

**SF 424 (R&R)**

<b>1. * TYPE OF SUBMISSION</b> <input type="radio"/> Pre-application <input checked="" type="radio"/> Application <input type="radio"/> Changed/Corrected Application		<b>2. DATE SUBMITTED</b>	<b>Applicant Identifier</b>
		<b>3. DATE RECEIVED BY STATE</b>	<b>State Application Identifier</b>
		<b>4. a. Federal Identifier</b>	<b>b. Agency Routing Number</b>
<b>5. APPLICANT INFORMATION</b> * Legal Name: PENNSYLVANIA STATE UNIV HERSHEY MED CTR Department: Division: College of Medicine * Street1: 500 University Drive Street2: P.O. Box 850 * City: Hershey County/Parish: Dauphin Province: * Country: USA: UNITED STATES			* Organizational DUNS:129348186 * State: PA: Pennsylvania * ZIP / Postal Code: 17033-0850
Person to be contacted on matters involving this application Prefix: * First Name: Middle Name: * Last Name: Suffix: Stephanie Johnson * Phone Number: 717-531-8495 Fax Number: 717-531-0040 Email: e-grants@hmc.psu.edu			
<b>6. * EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN):</b> 1-246000376-A3		<b>7. * TYPE OF APPLICANT</b> X: Other (specify) Other (Specify): State-related Institution of Higher Education <b>Small Business Organization Type</b> <input type="radio"/> Women Owned <input type="radio"/> Socially and Economically Disadvantaged	
<b>8. * TYPE OF APPLICATION:</b> <input checked="" type="radio"/> New <input type="radio"/> Resubmission <input type="radio"/> Renewal <input type="radio"/> Continuation <input type="radio"/> Revision		<b>9. * NAME OF FEDERAL AGENCY:</b> National Institutes of Health	
If Revision, mark appropriate box(es). <input type="radio"/> A. Increase Award <input type="radio"/> B. Decrease Award <input type="radio"/> C. Increase Duration <input type="radio"/> D. Decrease Duration <input type="radio"/> E. Other (specify):		<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b> TITLE:	
* Is this application being submitted to other agencies? <input type="radio"/> Yes <input checked="" type="radio"/> No What other Agencies?			
<b>11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b> ACES eRA Systems 10/11/12			
<b>12. PROPOSED PROJECT:</b> * Start Date * Ending Date 07/01/2013 06/30/2018		<b>13. CONGRESSIONAL DISTRICT OF THE APPLICANT:</b> PA-017	
<b>14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION</b> Prefix: * First Name: Middle Name: * Last Name: Suffix: Kent Eugene Vrana Position/Title: Elliot S. Vesell Professor & Chair * Organization Name: PENNSYLVANIA STATE UNIV HERSHEY MED CTR Department: Pharmacology Division: College of Medicine * Street1: 500 University Drive Street2: P.O. Box 850, MC R130 * City: Hershey County/Parish: Dauphin * State: PA: Pennsylvania Province: * Country: USA: UNITED STATES * ZIP / Postal Code: 17033-0850 * Phone Number: 717-531-8285 Fax Number: 717-531-0419 * Email: kev10@psu.edu			



## Project/Performance Site Location(s)

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### Project/Performance Site Primary Location

Organization Name: PENNSYLVANIA STATE UNIV HERSHEY MED CTR

\* Street1: 500 University Drive

Street2: P.O. Box 850

\* City: Hershey

County: Dauphin

\* State: PA: Pennsylvania

Province:

\* Country: USA: UNITED STATES

\* Zip / Postal Code: 17033-0850

DUNS Number: 129348186 \* Project/Performance Site Congressional District: PA-017

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File Name

Mime Type

**Additional Location(s)**



## 4.2 Cover Component

## 4.3 Project/Performance Site Locations Component

## 4.4 Other Project Information Component

### 1. Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.

### 2. Are Vertebrate Animals Used?

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

### 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.



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 .**

### 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.

### 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



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](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.



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.

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

PROFILE - Project Director/Principal Investigator				
Prefix	* First Name	Middle Name	* Last Name	Suffix
	Kent	Eugene	Vrana	
Position/Title: Elliot S. Vesell Professor & Chair		Department: Pharmacology		
Organization Name: PENNSYLVANIA STATE UNIV HERSHEY MED CTR Division: College of Medicine				
* Street1: 500 University Drive		Street2: P.O. Box 850, MC R130		
* City: Hershey	County: Dauphin		* State: PA: Pennsylvania	Province:
* Country: USA: UNITED STATES		* Zip / Postal Code: 17033-0850		
*Phone Number 717-531-8285		Fax Number 717-531-0419	* E-Mail kev10@psu.edu	
Credential, e.g., agency login: kvrana				
* Project Role: PD/PI		Other Project Role Category:		
Degree Type: PhD				
Degree Year: 1983				
		File Name	Mime Type	
*Attach Biographical Sketch				
Attach Current & Pending Support				

PROFILE - Senior/Key Person				
Prefix	* First Name	Middle Name	* Last Name	Suffix
	Sheila	L	Vrana	
Position/Title: Assoc Dean Research/Assoc Prof		Department: Office of Research Affairs		
Organization Name: PENNSYLVANIA STATE UNIV HERSHEY MED CTR Division: College of Medicine				
* Street1: 500 University Drive		Street2: P.O. Box 850, Mail Code H138		
* City: Hershey	County: Dauphin		* State: PA: Pennsylvania	Province:
* Country: USA: UNITED STATES		* Zip / Postal Code: 17033-0850		
*Phone Number 717-531-8495		Fax Number 717-531-0040	* E-Mail e-grants@hmc.psu.edu	
Credential, e.g., agency login:				
* Project Role: Co-Investigator		Other Project Role Category:		
Degree Type:				
Degree Year:				
		File Name	Mime Type	
*Attach Biographical Sketch				
Attach Current & Pending Support				

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

This component provides the ability to collect structured data for up to 40 senior/key persons. Data must be entered for the first 40 individuals (PD/PI + 39 others) before the Additional Senior/Key Person Form Attachments section becomes available. The information for the PD/PI continues to be pre-populated from the SF424 (R&R) Cover component. **Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.**



### Multiple PD/PIs

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 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 include their respective eRA Commons ID in the Credential field..**

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.



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.

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



Biographical Sketches should follow the format described below.



## Additional Current and Pending Support(s)



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

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

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

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other senior/key persons. In other federal forms this information is referred to as “Credential, e.g., agency login.”

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: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm). Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material).
- D. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and

responsibilities of the senior/key person identified on the Biographical Sketch. ***Do not include number of person months or direct costs.***

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

# PHS 398 Cover Page Supplement

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

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

## 2. Human Subjects

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

## 3. Applicant Organization Contact

Person to be contacted on matters involving this application

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

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



# PHS 398 Research Plan

## 1. Application Type:

From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.

\*Type of Application:

- New     Resubmission     Renewal     Continuation     Revision

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

- |   |                      |
|---|----------------------|
| 1. Introduction to Application<br>(for RESUBMISSION or REVISION only) | <input type="text"/> |
| 2. Specific Aims  | <input type="text"/> |
| 3. Research Strategy  | <input type="text"/> |
| 4. Inclusion Enrollment Report  | <input type="text"/> |
| 5. Progress Report Publication List                                   | <input type="text"/> |

### Human Subjects Sections

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

### Other Research Plan Sections

- |   |                      |
|---|----------------------|
| 10. Vertebrate Animals                  | <input type="text"/> |
| 11. Select Agent Research               | <input type="text"/> |
| 12. Multiple PD/PI Leadership Plan      | <input type="text"/> |
| 13. Consortium/Contractual Arrangements | <input type="text"/> |
| 14. Letters of Support                  | <input type="text"/> |
| 15. Resource Sharing Plan(s)            | <input type="text"/> |

16. Appendix

## 5.5 PHS 398 Research Plan Component

Field Name	Instructions
<p>1. Introduction to Application (for Resubmission or Revision only)</p>	<p>See specific instructions in Part I Section 2.7, Resubmission Applications and Part I Section 2.8, Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction.</p> <p>The Introduction is a required attachment for Resubmissions and Revisions. 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.</p>
<p>2. Specific Aims</p>	<p>State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>The Specific Aims attachment is required unless otherwise specified in the FOA. Specific Aims are limited to one page.</p>
<p>3. Research Strategy</p>	<p>Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (<u>Part I Section 4.4.9</u>).</p> <p>Follow the page limits for the Research Strategy in the table of page limits (Table 2.6-1), unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.</p> <p><i>(a) Significance</i></p> <ul style="list-style-type: none"> <li>• Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.</li> <li>• Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.</li> <li>• Describe how the concepts, methods, technologies,</li> </ul>

Field Name	Instructions
	<p>treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.</p> <p><i>(b) Innovation</i></p> <ul style="list-style-type: none"> <li>• Explain how the application challenges and seeks to shift current research or clinical practice paradigms.</li> <li>• Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.</li> <li>• Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.</li> </ul> <p><i>(c) Approach</i></p> <ul style="list-style-type: none"> <li>• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</li> <li>• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.</li> <li>• If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.</li> <li>• Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 11, below.</li> </ul> <p>If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.</p> <p>As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.</p> <p><b>Preliminary Studies for New Applications:</b> 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</p>

Field Name	Instructions
	<p>application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in application from Early Stage Investigators than on the preliminary data in applications from more established investigators).</p> <p><b>Progress Report for Renewal and Revision Applications.</b> 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.</p>
4. Inclusion Enrollment 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.
5. Progress Report Publication List (Renewal Applications Only)	<p>List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: <a href="http://publicaccess.nih.gov/submit_process_journals.htm">http://publicaccess.nih.gov/submit_process_journals.htm</a>.</p> <p>Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Part I Section 5.5.15 for more information).</p>

### Human Subjects Sections

Field Name	Instructions
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Field Name	Instructions
6. Protection of Human Subjects	<p>Refer to Part II, <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u>.</p> <p>This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&amp;R Other Project Information form. If the answer is “No” to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p>
7. Inclusion of Women and Minorities	<p>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&amp;R Other Project Information form and the research does not fall under Exemption 4.</p>
8. Targeted/Planned Enrollment	<p>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&amp;R Other Project Information Form and the research does not fall under Exemption 4, complete the Targeted/Planned Enrollment Table for each protocol.</p>
9. Inclusion of Children	<p>Refer to <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u>, Sections 4.4 and 5.7. For applicants answering “Yes” to the question “Are human subjects involved” on the R&amp;R Other Project Information Form and the research does not fall under Section 4, this section is required .</p>

#### Other Research Plan Sections

Field Name	Instructions
10. Vertebrate Animals	<p>This section is required for applicants answering “yes” to the question “Are vertebrate animals involved?” on the R&amp;R Other Project Information form.</p> <p>If Vertebrate Animals are involved in the project, address each of the five points below. This section should be a concise, complete description of</p>

Field Name	Instructions
	<p>the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected.</p> <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 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).</p> <p>The five points are as follows:</p> <ol style="list-style-type: none"> <li>1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.</li> <li>2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.</li> <li>3. Provide information on the veterinary care of the animals involved.</li> <li>4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.</li> <li>5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.</li> </ol> <p>Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.</p>

Field Name	Instructions
11. Select Agent Research	<p>Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See <a href="http://www.cdc.gov/od/sap/docs/salist.pdf">http://www.cdc.gov/od/sap/docs/salist.pdf</a>.</p> <p>If the activities proposed in 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>.</p> <p>If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> <li>1. Identify the select agent(s) to be used in the proposed research.</li> <li>2. Provide the registration status of all entities* where select agent(s) will be used. <ul style="list-style-type: none"> <li>• If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.</li> </ul> <p>*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”</p> </li> <li>3. Provide a description of all facilities where the select agent(s) will be used. <ul style="list-style-type: none"> <li>• Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s).</li> <li>• Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).</li> <li>• Describe the biocontainment resources available at all performance sites.</li> </ul> </li> </ol> <p>If you are responding to a specific funding opportunity announcement</p>

Field Name	Instructions
	<p>(e.g., PA or RFA), address any requirements specified by the FOA.</p> <p>Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.</p>
<p>12. Multiple PD/PI Leadership Plan</p>	<p>For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.</p> <p>If budget allocation is planned, the distribution of resources to specific 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.</p>
<p>13. Consortium/Contractual Arrangements</p>	<p>Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&amp;R) cover component (Item 17) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p style="padding-left: 40px;">The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.</p>

Field Name	Instructions
14. Letters of Support (e.g., Consultants)	<p>Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as senior/key personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rate/charge for consulting services.</p>
15. Resource Sharing Plan(s)	<p>NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.</p> <ol style="list-style-type: none"> <li>1. <i>Data Sharing Plan</i>: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&amp;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</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>.</li> <li>2. <i>Sharing Model Organisms</i>: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See <a href="#">Sharing Model Organisms Policy</a>, and <a href="#">NIH Guide NOT-OD-04-042</a>.</li> <li>3. <i>Genome Wide Association Studies (GWAS)</i>: Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, <a href="#">NIH Guide NOT-OD-07-088</a>, and <a href="http://gwas.nih.gov/">http://gwas.nih.gov/</a>.</li> </ol>

Field Name	Instructions
16. Appendix	<p>Only one copy of appendix material is necessary. Use the <b>Add Attachments</b> button to the right of this field to complete this entry.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details and <b>check the FOA</b> for any specific instructions), though not all grant activity codes allow publications to be included in the appendix.</p> <p><b>Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies..</b></p> <p>Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications <b>may</b> include the following materials in the Appendix (note, however, that some FOAs do not permit publications):</p> <ul style="list-style-type: none"> <li>• <b>Publications – No longer allowed as appendix materials except in the circumstances noted below.</b> Applicants may submit up to 3 of the following types of publications: <ul style="list-style-type: none"> <li>○ <b>Manuscripts and/or abstracts accepted for publication but not yet published:</b> The entire article should be submitted as a PDF attachment.</li> <li>○ <b>Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:</b> The entire article should be submitted as a PDF attachment.</li> <li>○ <b>Patents directly relevant to the project:</b> The entire document should be submitted as a PDF attachment.</li> </ul> </li> </ul> <p>(Do not include unpublished theses, or abstracts/manuscripts <b>submitted</b> (but not yet accepted) for publication.)</p> <ul style="list-style-type: none"> <li>• Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.</li> </ul>

Field Name	Instructions
	<ul style="list-style-type: none"> <li>• For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.</li> </ul> <p>Items that must <b>not</b> be included in the appendix:</p> <ul style="list-style-type: none"> <li>• Photographs or color images of gels, micrographs, etc., <b>are no longer accepted as Appendix material</b>. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.</li> <li>• Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.</li> </ul>

# PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001

Budget Period: 1				
Start Date: <input type="text" value="07/01/2014"/>		End Date: <input type="text" value="06/30/2015"/>		
<b>A. Direct Costs</b>				Funds Requested (\$)
* Direct Cost less Consortium F&A				<input type="text" value="275,000.00"/>
Consortium F&A				<input type="text" value="0.00"/>
* Total Direct Costs				<input type="text" value="275,000.00"/>
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input type="text" value="MTDC (Provisional)"/>	<input type="text" value="53.00"/>	<input type="text" value="241,620.00"/>	<input type="text" value="128,060.00"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number) <input type="text" value="Office of Naval Research, Chicago Office, 312-886-5423"/>				
Indirect Cost Rate Agreement Date <input type="text" value="07/02/2013"/>				Total Indirect Costs <input type="text" value="128,060.00"/>
<b>C. Total Direct and Indirect Costs (A + B)</b>				Funds Requested (\$) <input type="text" value="403,060.00"/>
Budget Period: 2				
Start Date: <input type="text" value="07/01/2015"/>		End Date: <input type="text" value="06/30/2016"/>		
<b>A. Direct Costs</b>				Funds Requested (\$)
* Direct Cost less Consortium F&A				<input type="text" value="275,000.00"/>
Consortium F&A				<input type="text" value="0.00"/>
* Total Direct Costs				<input type="text" value="275,000.00"/>
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input type="text" value="MTDC (Provisional)"/>	<input type="text" value="53.00"/>	<input type="text" value="217,854.00"/>	<input type="text" value="115,464.00"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number) <input type="text" value="Office of Naval Research, Chicago Office, 312-886-5423"/>				
Indirect Cost Rate Agreement Date <input type="text" value="07/02/2013"/>				Total Indirect Costs <input type="text" value="115,464.00"/>
<b>C. Total Direct and Indirect Costs (A + B)</b>				Funds Requested (\$) <input type="text" value="390,464.00"/>



# PHS 398 Modular Budget, Periods 3 and 4

OMB Number: 0925-0001

<b>Budget Period: 3</b>				
Start Date: <input style="width: 100px;" type="text" value="07/01/2016"/>		End Date: <input style="width: 100px;" type="text" value="06/30/2017"/>		
<b>A. Direct Costs</b>			Funds Requested (\$)	
* Direct Cost less Consortium F&A			<input style="width: 100px;" type="text" value="275,000.00"/>	
Consortium F&A			<input style="width: 100px;" type="text" value="0.00"/>	
* Total Direct Costs			<input style="width: 100px;" type="text" value="275,000.00"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 500px;" type="text" value="MTDC (Provisional)"/>	<input style="width: 50px;" type="text" value="53.00"/>	<input style="width: 100px;" type="text" value="221,677.00"/>	<input style="width: 100px;" type="text" value="117,489.00"/>
2.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
3.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
4.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number) <input style="width: 900px;" type="text" value="Office of Naval Research, Chicago Office, 312-886-5423"/>				
Indirect Cost Rate Agreement Date		<input style="width: 100px;" type="text" value="07/02/2013"/>	Total Indirect Costs <input style="width: 100px;" type="text" value="117,489.00"/>	
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$) <input style="width: 100px;" type="text" value="392,489.00"/>	
<b>Budget Period: 4</b>				
Start Date: <input style="width: 100px;" type="text" value="07/01/2017"/>		End Date: <input style="width: 100px;" type="text" value="06/30/2018"/>		
<b>A. Direct Costs</b>			Funds Requested (\$)	
* Direct Cost less Consortium F&A			<input style="width: 100px;" type="text" value="275,000.00"/>	
Consortium F&A			<input style="width: 100px;" type="text" value="0.00"/>	
* Total Direct Costs			<input style="width: 100px;" type="text" value="275,000.00"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 500px;" type="text" value="MTDC (Provisional)"/>	<input style="width: 50px;" type="text" value="53.00"/>	<input style="width: 100px;" type="text" value="225,600.00"/>	<input style="width: 100px;" type="text" value="119,568.00"/>
2.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
3.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
4.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number) <input style="width: 900px;" type="text" value="Office of Naval Research, Chicago Office, 312-886-5423"/>				
Indirect Cost Rate Agreement Date		<input style="width: 100px;" type="text" value="07/02/2013"/>	Total Indirect Costs <input style="width: 100px;" type="text" value="119,568.00"/>	
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$) <input style="width: 100px;" type="text" value="394,568.00"/>	

# PHS 398 Modular Budget, Period 5 and Cumulative

OMB Number: 0925-0001

<b>Budget Period: 5</b>				
Start Date: <input style="width: 100px;" type="text" value="07/01/2018"/>		End Date: <input style="width: 100px;" type="text" value="06/30/2019"/>		
<b>A. Direct Costs</b>			Funds Requested (\$)	
* Direct Cost less Consortium F&A			<input style="width: 100px;" type="text" value="250,000.00"/>	
Consortium F&A			<input style="width: 100px;" type="text" value="0.00"/>	
* Total Direct Costs			<input style="width: 100px;" type="text" value="250,000.00"/>	
<b>B. Indirect Costs</b>				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 500px;" type="text" value="MTDC (Provisional)"/>	<input style="width: 50px;" type="text" value="53.00"/>	<input style="width: 100px;" type="text" value="232,312.00"/>	<input style="width: 100px;" type="text" value="123,126.00"/>
2.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
3.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
4.	<input style="width: 500px;" type="text"/>	<input style="width: 50px;" type="text"/>	<input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/>
Cognizant Agency (Agency Name, POC Name and Phone Number) <input style="width: 900px;" type="text" value="Office of Naval Research, Chicago Office, 312-886-5423"/>				
Indirect Cost Rate Agreement Date <input style="width: 100px;" type="text" value="07/02/2013"/>				Total Indirect Costs <input style="width: 100px;" type="text" value="123,126.00"/>
<b>C. Total Direct and Indirect Costs (A + B)</b>			Funds Requested (\$) <input style="width: 100px;" type="text" value="373,126.00"/>	
<b>Cumulative Budget Information</b>				
<b>1. Total Costs, Entire Project Period</b>				
* Section A, Total Direct Cost less Consortium F&A for Entire Project Period		\$	<input style="width: 150px;" type="text" value="1,350,000.00"/>	
Section A, Total Consortium F&A for Entire Project Period		\$	<input style="width: 150px;" type="text"/>	
* Section A, Total Direct Costs for Entire Project Period		\$	<input style="width: 150px;" type="text" value="1,350,000.00"/>	
* Section B, Total Indirect Costs for Entire Project Period		\$	<input style="width: 150px;" type="text" value="603,707.00"/>	
* Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period		\$	<input style="width: 150px;" type="text" value="1,953,707.00"/>	
<b>2. Budget Justifications</b>				
Personnel Justification		<input style="width: 200px;" type="text"/>		
Consortium Justification		<input style="width: 200px;" type="text"/>		
Additional Narrative Justification		<input style="width: 200px;" type="text"/>		

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

\* ORGANIZATIONAL DUNS: 129348186

\* Budget Type:  Project  Subaward/Consortium

Enter name of Organization: PENNSYLVANIA STATE UNIV HERSHEY MED CTR

\* Start Date: 07-01-2013

\* End Date: 06-30-2014

Budget Period: 1

<b>A. Senior/Key Person</b>												
Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary (\$)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary (\$)	* Fringe Benefits (\$)	* Funds Requested (\$)
1.	Kent	Eugene	Vrana		PD/PI		2.4			35,940.00	12,040.00	47,980.00
2.	Sheila	L	Vrana		Co-Investigator		2.4			30,338.00	10,162.00	40,500.00
<b>Total Funds Requested for all Senior Key Persons in the attached file</b>												
<b>Additional Senior Key Persons:</b>						File Name:	Mime Type:	<b>Total Senior/Key Person</b>				<b>88,480.00</b>

<b>B. Other Personnel</b>													
* Number of Personnel					* Project Role		Cal. Months	Acad. Months	Sum. Months	* Requested Salary (\$)	* Fringe Benefits	* Funds Requested (\$)	
1					Post Doctoral Associates		6	0	0	20,122.00	1,570.00	21,692.00	
2					Graduate Students		0	4.5	2	24,545.00	3,407.00	27,952.00	
0					Undergraduate Students					0.00	0.00	0.00	
0					Secretarial/Clerical					0.00	0.00	0.00	
1					Mary Money - Technician		12	0	0	29,286.00	9,810.00	39,096.00	
<b>4</b>					<b>Total Number Other Personnel</b>					<b>Total Other Personnel</b>		<b>88,740.00</b>	
											<b>Total Salary, Wages and Fringe Benefits (A+B)</b>		<b>177,220.00</b>

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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

\* ORGANIZATIONAL DUNS: 129348186

\* **Budget Type:**     Project     Subaward/Consortium

**Enter name of Organization:** PENNSYLVANIA STATE UNIV HERSHEY MED CTR

\* **Start Date:** 07-01-2013

\* **End Date:** 06-30-2014

**Budget Period:** 1

### C. Equipment Description

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

	Equipment Item	* Funds Requested (\$)
1.	Autoclave	8,500.00
<b>Total funds requested for all equipment listed in the attached file</b>		
	<b>Total Equipment</b>	<b>8,500.00</b>
<b>Additional Equipment:</b>	File Name:	Mime Type:

### D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)	2,500.00
2. Foreign Travel Costs	0.00
	<b>Total Travel Cost</b>
	<b>2,500.00</b>

### E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	0.00
3. Travel	0.00
4. Subsistence	0.00
5. Other:	
<b>Number of Participants/Trainees</b>	<b>Total Participant/Trainee Support Costs</b>
	<b>0.00</b>

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

**RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1**

\* ORGANIZATIONAL DUNS: 129348186

\* **Budget Type:**     Project     Subaward/Consortium

**Enter name of Organization:** PENNSYLVANIA STATE UNIV HERSHEY MED CTR

\* **Start Date:** 07-01-2014

\* **End Date:** 06-30-2015

**Budget Period:** 1

<b>F. Other Direct Costs</b>	<b>Funds Requested (\$)</b>
1. Materials and Supplies	22,500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	30,000.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Tuition Remission	15,662.00
9. All Other Direct Costs	14,400.00
<b>Total Other Direct Costs</b>	<b>82,562.00</b>

<b>G. Direct Costs</b>	<b>Funds Requested (\$)</b>
<b>Total Direct Costs (A thru F)</b>	<b>270,782.00</b>

<b>H. Indirect Costs</b>			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1. MTDC (Provisional)	53	241,620.00	128,060.00
<b>Total Indirect Costs</b>			<b>128,060.00</b>
<b>Cognizant Federal Agency</b>		Office of Naval Research, Chicago Office, 312-886-5423	
<small>(Agency Name, POC Name, and POC Phone Number)</small>			

<b>I. Total Direct and Indirect Costs</b>	<b>Funds Requested (\$)</b>
<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>398,842.00</b>

<b>J. Fee</b>	<b>Funds Requested (\$)</b>
	0.00

<b>K. * Budget Justification</b>	File Name:	Mime Type:
	(Only attach one file.)	

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

## 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) PHS 398 Modular Budget Component.** NIH applications will include either the R&R Budget Component or the PHS 398 Modular Budget Component, but not both. (**Note AHRQ does not accept modular budgets.**)

### **Modular Budget Guidelines**

Modular budgets are applicable to certain research grant applications **requesting \$250,000 or less per year for direct costs (in modules of \$25,000)**. 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 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. For all modular budgets, request total direct costs 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.

*The modular budget is applicable only to R01, R03, R15, R21, and R34 applications*

### **Detailed Budget (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.

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.

This component accommodates a set number of separate subaward budgets (i.e., 10 or 30). If you are submitting an application with more subaward budgets than the component allows, the remaining budgets should be converted to PDF and included as part of Section K. Budget Justification of the parent budget. Reminder, the sum of all subaward budgets; e.g., those attached separately and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the parent budget.

**NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort.**

### **Budget Justifications:**

Personnel Justification

Consortium Justification

Additional Narrative Justification

# PHS 398 Checklist

## 1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

\* Type of Application:

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

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

\* Previously Reported:    Yes     No

**4. \* Program Income**

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

Yes       No

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

\*Budget Period    \*Anticipated Amount (\$)

\*Source(s)

<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

**5. \* Disclosure Permission Statement**

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

Yes       No



## 5.6 Checklist Component

### 5. Disclosure Permission Statement

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

Otherwise check the No box. *A selection is required.*

# PHS 398 Cover Letter

\* Mandatory Cover Letter Filename: \_\_\_\_\_