

### **Grant Application Package**

| Opportunity Title:   | Research Project Gra  | ant (Parent R01)                |   |   |  |
|--|---|---------------------------------|---|---|--|
| Offering Agency:   | National Institutes of Health   |                                 | This electronic grants application is intended to be used to apply for the specific Federal funding |   |  |
| CFDA Number:   |   |                                 |   | opportunity referenced here.  |  |
| CFDA Description:  |   |                                 |   | If the Federal funding opportunity listed is not  |  |
| Opportunity Number:  | PA-10-067   |                                 |   | the opportunity for which you want to apply,  |  |
| Competition ID:  | ADOBE-FORMS-B1  |                                 |   | close this application package by clicking on the<br>"Cancel" button at the top of this screen. You |  |
| Opportunity Open Date:                                       | 10/15/2010  |                                 |   | will then need to locate the correct Federal  |  |
| Opportunity Close Date:                                      | 01/07/2013  |                                 |   | funding opportunity, download its application and then apply.                                       |  |
| Agency Contact:  | Grants Info Grants Information E-mail: GrantsInfo@nih.gov Phone: 301-435-0714 |                                 |   |   |  |
|  | cademia, or other type of   |                                 | mitting grant applic  | ations on behalf of a company, state, local or  |  |
| Mandatory Documents  |   | Move Form to<br>Complete        | Mandatory Docu  | uments for Submission   |  |
|  |   | Move Form to<br>Delete          | Research And<br>Project/Perfo   | Page Supplement   |  |
| Optional Documents Research & Related & R & R Subaward Budge | Budget<br>et Attachment(s) Form   | Move Form to<br>Submission List |   | 1   |  |
|  |   | Move Form to<br>Delete          |   |   |  |
|  |   |                                 |   |   |  |

### Instructions



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.



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.



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.

OMB Number: 4040-0001 Expiration Date: 06/30/2011

| APPLICATION FOR FEDERAL ASSISTANCE  | 3. DATE RECEIVED BY STATE State Application Identifier           |  |  |
|---|--|--|--|
| SF 424 (R&R)  |  |  |  |
| 1.* TYPE OF SUBMISSION  | 4. a. Federal Identifier   |  |  |
| Pre-application Application Changed/Corrected Application   | b. Agency Routing Identifier                                     |  |  |
| 2. DATE SUBMITTED Applicant Identifier  |  |  |  |
| 5. APPLICANT INFORMATION  | • O  |  |  |
| *Legal Name: Pennsylvania State Univ Hershey Med Ctr  | * Organizational DUNS: 1293481860000                             |  |  |
|   | lege of Medicine   |  |  |
| * Street1: 500 University Drive   | rege of medicine   |  |  |
| Street2: P.O. Box 850   | <del></del>  |  |  |
| * City: Hershey County / Paris  | h: Dauphin   |  |  |
| * State: PA: Pennsylvania   | Province:  |  |  |
| * Country: USA: UNITED STATES   | * ZIP / Postal Code: 17033-0850                                  |  |  |
| Person to be contacted on matters involving this application  |  |  |  |
| Prefix: * First Name: Michael   | Middle Name: S   |  |  |
| * Last Name: Yarnell  | Suffix:  |  |  |
| * Phone Number: 717–531–8495 Fax Number: 717–   | 531-0040   |  |  |
| Email: e-grants@hmc.psu.edu   |  |  |  |
| 6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): 1246000376A3   |  |  |  |
| 7. * TYPE OF APPLICANT:   | X: Other (specify)   |  |  |
| Other (Specify): State-related Institution of Higher Educat   | ion  |  |  |
| Small Business Organization Type Women Owned Social   | illy and Economically Disadvantaged                              |  |  |
| 8. * TYPE OF APPLICATION: If Revision, mark a   |  |  |  |
| l   | ward B. Decrease Award C. Increase Duration D. Decrease Duration |  |  |
| Renewal Continuation Revision E. Other (spec  | cify):   |  |  |
| * Is this application being submitted to other agencies? Yes No X   | /hat other Agencies?   |  |  |
|   | OG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:                        |  |  |
| National Institutes of Health TITLE:  |  |  |  |
| 11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:   |  |  |  |
| How to Submit a Grant Application   |  |  |  |
|   |  |  |  |
| 12. PROPOSED PROJECT: *13. CONGRESSIONAL DISTRICT OF APPLICANT  * Start Date * Ending |  |  |  |
| 04/01/2012 03/31/2017 PA-017  |  |  |  |
| 14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION   |  |  |  |
| Prefix: * First Name: John Middle Name:   |  |  |  |
| * Last Name: Doe Suffix:  |  |  |  |
| Position/Title: Assistant Professor   |  |  |  |
| * Organization Name: Pennsylvania State Univ Hershey Med Ctr  |  |  |  |
| Department: Medicine Division: College of Medicine  |  |  |  |
| * Street1: 500 University Drive   |  |  |  |
| Street2: P.O. Box 850; MC H100  * City: Hershey County / Parish: Dauphin  |  |  |  |
| * 04-4  |  |  |  |
| * State: PA: Pennsylvania   | * ZIP / Postal Code: 17033-0850                                  |  |  |
| * Country: USA: UNITED STATES   |  |  |  |
| * Phone Number: 717-531-0000 Fax Number: 717-   | 23T-000T   |  |  |
| *Email: jdoe225@psu.edu   |  |  |  |

| 15. ESTIMATED PROJECT FUNDING  |  | 16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS? |  |  |
|--|--|--|--|--|
| a. Total Federal Funds Requested     b. Total Non-Federal Funds     c. Total Federal & Non-Federal Funds     d. Estimated Program Income   | 1,912,500.00<br>0.00<br>1,912,500.00<br>0.00 | a. YES   |  |  |
| 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 penalities. (U.S. Code, Title 18, Section 1001)    X   * 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 Doc   | umentation                                   | Add Attachment Delete Attachment View Attachment                               |  |  |
| 19. Authorized Representative  Prefix: *First Name: Michael Middle Name: S  *Last Name: Yarnell Suffix: Suffix |  |  |  |  |
| Street2: p.o. Box 850; MC  * City: Hershey   |  | arish: Dauphin   |  |  |
| +01.   | PA: Pennsylvania                             | Province:  |  |  |
| * Country: USA: UNITED STATES * ZIP / Postal Code: 17033-0850  |  |  |  |  |
| * Phone Number: 717-531-8495 Fax Number: 717-531-0040  |  |  |  |  |
| * Email: e-grants@hmc.psu.edu  |  |  |  |  |
| * Signature of Authorized Representative * Date Signed  Completed on submission to Grants.gov Completed on submission to Grants.gov  |  |  |  |  |
| 20. Pre-application  |  | Add Attachment Delete Attachment View Attachment                               |  |  |

# RESEARCH & RELATED Other Project Information

| 1. * Are Human Subjects Involved?   |
|---|
| 1. * Are Human Subjects Involved? X Yes No  1.a If YES to Human Subjects  |
| Is the Project Exempt from Federal regulations? Yes X No  |
| If yes, check appropriate exemption number.   |
| If no, is the IRB review Pending? X Yes No  |
| IRB Approval Date:  |
| Human Subject Assurance Number: 00004251  |
| 2.* Are Vertebrate Animals Used? X Yes No   |
| 2.a. If YES to Vertebrate Animals   |
| Is the IACUC review Pending? X Yes No   |
| IACUC Approval Date:  |
| Animal Welfare Assurance Number A3045-01  |
| 3.* Is proprietary/privileged information included in the application?  |
| 4.a. * Does this project have an actual or potential impact on the environment? Yes X 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? |
| 4.d. If yes, please explain:  |
| 5. * Is the research performance site designated, or eligible to be designated, as a historic place?  |
| 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 Project_Summary.pdf Add Attachment Delete Attachment View Attachment   |
| 8. * Project Narrative Project_Narrative.pdf Add Attachment Delete Attachment View Attachment   |
| 9. Bibliography & References Cited Bibliography_References_Cited.pdf   Add Attachment   Delete Attachment   View Attachment   |
| 10. Facilities & Other Resources Facilities.pdf Add Attachment Delete Attachment View Attachment  |
| 11. Equipment Equipment.pdf Add Attachment Delete Attachment View Attachment  |
| 12. Other Attachments Add Attachments Delete Attachments View Attachments   |

# 4.4 Other Project Information Component

#### 7. Project Summary/Abstract

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

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

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <a href="http://report.nih.gov">http://report.nih.gov</a>) and will become public information.

The attachment must be in PDF format. (See <u>Section 2.6</u> for additional information on preparing attachments.)

#### 8. Project Narrative

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

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

A separate Research Plan component is required for NIH and other PHS agencies applications. Refer to Section 5.5, Research Plan Component, for separate file uploads and instructions.

# 9. Bibliography & References Cited

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

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan 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 PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

#### 10. Facilities & Other Resources

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

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

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

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

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

#### 11. Equipment

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

#### 12. Other Attachments

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

OMB Number: 4040-0001 Expiration Date: 06/30/2011

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

|  |                                | PROFILE - Project Director/Principal Inve  | estigator                                    |
|--|--------------------------------|--|--|
| Prefix:  | * First Name                   | John   | Middle Name:                                 |
| * Last Name: Do  | o e                            |  | Suffix:                                      |
| Position/Title: As   | ssistant Professor             | Departmen  | nt: Medicine                                 |
| Organization Na  | me: Pennsylvania St            | ate Univ Hershey Med Ctr   | Division: College of Medicine                |
| * Street1: 500   | University Drive               |  |  |
| Street2: P.O.  | Box 850; MC H100               |  |  |
| * City: Hers   | hey                            | County/ Parish: Dauphin  |  |
|  | Pennsylvania                   |  | Province:                                    |
| I  | : UNITED STATES                |  | * Zip / Postal Code: 17033-0850              |
|  | 717-531-0000                   | Fax Number: 717-531-0001   |  |
| * E-Mail: jdoe2:   | 25@psu.edu                     |  |  |
| Credential, e.g.   | , agency login: jdoe           |  |  |
| * Project Role:  | PD/PI                          | Other Project Role Categ   | Jory:  |
| Degree Type:   | Ph.D.                          |  |  |
| Degree Year:   | 1995                           |  |  |
| *Attach Biog   | graphical Sketch               | Doe Biosketch.pdf Add  | Attachment Delete Attachment View Attachment |
| Attach Curre   | ent & Pending Support          | Add  | Attachment Delete Attachment View Attachment |
| 1  |                                |  |  |
|  |                                | PROFILE - Senior/Key Person 1  | 1  |
| Prefix:  | * First Name                   |  | Middle Name:                                 |
| * Last Name: Ja  |                                | - Control of the Cont | Suffix:                                      |
| ı =  | sistant Professor              | Departmen  | nt: Pharmacology                             |
|  |                                | ate Univ Hershey Med Ctr   | Division: College of Medicine                |
|  | University Drive               | •  |  |
| Street2: P.O.  | Street2: P.O. Box 850, MC H101 |  |  |
| * City: Hers   | hey                            | County/ Parish: Dauphin  |  |
| * State: PA:   | Pennsylvania                   |  | Province:                                    |
| * Country: USA:  | UNITED STATES                  |  | * Zip / Postal Code: 17033-0850              |
| * Phone Number: 717-531-0002 Fax Number: 717-531-0003        |                                |  |  |
| * E-Mail: jjanuary@psu.edu                                   |                                |  |  |
| Credential, e.g., agency login: jjanuary223                  |                                |  |  |
| * Project Role: Co-Investigator Other Project Role Category: |                                |  |  |
| Degree Type: M.D.  |                                |  |  |
| Degree Year:   | 1994                           |  |  |
| *Attach Biog   | ıraphical Sketch               | January biosketch.pdf Add  | Attachment Delete Attachment View Attachment |
| Attach Curre   | ent & Pending Support          |  | Attachment Delete Attachment View Attachment |
| Delete Entry   |                                |  | Next Person                                  |

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

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.

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

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

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

After providing data for each individual Senior/Key Person, click the **Next Person** button at the bottom of the form to enter data for the next Senior/Key Person. Continue in this manner until data has been provided for up to 40 Senior/Key Persons. To ensure proper performance of this form, after adding 20 additional Senior/Key Persons please save your application, close the Adobe reader, and reopen it. For applications involving more than 40 Senior/Key Persons, the "Additional Senior/Key Person Profiles" fields will become available once data for the first 40 Senior/Key Persons has been provided.

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

### Multiple PD/PIs

NIH is now accepting applications reflecting Multiple PD/PIs for all grant activity codes using the SF424 (R&R) application. When submitting an application involving Multiple PD/PIs, the Contact PI must be affiliated in the Commons with the applicant organization and should be listed as the PD/PI in the SF424 R&R Cover Component (see Section 4.2.14). That information automatically prepopulates the first Senior/Key Person Profile record in this component. For the additional PD/PIs, complete all the requested information. Each PD/PI must be assigned the PD/PI role, even those at subaward/consortium sites when applicable.

(Do **not** use the "Co-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 PD/PIs the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the Credential field.

#### **Other Significant Contributors**

If including individuals classified as "Other Significant Contributors (OSCs)," use the "Other" category and indicate "Other Significant Contributor" as the role in the "Other Project Role Category." OSCs should be listed last after all other Senior/Key Persons have been listed.

#### NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the <u>Biographical Sketch Format Page</u> 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 <a href="https://commons.era.nih.gov/commons/index.jsp">https://commons.era.nih.gov/commons/index.jsp</a>.

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

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

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

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

OMB Number: 4040-0010 Expiration Date: 08/31/2011

# **Project/Performance Site Location(s)**

| Project/Performane                    | e Site Primary Location I am submitting an a local or tribal govern  | application as an individual, and not on behalf of a company, state, amount and or other type of organization.     |
|---------------------------------------|--|--|
| Organization Name                     | Pennsylvania State Univ Hershey  | y Med Ctr  |
| DUNS Number:                          | 1293481860000  |  |
| * Street1: 500 C                      | niversity Drive  |  |
| Street2:                              |  |  |
| * City: Hersh                         | еу   | County: Dauphin  |
| * State: PA: P                        | ennsylvania  |  |
| Province:                             |  |  |
| * Country: USA:                       | UNITED STATES  |  |
| * ZIP / Postal Code                   | 17033-0850   | * Project/ Performance Site Congressional District: PA-017   |
|                                       |  |  |
| Project/Performand                    | local or tribal govern   | pplication as an individual, and not on behalf of a company, state, ment, academia, or other type of organization. |
| DUNS Number:                          |  |  |
| * Street1:                            |  | And And Antonia has a  |
| Street2:                              |  |  |
| * City:                               |  | County:  |
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| Province:                             | A Section of the Control of the Cont | •  |
|                                       |  |  |
| * Country: USA:                       | UNITED STATES  |  |
| * Country: USA:  * ZIP / Postal Code: |  | * Project/ Performance Site Congressional District:  |
| L                                     |  | * Project/ Performance Site Congressional District:  |
| L                                     |  | * Project/ Performance Site Congressional District:  |

OMB Number: 0925-0001

| PHS 398 Research Plan  |                                  |  |                        |                     |
|--|----------------------------------|--|------------------------|---------------------|
| 1. Application Type:  From SF 424 (R&R) Cover Page. The respreference, as you attach the appropriate set *Type of Application:    X   New   Resubmission   Renewal | ections of the Research Plan.    | the type of applicati                          | on being submitted, is | · repeated for your |
| 2. Research Plan Attachments:  |                                  |  |                        |                     |
| Please attach applicable sections of the re  | esearch plan, below.             |  |                        |                     |
| Introduction to Application  (for RESUBMISSION or REVISION only)   |                                  | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 2. Specific Aims   | Specific_Aims.pdf                | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 3. *Research Strategy  | Research_Strategy.pdf            | Add Altachment                                 | Delete Attachment      | View Attachment     |
| 4. Inclusion Enrollment Report   | :                                | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 5. Progress Report Publication List  |                                  | Add Attachment                                 | Delete Attachment      | View Attachment     |
| Human Subjects Sections  |                                  | <u>.                                      </u> |                        | -1144.49.4          |
| 6. Protection of Human Subjects  | Protection_of_Human_Subject      | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 7. Inclusion of Women and Minorities   | Inclusion_Women_Minorities.      | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 8. Targeted/Planned Enrollment Table   | Enrollment_Table.pdf             | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 9. Inclusion of Children   | Inclusion_of_Children.pdf        | Add Attachment                                 | Delete Attachment      | View Attachment     |
| Other Research Plan Sections   |                                  | // ************************************        |                        |                     |
| 10. Vertebrate Animals   | Vertebrate_Animals.pdf           | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 11. Select Agent Research  |                                  | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 12. Multiple PD/PI Leadership Plan   |                                  | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 13. Consortium/Contractual Arrangements  |                                  | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 14. Letters of Support   | Letters_Support.pdf              | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 15. Resource Sharing Plan(s)   | Resource Sharing_Plan.pdf        | Add Attachment                                 | Delete Attachment      | View Attachment     |
| 16. Appendix Add Attachments F   | Remove Attachments View Attachme | ents   |                        |                     |

#### 5.5 PHS 398 Research Plan Component

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

| Strategy, etc).   |   |  |
|---|---|--|
| Field Name  | Instructions  |  |
| 1. Introduction to<br>Application (for<br>Resubmission or Revision<br>only) | See specific instructions in Part I Section 2.7, Resubmission Applications and Part I Section 2.8, Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction.  |  |
|   | The Introduction is a required attachment for Resubmissions (except S10) and Revisions. The Introduction is limited to one page unless specified in the FOA, except that the Introduction of Resubmission applications is limited to 3 pages for R25 applications.  |  |
|   | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |  |
| 2. Specific Aims  | 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.  |  |
|   | 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.  |  |
|   | The Specific Aims attachment is required unless otherwise specified in the FOA. Specific Aims are limited to one page.  |  |
|   | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |  |
| 3. Research Strategy  | Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9). |  |
|   | 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.   |  |
|   | (a) Significance  |  |
|   | • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.   |  |
|   | <ul> <li>Explain how the proposed project will improve scientific<br/>knowledge, technical capability, and/or clinical practice in<br/>one or more broad fields.</li> </ul>   |  |

| Field Name | Instructions   |
|------------|--|
|            | Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.   |
|            | (b) Innovation   |
|            | <ul> <li>Explain how the application challenges and seeks to shift<br/>current research or clinical practice paradigms.</li> </ul>   |
|            | <ul> <li>Describe any novel theoretical concepts, approaches or<br/>methodologies, instrumentation or interventions to be<br/>developed or used, and any advantage over existing<br/>methodologies, instrumentation, or interventions.</li> </ul>  |
|            | <ul> <li>Explain any refinements, improvements, or new applications<br/>of theoretical concepts, approaches or methodologies,<br/>instrumentation, or interventions.</li> </ul>  |
|            | (c) Approach   |
|            | <ul> <li>Describe the overall strategy, methodology, and analyses to<br/>be used to accomplish the specific aims of the project. Unless<br/>addressed separately in Item 15 (Resource Sharing Plan),<br/>include how the data will be collected, analyzed, and<br/>interpreted as well as any resource sharing plans as<br/>appropriate.</li> </ul>  |
|            | <ul> <li>Discuss potential problems, alternative strategies, and<br/>benchmarks for success anticipated to achieve the aims.</li> </ul>  |
|            | • 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.  |
|            | <ul> <li>Point out any procedures, situations, or materials that may be<br/>hazardous to personnel and precautions to be exercised. A full<br/>discussion on the use of Select Agents should appear in Item<br/>11, below.</li> </ul>  |
|            | If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.   |
|            | As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.  |
|            | Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in application from Early Stage Investigators than on the preliminary data in applications from more established investigators). |

| Field Name  | Instructions  |
|---|---|
|   | Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant 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, and then click Open.  |
| 4. Inclusion Enrollment<br>Report                               | 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.  See Part II, Section 4.3 for more detailed instructions on which Target and Enrollment Report or Table to use.   |
| 5. Progress Report Publication List (Renewal Applications Only) | 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: <a href="http://publicaccess.nih.gov/submit_process_journals.htm">http://publicaccess.nih.gov/submit_process_journals.htm</a> . Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Part I Section 5.5.15 for more information). |

# **Human Subjects Sections**

| 6. Protection of Human Subjects      | 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. 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.   |
|                                      | Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.   |
|                                      | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |
| 7. Inclusion of Women and Minorities | Refer to Part II, <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u> . 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.   |
|                                      | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |
| 8. Targeted/Planned<br>Enrollment    | If this application involves the Inclusion of Women and Minorities, applicants must complete the <u>Targeted/Planned Enrollment Table</u> for each protocol; see Part II, <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u> , 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. |
|                                      | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |
| 9. Inclusion of Children             | 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.  |
|                                      | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .  |

# **Other Research Plan Sections**

| Field Name             | Instructions  |  |  |
|------------------------|---|--|--|
| 10. Vertebrate Animals | This section is required for applicants answering "yes" to the question "Are vertebrate animals involved?" on the R&R Other Project Information form.   |  |  |
|                        | If Vertebrate Animals are involved in the project, address each of the five points below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected. |  |  |
|                        | If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 above and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance then an appropriate Assurance will be required (See Part III, Section 2.2 Vertebrate Animals for more information).  |  |  |
|                        | The five points are as follows:   |  |  |
|                        | 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.   |  |  |
|                        | 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 American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.   |  |  |
|                        | Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.  |  |  |

| Field Name                | Instructions   |
|---------------------------|--|
|                           | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| 11. Select Agent Research | 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 <a href="http://www.cdc.gov/od/sap/docs/salist.pdf">http://www.cdc.gov/od/sap/docs/salist.pdf</a> .   |
|                           | If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at <a href="http://www.cdc.gov/od/sap/sap/exclusion.htm">http://www.cdc.gov/od/sap/sap/exclusion.htm</a> . |
|                           | If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.   |
|                           | 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.  |
|                           | 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> <li>If the performance site(s) is a foreign institution, provide the<br/>name(s) of the country or countries where Select Agent<br/>research will be performed.</li> </ul>  |
|                           | *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."   |
|                           | 3. Provide a description of all facilities where the Select Agent(s) will be used.   |
|                           | <ul> <li>Describe the procedures that will be used to monitor<br/>possession, use and transfer of the Select Agent(s).</li> </ul>  |
|                           | <ul> <li>Describe plans for appropriate biosafety, biocontainment, and<br/>security of the Select Agent(s).</li> </ul>   |
|                           | <ul> <li>Describe the biocontainment resources available at all performance sites.</li> </ul>  |
|                           | If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.   |
|                           | Reviewers will assess the information provided in this Section, and any  |

| Field Name                              | Instructions   |
|---|--|
|   | questions associated with Select Agent research will need to be addressed prior to award.  |
|   | Save this file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| 12. Multiple PD/PI<br>Leadership Plan   | For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.  If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated |
|   | in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.   |
|   | Save this file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| 13. Consortium/Contractual Arrangements | Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&R) cover component (Item 17) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:  |
|   | 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.   |
|   | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |

| Field Name                                 | Instructions   |
|--|--|
| 14. Letters of Support (e.g., Consultants) | 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.   |
|  | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| 15. Resource Sharing Plan(s)               | NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.  |
|  | 1. Data Sharing Plan: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why 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 <a href="Data-Sharing Policy">Data-Sharing Policy</a> or <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html</a> . |
|  | 2. Sharing Model Organisms: 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. Genome Wide Association Studies (GWAS): 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/.  |
|  | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |

# PHS 398 Cover Page Supplement OMB Number: 0925-0001

| 1. Project Di    | rector / Principal Investigator (PD/PI)  |
|------------------|--|
| Prefix:          | * First Name: John   |
| Middle Name:     | The state of the s |
| * Last Name:     | Doe ·  |
| Suffix:          |  |
| <u> </u>         |  |
| 2. Human Su      | bjects   |
| Clinical Trial?  | ⊠ No Yes   |
| * Agency-Defin   | ed Phase III Clinical Trial? No Yes  |
|                  | Organization Contact Intacted on matters involving this application  |
| Prefix:          | * First Name: Michael  |
| Middle Name:     | S.   |
| * Last Name:     | Yarnell  |
| Suffix:          |  |
|                  |  |
| * Phone Number:  | 717-531-8495 Fax Number: 717-531-0040  |
| Email: e-gran    | uts@hmc.psu.edu  |
|                  |  |
| * Title: Directo | r, Grants Administration   |
| * Street1:       | 500 University Drive   |
| Street2:         | P.O. Box 850, MC H138  |
| * City:          | Hershey  |
| County/Parish:   | Dauphin  |
| * State:         | PA: Pennsylvania   |
| Province:        |  |
| * Country: USA:  | UNITED STATES * Zip / Postal Code: 17033-0850  |

# PHS 398 Cover Page Supplement

| Does the proposed p       | project involve human embryonic stem cells?   | ⊠ No            | Yes                             |
|---------------------------|---|-----------------|---------------------------------|
| pecific cell line(s) fror | t involves human embryonic stem cells, list below the the following list: http://stemcells.nih.gov/researche referenced at this time, please check the box indi | n/registry/_Or_ | if a specific                   |
| Cell Line(s): [           | Specific stem cell line cannot be referenced at ti  | his time. One   | from the registry will be used. |
|                           |   |                 |                                 |
|                           |   |                 |                                 |
|                           |   |                 |                                 |
|                           |   |                 |                                 |
|                           |   |                 |                                 |

Close Form

Next

Print Page

About

# PHS 398 Checklist

OMB Number: 0925-0001

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

| 4. * Program Income  |  |
|--|--|
| Is program income anticipated during the p   | periods for which the grant support is requested?  |
| Yes X No   |  |
|  |  |
| If you checked "yes" above (indicating tha source(s). Otherwise, leave this section b  | t program income is anticipated), then use the format below to reflect the amount and lank.  |
| *Budget Period *Anticipated Amount (\$)  | *Source(s)   |
|  |  |
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|  |  |
| 5. * Disclosure Permission Staten  | nant   |
|  |  |
| address, telephone number and e-mail ad  | ard, is the Government permitted to disclose the title of your proposed project, and the name, idress of the official signing for the applicant organization, to organizations that may be ormation (e.g., possible collaborations, investment)? |
| X Yes No   |  |
|  |  |
| The same state of the same sta |  |
|  |  |

### 5.2 Cover Letter Component

| PHS Cover Letter   |                                     |
|--|-------------------------------------|
|  | OMB Numbers: 0925-0001<br>0925-0002 |
| *Mandatory Cover Letter Filename: Cover_Letter.pdf  Add Cover Letter File Delete Cover Letter File View Cover Letter | r File                              |
|  |                                     |

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 <u>awarding component(s)</u> or <u>Scientific Review Group (SRG)</u>. 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 <u>Section 2.14</u>) 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.

# PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001

| Pudget Povieds 4  |                           |                              |                        |
|---|---------------------------|------------------------------|------------------------|
| Budget Period: 1  Start Date: 04/01/2012 End Date:  | 3/31/2013                 |                              |                        |
| Otto Dato.  | -                         |                              |                        |
| A. Direct Costs   |                           | a. F                         | * Funds Requested (\$) |
| *1  | Direct Cost les           | ss Consortium F&A            | 250,000.00             |
|   |                           | Consortium F&A               | 050 000 00             |
|   |                           | * Total Direct Costs         | 250,000.00             |
| B. Indirect Costs Indirect Cost Type  | Indirect Cost<br>Rate (%) | t Indirect Cost<br>Base (\$) | * Funds Requested (\$) |
| 1. MTDC   | 53                        | 250,000.00                   | 132,500.00             |
| 2.  |                           |                              |                        |
| 3.  |                           |                              |                        |
| 4.  |                           |                              |                        |
|   | L                         |                              |                        |
| Cognizant Agency (Agency Name, POC Name and Phone Number)  Office of Naval R Deborah K. Rafi 703-696-5641   | esearch                   |                              |                        |
| Indicat Cost Data Assessment Data 106 /08 /2011   |                           | Total Indirect Costs         | 132,500.00             |
| Indirect Cost Rate Agreement Date 06/08/2011  |                           |                              |                        |
| C. Total Direct and Indirect Costs (A + B)  | F                         | Funds Requested (\$)         | 382,500.00             |
| Budget Period: 2  |                           |                              | - 1                    |
| Start Date: 04/01/2013  | 03/31/201                 | 4                            |                        |
| A. Direct Costs   |                           |                              | * Funds Requested (\$) |
|   | irect Cost les            | s Consortium F&A             | 250,000.00             |
|   |                           | Consortium F&A               |                        |
|   | ,                         | * Total Direct Costs         | 250,000.00             |
| B. Indirect Costs   |                           |                              |                        |
|   | Indirect Cost<br>Rate (%) | Indirect Cost<br>Base (\$)   | * Funds Requested (\$) |
| 1. MTDC   | 53                        | 250,000.00                   | 132,500.00             |
| 2.  |                           |                              |                        |
| 3.  |                           |                              |                        |
|   | ]                         |                              |                        |
| 4.  | ]                         |                              |                        |
| Cognizant Agency (Agency Name, POC Name and Phone Number)  Office of Naval R  Deborah K. Rafi  703-696-5641 | esearch                   |                              |                        |
| Indirect Cost Rate Agreement Date 06/08/2011  |                           | Total Indirect Costs         | 132,500.00             |
|   |                           |                              | 382,500.00             |
| C. Total Direct and Indirect Costs (A + B)  | H                         | unds Requested (\$)          | 302,300.00             |

# PHS 398 Modular Budget, Periods 3 and 4

| Budget Period: 3  |            |  |                        |
|---|------------|--|------------------------|
| Start Date: 04/01/2014 End Date:  | 03/31/2    | 015                                      |                        |
| A. Direct Costs   |            |  | * Funds Requested (\$) |
| * [   | irect Cost | t less Consortium F&A                    | 250,000.00             |
|   |            | Consortium F&A _<br>* Total Direct Costs | 250,000.00             |
| B. Indirect Costs   | Indirect C | L  | 230,000.00             |
| Indirect Cost Type  | Rate (%)   | Base (\$)                                | * Funds Requested (\$) |
| 1. MTDC   | 53         | 250,000.00                               | 132,500.00             |
| 2.  |            |  |                        |
| 3.  |            |  |                        |
| 4.  |            |  |                        |
|   |            |  |                        |
| Cognizant Agency (Agency Name, POC Name and Phone Number) Office of Naval R Deborah K. Rafi                 | esearch    |  |                        |
| 703-696-5641  |            |  |                        |
| Indirect Cost Rate Agreement Date 06/08/2011  |            | Total Indirect Costs                     | 132,500.00             |
|   |            |  |                        |
| C. Total Direct and Indirect Costs (A + B)  |            | Funds Requested (\$)                     | 382,500.00             |
| Budget Period: 4  |            |  |                        |
|   | 03/31/2    | 016                                      |                        |
| A. Direct Costs   |            |  | * Funds Requested (\$) |
| * D   | irect Cost | less Consortium F&A                      | 250,000.00             |
|   |            | Consortium F&A  * Total Direct Costs     | 250,000.00             |
|   |            | Total Direct Costs                       | 230,000.00             |
| B. Indirect Costs   | Indirect C | ost Indirect Cost                        |                        |
|   | Rate (%)   | Base (\$)                                | * Funds Requested (\$) |
| 1. MTDC   | 53         | 250,000.00                               | 132,500.00             |
| 2.  |            |  |                        |
| 3.  |            |  |                        |
| 4.  |            |  |                        |
|   |            |  |                        |
| Cognizant Agency (Agency Name, POC Name and Phone Number)  Office of Naval R  Deborah K. Rafi  703-696-5641 | esearcn    |  |                        |
| Indirect Cost Rate Agreement Date 06/08/2011  |            | Total Indirect Costs                     | 132,500.00             |
| C. Total Direct and Indirect Costs (A + B)  |            | Funds Requested (\$)                     | 382,500.00             |

# PHS 398 Modular Budget, Periods 5 and Cumulative

| Budget Period: 5  |                        |                                 |                        |
|---|------------------------|---------------------------------|------------------------|
| Start Date: 04/01/2016 End Date:  | 03/31/2                | 2017                            |                        |
| A. Direct Costs   |                        |                                 | * Funds Requested (\$) |
| *E  | Direct Cost            | t less Consortium F&A           | 250,000.00             |
|   |                        | Consortium F&A                  |                        |
|   |                        | * Total Direct Costs            | 250,000.00             |
| B. Indirect Costs  Indirect Cost Type                                       | Indirect C<br>Rate (%) | Cost Indirect Cost<br>Base (\$) | * Funds Requested (\$) |
| 1. MTDC   | 53                     | 250,000.00                      | 132,500.00             |
| 2.  |                        |                                 |                        |
| 3.  |                        |                                 |                        |
| 4.  |                        |                                 |                        |
| Cognizant Agency (Agency Name, POC Name and Phone Number) Office of Naval R | 10000                  |                                 |                        |
| Deborah K. Rafi 703-696-5641  | esearcn                |                                 |                        |
|   |                        |                                 |                        |
| Indirect Cost Rate Agreement Date 06/08/2011                                |                        | Total Indirect Costs            | 132,500.00             |
| C. Total Direct and Indirect Costs (A + B)                                  |                        | Funds Requested (\$)            | 382,500.00             |
| ,   |                        |                                 |                        |
|   |                        |                                 |                        |
|   |                        |                                 |                        |
|   |                        |                                 |                        |
| Cumulative Budget Information   |                        |                                 |                        |
| Total Costs, Entire Project Period  |                        |                                 |                        |
| *Section A, Total Direct Cost less Consortium F&A for Entire Project Period | \$                     | 1,250,000.00                    |                        |
| Section A, Total Consortium F&A for Entire Project Period                   | \$                     |                                 |                        |
| *Section A, Total Direct Costs for Entire Project Period                    | \$                     | 1,250,000.00                    |                        |
| *Section B, Total Indirect Costs for Entire Project Period                  | \$                     | 662,500.00                      |                        |
| *Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period | \$                     | 1,912,500.00                    |                        |
|   |                        |                                 |                        |
|   |                        |                                 |                        |
| 2. Budget Justifications  |                        |                                 |                        |
| Personnel Justification Personnel Justification.pdf Add                     | d Attachm              | ent Delete Attachme             | nt View Attachment     |
| Consortium Justification Ad   | d Attachm              | ent Delete Attachme             | nt View Attachment     |
| Additional Narrative Justification Add                                      | d Attachm              | Delete Attachme                 | View Attachment        |

# **Modular Budget Justifications**

| Personnel Justification               | 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.  |
|---------------------------------------|--|
|                                       | NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits, and tuition remission. This limit should also be used when estimating the number of modules. See: <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html</a> .  |
|                                       | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| Consortium Justification              | Provide an estimate of total costs (direct plus facilities and administrative) for each year, rounded to the nearest \$1,000. When more than one consortium is involved, provide this estimate for each. 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 <b>total</b> consortium/contractual costs must be included in the overall requested modular direct cost amount. |
|                                       | Save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |
| Additional Narrative<br>Justification | If the requested budget requires any additional justification, such as variations in the number of modules requested, or explanation of exclusions applied to the F&A base calculation, save this information in a single file in a location you remember. Click <b>Add Attachment</b> , browse to where you saved the file, select the file, and then click <b>Open</b> .   |

# 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.

<u>Modular Budget Guidelines.</u> 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.

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.

## **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.

# 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."

See section in the SF424 Guidelines for additional instructions.

# **4.8 Special Instructions for Preparing Applications with a Subaward/Consortium** See section in the SF424 Guidelines for instructions

Reminder: Save the file using the first ten letters of the consortium organization's name and use ".pdf" as the file extension.

# **Additional Information: SF424 (R&R) Application Guide**. Page Limits

| Page Limits  |  |
|--|--|
| SECTION OF APPLICATION   | PAGE LIMITS *  |
| Also refer to the relevant section of the application instructions and the FOA.  |  |
| Introduction to Resubmission Application   | 1 page   |
| (3 pages for R25 on PHS398 Research Plan and 3 pages for K12, T and D Training Grants on PHS398 Training Program Plan)   |  |
| Introduction to Revision Application   | 1 page   |
| Specific Aims  | 1 page   |
| Research Strategy (Item 5.5.3 of Research Plan)  | 6 pages  |
| For Activity Codes R03, R13, R21, R36, SC2, SC3  |  |
| Research Strategy (Item 5.5.3 of Research Plan)  | 12 pages   |
| For Activity Codes R01, R10, R15, R18, R21/R33, R24, R33, R34, DP3, G08, G11, G13, SC1, X01  |  |
| Research Strategy (Item 5.5.3 of Research Plan)  | Follow FOA instructions  |
| For all other Activity Codes, including S Activity Codes   |  |
| Research Education Program Plan  | 25 pages   |
| For R25 Research Education Grant Applications  |  |
| Plan for Instruction in the Responsible Conduct of Research  |  |
| Required for all Training Grant Activity Codes except T36  | 3 pages (for Training<br>Grants – May 25 and<br>subsequent due dates)                                  |
| Required for all Individual Career Development Grant Activity Codes  | 1 page (for Individual<br>Career Development<br>Grants – June 12, 2011<br>and subsequent due<br>dates) |
| Biosketch (per person)   | 4 pages  |
| (2 pages for DP1 and DP2 Activity Codes)   |  |
| Career Development Award (K) Application   | 12 pages   |
| Upload to PHS 398 Career Development Award Supplemental Form: For applications intended for June 11, 2011 and prior due dates, Combined Candidate Information (Items 2-5: Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training in the Responsible Conduct of Research) and Research Strategy (Item 11).  For applications intended for June 12, 2011 and subsequent due dates, Combined Candidate Information (Items 2-4: Candidate's Background, Career Goals and Objectives, and Career Development/Training Activities During Award Period) and Research Strategy (Item 11). |  |
| Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Application  Research Training Program Plan: Combined Sections 8.7.2.2 – 8.7.2.4 (Background, Program Plan, and Recruitment and Retention Plan to Enhance Diversity)   | 25 pages   |

<sup>\*</sup> FOA instructions always supersede these instructions.

### **Paper Size and Page Margins**

Use standard paper size (8 ½" x 11).

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

#### **Page Formatting**

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

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

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

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

### Format Specifications for Text (PDF) Attachments

#### File Name

Save all files with descriptive file names of 50 characters or less and be sure to only use standard characters in file names: A through Z, a through z, 0 through 9, and underscore (\_). Do not use any special characters (example: "&", "-", "\*", "%", "/", and "#") or spacing in the file name, and for word separation use underscore (example: "My Attached File.pdf") in naming the attachments.

#### **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.

#### Form Fields

As you navigate through the forms, required fields are highlighted in yellow, outlined in red, and noted with an asterisk (\*).

#### **Deadlines**

**See:** <a href="http://grants.nih.gov/grants/funding/submissionschedule.htm">http://grants.nih.gov/grants/funding/submissionschedule.htm</a> for standard due dates for competing applications, and review and award cycles.

| For example: | New R01 | Cycle I Due | Date Feb                    | February 5             |  |
|--------------|---------|-------------|-----------------------------|------------------------|--|
|              |         |             | Earliest Project Start Date | September or December* |  |
|              | New R01 | Cycle II    | Due Date                    | June 5                 |  |
|              |         |             | Earliest Project Start Date | April 1                |  |
|              | New R01 | Cycle III   | Due Date                    | October 5              |  |
|              |         |             | Earliest Project Start Date | July 1                 |  |

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