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PART I. INSTRUCTIONS FOR PREPARING AND SUBMITTING AN APPLICATION

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Items in red relate specifically to USC or the College.
Items in purple relate to recent changes announced by NIH or PHS.
Foreword

Version 2 — Released July 5, 2006

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

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

Other changes of note to specific components include:

SF424 (R&R) Cover

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

PHS398 Research Plan Component

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

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

PHS398 Checklist Component

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

General Text Edits

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

- All references to the eRA Commons verification steps for the PD/PI and AOR have been changed to now reflect the 2-day period to view an application.
- Additional agency-specific instructions have been included in 4.7 R&R Budget Component for Person Months, Requested Salary, Consultants, Subawards/Consortium, Patient Care Costs, Joint University/VA Appointments, Budget Justification and Supplemental/Revision Applications.
Instruction text throughout Part II. Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan has been revised to reflect the revised sections of the PHS398 Research Plan component.

A number of text edits have been made to the instruction text of specific R&R data elements so that it reflects revised text used by Grants.gov in the actual forms.

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

Public Health Service (PHS) Research Grants

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

The use of these new forms also involves electronic submission of completed applications through Grants.gov. NIH and other PHS agencies will gradually transition all mechanisms to the new application forms and Grants.gov submission. Specific Funding Opportunity Announcements (FOAs) will clearly indicate which forms and submission process an applicant should use. NIH will continue to use Requests for Applications (RFAs) and Program Announcements (PAs) as categories of FOAs. See Section 2.4.2 for definitions.

Applicants must carefully review FOAs for guidance on when to use the 424 (R&R) forms, instructions, and electronic submission for a specific mechanism (i.e., R13, R15, etc.). This new process will apply to all types of submissions for the announced mechanism—new, resubmission (formerly “revised/amended”), renewal (formerly “competing continuation”), and revision (formerly “competing supplemental”) grant applications. Each FOA will include a link to the most current version of these instructions. Applicants are encouraged to check the Web site frequently for the most current version.

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

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

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

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

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

Font

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

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

Type may be no more than six lines per inch.

Page Margins

Use standard paper size (8 ½" x 11).

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

Page Formatting

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

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

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

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

Use English and avoid jargon.

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

Separate Attachments

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

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

Page Limits

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

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

Observe the page number limitations given in Table 2.6-1. Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See Table 1.4-1. Agency contact Table in full guide. ) The page number limitations may also be different for other specialized grant applications (e.g., R03 and R21 applications). Consult and follow the additional instructions for those applications.
<table>
<thead>
<tr>
<th>Section</th>
<th>Page Limit</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- New applications</td>
<td>Not required/Not to be submitted</td>
<td>See Instructions</td>
</tr>
<tr>
<td>- Resubmission applications</td>
<td>1-3 (check announcement for specific guidance)</td>
<td></td>
</tr>
<tr>
<td>- Revision applications</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Research Plan</strong></td>
<td>25*</td>
<td>Text including all figures, charts, tables, and diagrams.</td>
</tr>
<tr>
<td>Sections 2-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sections 6 - 17</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td><strong>Biographical Sketches</strong></td>
<td>4</td>
<td>No more than four pages for each person listed as Senior/Key Persons.</td>
</tr>
<tr>
<td><strong>Appendix</strong></td>
<td>none</td>
<td>New requirements effective 1/3/2007. See Instructions for specifics.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generally limited publications are allowed now only in certain situations. Only questionnaires and other materials are allowed.</td>
</tr>
<tr>
<td><strong>PAs and RFAs</strong></td>
<td>Page limitations specified in the PA and RFA announcement in the NIH Guide take precedence.</td>
<td>See specific instructions in PAs and RFAs published in the NIH Guide.</td>
</tr>
</tbody>
</table>
4. Completing the SF424 Research and Related (R&R) Forms

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

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

- Required fields are highlighted in yellow and noted with an asterisk (*).
- Optional (grants.gov) fields and completed fields are displayed in white. Complete all fields whether noted as required or optional.
- Data entered into a specific field is not accepted until you have navigated to the next field.
- If you enter invalid or incomplete information in a field, you will receive an error message.
- Click the “Next” button at the top of the form to navigate to a subsequent page.
- Click the “Close Form” button at the top of the form to be returned to the Grant Application Package screen.
- Click the “Save” button at the top of the form to save the entire package. You will receive an error message indicating “One or more of the items in this form contains an invalid. Do you want to proceed anyway?” Applicants should always answer “Yes”. This error message shows because not all data has been entered yet.
- Do Not Click the “Print” button. This will attempt to print the entire package. Printing each page individually will produce a superior set of documents.
- Click on the form/document that you have just completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box.

4.2 Cover Component
1. Type of Submission
Select Type of Submission boxes. If this submission is to change or correct a previously submitted application, click the Changed/Corrected Application box and enter the Grants.gov tracking number in the Federal Identifier field. This number is in your email confirmation and begins with “GRANT”. Unless requested by the agency, applicants may not use this to submit changes after the closing date.

2. Date Submitted and Applicant Identifier – Contracts & Grants Administrator will enter these.

3. Date Received by State and State Application Identifier
Enter the date received by state (if applicable). In the State Application Identifier field, enter the state application identifier, if applicable. For submissions to NIH and other PHS agencies, leave these fields blank.

4. Federal Identifier
New project applications should leave this field blank, unless you are submitting a Changed/Corrected application. When submitting a changed/corrected “new” application, enter the Grants.gov tracking number. If this is a continuation, revision, or renewal application, enter the assigned Federal Identifier number (for example, award number) even if submitting a changed/corrected application.

For submissions to NIH and other PHS agencies, an example of an award number is CA123456.
Existing definitions for NIH and other PHS agencies applications are somewhat different:

- New is an application that is submitted for the first time.
- Resubmission is equivalent to NIH and other PHS agencies Revision; i.e., a revised or amended application.
- Renewal is equivalent to NIH and other PHS agencies Competing Continuation.
- Continuation is equivalent to NIH and other PHS agencies Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will not be used.
- Revision is somewhat equivalent to NIH and other PHS agencies Competing Supplement. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Applicants to NIH and other PHS agencies should complete this field when submitting a resubmission, renewal or revision application. When submitting a “New” application, this field should remain blank unless you are submitting a Changed/Corrected Application. In this case, where Item 1 = Changed/Corrected Application and Item 8 = New, the Federal Identifier field becomes a required field. Therefore you must enter the Grants.gov tracking number assigned to the application that you are correcting. If you are unable to recall the tracking number, enter “N/A.”

5. Applicant Information

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

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational DUNS</td>
<td>072933393</td>
</tr>
<tr>
<td>Legal Name</td>
<td>University of Southern California</td>
</tr>
<tr>
<td>Department</td>
<td>Contracts &amp; Grants</td>
</tr>
<tr>
<td>Division</td>
<td>Compliance</td>
</tr>
<tr>
<td>Street1</td>
<td>837 Downey Way</td>
</tr>
<tr>
<td>Street2</td>
<td>STO-330</td>
</tr>
<tr>
<td>City</td>
<td>Los Angeles</td>
</tr>
<tr>
<td>County</td>
<td>Los Angeles</td>
</tr>
<tr>
<td>State</td>
<td>CA</td>
</tr>
<tr>
<td>ZIP Code</td>
<td>90089-1147</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
</tbody>
</table>

Person to be contacted on matters involving this application:

This information is for the Administrative Official, not the PD/PI. This person is the individual to be notified if additional information is needed and/or if an award is made. Your Contracts and Grants Administrator is the Administrative Official. [http://www.usc.edu/dept/contracts/staff.htm](http://www.usc.edu/dept/contracts/staff.htm)
### Field Name | Instructions
--- | ---
Prefix |  
First Name | [enter DCG administrator’s first name ]
Middle Name |  
Last Name | [enter DCG administrator’s last name ]
Suffix |  
Phone Number | 213-740-6672
Fax Number | 213-740-6070
Email | [enter DCG administrator’s email address ]

6. **Employer Identification** – Enter the TIN assigned by the Internal Revenue Service. If you have a 12-digit EIN established for grant awards from NIH or other PHS agencies, enter all 12 digits.

   195-1642394A1

7. **Type of Applicant** – This information is for the Applicant Organization, not a specific individual.

   **Type of Applicant** | **Private Institution of Higher Education**
   --- | ---
   Other (Specify) | n/a
   Woman Owned | n/a
   Socially and Economically Disadvantaged | n/a

8. **Type of Application** – New, Resubmission, Renewal, Continuation or Revision. Refer to the full SF424 guidelines for complete definitions of Type of Application.

   This field also affects how you complete Item 4. Federal Identifier. If “Type of Application” is “New”, you can leave the Federal Identifier field blank on the first submission attempt. However, the Federal Identifier field becomes a required field when submitting a Changed/Corrected application to address errors/warnings. When submitting a Changed/Corrected “New” application, enter the Grants.gov tracking number of the previous submission attempt (e.g. GRANT12345678). If you are unable to find the tracking number, enter “N/A”.

   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) A. Increase Award, B. Decrease Award, C. Increase Duration, D. Decrease Duration, or E. Other (enter text to explain) May select more than one.

   Is this application being submitted to other agencies? Yes or No. If yes, enter agency name.

9. **Name of Federal Agency** - This information is pre-populated by Grants.gov.

10. **Catalog of Federal Domestic Assistance (CFDA) Number and Title (CFDA)** - These fields are pre-populated by Grants.gov. This field may be blank if you are applying to an opportunity that references multiple CFDA numbers. When this field is blank, leave it blank.

11. **Descriptive Title of Applicant’s Project** – Enter a brief descriptive title of the project. For NIH and other PHS agencies, titles in excess of 81 characters will be truncated.

12. **Areas Affected by Project (Cities, Counties, States, Etc.)** – List only the largest political entities affected by the project (for example, state, counties, cities). Enter “N/A” for not applicable.
13. **Start Date and Ending Date** – Enter the proposed start date and the end date of the project using the following format: MM/DD/YYYY.

14. **Congressional District Applicant and Congressional District Project** – CA-033 for UPC

15. **Project Director/Principal Investigator (PD/PI) Contact Information** – If submitting an application reflecting Multiple PDs/PIs, the individual designated as the Contact PI should be entered here. See Section 4.5 Senior/Key Person Profile Components for additional instructions for Multiple PDs/PIs.

Enter information specific to the PD/PI, including department name and address. Organization Name is University of Southern California, Division is College of LAS. Also include the phone, fax and email of the PD/PI.

16. **Estimated Project Funding**
   a. **Total Estimated Project Funding** – Enter the total Federal funds requested for the entire project period.
   b. **Total Federal & Non-Federal Funds** – Enter the total estimated funds for the entire project period, including both Federal and non-Federal funds. If using the Funds Requested Budget Component, item 16b will be the same as item 16a. This amount would include cost share if required.
   c. **Estimated Program Income** – Identify any Program Income estimated for this project period, if applicable.

17. **Is Application Subject to Review by State Executive Order 12372 Process?**
   If the announcement indicates that the program is covered under Executive Order 12372, check the “Yes” box and contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372. If no, check the appropriate box. This field is required.

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

18. **Complete Certification** - Check the “I agree” box to provide the required certifications and assurances. **This field is required.**

19. **Authorized Representative** – The Contracts and Grants Administrator is the Authorized Organizational Representative (AOR).

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td>Select from the list the prefix. (Ms. or Mr.)</td>
</tr>
<tr>
<td>First Name</td>
<td>[ enter DCG administrator’s first name ]</td>
</tr>
<tr>
<td>Middle Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td>[ enter DCG administrator’s last name ]</td>
</tr>
<tr>
<td>Suffix</td>
<td></td>
</tr>
<tr>
<td>Position/Title</td>
<td>C&amp;G Administrator</td>
</tr>
<tr>
<td>Organization</td>
<td>University of Southern California</td>
</tr>
<tr>
<td>Department</td>
<td>Contracts &amp; Grants</td>
</tr>
<tr>
<td>Division</td>
<td></td>
</tr>
<tr>
<td>Street1</td>
<td>837 Downey Way</td>
</tr>
<tr>
<td>Street2</td>
<td>STO-330</td>
</tr>
<tr>
<td>Field Name</td>
<td>Instructions</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>City</td>
<td>Los Angeles</td>
</tr>
<tr>
<td>County</td>
<td>Los Angeles</td>
</tr>
<tr>
<td>State</td>
<td>CA</td>
</tr>
<tr>
<td>ZIP Code</td>
<td>90089-1147</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Phone Number</td>
<td>213-740-7762</td>
</tr>
<tr>
<td>Fax Number</td>
<td>213-740-6070</td>
</tr>
<tr>
<td>Email</td>
<td>[enter DCG administrator’s email address]</td>
</tr>
<tr>
<td>Signature of Authorized Representative</td>
<td>Your DCG administrator will sign electronically It is the organization’s responsibility to assure that only properly authorized individuals sign in this capacity and/or submit the application to Grants.gov. If this application is submitted through Grants.gov, leave this field blank. If a hard copy is submitted, the AOR must sign here.</td>
</tr>
<tr>
<td>Date Signed</td>
<td>If this application is submitted through Grants.gov, the system will generate this date. If submitting a hard copy, enter the date the AOR signed the application.</td>
</tr>
</tbody>
</table>

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

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

4.3 Project/Performance Site Locations Component

Project/Performance Site Primary Location – 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. Click Next Site to display the fields for Project/Performance Site Locations 3 through 8. Be sure to include complete mailing address, including street, city, state and country.

If you need to add more than eight locations, enter the information in a separate file. On the form, click Add Attachment, select the file, and then click Open. A sample Additional Performance Sites format page for greater than 8 locations is found under “Additional Format Pages” at: http://grants.nih.gov/grants/funding/424/index.htm.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.
4.4 Other Project Information Component

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

1.a. Is the IRB review Pending?
If the Institutional Review Board (IRB) review is pending, check the Yes box. Otherwise, check the No
box. Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB
review/approval process has not yet begun at the time of submission. In the IRB Approval Date field,
enter the latest IRB approval date, if available. Leave blank if Pending. Also note that an IRB Approval
Date is not required at the time of submission.

If human subject activities are exempt from Federal regulations, provide the exemption numbers.
For Human Subject Assurance Number – 00007099 for UPC or 00005906 for HSC

2. Are Vertebrate Animals Used?
If activities involving vertebrate animals are planned at any time during the proposed project at any
performance site, check the Yes box. Otherwise, check the No box, and skip the rest of block 2. This field
is required.

2.a. If YES to Vertebrate Animals
For the “Is the IACUC review Pending” field, if an Institutional Animal Care and Use Committee
(IACUC) review is pending, check the Yes box. Otherwise check the No box. Applicants should check
“Yes” to the question “Is the IACUC review Pending?” even if the IACUC review/approval process has
not yet begun at the time of submission. For IACUC Approval Date, enter the IACUC approval date, if
available. Leave blank if Pending. Also note that an IACUC Approval Date is not required at the time of
submission.

For Animal Welfare Assurance Number – A3518-01

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

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

4.a. Does this project have an actual or potential impact on the environment?
If your project will have an actual or potential impact on the environment, check the Yes box, and then
explain in the box provided in 4.b. Otherwise, check the No box.
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

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

5. Activities Outside US or with International Collaborators Questions

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

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

5.c. Optional Explanation

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

6. Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. This Summary must not include any proprietary/confidential information. This section must be no longer than 30 lines of text, and follow the required font and margin specifications.

To attach a project summary/abstract file, click Add Attachment, browse to where you saved the file, select the file, and then click Open. The attachment must be in PDF format. (See Section 2.6 for additional information on preparing attachments.)

7. Project Narrative

For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary. The second component of the Project Summary/Abstract (i.e., “Description”) is Relevance. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience. Add Attachment.

8. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly “Literature Cited”) should include any references cited in the PHS 398 Research Plan component(see Section 5.5 for details on completing that component). The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material. Add Attachment.

9. Facilities & Other Resources

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. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If there are multiple performance sites, then resources available at each site should be described. Add Attachment.
10. Equipment
List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Add Attachment

11. Other Attachments
Attach a file to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction by clicking Add Attachment.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

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

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

Multiple PDs/PIs

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

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

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

The first section (Prefix through e-mail) for the PD/PI is automatically populated from the SF 424 (R&R).

Credential, e.g., agency login – If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank.

For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. 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.

Project Role – Select a project role from the list.
Biographical Sketch – Provide a biographical sketch for the PD/PI. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach by clicking Add Attachment.

Current & Pending Support – 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.

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

Credential, e.g., agency login – If you are submitting to an agency (e.g., NIH and other PHS agencies) where you have an established personal profile, enter the agency ID. If not, leave blank.

For NIH and other PHS agencies, registration in the eRA Commons for all PDs/PIs is required. The assigned Commons User Name (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.

Project Role – Select a project role from the list. Select “Other” if an appropriate project role is not listed.

At this time, NIH and other PHS agencies continues to only recognize a single PD/PI. The role of “Co-PD/PI” is not currently used by NIH and other PHS agencies. Do not assign any individual this role.

Biographical Sketch – Provide a biographical sketch for the Senior/Key Person. Add Attachment.

Current & Pending Support – Unless otherwise required in a specific FOA, do not use this attachment upload for NIH and other PHS agency submissions.

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

Additional Senior/Key Person Profile(s) – If more than eight Senior/Key Person profiles are proposed, enter the information in a separate file. Add Attachment.

Additional Biographical Sketch(es) (Senior/Key Person) – Save the information in a single file and attach by clicking Add Attachment.

Additional Current and Pending Support(s) – If appropriate, save the information in a single file and attach by clicking Add Attachment.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.
4.5.2 Senior/Key Person Profile (Expanded) Component

This component provides the ability to collect structured data for up to 40 Senior/Key Persons. Data must be entered for the first 8 individuals (PD/PI + seven others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover component. See instructions in section 4.2 Cover Component if these fields are empty.

Starting with the PD/PI, provide a profile for each senior/key person proposed. Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Profile – Senior/Key Person [n]

The remaining Senior/Key Person Profiles should be listed in alphabetical order. Also use this section to list any Other Significant Contributors (OSCs). OSCs should be listed after all Key Persons. OSCs are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project. These individuals are typically presented at “effort of zero person months” or “as needed” (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

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

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

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

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

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

The following instructions are provided on this form: Additional Senior/Key Person Form Attachments When submitting senior/key persons in excess of 8 individuals, please attach additional senior/key person forms. Each additional form attached will provide you with the ability to identify another 8 individuals, up to a maximum of 4 attachments (32 people). See the full SF 424 Guide for more complete instructions.

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample format on the Biographical Sketch Format Page to prepare this section for all (modular and other) grant applications. Include biographical sketches of all Senior/Key Personnel and Other Significant Contributors. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a completed Biographical Sketch.
If the individual is registered in the eRA Commons, include the assigned Commons User Name. This data item is currently optional. (For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.)

Complete the educational block at the top of the format page, and complete Sections A, B, and C.

A. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

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

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

### 4.6 Selecting the Appropriate Budget Component

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

To determine which budget component to use for NIH applications, consult the modular budget guidelines below. Additional guidance may also be provided in the specific funding opportunity announcement. **You only need to complete the budget component appropriate to your submission as identified in the FOA.**

**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 application. Completed NIH applications will include only one component.

### 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. You must complete a separate detailed budget for each year of support requested. The form will generate a cumulative budget for the total project period. You must complete all the required information (i.e., those fields that are highlighted and noted with an “*”) before the “Next Period” button is activated. If no funds are requested for a required field, enter “0.”

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

The concept of person months as a metric for determining percent of effort is a new business process for the applicant community of the NIH and other PHS agencies. To assist with this transition, resources are
If funds are being requested for more than one budget period, click the “Next Period” button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.

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

### 4.7.1 Section A and B

**Organizational DUNs**

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

**Budget Type**

Check Project if the budget requested is for the primary applicant organization. Check Subaward/Consortium if the budget requested is for subawardee/consortium organization(s).

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

**Enter name of Organization**

Pre-populated from the R&R SF424. For subaward applicants, enter the name of your organization.

**Start Date**

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

**End Date**

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

**Budget Period**

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

**A. Senior/Key Person**

**Enter name and project role for each Senior/Key persons** supported on the project. This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year, regardless of whether a salary is requested. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions will be provided in the Subaward budget for each subaward/consortium organization. Also include:

**Base Salary ($)** – Enter the annual compensation paid by the employer for each Senior/Key person. You may choose to leave this column blank. For NIH and other PHS agencies, an applicant organization may choose to leave this blank; however, PHS staff will request this information prior to award.

**Cal Months** – If effort does not change throughout the year, it is OK to use only the calendar months column. However, you may use both academic and summer months columns if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic
and summer months, leave the calendar months column blank and use only the academic and summer months columns.

**Acad. Months** – Enter the number of academic months devoted to the project for each Senior/Key person.

**Sum. Months** – Enter the number of summer months devoted to the project for each Senior/Key person.

*Convert Percent effort to Person months be multiplying the percent effort by the number of months of effort. Ex: 10% effort for 9 months is equal to 0.9 person months.*

**Requested Salary** – Enter Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each Senior/Key person. Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations, see the *Salary Cap Summary* on the NIH grants Web site or contact your office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: [http://grants.nih.gov/grants/ guide/notice-files/NOT-OD-02-017.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html).

**Fringe Benefits** – Enter the dollar amount of fringe benefits.

**Funds Requested (S)** – Calculates and populates automatically.

If funds are requested for more than eight Senior/Key persons, include all pertinent budget information and attach a separate file. Enter the total funds requested for additions persons on line 9. Add Attachment.

**Total Senior/Key Person** – Calculates and populates automatically.

**B. Other Personnel**

For each project role category identify:

- The number of personnel proposed
- Associated months
- Requested salary
- Fringe benefits
- Funds requested (calculates automatically)

For all Postdoctoral Associates and Graduate Students not already named in Section A. Senior/Key Person, individually list names, roles (e.g., PostDoc or Graduate Student), associated months, and salary & fringe benefits requested in the Budget Justification.

**Total Other Personnel** – Calculates and populates automatically

**Total Salary, Wages and Fringe Benefits (A+B)** – Calculates and populates automatically.

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

### 4.7.2 Sections C through E

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.

**C. Equipment Description**

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.

List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.

Additional Equipment – If the proposal includes more than eight equipment items, include the additional information in a separate file and enter the total as item 11. Add attachment.

Total Equipment – Calculates and populates automatically.

D. Travel

1. Domestic Travel Costs – Enter total funds requested for domestic travel. Provide details in justification.
2. Foreign Travel Costs – Enter total funds requested for foreign travel. Provide details in justification.
3. Total Travel Costs – Calculates and populates automatically.

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.

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other – Describe any other participant trainee funds requested.

Enter number of Participants/Trainees

Total Participant/Trainee Support Costs – Calculates and populates automatically.

4.7.3 Sections F through K

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.

F. Other Direct Costs

1. Materials and Supplies – Categories less than $1,000 do not have to be itemized.
2. Publication Costs
3. Consultant Services
4. Computer Services
5. Subawards/Consortium/Contractual Costs – Enter the total funds requested for 1) all subaward/consortium organization(s) proposed for the project and 2) any other contractual costs proposed for the project.
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8 – 10 Describe any other direct costs not requested above, such as patient care and tuition remission.

Total Other Direct Costs – Calculates and populates automatically.
Provide appropriate detailed information for Other Direct Costs in Budget Justification.

**G. Total Direct Costs (A through F)**

The total funds requested for all direct costs – Calculates and populates automatically.

**H. Indirect Costs**

Indirect Costs Type – **Modified Total Direct Costs is typical.** Enter other cost type if appropriate.

Indirect Cost Rate – Enter the appropriate F&A rate for the budget period. If more than one rate applies to the budget period enter two separate lines. The current rate for on-campus research is 63% until June 30, 2010. The rate beyond June 30, 2010 is 62%.

Indirect Cost Base ($) – Enter the amount of base for each indirect cost type (or each rate).

Funds Requested – Enter the amount of F&A amount for each indirect cost type (or each rate). This must be entered, it is not calculated for you.

Total Indirect Costs – Calculates and populates automatically.

Cognizant Federal Agency – **DHHS, TOM LENAHAN, 323-261-7218, Ext 604**

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

The total funds requested for direct and indirect costs. – Calculates and populates automatically.

**J. Fee**

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

**K. Budget Justification**

Use the budget justification to provide the additional information requested in each budget category identified above and any other information you wish to submit to support your budget request. Note this is a single justification for all budget years so include all justification information for all years in the same file. Click Add Attachment to attach the file.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See section 4.8 below.

**Completing Budget Periods 2-5**

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

**Supplemental/Revision Application**

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

**4.7.4 Cumulative Budget**

All values on this form are calculated automatically.
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.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

4.8 Special Instructions for Preparing Applications with a Subaward/Consortium

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

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

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

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

This component currently accommodates up to 10 separate subaward budgets. If you are submitting an application with >10 subaward budgets, budgets 11 and above should be converted to PDF and included as part of Section K. Budget Justification of the parent budget (R&R Budget Component). Reminder, the sum of all subaward budgets; e.g., those attached separately and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the parent budget.

To start the process, the applicant organization should:

Select the Subaward Budget Attachment Form from the Optional Documents in the Grant Application Package.

Open the form, and click the “Click here to extract the R&R Subaward Budget Attachment” button in the middle of the form.
Save the file using the first 10 letters of the consortium organization’s name as the file name and leave “.xfd” as the file extension. (The extracted file is a PureEdge document.)

Email the form to the consortium grantee. Note: consortium grantees must have installed the PureEdge Viewer before they can complete the form. The consortium grantee should complete all the budget information as instructed in the R&R Budget component instructions in Section 4.7. Note: Organizational DUNS and Name of Organization fields must reflect that of the subaward/consortium grantee.

The consortium grantee must complete the budget component and email it back to the applicant organization.

Return to the Subaward Budget Attachment Form and attach the consortium grantee’s budget to one of the blocks provided on the form. Do not convert this attachment to PDF.

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

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

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

Complete each component using the instructions provided below.

5.2 Cover Letter Component

Cover Letter File Name

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

1. Application title.
2. PA or RFA title, if you are responding to an NIH initiative.
3. Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.

4. List of people (e.g., competitors) who should not review your application and why.

5. Disciplines involved, if multidisciplinary.

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

When submitting a Changed/Corrected Application, a cover letter is required explaining the reason for the Changed/Corrected Application.

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. You will be returned to the Grant Application Package screen.

### 5.3 Cover Page Supplement Component

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

   Name and contact information is pre-populated from SF424 (R&R).

   **New Investigator** - Check the Yes box only if the PD/PI has not previously competed successfully as such on any NIH-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), a Shannon Award (R55), an NIH High Priority, Short-Term Project Award (R56), or mentored career development awards for persons at the beginning of their research career (K01, K08, K22, K23, K25, K99/R00). **If the PD/PI is not a new investigator, check the No box.** Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K05, K24, K26) are not considered new investigators.

   When Multiple Principal Investigators are proposed, all PIs must meet the definition of New Investigator for this box to be checked.

   **Degrees** - Indicate up to three academic and professional degrees or other credentials, such as licenses (for example, R.N.). These degrees should be a subset of the degrees that are listed on the PD/PI’s Commons account. If the PD/PI’s Commons account does not include the degrees listed here, please update the Commons account information accordingly.

2. **Human Subjects**

   Clinical Trial – Yes or No. The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

   **Agency-Defined Phase III Clinical Trial** – Yes or No.

3. **Applicant Organization Contact**

   Person to be contacted on matters involving this application:
Pre-populated from SF424 (R&R). Must include a phone number.

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td>[ enter DCG administrator’s first name ]</td>
</tr>
<tr>
<td>Middle Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td>[ enter DCG administrator’s last name ]</td>
</tr>
<tr>
<td>Suffix</td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td>213-740-6672</td>
</tr>
<tr>
<td>Fax Number</td>
<td>213-740-6070</td>
</tr>
<tr>
<td>Email</td>
<td>[ enter DCG administrator’s email address ]</td>
</tr>
<tr>
<td>Title</td>
<td>C&amp;G Administrator</td>
</tr>
<tr>
<td>Street1</td>
<td>837 Downey Way</td>
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</tr>
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</tr>
</tbody>
</table>

4. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells? Yes or No. If yes, complete next section.

Cell Line(s) – List NIH Human Embryonic Stem Cell Registry number for specific cell line(s)
Specific stem cell line cannot be referenced at this time, check this box.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

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. To determine which budget component to use for NIH applications, consult the modular budget guidelines in
the Full Grants.gov Application Guide. Additional guidance may also be provided in the specific funding opportunity announcement.

**Using the Modular Budget Component**

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

### 5.4.1 Periods 1 through 4

NOTE: The fields are the same for budget periods 1 through 5, the following instructions can be used for each. Some information may need to be repeated for subsequent budget periods.

**Budget Period 1, 2, 3, or 4**

- **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**

- **Direct Costs less Consortium F&A**: 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**

- **Indirect Cost Type**: Indicate the type of base (Modified Total Direct Costs) and indicate if Off-site.
- **Indirect Cost Rate (%)**: Indicate the Indirect Cost rate 63% until June 30, 2010 and 62% beyond June 30, 2010.
- **Indirect Cost Base**: Enter the amount of the base for each indirect cost type.
- **Funds Requested ($)**: Enter funds requested for each indirect cost type. (Base * Rate )
- **Cognizant Agency**: DHHS, TOM LENAHAN, 323-261-7218, Ext 604
- **Indirect Cost Rate Agreement Date**: March 21, 2007 and June 7, 2007
- **Total Indirect Costs**: The total funds requested for indirect costs. This field auto-calculates.

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

The total funds requested for direct and indirect costs. This field auto-calculates.

### 5.4.2 Period 5 and Cumulative

**Cumulative Budget Information**

All values for the Cumulative Budget Information are calculated automatically. 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 revisiting the appropriate budget period form(s), to enter corrected values.

**Modular Budget Justifications**

Include the following as attachments:

- Personnel Justification
- Consortium Justification
- Additional Narrative Justification

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

### 5.5 Research Plan Component

1. **Application Type**

   This field is pre-populated from the SF 424 (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)*

   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.

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

   Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application.

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

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

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

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

**Separate Attachments**

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.

Following is a list of separate attachments that represent the Research Plan. Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Background & Significance, etc). **Unless otherwise referenced in the funding announcement, do not exceed 25 pages for Items 2 – 5.**

**Research Plan Attachments**

1. Introduction - Use only if submitting an R&R Resubmission or Revision (Cover Page Item 8)
2. Specific Aims
3. Background & Significance
4. Preliminary Studies / Progress Report
5. Research Design & Methods
6. Inclusion Enrollment Report
7. Progress Report Publication List

**Human Subjects Section**

8. Protection of Human Subjects
9. Inclusion of Women & Minorities
10. Targeted/Planned Enrollment Table
11. Inclusion of Children

**Other Research Plan Sections**

12. Vertebrate Animals
13. Select Agents
14. Multiple PI Leadership Plan
15. Consortium/contractual Arrangements
16. Letters of Support
17. Resource Sharing Plan(s)

18. Appendix - A maximum of 10 PDF attachments is allowed. If more than 10 are needed, combine the remaining information into attachment #10.

Follow the instructions in the Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan in the full Application Guide to determine if sections 8 - 11 apply to your application.

Refer to the Grants.gov Application Guide SF424 (R&R) for more detailed information on preparing and submitting your application via Grants.gov.

Once all data have been entered, click the “Close Form” button at the top of the form. You will be returned to the Grant Application Package screen.

**5.6 Checklist Component**

1. Application Type
**Type of Application** – This field is pre-populated from the SF 424 (R&R) Cover Component. Corrections to this field must be made in that component.

**Federal Identifier** - This field is pre-populated from the SF 424 (R&R). Corrections to this field must be made in that component. For New applications this field will be blank.

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

   **Change of Principal Investigator/Program Director** – Check this box if this application reflects a change in PD/PI from the one who was indicated on a previous application. This is not generally applicable to a “New” application. Complete former PI section.

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

   Inventions and Patents: Yes or No.
   Previously Reported: Yes or No.

4. **Program Income**

   Is program income anticipated: Yes or No. If yes then complete the section below for Budget Period, Anticipated Amount ($), Source(s).

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. You will be returned to the Grant Application Package screen.

From this main screen, click on the form/document that you have completed, and then click the => button. This will move the form/document to the Completed Documents box. To remove a form/document from the Completed Documents box, click the form/document name to select it, and then click the <= button. This will return the form/document to the Mandatory Documents or Optional Documents box. Only those documents in the Completed Documents box will be included in the final application package.