you remember the content of the supplemental form that you are creating. When assigning a name to the file, please remember to give it the extension ".xfd" (for example, "My\_Senior\_Key.xfd"). If you do not name your file with the ".xfd" extension you will be unable to open it later, using your PureEdge viewer software.
- Using the "Open Form" tool on your PureEdge viewer, open the new form that you have just saved.
- Enter your additional Senior/Key Person information in this supplemental form. It is essentially the same as the Senior/Key person form that you see in the main body of your application.
- When you have completed entering information in the supplemental form, save it and close it.
- Return to this "Additional Senior/Key Person Form Attachments" page.
- Attach the saved supplemental form, that you just filled in, to one of the blocks provided on this "attachments" form.

**Select to Extract the R&R Additional Senior/Key Person Form**

**Important:** Please attach additional Senior/Key Person forms, using the blocks below. Please remember that the files you attach must be Senior/Key Person Pure Edge forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

1) Please attach Attachment 1	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

<b>ADDITIONAL SENIOR/KEY PERSON PROFILE(S)</b>	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Additional Biographical Sketch(es) (Senior/Key Person)</b>	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Additional Current and Pending Support(s)</b>	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

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The following instructions are provided on this form:

### Additional Senior/Key Person Form Attachments

When submitting senior/key persons in excess of 8 individuals, please attach additional senior/key person forms. Each additional form attached will provide you with the ability to identify another 8 individuals, up to a maximum of 4 attachments (32 people).

The means to obtain a supplementary form is provided on this form, by the button below. In order to extract, fill, and attach each additional form, simply follow these steps:

- Select the “Select to Extract the R&R Additional Senior/Key Person Form” button, which appears below.
- Save the file using a descriptive name that will help you remember the content of the supplemental form that you are creating. When assigning a name to the file, please remember to give it the

extension “.xfd” (for example, “My\_Senior\_Key.xfd”). If you do not name your file with the “.xfd” extension you will be unable to open it later using your PureEdge viewer software.

- Using the “Open Form” tool on your PureEdge viewer, open the new form that you have just saved.
- Enter your additional Senior/Key Person information in this supplemental form. It is essentially the same as the Senior/Key person form that you have seen in the main body of your application.
- When you have completed entering information in the supplemental form, save it and close it.
- Return to this “Additional Senior/Key Person Form Attachments” page.
- Attach the saved supplemental form that you have just filled in to one of the blocks provided on this “attachments” form.

**Important:** Please attach additional Senior/Key Person forms using the blocks below. Please remember that the files you attach must be Senior/Key Person Pure Edge forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

Clicking on the “Select to Extract the R&R Additional Senior/Key Person Form” button produces the PureEdge form shown below.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)				
PROFILE - Senior/Key Person 1				
Prefix	* First Name	Middle Name	* Last Name	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Position/Title: <input type="text"/>		Department: <input type="text"/>		
Organization Name: <input type="text"/>		Division: <input type="text"/>		
* Street1: <input type="text"/>		Street2: <input type="text"/>		
* City: <input type="text"/>	County: <input type="text"/>	* State: <input type="text"/>	* Zip Code: <input type="text"/>	* Country: <input type="text" value="USA"/>
* Phone Number <input type="text"/>		Fax Number <input type="text"/>		* E-Mail <input type="text"/>
Credential, e.g., agency login: <input type="text"/>				
* Project Role: <input type="text"/>		Other Project Role Category: <input type="text"/>		
*Attach Biographical Sketch	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
Attach Current & Pending Support	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
Reset Entry		Next Person		
OMB Number: 4040-0001 Expiration Date: 04/30/2008				

### Additional Senior/Key Person Profile(s)

If more than forty 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 40 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](#).\*

\*See Resources at <http://www.ornl.gov/adm/nih/package.shtml>.

### 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 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 assigned Commons User Name. This data item is currently optional. (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, and complete Sections A, B, and C.

- A. 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.
- B. Selected peer-reviewed publications or manuscripts in press (in chronological order).** Do not include manuscripts submitted or in preparation. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material.
- C. 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 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.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 4.6 Selecting the Appropriate Budget Component



The application forms package associated with most NIH funding opportunities includes two optional budget components—(1) R&R Budget Component; and, (2) PHS398 Modular Budget Component. NIH applications will include either the R&R Budget Component or the PHS398 Modular Budget Component, but not both. (**Note AHRQ does not accept modular budgets.**)

To determine which budget component 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 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 R01, R03, R15, R21, and R34 applications.

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

## 4.7 R&R Budget Component

The R&R Budget component 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. Complete the R&R Budget component 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 noted with an “\*”) 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.

The concept of person months as a metric for determining percent of effort is a new business process for the applicant community of the NIH and other PHS agencies. To assist with this transition, resources are



perform a substantive portion of the project. If creating a 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](#).

**Enter name of Organization**

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

**Start Date**

Pre-populated from the R&R SF424. Enter the requested/proposed start date of each budget period. Use the following format: MM/DD/YYYY. **This field is required.**

**End Date**

Enter the requested/proposed end date of each budget period. Use the following format: MM/DD/YYYY.

**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.

**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, regardless of whether a salary is requested. 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.

Field Name	Instructions
Prefix	Select from the list the prefix (for example, Mr., Mrs., Rev.) of the Senior/Key Person.
First Name	Enter the first (given) name of each Senior/Key Person. This field is required.
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	Select from the list the suffix (for example, Jr., Sr., PhD) of each Senior/Key Person.
Project Role	Enter the project role of the Senior/Key person. This field could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals.   <b>The role of the PD/PI is auto-populated in the 01 year budget only. Do not change or edit this field for the PD/PI. For future year budgets, use consistent terminology.</b>
Base Salary (\$)	Enter the annual compensation paid by the employer for each Senior/Key

Field Name	Instructions
	<p>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>Enter the number of months devoted to the project for each Senior/Key person (for example, 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.</p>
Acad. Months	<p>Enter 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 9-month academic year, indicate your institution's definition of academic year in the budget justification.</p>
Sum. Months	<p>Enter 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.</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.</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 <a href="#">Salary Cap Summary</a> on the NIH grants Web site 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: <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</a>.</p>
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for each Senior/Key person.

Field Name	Instructions
Funds Requested (\$)	Enter the requested salary and fringe benefits for each Senior/Key person.
Total Funds requested for all Senior Key Persons in the attached file	Enter the total funds requested for all Senior/Key persons listed in the attached file.
Total Senior/Key Person	The total funds requested for all Senior/Key persons.
Additional Senior Key Persons	<p>If funds are requested for more than eight Senior/Key persons, include all pertinent budget information and attach as a file here. Enter the total funds requested for all additional senior/key persons in line 9 of Section A.</p>  Use the same format as the budget component and include all required information.



**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. Note, for Secretarial/Clerical Personnel, 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 where direct charging of administrative or clerical staff salaries may be appropriate may be found at: <a href="http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html">http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html</a>. 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>If Project Role is other than Post Doctoral Associates, Graduate Students, Undergraduate Students, or Secretarial/Clerical, enter the appropriate project role (for example, Engineer, IT Professional, etc.) in the blanks.</p>  Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.
Cal. Months	Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer).
Acad. Months	<p>Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer).</p>  If your institution does not use a 9-month academic year, indicate your institution's definition of academic year in the budget justification.
Sum. Months	<p>Enter the number of months devoted to the project in the applicable box for each project role category (for example, calendar, academic, summer).</p>  If your institution does not use a 3-month summer period, indicate your institution's definition of summer in the budget justification.
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>  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 <a href="#">Salary Cap Summary</a> on the NIH grants Web site or contact your office of sponsored programs. <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: <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</a>.</p>
Fringe Benefits (\$)	Enter applicable fringe benefits, if any, for this project role category.
Funds Requested	Enter requested salary/wages & fringe benefits for each project role.
Total Number of Other Personnel	The total number of other personnel.
Total Other Personnel	The 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.

To navigate to the next page (Sections C through E), click the “Next” button at the top of the form.

### 4.7.2 Sections C through E

**RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1**

\* ORGANIZATIONAL DUNS:

\* Budget Type:  Project  Subaward/Consortium

Enter name of Organization:

\* Start Date:  \* End Date:  Budget Period: 1

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

**C. Equipment Description**

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

	Equipment Item	* Funds Requested (\$)
1.	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>
8.	<input type="text"/>	<input type="text"/>
9.	<input type="text"/>	<input type="text"/>
10.	<input type="text"/>	<input type="text"/>
11.	Total funds requested for all equipment listed in the attached file	<input type="text"/>
	Total Equipment	<input type="text"/>

Additional Equipment:

**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 style="width: 300px;" type="text"/>	<input type="text"/>
<input type="checkbox"/> Number of Participants/Trainees      Total Participant/Trainee Support Costs	<input type="text"/>

OMB Number: 4040-0001  
Expiration Date: 04/30/2008

RESEARCH & RELATED Budget (C-E) (Funds Requested)

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**

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. <b>This is required information.</b>
Total funds requested for all equipment listed in the attached file	Total funds requested for all equipment listed in the attached file. <b>Dollar amount for each item should exceed \$5000.</b>
Total Equipment	Total Funds requested for all equipment.
Additional Equipment	If the space provided cannot accommodate all the equipment proposed, attach a file by clicking Add Attachment. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested on line 11 of this section.

**D. Travel**

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and US Possessions)	Enter the total funds requested for domestic travel. Domestic travel includes Canada, Mexico, and US 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 (for example, 3 days).
Foreign Travel Costs	Enter the total funds requested for foreign travel. Foreign travel includes any travel outside of North America and/or US 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 (for example, 3 days).
Total Travel Cost	The 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	Enter the total amount of funds requested for Participant/Trainee tuition / fees / health insurance.
Stipends	Enter the total funds requested for Participant/Trainee stipends.
Travel	Enter the total funds requested for Participant/Trainee travel.
Subsistence	Enter the total funds requested for Participant/Trainee subsistence.
Other	Describe any other participant trainee funds requested. Enter the total funds requested for any other Participant/Trainee costs described.
Number of Participants/Trainees	Enter the total number of proposed Participants/Trainees.
Total Participant/Trainee Support Costs	The total funds requested for all trainee costs.

### 4.7.3 Sections F through K

**RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1**
Next Period

\* ORGANIZATIONAL DUNS:

\* Budget Type:  Project  Subaward/Consortium

Enter name of Organization:

\* Start Date:  \* End Date:  Budget Period: 1

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

<b>F. Other Direct Costs</b>	<b>Funds Requested (\$)</b>
1. Materials and Supplies	<input style="width: 80px;" type="text"/>
2. Publication Costs	<input style="width: 80px;" type="text"/>
3. Consultant Services	<input style="width: 80px;" type="text"/>
4. ADP/Computer Services	<input style="width: 80px;" type="text"/>
5. Subawards/Consortium/Contractual Costs	<input style="width: 80px;" type="text"/>
6. Equipment or Facility Rental/User Fees	<input style="width: 80px;" type="text"/>
7. Alterations and Renovations	<input style="width: 80px;" type="text"/>
8. <input style="width: 150px;" type="text"/>	<input style="width: 80px;" type="text"/>
9. <input style="width: 150px;" type="text"/>	<input style="width: 80px;" type="text"/>
10. <input style="width: 150px;" type="text"/>	<input style="width: 80px;" type="text"/>
<b>Total Other Direct Costs</b>	<input style="width: 80px;" type="text"/>

<b>G. Direct Costs</b>	<b>Funds Requested (\$)</b>
<b>Total Direct Costs (A thru F)</b>	<input style="width: 80px;" type="text"/>

<b>H. Indirect Costs</b>					
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	*	Funds Requested (\$)	
1. <input style="width: 150px;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>
2. <input style="width: 150px;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>
3. <input style="width: 150px;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>
4. <input style="width: 150px;" type="text"/>	<input style="width: 40px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>
<b>Total Indirect Costs</b>					<b>0.00</b>

Cognizant Federal Agency   
 (Agency Name, POC Name, and POC Phone Number)

<b>I. Total Direct and Indirect Costs</b>	<b>Funds Requested (\$)</b>
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<input style="width: 80px;" type="text" value="0.00"/>

<b>J. Fee</b>	<b>Funds Requested (\$)</b>
	<input style="width: 80px;" type="text"/>

**K. \* Budget Justification**

(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001  
Expiration Date: 04/30/2008

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.

**F. Other Direct Costs**

Field Name	Instructions
1. Materials and Supplies	Enter the 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 do not have to be itemized.
2. Publication Costs	Enter 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>Enter the total costs for all consultant services. In the budget justification, identify each consultant, the services he or she will perform, total number of days, travel costs, and the total estimated costs.</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	Enter 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.
5. Subawards/Consortium/ Contractual Costs	<p>Enter the 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>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>
6. Equipment or Facility Rental/User Fees	Enter the total funds requested for equipment or facility rental/user fees. In the budget justification, identify each rental user fee and justify.

Field Name	Instructions
7. Alterations and Renovations	Enter the 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.
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>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> <p>If line space is an issue, combine all remaining “other direct costs” together on the last line and include details in the budget justification (description and funds requested).</p>
Total Other Direct Costs	The 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)**

The total funds requested for all direct costs.

**H. Indirect Costs**

Field Name	Instructions
Indirect Cost Type	Indicate the type of cost (for example, 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—

Field Name	Instructions
	will negotiate” and include information for a proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%)	<p>Indicate the most recent indirect cost rate(s) (also known as Facilities &amp; Administrative Costs [F&amp;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.</p>  <p>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.”</p>
Indirect Cost Base (\$)	Enter the amount of the base for each indirect cost type.
Funds Requested	Enter the funds requested for each indirect cost type.
Total Indirect Costs	The total funds requested for indirect costs.
Cognizant Federal Agency	Enter the name of the cognizant Federal Agency, name and telephone number of the individual responsible for negotiating your rate. If no cognizant agency is known, enter “None.”

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

The 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” (for example, 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 you wish to submit to support your budget request. Note this is a single justification for all budget years so include all justification information for all years in the same file. Click Add Attachment to attach the file.



Use this section to also 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. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

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 3<sup>rd</sup> budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and noted with an “\*”) 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.

## 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.

<b>RESEARCH &amp; RELATED BUDGET - Cumulative Budget</b>		<b>Totals (\$)</b>
<b>Section A, Senior/Key Person</b>		<input type="text"/>
<b>Section B, Other Personnel</b>		<input type="text"/>
Total Number Other Personnel	<input type="text"/>	
<b>Total Salary, Wages and Fringe Benefits (A+B)</b>		<input type="text"/>
<b>Section C, Equipment</b>		<input type="text"/>
<b>Section D, Travel</b>		<input type="text"/>
1. Domestic	<input type="text"/>	
2. Foreign	<input type="text"/>	
<b>Section E, Participant/Trainee Support Costs</b>		<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"/>	
<b>Section F, Other Direct Costs</b>		<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"/>	
<b>Section G, Direct Costs (A thru F)</b>		<input type="text"/>
<b>Section H, Indirect Costs</b>		<input type="text"/>
<b>Section I, Total Direct and Indirect Costs (G + H)</b>		<input type="text"/>
<b>Section J, Fee</b>		<input type="text"/>

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium

**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 Pure Edge document.

Click here to extract the R&R Subaward Budget Attachment

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	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
2) Please attach Attachment 2	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
3) Please attach Attachment 3	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
4) Please attach Attachment 4	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
5) Please attach Attachment 5	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
6) Please attach Attachment 6	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
7) Please attach Attachment 7	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
8) Please attach Attachment 8	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
9) Please attach Attachment 9	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
10) Please attach Attachment 10	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

OMB Number: 4040-0001  
Expiration Date: 04/30/2008

A complete subaward/consortium budget component (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 component is only required when the prime grantee is submitting a detailed budget using the R&R Budget Component. Do not use this subaward/consortium budget component for applications using the PHS398 Modular Budget Component. Applicants using the Modular Budget Component should see Section 5.4 for instructions concerning information on consortium budgets.

When completing the Project Role for the investigator leading the portion of the project at the consortium site, the project role of “PD/PI” should only be used if the entire application is being submitted under the Multiple PI policy. Also, the role of Co-PD/PI is not currently used by NIH and other PHS agencies. Do not assign any individual this role. If applicants wish to use roles of “Co-Investigator” or “Consortium PI”, 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.

This component currently accommodates up to 10 separate subaward budgets. If you are submitting an application with >10 subaward budgets, budgets 11 and above should be converted to PDF and included as part of Section K. Budget Justification of the parent budget (R&R Budget Component). 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 10 letters of the consortium organization’s name as the file name and leave “.xfd” as the file extension. (The extracted file is a PureEdge document.) **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.**
- Email the **extracted, saved** form to the consortium grantee. Note: consortium grantees must have installed the PureEdge Viewer before they can complete the form. The consortium grantee should complete all the budget information as instructed in the R&R Budget component instructions in [Section 4.7](#). Note: Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.
- The consortium grantee must complete the budget component and email 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. *Do not convert this attachment to PDF.*

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Only text attachments must be converted to PDFs. Attachments generated from PureEdge forms, such as the R&R SubAward Budget Attachment Form, should *not* be converted to PDFs.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 5. Completing PHS398 Components

### 5.1 Overview

In conjunction with the SF424 (R&R) components, NIH and other PHS agencies grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 components include additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS398 components. The PHS398 components include:

- PHS398 Cover Letter Component (optional, however applicants are strongly encouraged to include this component)
- PHS398 Cover Page Supplement (this supplements the data requirements in the R&R Cover component)
- PHS398 Modular Budget Component (use only when a modular budget is submitted instead of a detailed budget)
- PHS398 Research Plan Component
- PHS398 Checklist Component

Complete each component using the instructions provided below.

### 5.2 Cover Letter Component

**PHS 398 Cover Letter**

OMB Number: 0925-0001  
Expiration Date: 9/30/2007

\*Mandatory Cover Letter Filename:

#### Cover Letter File Name

Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal agency 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 people (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. 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.

Two types of approval documentation are cited as examples in item 6 above: NIH IC approval for an application \$500,000 or more and NIH institute approval for a Conference Grant or Cooperative Agreement application (R13 or U13). To attach the approval documents to this submission, please append those referenced documents to your Cover Letter File, and upload as one attachment.

For late applications (see Late Application policy in [Section 2.14](#)) include an explanation of the delay as part of the cover letter attachment.

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 until after an application is verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.

Save this information in a single file in a location you remember and convert the file to PDF. Click Add Cover Letter File, browse to where you saved the file, select the file, and then click Open. The name of the file attached will automatically appear in the “Mandatory Cover Letter Filename” field.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 5.3 Cover Page Supplement Component

### PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 9/30/2007

<b>1. Project Director / Principal Investigator (PD/PI)</b>	
Prefix:	<input type="text"/>
* First Name:	<input type="text"/>
Middle Name:	<input type="text"/>
* Last Name:	<input type="text"/>
Suffix:	<input type="text"/>
* New Investigator? <input type="radio"/> No <input type="radio"/> Yes	
Degrees:	<input type="text"/> <input type="text"/> <input type="text"/>
<b>2. Human Subjects</b>	
Clinical Trial?	<input type="radio"/> No <input type="radio"/> Yes
* Agency-Defined Phase III Clinical Trial?	<input type="radio"/> No <input type="radio"/> Yes
<b>3. Applicant Organization Contact</b>	
Person to be contacted on matters involving this application	
Prefix:	<input type="text"/>
* First Name:	<input type="text"/>
Middle Name:	<input type="text"/>
* Last Name:	<input type="text"/>
Suffix:	<input type="text"/>
* Phone Number:	<input type="text"/>
Fax Number:	<input type="text"/>
Email:	<input type="text"/>
* Title:	<input type="text"/>
* Street1:	<input type="text"/>
Street2:	<input type="text"/>
* City:	<input type="text"/>
County:	<input type="text"/>
* State:	<input type="text"/>
Province:	<input type="text"/>
* Country:	<input type="text"/>
* Zip / Postal Code:	<input type="text"/>

**1. Project 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.
New Investigator	<p>Check the Yes box only if the PD/PI has not previously <b>completed successfully</b> as such on any NIH-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), a <b>Shannon Award (R55)</b>, an <b>NIH High Priority, Short-Term Project Award (R56)</b>, or mentored career development awards for persons at the beginning of their research career (K01, K08, K22, K23, K25, <b>K99/R00</b>). <b>If the PD/PI is not a new investigator, check the No box.</b> Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K05, K24, K26) are not considered new investigators.</p> <p>When Multiple Principal Investigators are proposed, <b>all</b> PIs must meet the definition of New Investigator for this box to be checked.</p>
Degrees	Indicate up to three academic and professional degrees or other credentials, such as licenses (for example, R.N.). These degrees should be a subset of the degrees that are listed on the PD/PI's Commons account. If the PD/PI's Commons account does not include the degrees listed here, please update the Commons account information accordingly.

**2. Human Subjects**

Field Name	Instructions
Clinical Trial	Check the Yes or No box to indicate whether the project is a clinical trial. The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
Agency-Defined Phase III Clinical Trial	Check the Yes or No box to indicate whether the project is an NIH-defined Phase III clinical trial. An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually

Field Name	Instructions
	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.

### 3. Applicant Organization Contact

Person to be contacted on matters involving this application

Field Name	Instructions
Prefix	Pre-populated from the SF424 (R&R). The prefix (e.g., Mr., Mrs., Rev.) for the person to contact on matters related to this application.
First Name	Pre-populated from the SF424 (R&R). The first (given) name for the person to contact on matters related to this application. This field is required.
Middle Name	Pre-populated from the SF424 (R&R). The middle name for the person to contact on matters related to this application.
Last Name	Pre-populated from the SF424 (R&R). The last (family) name for the person to contact on matters related to this application. This field is required.
Suffix	Pre-populated from the SF424 (R&R). The suffix (e.g., Jr., Sr., PhD) for the person to contact on matters related to this application.
Phone Number	Pre-populated from the SF424 (R&R). The daytime phone number for the person to contact on matters related to this application. <b>This field is required.</b>
Fax Number	Pre-populated from the SF424 (R&R). The fax number for the person to contact on matters related to this application.
Email	Pre-populated from the SF424 (R&R). The email address for the person to contact on matters related to this application.
Title	Enter the title for the person to contact on matters related to this application. This field is required.
Street1	Enter first line of the street address for the person to contact on matters related to this application. This field is required.

Field Name	Instructions
Street2	Enter second line of the street address for the person to contact on matters related to this application. <b>This field is optional.</b>
City	Enter the city for address for the person to contact on matters related to this application. This field is required.
County	Enter the county for address for the person to contact on matters related to this application.
State	Enter the state for address for the person to contact on matters related to this application.
Province	Enter the province.
Country	Select the country for the person to contact on matters related to this application. This field is required.
Zip Code	Enter the Postal Code (e.g., ZIP code) for the person to contact on matters related to this application.



Field Name	Instructions
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.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 5.4 Modular Budget Component

### Selecting the Appropriate Budget Component

The application forms package associated with most NIH funding opportunities includes two optional budget components—(1) R&R Budget Component; and, (2) PHS398 Modular Budget Component. NIH applications will include either the R&R Budget Component or the PHS398 Modular Budget Component, but not both. (**Note AHRQ does not accept modular budgets.**)

To determine which budget component 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 requesting \$250,000 or less per year for direct costs. 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. The modular budget is applicable only to R01, R03, R15, R21, and R34 applications.

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](http://grants.nih.gov/grants/funding/modular/modular_review.htm).

### Using the Modular Budget Component

The Modular Budget Component 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.

### 5.4.1 Periods 1 through 4

#### PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001  
 Expiration Date: 9/30/2007

<b>Budget Period: 1</b>				
<input type="button" value="Reset Entries"/>	Start Date: <input style="width: 100px;" type="text"/>	End Date: <input style="width: 100px;" type="text"/>		
<b>A. Direct Costs</b>		* Funds Requested (\$)		
		* Direct Cost less Consortium F&A	<input style="width: 100px;" type="text"/>	
		Consortium F&A	<input style="width: 100px;" type="text"/>	
		* Total Direct Costs	<input style="width: 100px;" type="text"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
2.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
3.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
4.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number)		<input style="width: 95%;" type="text"/>		
Indirect Cost Rate Agreement Date	<input style="width: 100px;" type="text"/>	Total Indirect Costs		<input style="width: 100px;" type="text"/>
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$)	<input style="width: 100px;" type="text"/>
<b>Budget Period: 2</b>				
<input type="button" value="Reset Entries"/>	Start Date: <input style="width: 100px;" type="text"/>	End Date: <input style="width: 100px;" type="text"/>		
<b>A. Direct Costs</b>		* Funds Requested (\$)		
		* Direct Cost less Consortium F&A	<input style="width: 100px;" type="text"/>	
		Consortium F&A	<input style="width: 100px;" type="text"/>	
		* Total Direct Costs	<input style="width: 100px;" type="text"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
2.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
3.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
4.	<input style="width: 95%;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number)		<input style="width: 95%;" type="text"/>		
Indirect Cost Rate Agreement Date	<input style="width: 100px;" type="text"/>	Total Indirect Costs		<input style="width: 100px;" type="text"/>
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$)	<input style="width: 100px;" type="text"/>

NOTE: The fields are the same for budget periods 1 through 5, 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. Actual consortium F&A costs are excluded from this figure.
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	The total direct costs. This field auto-calculates.

**B. Indirect Costs**

Field Name	Instructions
Indirect Cost Type	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 (%)	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.  Currently this field will not allow a figure greater than 100% to be entered. If the Indirect Cost Rate exceeds 100%, use 2 lines to show the entire calculation.

Field Name	Instructions
Indirect Cost Base (\$)	Enter the amount of the base for each indirect cost type.
Funds Requested (\$)	Enter funds requested for each indirect cost type.
Cognizant Agency (Agency Name, POC Name and Phone Number)	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."
Indirect Cost Rate Agreement Date	If you have a negotiated rate agreement, enter the agreement date.
Total Indirect Costs	The total funds requested for 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 auto-calculates.

## 5.4.2 Period 5 and Cumulative

### PHS 398 Modular Budget, Period 5 and Cumulative

OMB Number: 0925-0001  
Expiration Date: 9/30/2007

<b>Budget Period: 5</b>				
<input type="button" value="Reset Entries"/>	Start Date: <input style="width: 100px;" type="text"/>	End Date: <input style="width: 100px;" type="text"/>		
<b>A. Direct Costs</b>			* Funds Requested (\$)	
* Direct Cost less Consortium F&A			<input style="width: 100px;" type="text"/>	
Consortium F&A			<input style="width: 100px;" type="text"/>	
* Total Direct Costs			<input style="width: 100px;" type="text"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 400px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
2.	<input style="width: 400px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
3.	<input style="width: 400px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
4.	<input style="width: 400px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 50px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number)		<input style="width: 350px; height: 40px;" type="text"/>		
Indirect Cost Rate Agreement Date		<input style="width: 80px;" type="text"/>	Total Indirect Costs	
			<input style="width: 100px;" type="text"/>	
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$)	
			<input style="width: 100px;" type="text"/>	
<b>Cumulative Budget Information</b>				
<b>1. Total Costs, Entire Project Period</b>				
* Section A, Total Direct Cost less Consortium F&A for Entire Project Period		\$	<input style="width: 100px;" type="text"/>	
Section A, Total Consortium F&A for Entire Project Period		\$	<input style="width: 100px;" type="text"/>	
* Section A, Total Direct Costs for Entire Project Period		\$	<input style="width: 100px;" type="text"/>	
* Section B, Total Indirect Costs for Entire Project Period		\$	<input style="width: 100px;" type="text"/>	
* Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period		\$	<input style="width: 100px;" type="text"/>	
<b>2. Budget Justifications</b>				
Personnel Justification	<input style="width: 150px;" type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input style="width: 150px;" type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input style="width: 150px;" type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

## 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.

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, number of person months devoted to the project (indicate academic, calendar, and/or summer) and roles on the project. Do not provide individual salary information. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, you 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: <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</a>.</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>
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, along with all personnel, including percent of effort (<b>in person months</b>) and roles on the project. Do not provide individual salary information. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the <b>total</b> 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, such as variations in the number of modules requested, 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>

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 5.5 Research Plan Component

<b>PHS 398 Research Plan</b>																																											
<p><b>1. Application Type:</b></p> <p>From SF 424 (R&amp;R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.</p> <p>*Type of Application:</p> <p style="margin-left: 20px;"> <input type="radio"/> New                       <input type="radio"/> Resubmission                       <input type="radio"/> Renewal                       <input type="radio"/> Continuation                       <input type="radio"/> Revision                 </p>																																											
<p><b>2. Research Plan Attachments:</b></p> <p>Please attach applicable sections of the research plan, below.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 2px;">1. Introduction to Application</td> <td style="width: 15%; padding: 2px;"><input type="text"/></td> <td style="width: 15%; padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="width: 15%; padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="width: 20%; padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td colspan="5" style="padding: 2px;"><small>(for RESUBMISSION or REVISION only)</small></td> </tr> <tr> <td style="padding: 2px;">2. Specific Aims</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">3. Background and Significance</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">4. Preliminary Studies / Progress Report</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">5. Research Design and Methods</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">6. Inclusion Enrollment Report</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">7. Progress Report Publication List</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> </table>				1. Introduction to Application	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	<small>(for RESUBMISSION or REVISION only)</small>					2. Specific Aims	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	3. Background and Significance	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	4. Preliminary Studies / Progress Report	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	5. Research Design and Methods	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	6. Inclusion Enrollment Report	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	7. Progress Report Publication List	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
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<p><u>Human Subjects Sections</u></p> <p>Attachments 8-11 apply only when you have answered "yes" to the question "are human subjects involved" on the R&amp;R Other Project Information Form. In this case, attachments 8-11 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 2px;">8. Protection of Human Subjects</td> <td style="width: 15%; padding: 2px;"><input type="text"/></td> <td style="width: 15%; padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="width: 15%; padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="width: 20%; padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">9. Inclusion of Women and Minorities</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">10. Targeted/Planned Enrollment</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> <tr> <td style="padding: 2px;">11. Inclusion of Children</td> <td style="padding: 2px;"><input type="text"/></td> <td style="padding: 2px;"><input type="button" value="Add Attachment"/></td> <td style="padding: 2px;"><input type="button" value="Delete Attachment"/></td> <td style="padding: 2px;"><input type="button" value="View Attachment"/></td> </tr> </table>				8. Protection of Human Subjects	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	9. Inclusion of Women and Minorities	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	10. Targeted/Planned Enrollment	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>	11. Inclusion of Children	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>																				
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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.

### 1. Application Type

This field is pre-populated from the SF424 (R&R) Cover Component. Corrections to this field must be made in that component.

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

Although many of the sections of this application are separate PDF attachments, page limitations referenced in the instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits (and use of appropriate font). Some accommodation will be made for sections that, when combined, must fit within a specified limitation.

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.

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 limitations of the Research Plan. **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 PMG. 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.

While each section of the Research Plan needs to eventually be uploaded separately, applicants are encouraged to construct the Research Plan as a single document, separating sections into distinct PDF attachments just before uploading the files. In this way the applicant can better monitor formatting requirements such as page limits. When validating for page limits, the eRA Commons will not count the white space created by breaking the text into separate files for uploading.

**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 Limitations

**Do not exceed 25 pages for Items 2 – 5.** All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. Be succinct and remember that there is no requirement to use all 25 pages allotted to items 2-5 of the Research Plan.

**Follow page limitations as specified in Funding Opportunity Announcements.**

All applications and proposals for NIH funding must be self-contained within specified page limitations. Agency validations will include 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 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 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.

**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 the “Yes” box of question #3 in the “Other Project Information” component. Identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (\*) in the left-hand margin. Include a legend at the beginning of Section 2, similar to “The following sections marked with an asterisk contain proprietary/privileged information that (name of Applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.”

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. 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.

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

Field Name	Instructions
1. Introduction to Application (for Resubmission or Revision only)	<p>Use only if you are submitting an R&amp;R Resubmission or Revision (Cover Page Item 8). The Introduction may not exceed 1-3 pages for resubmissions (previously known as a revision or amendment) or one page for revisions (previously known as competing supplements). Page limits for the Introduction vary for specialized mechanisms (e.g., R03 and R21 applications). Applicants <b>must</b> follow the page limits that are outlined in the specific announcement.</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	<p>List the broad, long-term objectives and the goal of the specific research proposed, for example, 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</p>

Field Name	Instructions
	<p>technology. One page is recommended.</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>
3. Background and Significance	<p>Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. Two to three pages are recommended.</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. Preliminary Studies/Progress Report	<p><i>Preliminary Studies.</i> For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.</p> <p>Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.</p> <p><i>Progress Report for Renewal (previously known as Competing Continuation) and Revision (previously known as Supplemental Applications).</i> A Progress Report must be provided for renewal and revision applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions. <b>A list of publications, manuscripts accepted for publication, patents, and other printed materials will be included in Section 7; do not include that information here.</b></p> <p><b>Six to eight pages are recommended</b> for the narrative portion of this 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</p>

Field Name	Instructions
	then click Open.
5. Research Design and Methods	<p>Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 17, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.</p> <p>Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 pages allotted for items 2-5 be used.</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 Enrollment Report	<p>If the renewal or revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender.</p> <p>See <a href="#">“What Form Should PDs/PIs Use for Population Tracking? (New Versus Old)”</a> for more detailed instructions on which Target and Enrollment Report or Table to use.</p>
7. Progress Report Publication List	<p>List the titles and complete references to all <b>appropriate</b> publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. <b>For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material.</b></p> <p><b>As part of the Appendix material you may include only up to 3 of the following types of publications:</b></p> <ul style="list-style-type: none"> <li>• <b>Manuscripts and/or abstracts accepted for publication but not yet published:</b> The entire article should be submitted as a PDF attachment.</li> <li>• <b>Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:</b> The entire article should be submitted as a PDF attachment.</li> <li>• <b>Patents directly relevant to the project:</b> The entire document should be submitted as a PDF attachment.</li> </ul> <p><b>(Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)</b></p>

Field Name	Instructions
	Note, publications and/or abstracts in press should no longer be included in the appendix material. Include the URL or PMC submission identification numbers along with the full reference in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

### Human Subjects Sections

Field Name	Instructions
8. Protection of Human Subjects	<p>This section covers only the initial information regarding the Protection of Human Subjects. Follow the instructions in Part II, <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>. See separate sections below for other human subjects related sections that may apply.</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>Unless an explanation is necessary, if Human Subjects research is not involved, and you have checked the box marked “No” on the Other Project Information Component, you need not include any additional information in this section.</p>
9. Inclusion of Women and Minorities	<p>To determine if Inclusion of Women and Minorities applies to this application, follow the instructions in Part II, <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>.</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>
10. Targeted/Planned Enrollment Table	<p>If this application involves the Inclusion of Women and Minorities, complete the <a href="#">Targeted/Planned Enrollment Table</a>.</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>
11. Inclusion of Children	<p>To determine if Inclusion of Children applies to this application, follow the instructions in the <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>.</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 Sections

Field Name	Instructions

Field Name	Instructions
12. Vertebrate Animals	<p>If you indicated that Vertebrate Animals are involved in this project, address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.</p> <ol style="list-style-type: none"> <li>1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.</li> <li>2. 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.</li> <li>3. Provide information on the veterinary care of the animals involved.</li> <li>4. 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.</li> <li>5. 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 Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.</li> </ol> <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>For those applicants familiar with the PHS398, please note that the Literature Cited section of the Research Plan is now captured as “Bibliography &amp; References Cited.” Refer to Item 8 in the Other Project Information Component for instructions.</p>
13. Select Agents	<p>Select Agents are hazardous biological agents and toxins that have been identified by HHS 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 maintains a list of these agents. See <a href="http://www.cdc.gov/od/sap/docs/salist.pdf">http://www.cdc.gov/od/sap/docs/salist.pdf</a>.</p> <p>If the activities proposed in your 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 73.4(f)(5), the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent</p>

Field Name	Instructions
	<p>that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at <a href="http://www.cdc.gov/od/sap/sap/exclusion.htm">http://www.cdc.gov/od/sap/sap/exclusion.htm</a>.</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 HHS 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 page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> <li>1. Identify the Select Agent(s) to be used in the proposed research.</li> <li>2. Provide the registration status of all entities* where Select Agent(s) will be used. <ul style="list-style-type: none"> <li>• 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.</li> </ul> <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> </li> <li>3. Provide a description of all facilities where the Select Agent(s) will be used. <ul style="list-style-type: none"> <li>• Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s).</li> <li>• Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).</li> </ul> </li> </ol> <p>If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the solicitation.</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>
<p>14. Multiple PD/PI Leadership Plan</p>	<p>For applications designating multiple PDs/PIs, a leadership plan must be included. 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</p>

Field Name	Instructions
	<p>direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.</p> <p>If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/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> <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>
<p>15. Consortium/Contractual Arrangements</p>	<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 organizational official on the SF424 (R&amp;R) cover component (Item 18) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p style="padding-left: 40px;"><i>The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the <b>agency's</b> consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.</i></p> <p>A separate statement is no longer required.</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>16. Letters of Support</p>	<p>Attach appropriate letters here from all individuals confirming their roles in the project. <b>For consultants, letters should include</b> rate/charge for consulting services.</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>17. Resource Sharing Plan(s)</p>	<p>This section includes Data Sharing Plan, when applicable, and Sharing Model Organisms. <i>These descriptions are not included in the Research Plan page limits.</i></p> <p>1) <i>Data Sharing Plan:</i> Investigators seeking \$500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific funding opportunity announcements may also require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity</p>

Field Name	Instructions
	<p>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.</p> <p>(2) <i>Sharing Model Organisms</i>: Regardless of the amount requested, all applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Note unlike the data sharing requirement above, this requirement is for all applications where the development of model organisms is anticipated. See <a href="#">Sharing Model Organisms Policy</a>. If model organisms are not planned as part of the research proposal, omit this 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>
18. Appendix	<p>Do not use the Appendix to circumvent the page limitations of the Research Plan. Only one set of appendix materials is necessary. Use filenames for these attachments that are descriptive of the content. Use the add attachments button to the right of this field to complete this entry. A maximum of 10 PDF attachments is allowed. Note this is the total number of allowable appendix attachments, not the total number of publications. Not all grant mechanisms allow publications to be included in the appendix. 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). If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. A summary sheet listing all of the items included in the appendix is encouraged, but not required. When including a summary sheet, it should be included in the first appendix attachment. Appendix material may not appear in the assembled application in the order attached. Applications that do not follow the appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications <b>may</b> include the following materials in the Appendix:</p> <ul style="list-style-type: none"> <li>• <b>Publications – No longer allowed as appendix materials except in the circumstances noted below.</b> Applicants may submit up to 3 of the following types of publications: <ul style="list-style-type: none"> <li>○ <b>Manuscripts and/or abstracts accepted for publication but not yet published:</b> The entire article should be submitted as a PDF attachment.</li> <li>○ <b>Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:</b> The entire article should be submitted as a PDF attachment.</li> </ul> </li> </ul>

Field Name	Instructions
	<ul style="list-style-type: none"> <li>○ <b>Patents directly relevant to the project:</b> The entire document should be submitted as a PDF attachment. (Do not include unpublished theses, or abstracts/manuscripts <b>submitted</b> (but not yet accepted) for publication.)</li> <li>• Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.</li> <li>• 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 Administrator for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.</li> </ul> <p>Items that must <b>not</b> be included in the appendix:</p> <ul style="list-style-type: none"> <li>• Photographs or color images of gels, micrographs, etc., <b>are no longer accepted as Appendix material.</b> These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.</li> <li>• 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.</li> </ul>

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 5.6 Checklist Component

### PHS 398 Checklist

OMB Number: 0925-0001  
Expiration Date: 9/30/2007

<p><b>1. Application Type:</b></p> <p>From SF 424 (R&amp;R) Cover Page. The responses provided on the R&amp;R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.</p> <p>* Type of Application:</p> <p><input type="checkbox"/> New   <input type="checkbox"/> Resubmission   <input type="checkbox"/> Renewal   <input type="checkbox"/> Continuation   <input type="checkbox"/> Revision</p> <p>Federal Identifier: <input type="text"/></p>
<p><b>2. Change of Investigator / Change of Institution Questions</b></p> <p><input type="checkbox"/> Change of principal investigator / program director</p> <p>Name of former principal investigator / program director:</p> <p>Prefix: <input type="text"/></p> <p>* First Name: <input type="text"/></p> <p>Middle Name: <input type="text"/></p> <p>* Last Name: <input type="text"/></p> <p>Suffix: <input type="text"/></p> <p><input type="checkbox"/> Change of Grantee Institution</p> <p>* Name of former institution: <input type="text"/></p>
<p><b>3. Inventions and Patents (For renewal applications only)</b></p> <p>* Inventions and Patents:    Yes <input type="checkbox"/>    No <input type="checkbox"/></p> <p>If the answer is "Yes" then please answer the following:</p> <p>* Previously Reported:    Yes <input type="checkbox"/>    No <input type="checkbox"/></p>

### 1. Application Type

Field Name	Instructions
Type of Application	This field is pre-populated from the SF424 (R&R) Cover Component. Corrections to this field must be made in that component.
Federal Identifier	This field is pre-populated from the SF424 (R&R). Corrections to this field must be made in that component. For New applications this field will be blank.

**2. Change of Investigator/Change of Institution Questions**

Field Name	Instructions
Change of Principal Investigator/Program Director	Check this box if this application reflects a change in PD/PI from the one who was 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 this box if this application reflects a change in grantee institution from the one that was 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, enter the name of the former institution.

**3. Inventions and Patents (For renewal applications only)**

Field Name	Instructions
Inventions and Patents	This block need only be completed if submitting an R&R “Renewal” application. If no inventions were conceived or reduced to practice during the course of work under this project, check the No box. 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 the Yes box.
Previously Reported	If you checked the Yes box for Inventions and Patents, above, indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

**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"/>

**5. Assurances/Certifications (see instructions)**

In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the agency's application guide, when applicable. Descriptions of individual assurances/certifications are provided at: <http://grants.nih.gov/grants/funding/424>

*If unable to certify compliance*, where applicable, provide an explanation and attach below.

Explanation:

#### 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 the Yes box, and then complete the section below. If no program income is anticipated, check the No box and leave the following section blank.
Budget Period	If program income is anticipated, enter the budget periods. If the application is funded, the Notice of 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.

#### 5. Assurances/Certifications

In agreeing to the assurances/certification section 18 of the SF424 (R&R) form, the authorized organizational representative agrees to comply with the following policies, assurances and certifications when applicable. Descriptions of individual assurances/certifications are provided in [Part III: Policies, Assurances, Definitions, and Other Information](#).

Human Subjects Research; Research on Transplantation of Human Fetal Tissue; Research Using Human Embryonic Stem Cells; Women and Minority Inclusion Policy; Inclusion of Children Policy; Vertebrate Animals; Debarments and Suspension; Drug Free Workplace; Lobbying; Non-Delinquency of Federal Debt; Research Misconduct; Civil Rights; Handicapped Individuals; Sex Discrimination; Age Discrimination; Recombinant DNA, including Human Gene Transfer Research; Financial Conflict of Interest; Smoke-Free Workplace; Prohibited Research; Select Agent Research; Principal Investigator Assurance

If you are unable to certify compliance with the applicable policies, assurances, and certifications listed, please provide an explanation in a separate file. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

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Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen. From this main screen, click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

## 6. Peer Review Process

A description of what happens to your research project grant application after it is received for peer review can be found at the following location:

<http://cms.csr.nih.gov/ResourcesforApplicants/Submission+And+Assignment+Process.htm>.

## Overview

Most applications submitted to the PHS will be reviewed through a two-tier system. The first level of review will be performed by a Scientific Review Group (SRG), often called a “study section” or “review committee.” The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions. Additional detailed information on review procedures for scientific review group meetings is located at: <http://www.csr.nih.gov/guidelines/proc.pdf>. The complete listing of [Rosters for NIH Scientific Review Groups \(SRGs\)](http://era.nih.gov/roster/index.cfm) is available at <http://era.nih.gov/roster/index.cfm>.

## Streamlining

The initial scientific peer review of most research applications also will include a process in which only those applications deemed by the reviewers to have the highest scientific merit, generally the top half of the applications under review, will be discussed at the SRG meeting, assigned a priority score, and receive a second level review. Applications in the lower half are not discussed or scored at the SRG meetings. This process allows the reviewers to focus their discussion on the most meritorious applications.

SRG members will be instructed to evaluate research applications by addressing five review criteria (see below) and assigning a single, global score for each scored application. The score will reflect the overall impact that the proposed research could have on the field. Requests for Applications (RFAs) and other types of funding opportunities may have different and/or additional review criteria.

As part of the initial merit review and regardless of whether an application is scored or unscored (streamlined), all applicants will receive a written critique, called a “Summary Statement.” The Summary Statement represents a combination of the reviewers’ written comments and, for non-streamlined applications, includes the SRA’s summary of the members’ discussion during the study section meeting as well as the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Information about charters and membership of SRGs, Councils, and Boards may be obtained from the appropriate agency.

## Research Project Evaluation Criteria

**Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? *For applications designating multiple PDs/PIs, is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PDs/PIs?*

In conducting an evaluation of the scientific assessment of Approach criterion, SRGs will also evaluate the involvement of human/animal subjects, the proposed plans for inclusion of minorities and members of both sexes/genders. The evaluation will be factored into the overall score for scientific and technical merit of the application.

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

**Investigator:** Are the **PD/PI(s) and other key personnel** appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the **PD/PI(s) and** investigative team bring complementary and integrated expertise to the project (if applicable)?

**Environment:** Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

While these review criteria are intended for use primarily with unsolicited research project applications (e.g., R01 or P01), to the extent reasonable, they will also form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), use of these criteria as stated may not be feasible.

**Note: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score.**

**Protection of Human Subjects:** In conducting peer review for scientific and technical merit, SRGs also will evaluate the involvement of human subjects and proposed protections from research risk relating to their participation in the proposed non-exempt Research Plan according to the following five review criteria: (1) Risk to subjects, (2) Adequacy of protection against risks (3) Potential benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

When human subjects are involved in research that involves one of the six categories of research that are exempt under [45 CFR Part 46](#), the SRG will evaluate the justification for the exemption and (1) Human Subjects Involvement and Characteristics, and (2) Sources of Materials.

**Inclusion of Women, Minorities, and Children:** When human subjects are involved in the proposed clinical research, the SRG will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of children in clinical research, as part of the scientific assessment of Approach criterion.

**Vertebrate animals:** As part of the peer review process, the SRG will evaluate the proposed involvement and protection of vertebrate animals as part of the scientific assessment of Approach and Environment criteria and according to the following five points: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) procedures for limiting pain and distress to that which is unavoidable; and (5) methods of euthanasia.

### **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.