



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

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

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

**An Abridged and Annotated Version, prepared for the
School of Medicine, December 2009**

Annotations are indicated by text in red

Emphasis points are indicated in blue

Adobe Forms Version B (to be used with FOAs specifying use of
Adobe-Forms-B application packages)

Software Requirements

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

Applicants should prepare text attachments using any word processing program (following the format requirements in Section 2-6 and then convert those files to PDF before attaching the files to the appropriate component in the application package. (The PDF format is used to preserve document formatting.) In addition, be sure to save files with descriptive file names.

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).

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.

At this time, the very best way to create PDF's appears to be to purchase Adobe Professional version 9.0. This software is available at the UVA bookstore for those on an ITC computing system on the academic side, or from Health System Computing Services on the clinical side. The cost is less than \$60.

Adobe Reader Software Versioning Information

Adobe Professional Versions	Adobe Reader Version	Compatible	Broken Pipe Resolved	Vista Compatible	Mac Compatible
8.0*	8.1.1	Yes	No	Yes	Yes
	8.1.2	Yes	No	Yes	Yes
	8.1.3	Yes	Yes	Yes	Yes
	8.1.4	Yes	Yes	Yes	Yes
	8.1.5	Yes	Yes	Yes	Yes
	8.1.6	Yes	Yes	Yes	Yes
9.0	9.0	Yes	No	Yes	Yes
	9.1	Yes	Yes	Yes	Yes
	9.1.1	Yes	Yes	Yes	Yes
	9.1.2	Yes	Yes	Yes	Yes

2.4.3 Finding a Funding Opportunity Announcement (FOA) for 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 “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.

Grants.gov - Download Application Package - Windows Internet Explorer

https://apply07.grants.gov/apply/forms_apps_idx.html

Grants.gov - Download Application Package

GRANTS.GOVSM Contact Us SiteMap Help RSS Home

Home > Applicants > Apply for Grants >

FOR APPLICANTS

- Find Grant Opportunities
- Get Registered
- Apply for Grants
- Track Your Application
- Applicant Resources
- Search FAQs, User Guides and Site Information

APPLICANT SYSTEM-TO-SYSTEM

FOR GRANTORS

ABOUT GRANTS.GOV

HELP

CONTACT US

SITE MAP

DOWNLOAD APPLICATION PACKAGE

Note: You will need to download and install [PureEdge Viewer](#) / [Adobe Reader](#), prior to downloading an Application Package.

To download an application package, **enter the appropriate CFDA Number OR Funding Opportunity Number** and click the “Download Package” button.

CFDA Number:

Funding Opportunity Number:

Funding Opportunity Competition ID:

If you do not remember the Funding Opportunity Number for the grant opportunity, return to the [Find Grant Opportunities](#) section to locate the grant opportunity and then return to this screen to enter the number.

A Funding Opportunity 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.

Download Grant Applications - Windows Internet Explorer

https://apply07.grants.gov/apply/GetGrant

GRANTS.GOVSM Contact Us SiteMap Help RSS Home

Home » Applicants » Apply for Grants »

SELECTED GRANT APPLICATIONS FOR DOWNLOAD

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

READ BELOW BEFORE YOU APPLY FOR THIS GRANT!

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

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

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

Additional Resources:

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

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

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

CFDA	Opportunity Number	Competition ID	Competition Title	Agency	Instructions & Application
	PA-06-180	ADOBE-FORMS-A	Adobe-Forms-A	National Institutes of Health	download

Downloading the correct SF424 form

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

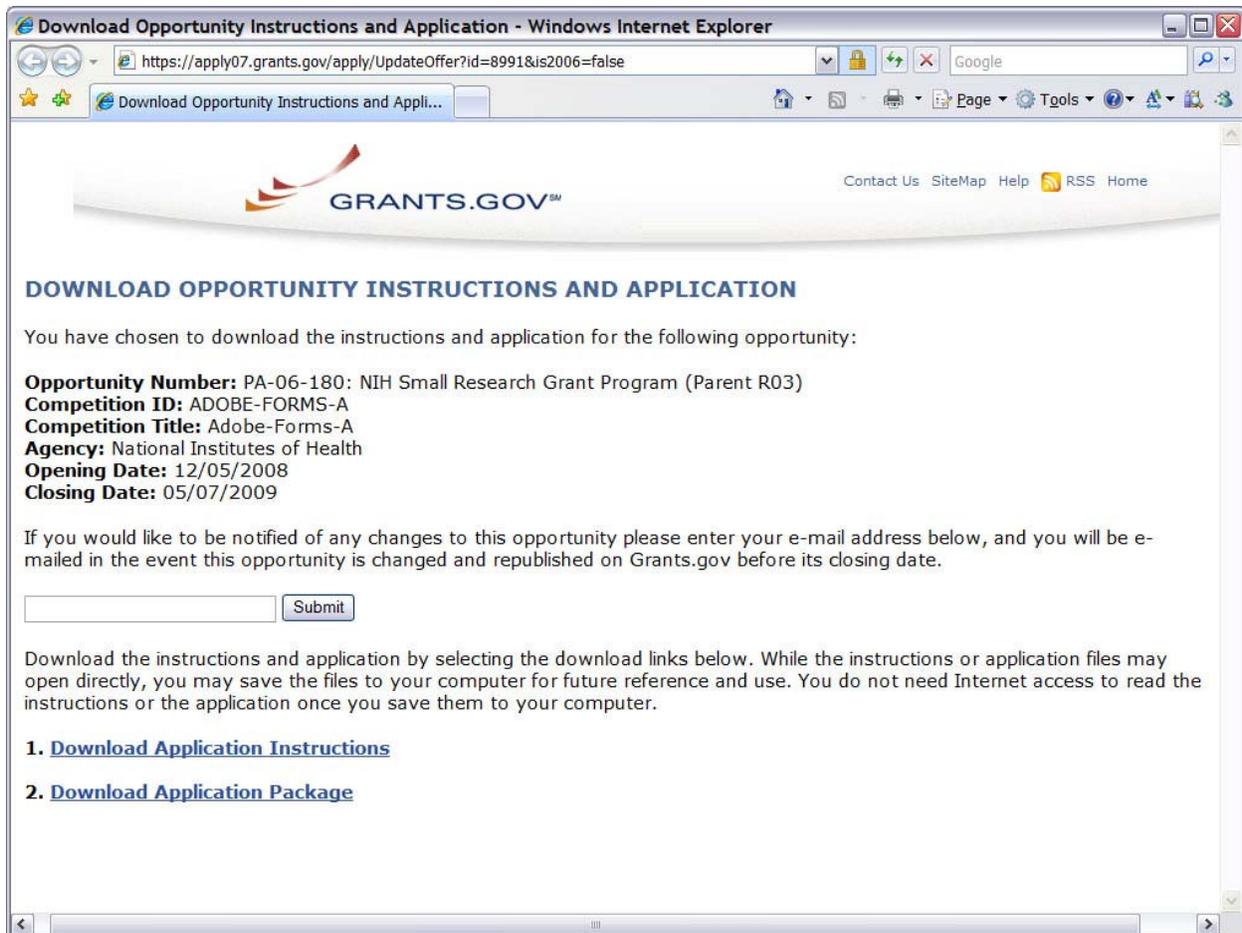
The link on the NIH website to parent (unsolicited) grant applications is:

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

The link to the parent announcement for unsolicited ROIs is on the School of Medicine Office of Grants & Contracts website at

<http://www.healthsystem.virginia.edu/internet/grants/>

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.” [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.](#) ***We advise you to do this to avoid unnecessary last minute crises with software packages.***

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
SF424 (R&R) Cover	X	
SF424 (R&R) Project/Performance Site Locations	X	
SF424 (R&R) Other Project Information	X	
SF424 (R&R) Senior / Key Person Profile(s)	X	
SF424 (R&R) Budget <i>(If NOT using PHS398 Modular Budget.)</i>	*	
SF424 (R&R) Subaward Budget Attachment Form		X
PHS398 Cover Letter		X
PHS398 Cover Page Supplement	X	
PHS398 Modular Budget <i>(If NOT using SF424 (R&R) Budget)</i>	*	
PHS398 Research Plan <i>(Not required for Career Development Award (K) applications)</i>	X	
PHS398 Career Development Award Supplemental Form <i>(Required only for Career Development Award (K) applications)</i>	X	
PHS398 Checklist	X	

* 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).

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

2.6 Format Specifications for Text (PDF) Attachments

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

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for creating PDF files can be found at http://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 1/2" 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.

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.

NOTE: No headers or footers on PDF attachments

Separate Attachments

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

Page limits change depending on PA, RFA. Please check this on each application. The limits listed below are for parent ROIs, but may not be true for a different funding mechanism.

Table 2.6-1. Page Limits

<p style="text-align: center;">SECTION OF APPLICATION</p> <p style="text-align: center;">Also refer to the relevant section of the application instructions and the FOA.</p>	<p style="text-align: center;">PAGE LIMITS *</p>
<p><u>Introduction to Resubmission Application</u> (3 pages for R25 on PHS398 Research Plan and 3 pages for K12, T and D Training Grants on PHS398 Training Program Plan)</p>	<p style="text-align: center;">1 page</p>
<p><u>Introduction to Revision Application</u></p>	<p style="text-align: center;">1 page</p>
<p><u>Specific Aims</u></p>	<p style="text-align: center;">1 page</p>
<p><u>Research Strategy (Item 5.5.3 of Research Plan)</u> For Activity Codes R03, R13, R21, R36, SC2, SC3</p>	<p style="text-align: center;">6 pages</p>
<p><u>Research Strategy (Item 5.5.3 of Research Plan)</u> For Activity Codes R01, R10, R15, R18, R21/R33, R24, R33, R34, DP3, G08, G11, G13, SC1, X01</p>	<p style="text-align: center;">12 pages</p>
<p><u>Research Strategy (Item 5.5.3 of Research Plan)</u> For all other Activity Codes, including S Activity Codes</p>	<p style="text-align: center;">Follow FOA instructions</p>
<p><u>Research Education Program Plan</u> For R25 Research Education Grant Applications</p>	<p style="text-align: center;">25 pages</p>
<p><u>Biosketch (per person)</u> (2 pages for DP1 and DP2 Activity Codes)</p>	<p style="text-align: center;">4 pages</p>
<p><u>Career Development Award (K) Application</u> Upload to PHS 398 Career Development Award Supplemental Form: Combined Candidate Information (Items 3-5: Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training on the Responsible Conduct of Research) and Research Strategy (Item 11)</p>	<p style="text-align: center;">12 pages</p>
<p><u>Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Application</u> Research Training Program Plan: Combined Sections 8.7.2.2 – 8.7.2.5 (Background, Program Plan, Recruitment and Retention Plan to Enhance Diversity, and Plan for Instruction in the Responsible Conduct of Research)</p>	<p style="text-align: center;">25 pages</p>

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 activity codes, regardless of which application is currently used. Some of the activity codes 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 activity codes that have transitioned to electronic submission using the SF424 (R&R) application.

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

NEW SCHEDULE EFFECTIVE JANUARY 3, 2007	RECEIPT CYCLE I	RECEIPT CYCLE II	RECEIPT CYCLE III
Program Project Grants and Center Grants – all P Series*** <i>new, renewal, resubmission, revision</i>	January 25	May 25	September 25
Research Grants –R10, R18, R24, R25 <i>new, renewal, resubmission, revision</i>	January 25	May 25	September 25
Research-Related and Other Programs – all S and G Series, C06, M01 <i>new, renewal, resubmission, revision</i>	January 25	May 25	September 25
Institutional Ruth L. Kirschstein National Research Service – T Series (Training)** <i>new, renewal, resubmission, revision</i>	January 25	May 25	September 25
Research Grants –R01 <i>new</i>	February 5	June 5	October 5
Research Career Development –all K Series <i>new</i>	Feb. 12	June 12	October 12
Research Grants –R03, R21, R33, R21/R33, R34, R36 <i>new</i>	February 16	June 16	October 16
Academic Research Enhancement Award (AREA) – R15 <i>new, renewal, resubmission, revision</i>	February 25	June 25	October 25
Research Grants –R01 <i>renewal, resubmission, revision</i>	March 5	July 5	November 5
Research Career Development –all K Series <i>renewal, resubmission, revision</i>	March 12	July 12	November 12
Research Grants –R03, R21, R33, R21/R33, R34, R36 <i>renewal, resubmission, revision</i>	March 16	July 16	November 16
New Investigator –R01 <i>resubmission for those applications involved in pilot ONLY (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html)</i>	March 20	July 20	November 20

NEW SCHEDULE EFFECTIVE JANUARY 3, 2007	RECEIPT CYCLE I	RECEIPT CYCLE II	RECEIPT CYCLE III
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants – R41, R42, R43 and R44 <i>new, renewal, resubmission, revision</i>	April 5	August 5	December 5
Individual Ruth L. Kirschstein National Research Service Awards (Standard) – all F Series Fellowships**** <i>new, renewal, resubmission</i>	April 8	August 8	December 8
Conference Grants and Conference Cooperative Agreements – R13, U13 <i>new, renewal, resubmission, revision</i>	April 12	August 12	December 12
AIDS and AIDS-Related Grants All of the activity codes cited above <i>new, renewal, resubmission, revision</i>	May 7	September 7	January 7
<p>NOTE for all applications:</p> <ul style="list-style-type: none"> • RFAs and some PARs have special receipt dates indicated in the specific NIH Guide Announcement. • **Institutional Research Training Grants (T32) are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates. • ***Program Project and Center Grants – Applicants should check with individual ICs since some ICs do not accept P series applications three times a year. • ****Individual Pre-Doctoral Fellowships (F31) to promote diversity in health-related research has special receipt dates. • All AIDS and AIDS-related applications (no matter the type) are submitted on the AIDS and AIDS-related dates. 			

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

Match the due date with the correct cycle to find your anticipated start date. For example, a July 5 due date falls within Cycle II, so the earliest project start date is April 1, of the following year. A proposal due October 5 would fall within Cycle III, so would have a projected start date of July 1.

3. Using the Grant Application Package

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

3.1 Verify Grant Information

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

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

Save & Submit Save Print Cancel Check Package for Errors

GRANTS.GOV®

Grant Application Package

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

Opportunity Title:	NIH Small Research Grant Program (Parent R03)
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PA-06-180
Competition ID:	ADOBE-FORMS-A
Opportunity Open Date:	12/05/2008
Opportunity Close Date:	05/07/2009
Agency Contact:	Grants Info TTY 301.451.0088 E-mail: GrantsInfo@nih.gov Phone: 301.435.0714

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 normally not be held over into the next review cycle. Instead, the PD/PI will be notified and will have to submit the application again. See Part I, Section 2.14 of this Guide for more information on the late application policy.

3.2 Enter the Name for the Application

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

UVA NAMING CONVENTION:

PILASTNAMEFIRSTNAME.AGENCY.PANUMBER.DUEDATE

Example: SMITH_JOHN.NIH.PA07070.5JUN09

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: **Smith John.NIH.PA07070.5JUN09**

3.3 Open and Complete Mandatory Documents

Consult the Program Announcement for a list of Mandatory Documents, do not rely on the package to tell you what they are.

Mandatory Documents		Mandatory Documents for Submission
SF424 (R & R)	Move Form to Complete	
Research & Related Other Project Information	=>	
Research & Related Senior/Key Person Profile (E	Move Form to Delete	
Research & Related Project/Performance Site Loc.	=<	
PHS 398 Research Plan		
PHS 398 Cover Page Supplement		
PHS 398 Checklist		
		Open Form

To open an item:

1. Click the document name in the Mandatory Documents box.
2. Click **Move Form to Complete**.
3. Click the document name in the Mandatory Documents for Submission box and click **Open Form**.
4. To remove a document from the Mandatory Documents for Submission box, click the document name to select it and then click the **Move Form to Delete** box. This returns the document to the Mandatory Documents box.

Opportunity Title:	Development and Application of PET and SPECT Imaging Li
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PAR-10-024
Competition ID:	ADOBE-FORMS-B
Opportunity Open Date:	01/16/2010
Opportunity Close Date:	01/07/2013
Agency Contact:	Grants Info Grants Information E-mail: GrantsInfo@nih.gov Phone: 301-435-0714

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

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:**

Mandatory Documents

Research & Related Budget

Move Form to Complete

Move Form to Delete

Mandatory Documents for Submission

SF424 (R & R)
Project/Performance Site Location(s)
Research And Related Other Project Information
Research And Related Senior/Key Person Profile
PHS 398 Research Plan
PHS 398 Cover Page Supplement
PHS 398 Checklist

Optional Documents

PHS Cover Letter
R & R Subaward Budget Attachment(s) Form

Move Form to Submission List

Move Form to Delete

Optional Documents for Submission

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Instructions

- 1 Enter a name for the application in the Application Filing Name field.**

 - This application can be completed in its entirety offline; however, you will need to login to the Grants.gov website during the submission process.
 - You can save your application at any time by clicking the "Save" button at the top of your screen.
 - The "Save & Submit" button will not be functional until all required data fields in the application are completed and you clicked on the "Check Package for Errors" button and confirmed all data required data fields are completed.
- 2 Open and complete all of the documents listed in the "Mandatory Documents" box. Complete the SF-424 form first.**

 - It is recommended that the SF-424 form be the first form completed for the application package. Data entered on the SF-424 will populate data fields in other mandatory and optional forms and the user cannot enter data in these fields.
 - The forms listed in the "Mandatory Documents" box and "Optional Documents" may be predefined forms, such as SF-424, forms where a document needs to be attached, such as the Project Narrative or a combination of both. "Mandatory Documents" are required for this application. "Optional Documents" can be used to provide additional support for this application or may be required for specific types of grant activity. Reference the application package instructions for more information regarding "Optional Documents".
 - To open and complete a form, simply click on the form's name to select the item and then click on the => button. This will move the document to the appropriate "Documents for Submission" box and the form will be automatically added to your application package. To view the form, scroll down the screen or select the form name and click on the "Open Form" button to begin completing the required data fields. To remove a form/document from the "Documents for Submission" box, click the document name to select it, and then click the <= button. This will return the form/document to the "Mandatory Documents" or "Optional Documents" box.
 - All documents listed in the "Mandatory Documents" box must be moved to the "Mandatory Documents for Submission" box. When you open a required form, the fields which must be completed are highlighted in yellow with a red border. Optional fields and completed fields are displayed in white. If you enter invalid or incomplete information in a field, you will receive an error message.
- 3 Click the "Save & Submit" button to submit your application to Grants.gov.**

 - Once you have properly completed all required documents and attached any required or optional documentation, save the completed application by clicking on the "Save" button.
 - Click on the "Check Package for Errors" button to ensure that you have completed all required data fields. Correct any errors or if none are found, save the application package.
 - The "Save & Submit" button will become active; click on the "Save & Submit" button to begin the application submission process.
 - You will be taken to the applicant login page to enter your Grants.gov username and password. Follow all onscreen instructions for submission.

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

3. DATE RECEIVED BY STATE	State Application Identifier
<input type="text"/>	<input type="text"/>

1. * TYPE OF SUBMISSION

Pre-application Application Changed/Corrected Application

4. a. Federal Identifier

b. Agency Routing Identifier

2. DATE SUBMITTED

Applicant Identifier

5. APPLICANT INFORMATION *** Organizational DUNS:**

* Legal Name:

Department: Division:

* Street1:

Street2:

* City: County / Parish:

* State: Province:

* Country: * ZIP / Postal Code:

Person to be contacted on matters involving this application

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

* Phone Number: Fax Number:

Email:

6. * EMPLOYER IDENTIFICATION (EIN) or (TIN):

7. * TYPE OF APPLICANT:

Other (Specify):

Small Business Organization Type Women Owned Socially and Economically Disadvantaged

8. * TYPE OF APPLICATION:

New Resubmission Renewal Continuation Revision

If Revision, mark appropriate box(es):

A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration

E. Other (specify):

* Is this application being submitted to other agencies? Yes No What other Agencies?

9. * NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:

* Start Date * Ending Date

*** 13. CONGRESSIONAL DISTRICT OF APPLICANT**

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

Position/Title:

* Organization Name:

Department: Division:

* Street1:

Street2:

* City: County / Parish:

* State: Province:

* Country: * ZIP / Postal Code:

* Phone Number: Fax Number:

* Email:

1. Type of Submission

Check one of the Type of Submission boxes. If this submission is to change or correct a previously submitted “New” application, click the Changed/Corrected Application box and enter the Grants.gov tracking number in the Federal Identifier field. If this submission is to change or correct a “resubmission,” “renewal,” “continuation,” or “revision” application, leave the Federal identifier field as previously filled with the existing identifier. Do NOT insert the Grants.gov tracking number in these cases.

8. Type of Application

Field Name	Instructions
Type of Application	<p>Select the type from the following list. Check only one. This field is required.</p> <ul style="list-style-type: none">• New: An application that is being submitted to an agency for the first time.• Resubmission: An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration.• Renewal: is equivalent to NIH and other PHS agencies Competing Continuation. An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time.• Continuation: is equivalent to NIH and other PHS agencies Progress Report, a non-competing application for an additional funding/budget period within a previously approved project period. <i>For the purposes of NIH and other PHS agencies, the box for Continuation will not be used and should not be checked.</i>• Revision: An application that proposes a change in<ol style="list-style-type: none">1) the Federal Government’s financial obligations or contingent liability from an existing obligation, or2) any other change in the terms and conditions of the existing award.Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement, but would also include other changes as noted in the definition above. In general, changes to the “terms and conditions of the existing award” (as noted in example 2 above) would not require the submission of another application through Grants.gov. Applicants should contact the awarding agency for advice on submitting any revision/supplement application. <p><i>This field also affects how you complete Item 4.</i> Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank.</p>

Field Name	Instructions
	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.
If Revision, mark appropriate box(es)	<p>If Revision, mark appropriate box(es). May select more than one:</p> <p>A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other</p> <p>If "Other" is selected, please specify in the text box provided.</p>  For the purposes of NIH and other PHS agencies, the boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA.
Other	If "Other" is selected for Revision, add text to explain.
Is this application being submitted to other agencies?	Check applicable box. This field is required.
What Other Agencies?	Enter Agency name.

Application Identification Numbers The application number identifies:

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

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

Type 1	New
Type 2	Competing continuation (a.k.a. renewal, re-competing)
Type 3	Application for additional (supplemental) support
Type 4	Competing extension for an R37 award or first non competing year of a Fast Track SBIR/STTR award
Type 5	Non-competing continuation
Type 7	Change of grantee institution
Type 9	Change of NIH awarding Institute or Division (competing continuation)

<p>15. ESTIMATED PROJECT FUNDING</p> <p>a. Total Federal Funds Requested <input style="width:150px;" type="text" value="1,016,074.00"/></p> <p>b. Total Non-Federal Funds <input style="width:150px;" type="text" value="0.00"/></p> <p>c. Total Federal & Non-Federal Funds <input style="width:150px;" type="text" value="1,016,074.00"/></p> <p>d. Estimated Program Income <input style="width:150px;" type="text" value="0.00"/></p>	<p>16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</p> <p>a. YES <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: <input style="width:100px;" type="text"/></p> <p>b. NO <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR <input checked="" type="checkbox"/> PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</p>
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17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

* I agree

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

18. SFLLL or other Explanatory Documentation

19. Authorized Representative

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

* Position/Title:

* Organization:

Department: Division:

* Street1:

Street2:

* City: County / Parish:

* State: Province:

* Country: * ZIP / Postal Code:

* Phone Number: Fax Number:

* Email:

<p>* Signature of Authorized Representative</p> <div style="border: 1px solid black; padding: 5px; width: 90%; margin: 0 auto;">Completed on submission to Grants.gov</div>	<p>* Date Signed</p> <div style="border: 1px solid black; padding: 5px; width: 90%; margin: 0 auto;">Completed on submission to Grants.gov</div>
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20. Pre-application

15. Estimated Project Funding

Field Name	Instructions
Total Federal Funds Requested	Enter total Federal funds requested for the entire project period. This field is required. <i>This should match the total costs on the cumulative budget page.</i>
Total Non-Federal Funds	Enter total non-Federal funds proposed for the entire project period.  For NIH and other PHS agencies applicants, this field should be left blank unless the specific announcement indicates that cost sharing is a requirement.
Total Federal & Non-Federal Funds	Enter total estimated funds for the entire project period, including both Federal and non-Federal funds. This is required information.  For NIH and other PHS agencies applicants, this field will be the same as item 15a 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. This field is required. <i>This field is usually zero.</i>

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

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

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



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

17. Certification

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

18. SFLLL or Other Explanatory Documentation

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



Attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities) or other documents as appropriate.

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.

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

Project/Performance Site Location(s)

Project/Performance Site Primary Location I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country:

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Project/Performance Site Location 1 I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country:

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Additional Location(s)

List only one location per site, even if there are multiple locations at that site. For example, if the University of Virginia is the main site, list only the primary address, even if multiple departments are involved.

4.3 Project/Performance Site Locations Component

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.



Project/Performance Site Primary Location

Generally, the Primary Location should be that of the applicant organization or identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Checklist Form Page of the application. If there is more than one performance site, including any Department of Veterans Affairs (VA) facilities and foreign sites, list them in the fields provided for Location 1 - # below. Applicants should also provide an explanation of resources available from each Project/Performance Site in Item 9, Facilities and Resources of the Other Project Information form, and describe any consortium/contractual arrangements in Item 15 of the PHS 398 Research Plan.

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

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

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold OLAW-approved Assurances. If the applicant organization does not have an animal program or facilities and the animal work will be conducted at an institution with an Assurance, the applicant must obtain an Assurance from OLAW prior to an award.

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? Yes No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

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

If no, is the IRB review Pending? Yes No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? Yes No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? Yes No

IACUC Approval Date:

Animal Welfare Assurance Number

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

4.a. * Does this project have an actual or potential impact on the environment? Yes No

4.b. If yes, please explain:

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

4.d. If yes, please explain:

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

5.a. If yes, please explain:

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

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract

8. * Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

4.4 Other Project Information Component

1. Are Human Subjects Involved?

UVA's IRB advises that you must first determine whether your research is HUMAN SUBJECTS. Here are two links which help PI's determine this:

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

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

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

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1>

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt** from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. ***PI's cannot self exempt. Any exemption requires IRB review.*

1.a. If YES, Mark yes to pending because with a new submission, the funding has not been reviewed and approved by UVA's IRB, regardless of whether there is an approved protocol.

If your submission receives a score within the fundable range, UVA's IRB advises that the science be submitted for review at that time. This link will guide you in that process:

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

Human Subject Assurance Number:

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

UVA's Human Subject Assurance Number: 00006183



Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.

One final important note: If you have answered YES to human subjects, you MUST upload 4 attachments on the research plan in boxes 6-9.

2. Are Vertebrate Animals Used?

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

2.a. If YES to Vertebrate Animals Is the IACUC review Pending? Indicate if an Institutional Animal Care and Use Committee (IACUC) review is pending. Yes or No.

If yes, IACUC Approval Date Enter the latest IACUC approval date (if available). Leave blank if Pending.

Animal Welfare Assurance Number *UVA's Animal Assurance Number: A3245-01*

One final important note: If you have answered YES to vertebrate animals, you MUST upload 1 attachment on the research plan in box 10.

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. Please click the add attachment button to the right of this field to complete this entry.

This project summary is very important! It should be a well written, interesting piece of work that grabs the reader's attention and tells them that they need to read more.

NOTE: If it exceeds 30 lines of text, it will generate an error. This includes the title and lines after the title! Hint: Don't repeat the title on the abstract, it is unnecessary.

7. Project Narrative

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.

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. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click "Add Attachment."



Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan component(see [Section 5.5](#) for details on completing that component). **When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article.** If the PMCID is not yet available because the Journal submits articles directly to PMC on

behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

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

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. Please click the add attachment button to the right of this field to complete this entry.



No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. 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. Please click the add attachment button to the right of this field to complete this entry.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator				
Prefix:	<input type="text" value="Dr."/>	* First Name:	<input type="text" value="Ivan"/>	
		Middle Name:	<input type="text" value="A"/>	
* Last Name:	<input type="text" value="Grant"/>	Suffix:	<input type="text" value="Ph.D."/>	
Position/Title:	<input type="text" value="PI's title"/>	Department:	<input type="text" value="PI's Dept"/>	
Organization Name:	<input type="text" value="The Rector and Visitors of the University of Virginia"/>		Division:	<input type="text" value="School of Medicine"/>
* Street1:	<input type="text" value="PI's mailing address"/>			
Street2:	<input type="text"/>			
* City:	<input type="text" value="Charlottesville"/>	County/ Parish:	<input type="text"/>	
* State:	<input type="text" value="VA: Virginia"/>	Province:	<input type="text"/>	
* Country:	<input type="text" value="USA: UNITED STATES"/>	* Zip / Postal Code:	<input type="text" value="22908-1234"/>	
* Phone Number:	<input type="text" value="434-924-8888"/>	Fax Number:	<input type="text"/>	
* E-Mail:	<input type="text" value="PIemail@virginia.edu"/>			
Credential, e.g., agency login:	<input type="text" value="PI era Commons USER ID"/>			
* Project Role:	<input type="text" value="PD/PI"/>	Other Project Role Category:	<input type="text"/>	
Degree Type:	<input type="text"/>			
Degree Year:	<input type="text"/>			
*Attach Biographical Sketch	<input type="text" value="PI_Bio.pdf"/>	<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"/>

PROFILE - Senior/Key Person 1				
Prefix:	<input type="text"/>	* First Name:	<input type="text"/>	
		Middle Name:	<input type="text"/>	
* Last Name:	<input type="text"/>	Suffix:	<input type="text"/>	
Position/Title:	<input type="text"/>	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/ Parish:	<input type="text"/>	
* State:	<input type="text"/>	Province:	<input type="text"/>	
* Country:	<input type="text" value="USA: UNITED STATES"/>	* 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"/>	
Degree Type:	<input type="text"/>			
Degree Year:	<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"/>

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

4.5 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 40 individuals (PD/PI + 39 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. Unless otherwise specified in an agency announcement, **senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested.** Consultants should be included if they meet this definition.

UVA has further clarified the role of “KEY PERSON” as follows: “Key Personnel are individuals whose effort is absolutely essential to the success of the proposed activity, either because of their critical leadership position within the proposal (and consequently their intellectual guidance) or because of the uniqueness of the expertise they are contributing relative to the proposed scope of activity. Typically, replacement of any of these individuals requires approval from the sponsor. Graduate Students and Postdoctoral Research Associates usually do not meet the definition of KEY. A key person has measurable effort and will have a defined role with salary to match the committed effort. A key person who does not have committed effort, but who is absolutely essential to the success of the proposed activity, has the role of “Significant Contributor”. This person does not receive salary support from the grant. A consultant can be a significant contributor. (see below)

Credential, e.g., agency login: This must be completed for NIH and DOD applications.

NOTE: Type in the PI’s eRA Commons User ID in this field. If this field is left blank, it will generate an error.

For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. The assigned Commons UserName (the unique name used to log into the system) for anyone assigned the PD/PI role must be entered here. This is a required field for applications submitted to NIH and other PHS agencies. **Applications will not pass agency validation requirements without this field.** Note for applications reflecting Multiple PDs/PIs, the Commons UserName must be provided for all individuals assigned the PD/PI Role.



Multiple PDs/PIs

NIH is now accepting applications reflecting Multiple PDs/PIs for all grant activity codes 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.

For MultiplePI proposals, EACH PI must provide a signed goldenrod.

UVA Policy found here:

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

Profile – Senior/Key Person [n]



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

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

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

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

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



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

Additional Current and Pending Support(s)

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



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

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the [Biographical Sketch Format Page](#) to prepare this section for **all** (modular *and* other) grant applications. Include biographical sketches of all **Senior/Key Personnel and Other Significant Contributors**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a [completed Biographical Sketch](#).

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other Senior/Key Persons. In other federal forms

this information is referred to as “Credential, e.g., agency login.” For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

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

- A. **Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application. *NOTE: This is a completely new requirement!!*
- B. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. **Peer-reviewed publications or manuscripts in press (in chronological order).** NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. *NOTE: This is a completely new requirement!!* Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material).
- D. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

Don’t confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

BIOGRAPHICAL SKETCH

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

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

A. Personal Statement

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

B. Positions and Honors

Positions and Employment

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

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-04	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2005-09	NIH Risk, Adult Addictions Study Section, member

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2005	Excellence in Teaching, Washington University, St. Louis, MO
2008	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

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

Most relevant to the current application

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

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

1. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, V.L. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
2. Shaft, B.M., Hunt, V.L., Merrylye, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
3. Hunt, V. L., Marks, A.E., Shaft, B.M., Merrylye, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2),26-37.
4. Hunt, V.L., Merrylye, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *Journal of the American Geriatrics Society*, 57(4), 15-23.
5. Hunt, V.L., Pour, B., Marks, A.E., Merrylye, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
6. Hunt, V.L, Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2006). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
7. Merrylye, R. & Hunt, V.L. (2006). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
8. Hunt, V.L., Jensen, J.L. & Merrylye, R. (2008). *The aging addict: ethnographic profiles of the elderly drug user*. NY, NY: W. W. Norton & Company.
9. Hunt, V.L. (2009). Contrasting ethnicity with race in the older alcoholic. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, in press. PMID: PMC Journal – In Process.
10. Hunt, V.L. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.

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 and foreign grantee guidelines below. Additional guidance may also be provided in the specific funding opportunity announcement.

[Modular Budget Guidelines](#). Modular budgets are applicable to certain research grant applications requesting \$250,000 or less per year for direct costs. Note, consortium/contractual F&A costs are not factored into the direct cost limit. Consortium F&A costs may be requested in addition to the \$250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application. The modular budget is applicable only to 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 in the next section.

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 or use the scroll bar on the side of the screen. 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 in yellow, outlined in red 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.

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

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: Project Subaward/Consortium

Enter name of Organization:

* Start Date: * End Date: Budget Period 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary (\$)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary (\$)	* Fringe Benefits (\$)	* Funds Requested (\$)
1.	Dr.	Ivan	A	Grant		PD/PI	196,700.00	1.20			19,670.00	5,409.00	25,079.00
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9. Total Funds requested for all Senior Key Persons in the attached file													
Total Senior/Key Person												25,079.00	

Additional Senior Key Persons:

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary (\$)	* Fringe Benefits (\$)	* Funds Requested (\$)	
<input type="text" value="1"/>	Post Doctoral Associates	6.00			17,750.00	4,881.00	22,631.00	
<input type="text"/>	Graduate Students							
<input type="text"/>	Undergraduate Students							
<input type="text"/>	Secretarial/Clerical							
<input type="text" value="1"/>	Laboratory Specialist II	2.16			8,640.00	3,361.00	12,001.00	
<input type="text" value="1"/>	Research Coordinator	3.60			21,360.00	8,309.00	29,669.00	
<input type="text"/>								
<input type="text"/>								
<input type="text"/>								
<input type="text"/>								
<input type="text" value="3"/>	Total Number Other Personnel						Total Other Personnel	64,301.00
Total Salary, Wages and Fringe Benefits (A+B)							89,380.00	

4.7.1 Section A and B

Organizational DUNS

For project applicant, this field is pre-populated from the R&R SF424 Cover Page. For subaward applicants, this field is a required enterable field.

Budget Type

Project, Subaward/Consortium: Check the appropriate block.

Project: The budget requested for the primary applicant organization.

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

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



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

Start Date

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

REFER TO THE PROGRAM ANNOUNCEMENT AND/OR THE STANDARD RECEIPT DATES FOR THE EARLIEST START DATE. THE END DATE WILL BE ONE DAY BEFORE THE START DATE, AT THE YEAR THAT IT WILL BE WHEN THE PROJECT IS COMPLETE.

EXAMPLE: For a 5 year project, Project Start Date 7/1/09, project end date 6/30/14.

End Date

Enter the requested/proposed end date of each budget period. This field is required. *This will be the day before the start date, the year of the last year of the project.*

A. Senior/Key Person



This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions will be provided in the Subaward budget for each subaward/consortium organization. Personnel listed as Other Significant Contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as Senior/Key Persons in the Senior/Key Person Profile Component can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in F.3 Consultant Services.

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

C. Equipment Description

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

Equipment item	* Funds Requested (\$)
1. <input type="text" value="Cell Separator"/>	<input type="text" value="6,000.00"/>
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" value="6,000.00"/>

Additional Equipment:

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	<input type="text" value="1,000.00"/>
2. Foreign Travel Costs	<input type="text"/>
Total Travel Cost	<input type="text" value="1,000.00"/>

E. Participant/Trainee Support Costs

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

4.7.2 Sections C through E

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

C. Equipment Description

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

Field Name	Instructions
Equipment Item	Equipment is defined as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.
Funds Requested	List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.
Total funds requested for all equipment listed in the attached file	Total funds requested for all equipment listed in the attached file. Dollar amount for each item should exceed \$5000.
Total Equipment	Total Funds requested for all equipment.
Additional Equipment	If the space provided cannot accommodate all the equipment proposed, attach a file in the block provided. List each additional item and the funds requested. For all additional items in the attached file, list the total funds requested on line 11 of this section.

D. Travel

Field Name	Instructions
Domestic Travel Costs (Incl. Canada, Mexico, and US Possessions)	Identify 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 (e.g., 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 (e.g., 3 days).

Field Name	Instructions
Total Travel Cost	Total Funds requested for all travel.

E. Participant/Trainee Support Costs



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

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: Project Subaward/Consortium

Enter name of Organization:

* Start Date: * End Date: Budget Period 1

F. Other Direct Costs	Funds Requested (\$)
1. Materials and Supplies	<input type="text" value="18,620.00"/>
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. <input type="text" value="Animals/per diem"/>	<input type="text" value="16,000.00"/>
9. <input type="text"/>	<input type="text"/>
10. <input type="text"/>	<input type="text"/>
Total Other Direct Costs	<input type="text" value="34,620.00"/>

G. Direct Costs	Funds Requested (\$)
Total Direct Costs (A thru F)	<input type="text" value="131,000.00"/>

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1. <input type="text" value="MTDC"/>	<input type="text" value="54.00"/>	<input type="text" value="125,000.00"/>	<input type="text" value="67,500.00"/>
2. <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3. <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4. <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total Indirect Costs			<input type="text" value="67,500.00"/>

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

I. Total Direct and Indirect Costs	Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)	<input type="text" value="198,500.00"/>

J. Fee	Funds Requested (\$)
	<input type="text"/>

K. * Budget Justification
(Only attach one file.)

4.7.3 Sections F through K

F. Other Direct Costs

Field Name	Instructions
1. Materials and Supplies	List total funds requested for materials and supplies. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than \$1,000 are not required to be itemized.
2. Publication Costs	List the total publication funds requested. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. In the budget justification include supporting information.
3. Consultant Services	<p>List the total costs for all consultant services. In the budget justification, identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs.</p> <p><i>This is a PAID service having no sponsored research activity occurring in the consultant's institution's facilities or using that institution's resources and must be consistent with that institution's policies.</i></p>  <p>In the budget justification also provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.</p>
4. ADP/Computer Services	List total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical and education information may be requested. In the budget justification, include the established computer service rates at the proposing organization if applicable.
5. Subawards/Consortium/Contractual Costs	<p>List total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project.</p>  <p>This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.</p>

Field Name	Instructions
6. Equipment or Facility Rental/User Fees <i>Rarely used at UVA</i>	List total funds requested for equipment or facility rental/user fees. In the budget justification, identify each rental user fee and justify.
7. Alterations and Renovations <i>Rarely used at UVA</i>	List total funds requested for alterations and renovations. In the budget justification, itemize by category and justify the costs of alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.
8-10 Other	Add text to describe any “other” direct costs not requested above. Use the budget justification to further itemize and justify. List total funds requested for items 8-10 “Other.”  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.
Total Other Direct Costs	Total Funds requested for all other direct costs.



Special Instructions for Patient Care Costs

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

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

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

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

G. Total Direct Costs (A through F)

Total Funds requested for all direct costs.

H. Indirect Costs

Field Name	Instructions
Indirect Cost Type <i>MTDC</i>	Indicate the type of cost (e.g., Salary & Wages, Modified Total Direct Costs, MTDC , <i>This is UVAs Indirect cost type</i> or Other [explain]). Also indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, “None—will negotiate” and include information for a proposed rate. Use the budget justification if additional space is needed.
Indirect Cost Rate (%) <i>54%, on grounds</i> <i>26% off grounds</i> <i>Effective 7/10/2009</i>	Indicate the most recent indirect cost rate(s) (also known as Facilities & Administrative Costs [F&A]) established with the cognizant Federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. If you have a cognizant/oversight agency and are selected for an award, you must submit your indirect rate proposal to that office for approval. If you do not have a cognizant/oversight agency, contact the awarding agency.  If this field does not allow a figure greater than 100% to be entered, use two lines to show the entire calculation. This field should be entered using a rate such as “55.5.”
Indirect Cost Base (\$)	Enter the amount of the base for each indirect cost type. The Base is the amount of direct costs requested less excluded categories, such as capital equipment and graduate student tuition.
Funds Requested	Enter funds requested for each indirect cost type.
Total Indirect Costs	Total Funds requested for indirect costs.
Cognizant Federal Agency <i>UVA’s Cognizant Agency is the Dept. of Health and Human Services (DHHS)</i>	Enter the name of the cognizant Federal Agency, name and phone number of the individual responsible for negotiating your rate. <i>Department of Health and Human Services (DHHS)</i> <i>Darryl Mayes, Director</i> <i>Division of Cost Allocation</i> <i>Tel: (202) 401-2808</i>

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

Total Funds requested for direct and indirect costs.

K. Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request.

The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories. Only one file may be attached.



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 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted in yellow, outlined in red 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**”

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals (\$)
Section A, Senior/Key Person		125,395.00
Section B, Other Personnel		341,387.00
Total Number Other Personnel	15	
Total Salary, Wages and Fringe Benefits (A+B)		466,782.00
Section C, Equipment		6,000.00
Section D, Travel		5,310.00
1. Domestic	5,310.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		183,801.00
1. Materials and Supplies	98,857.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	84,944.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		661,893.00
Section H, Indirect Costs		354,181.00
Section I, Total Direct and Indirect Costs (G + H)		1,016,074.00
Section J, Fee		

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

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.

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

Once all data have been entered, click the Close Form button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the Move Form to Delete button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

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

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

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

Using the Modular Budget 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.

PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001

Budget Period: 1	<input type="button" value="Reset Entries"/>	Start Date: <input type="text" value="04/01/2010"/>	End Date: <input type="text" value="03/31/2011"/>
-------------------------	--	---	---

A. Direct Costs	* Funds Requested (\$)	
* Direct Cost less Consortium F&A		250,000.00
Consortium F&A		
* Total Direct Costs		250,000.00

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	MTDC	54	243,013.00	131,227.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number)	Department of Health & Human Services (DHHS) Darryl Mayes, Director Division of Cost Allocation Tel: (202) 401-2808
Indirect Cost Rate Agreement Date <input type="text" value="07/10/2009"/>	Total Indirect Costs <input type="text" value="131,227.00"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)	381,227.00
---	-----------------------------	------------

Budget Period: 2	<input type="button" value="Reset Entries"/>	Start Date: <input type="text" value="04/01/2011"/>	End Date: <input type="text" value="03/31/2012"/>
-------------------------	--	---	---

A. Direct Costs	* Funds Requested (\$)	
* Direct Cost less Consortium F&A		250,000.00
Consortium F&A		
* Total Direct Costs		250,000.00

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	MTDC	54	242,014.00	130,687.00
2.				
3.				
4.				

Cognizant Agency (Agency Name, POC Name and Phone Number)	Department of Health & Human Services (DHHS) Darryl Mayes, Director Division of Cost Allocation Tel: (202) 401-2808
Indirect Cost Rate Agreement Date <input type="text" value="07/10/2009"/>	Total Indirect Costs <input type="text" value="130,687.00"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)	380,687.00
---	-----------------------------	------------

5.4.1 Periods 1 through 4

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 MTDC	Indicate the type of base (for example, Salary & Wages, Modified Total Direct Costs, Other [explain]), and indicate if Off-site. If more than one rate/base is involved, use separate lines for each. If you do not have a current indirect rate(s) approved by a Federal agency, indicate, "None—will negotiate" and include information for a proposed rate. Use the budget justification if additional space is needed.

Field Name	Instructions
Indirect Cost Rate (%) <i>54%</i>	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.
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) <i>UVA's Cognizant Agency is the Dept. of Health and Human Services (DHHS)</i>	<i>Department of Health and Human Services (DHHS)</i> <i>Darryl Mayes, Director</i> <i>Division of Cost Allocation</i> <i>Tel: (202) 401-2808</i>
Indirect Cost Rate Agreement Date	<i>7/10/2009</i>
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.

Once you have entered all required information for budget periods 1 and 2, press the **Next** button or scroll down to enter information for subsequent budget periods.

PHS 398 Modular Budget, Periods 5 and Cumulative

Budget Period: 5

[Reset Entries](#)

Start Date:

End Date:

A. Direct Costs

	* Funds Requested (\$)
* Direct Cost less Consortium F&A	<input type="text" value="250,000.00"/>
Consortium F&A	<input type="text"/>
* Total Direct Costs	<input type="text" value="250,000.00"/>

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input type="text" value="MTDC"/>	<input type="text" value="54"/>	<input type="text" value="242,014.00"/>	<input type="text" value="130,687.00"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

Indirect Cost Rate Agreement Date

Total Indirect Costs

C. Total Direct and Indirect Costs (A + B)

Funds Requested (\$)

Cumulative Budget Information

1. Total Costs, Entire Project Period

*Section A, Total Direct Cost less Consortium F&A for Entire Project Period	\$	<input type="text" value="1,250,000.00"/>
Section A, Total Consortium F&A for Entire Project Period	\$	<input type="text"/>
*Section A, Total Direct Costs for Entire Project Period	\$	<input type="text" value="1,250,000.00"/>
*Section B, Total Indirect Costs for Entire Project Period	\$	<input type="text" value="653,975.00"/>
*Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period	\$	<input type="text" value="1,903,975.00"/>

2. Budget Justifications

Personnel Justification	<input type="text" value="Budget.Justification.pdf"/>	Add Attachment	Delete Attachment	View Attachment
Consortium Justification	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Period 5 and Cumulative

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.

Total Costs, Entire Project Period, Section C. This figure goes on the SF424 cover page 2 in Box 15 a and 15 c. Box 15 b and 15 d will usually be 00.00 unless there are matching funds or program income.

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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.</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 (in person months) 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 total consortium/contractual costs must be included in the overall requested modular direct cost amount.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
Additional Narrative Justification	<p>If the requested budget requires any additional justification, 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>

4.8 Special Instructions for Preparing Applications with a Subaward/Consortium

Close Form	Print Page	About		
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM				
<p>Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.</p>				
<p>Click here to extract the R&R Subaward Budget Attachment</p>				
<p>Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.</p>				
1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment
<p>OMB Number: 4040-0001 Expiration Date: 04/30/2008</p>				

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.

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 ten letters of the consortium organization’s name and use “.pdf” as the file extension. (The extracted file is an Adobe PDF file.) Once you have saved the file there is no need to extract another budget attachment. Doing so may cause you to lose any data already stored in the saved file.
- Email the extracted, saved form to the consortium grantee. Note: consortium grantees must have installed Adobe Reader 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.

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

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

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.

PHS 398 Cover Letter

OMB Number: 0925-0001

*Mandatory Cover Letter Filename:

Add Cover Letter File

Delete Cover Letter File

View Cover Letter File

5.2 Cover Letter Component

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

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in Section 2.14) include specific information about the timing and nature of the cause of the delay.
7. When submitting a Changed/Corrected Application **after** the submission date, a cover letter is **required** explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
8. Explanation of any subaward budget components that are not active for all periods of the proposed grant.
9. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications \$500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc.

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.

Suggested Cover Letter Format

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

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

- Provide explanations for each request in a separate paragraph.

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

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

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.

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

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

Prefix: * First Name:
Middle Name:
* Last Name:
Suffix:

2. Human Subjects

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

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: * First Name:
Middle Name:
* Last Name:
Suffix:
* Phone Number: Fax Number:
Email:

* Title:

* Street1:
Street2:
* City:
County/Parish:
* State:
Province:
* Country: * Zip / Postal Code:

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). Note that Public Law 110-85, enacted 09/27/2007, mandates registration and results reporting of applicable clinical trials in ClinicalTrials.gov (see Part II and Part III).
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 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.

4. Human Embryonic Stem Cells

Field Name	Instructions
Does the proposed project involve human embryonic stem cells?	If the proposed project does not involve human embryonic stem cells, check the No box. If the proposed project involves human embryonic stem cells, check the Yes box, and then complete the section below.
Cell Line(s)	List in this section the registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry.
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.

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

- New
 Resubmission
 Renewal
 Continuation
 Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application <small>(for RESUBMISSION or REVISION only)</small>	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
2. Specific Aims	<input type="text" value="specific_aims.pdf"/>	Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy	<input type="text" value="research_plan.pdf"/>	Add Attachment	Delete Attachment	View Attachment
4. Inclusion Enrollment Report	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

6. Protection of Human Subjects	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

10. Vertebrate Animals	<input type="text" value="animals.pdf"/>	Add Attachment	Delete Attachment	View Attachment
11. Select Agent Research	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
12. Multiple PD/PI Leadership Plan	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
13. Consortium/Contractual Arrangements	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
14. Letters of Support	<input type="text" value="letters.pdf"/>	Add Attachment	Delete Attachment	View Attachment
15. Resource Sharing Plan(s)	<input type="text" value="Resource_sharing.pdf"/>	Add Attachment	Delete Attachment	View Attachment

16. Appendix	Add Attachments	Remove Attachments	View Attachments
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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 limits 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. In addition, be sure to save files with descriptive file names.

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

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

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

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

Separate Attachments

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

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.

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, Research Strategy)

Field Name	Instructions
1. Introduction to Application (for Resubmission or Revision only)	<p>Use only if you are submitting an R&R Resubmission or Revision (Cover Page Item 8). The Introduction may not exceed 1-3 pages for resubmissions or one page for revisions. Page limits for the Introduction vary for specialized programs (e.g., R03 and R21 applications). Applicants must 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>

Field Name	Instructions
2. Specific Aims	<p>State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>Specific Aims are limited to one page. <i>This is a completely new requirement!</i></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. Research Strategy	<p><i>This is a completely new requirement!</i></p> <p>Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9).</p> <p>Follow the page limits for the Research Strategy in the table of page limits (Table 2.6-1), unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.</p> <p><i>(a) Significance</i></p> <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. <p><i>(b) Innovation</i></p> <ul style="list-style-type: none"> • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Field Name	Instructions
	<p data-bbox="586 260 753 296"><i>(c) Approach</i></p> <ul data-bbox="634 310 1395 867" style="list-style-type: none"> <li data-bbox="634 310 1395 512">• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. <li data-bbox="634 533 1395 596">• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. <li data-bbox="634 617 1395 716">• If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. <li data-bbox="634 737 1395 867">• Point any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in Item 11, below. <p data-bbox="537 932 1395 1367">Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in application from Early Stage Investigators than on the preliminary data in applications from more established investigators).</p> <p data-bbox="537 1388 1395 1866">Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List); do not include that information here. 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, then click Open.</p>

Field Name	Instructions
4. 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 Part II, Section 4.3 for more detailed instructions on which Target and Enrollment Report or Table to use.</p>
5. Progress Report Publication List (Renewal Applications Only)	<p>List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.</p> <p>Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Part I Section 5.5.15 for more information).</p>

Human Subjects Sections *NOTE: If you have answered yes to Human Subjects on the Other Project Information page, you must attach a PDF for Box 6, 7, 8 and 9.*

Field Name	Instructions
6. Protection of Human Subjects	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.</p> <p>This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form. If the answer is “No” to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>

Field Name	Instructions
7. Inclusion of Women and Minorities	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
8. Targeted/Planned Enrollment	<p>If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table for each protocol; see Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Section 4.3. For applicants answering “Yes” to the question “Are human subjects involved?” on the R&R Other Project Information Form and the research does not fall under Exemption 4, complete the Targeted/Planned Enrollment Table for each protocol.</p> <p>Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</p>
9. Inclusion of Children	<p>Refer to Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Sections 4.4 and 5.7. For applicants answering “Yes” to the question “Are human subjects involved” on the R&R Other Project Information Form and the research does not fall under Section 4, this section is 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>

Other Sections

Field Name	Instructions
10. 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"> 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

Field Name	Instructions
	<p>numbers of animals to be used in the proposed work.</p> <ol style="list-style-type: none"> 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. 3. Provide information on the veterinary care of the animals involved. 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. 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. <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><i>NOTE: If you have answered yes to Vertebrate Animals on the Other Project Information page, you must attach a PDF for Box 10.</i></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 & References Cited.” Refer to Item 8 in the Other Project Information Component for instructions.</p>
<p>11. Select Agent Research</p>	<p>Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.</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 that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.cdc.gov/od/sap/sap/exclusion.htm.</p> <p>If the strain(s) is not currently excluded from the list of select</p>

Field Name	Instructions
	<p>agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> 1. Identify the Select Agent(s) to be used in the proposed research. 2. Provide the registration status of all entities* where Select Agent(s) will be used. <ul style="list-style-type: none"> • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed. <p>*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”</p> 3. Provide a description of all facilities where the Select Agent(s) will be used. <ul style="list-style-type: none"> • Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). <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>
12. Multiple PD/PI Leadership Plan	<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 direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific</p>

Field Name	Instructions
	<p>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>
13. Consortium/Contractual Arrangements	<p>Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the authorized organizational official on the SF424 (R&R) cover component (Item 18) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p><i>The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.</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>
14. Letters of Support	<p>Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include 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>
15. Resource Sharing Plan(s)	<p>NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When</p>

Field Name	Instructions
	<p>resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.</p> <ol style="list-style-type: none"> 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 require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html. 2. <i>Sharing Model Organisms</i>: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042. 3. <i>Genome Wide Association Studies (GWAS)</i>: Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/. <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>
16. Appendix	<p>Only one copy of appendix material is necessary. Use the add attachments button to the right of this field to complete this entry.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that</p>

Field Name	Instructions
	<p>are not publicly available (see below for further details and check the FOA for any specific instructions), though not all grant activity codes allow publications to be included in the appendix.</p> <p>Do not use the appendix to circumvent the page limitations of the research plan.</p> <p>Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications may include the following materials in the Appendix:</p> <ul style="list-style-type: none"> • Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications: <ul style="list-style-type: none"> ○ Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment. ○ Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment. ○ Patents directly relevant to the project: The entire document should be submitted as a PDF attachment. <p>(Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)</p> • Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary. • For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Field Name	Instructions
	<p data-bbox="594 264 1162 291">Items that must <i>not</i> be included in the appendix:</p> <ul data-bbox="639 317 1385 663" style="list-style-type: none"><li data-bbox="639 317 1385 443">• Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.<li data-bbox="639 468 1385 663">• Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

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.

Once all data have been entered, click the **Close Form** button at the top of the form or use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.