WUSM RA Forum
November 10, 2005

Grants & Contracts
General Information

- The Nightmare before Funding (handout)
- The Hand that Feeds (handout)
- Congress Asks HHS IG to Investigate Use of NIH Funds (handout)
- Government Representatives Brief FDP on Electronic Proposal Progress (handout)
- NIH Rolls Out Electronic Grant Submission (handout)
General Information (cont.)

- How do I address the Human Subject issue on the NIH Face Page when the PI’s IRB protocol is exempt (Exempt #4)?
  - Exempt #4 means that when the data goes to the PI, there is some private identifiable information, but that the PI “de-identifies” the data before doing the research.
  - For Exempt #4 issues/situations, you should indicate “yes” on the Face Page to Human Subjects and indicate Exempt #4.
  - PC Form and Face Page need to ALWAYS match.
General Information (cont.)

- Who is required to complete Human Subject Education?
  - All Key Personnel identified by WUSM if the Research Plan involves Human Subjects

- What if one of my Key people will not actually be involved with Human Subjects research?
  - Use the G&C “Engaged” template letter and have the PI of the award and the individual(s) sign-off on the letter
Definition of Engaged

**Engaged:** An institution or individual becomes “engaged” in human subjects research when the institution’s employees or agents, or the individual (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

**G&C Web Site - Forms and Letters:**

INSTRUCTIONS FOR PRINCIPAL INVESTIGATORS AND DEPARTMENT ADMINISTRATORS:

This letter is required for G&C to establish an account for expenditure of funds in certain situations where human subjects are involved and specific key personnel are not engaged in human subjects research and will not be taking the online IRB Education Courses (CITI).

Using Departmental letterhead and the format outlined below, this letter must be signed by the Principal Investigator and submitted to G&C. If all applicable conditions are met, G&C will establish the account for expenditure of funds.

The letter should be signed by the PI of the grant and any Key individual(s) classified as not engaged in human subjects research.

Submit the signed original letter to:
Grants & Contracts Office
Cancer Research Bldg., Room 114
Campus Box 8018
Phone: 747-4134  Fax: 362-0315

Please contact your G&C Grant Analyst with any questions.

Template Letter Format:

To: Grants & Contracts Office
From: Principal Investigator Name
Date: 
Grant number: 
Sponsoring agency:

I certify under this research project, (list key personnel not engaged in human subjects research) is not engaged* in human subjects research and does not need to take the online IRB Education Course (CITI).

I attest that the personnel listed above will not interact or intervene with living individuals for research purposes nor will they use or have access to any individually identifiable private information.

Signature ___________________________  Signature ___________________________
Principal Investigator name  Date  —  Key Individual(s) listed above  Date
An SF424 (R&R) Walk Through

Courtesy of the Office of Policy for Extramural Research Administration, OER

WUSM RA Forum

November 10, 2005
## New Terminology: Type of Application

<table>
<thead>
<tr>
<th>NIH Term</th>
<th>(R&amp;R) Term</th>
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<tbody>
<tr>
<td>New (T-1)</td>
<td>New</td>
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<tr>
<td>Competing Continuation (T-2)</td>
<td>Renewal</td>
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<tr>
<td>Revision or Amendment</td>
<td>Resubmission</td>
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<tr>
<td>Competing Supplement</td>
<td>Revision</td>
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</table>

R&R Type of Application also include “Continuation”. This is equivalent to our Progress Report or T-5. NIH will not use the R&R for progress reports.
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<tr>
<th>NIH Term</th>
<th>(R&amp;R) Term</th>
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<tbody>
<tr>
<td>PA and/or RFA</td>
<td>Funding Opportunity Announcement (FOA)—general term for all PAs and RFAs</td>
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<tr>
<td>PI</td>
<td>PD/PI: Combined term</td>
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<tr>
<td>Authorized Organizational Official (AOO) or Signing Official (SO)</td>
<td>Authorized Organizational Representative (AOR)</td>
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<tr>
<td>Other Support</td>
<td>Current &amp; Pending Support</td>
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</table>
# New Terminology

<table>
<thead>
<tr>
<th>NIH Term</th>
<th>(R&amp;R) Term</th>
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<tbody>
<tr>
<td>Literature Cited (Part G. of 398 Research Plan)</td>
<td>“Bibliography &amp; References Cited” in R&amp;R Other Project Information Component</td>
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<tr>
<td>Consortium Budget</td>
<td>Subaward Budget</td>
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Features of the SF424 (R&R)

- The SF424 (R&R) is an application form that is comprised of common data elements developed for use by the various Federal agencies funding Research and Research-Related programs.
- Provides a consistent electronic submission process through Grants.gov.
Features of the SF424 (R&R) (cont.)

- SF424 (R&R) data is arranged in components
- Not all components will be used for every Funding Opportunity Announcement (FOA)
- Agencies “construct” application packages for each FOA
- NIH will use several “standard” packages
- The FOA will indicate which components are required and which are optional
- Each FOA will have the appropriate application package attached
Features of the SF424 (R&R) (cont.)

- A complete application to NIH will include a combination of (R&R) & PHS398 components
- The applicant **must** complete the application using the package attached to that particular FOA (*Information is drawn from the specific FOA and used in the forms*)
- The applicant will complete data entry in all necessary components and upload appropriate attachments
Features of the SF424 (R&R) (cont.)

- **SF424 (R&R) Components include:**
  - SF424 (R&R)—An application cover component
  - Research & Related Project/Performance Site Location (s)
  - Research & Related Other Project Information
  - Research & Related Senior/Key Person
  - Research & Related Budget
  - Research & Related Personal Data (*NIH will not use*)
  - R&R Subaward Budget Attachment Form
  - SBIR/STTR Information
Features of the SF424 (R&R) (cont.)

- NIH requires additional data collection to accommodate the unique information required for review of its biomedical research portfolio. Therefore, NIH has also developed agency-specific components (titled PHS398):
  - PHS398 Cover Letter File
  - PSH398 Cover Page Supplement *(supplements the R&R Cover)*
  - PHS 398 Modular Budget
  - PHS 398 Research Plan
  - PHS 398 Checklist

- Why call them PHS398?
  - Needed a generic term since other HHS agencies will use
  - It’s the OMB-cleared data collection instrument that gives us the authority to request these additional data elements
Features of the SF424 (R&R) (cont.)

- Most attachments are text
- NIH will require PDF for text attachments
- Attachments can be generated using any word processing software **but** will need to be **converted** to PDF before they can be attached to the actual application form

  *(Applicants will need some type of PDF-creation software)*
Features of the SF424 (R&R) (cont.)

- After submission, the NIH eRA system will:
  - Generate a Table of Contents
  - Assemble the grant image
  - Include headers (PI name) & footers (page numbers) on all pages

- Applicants (PD/PI & Authorized Organizational Representative) will review and verify this grant image in the eRA Commons
Features of the SF424 (R&R): Application Guide

- NIH has developed (2) Application Guides specific to the SF424 (R&R): 1) General Instructions; 2) General +SBIR/STTR
- Includes instructions that are imbedded in the actual forms as well agency-specific instructions
- Agency-specific instructions denoted with the HHS Logo

- Documents have same part structure as PHS 398 Instructions:
  - Part I: Instructions for Preparing and Submitting an Application
  - Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan
  - Part III: Policies, Assurances, Definitions
Features of the SF424 (R&R):

Application Package Header

- Header page is attached to every posted application package
- Header data is pre-filled from the actual announcement
- Notes which components are required (mandatory) and which are optional for this particular announcement
- Includes basic instructions
- Includes Application Submission Verification & Signature screen
<table>
<thead>
<tr>
<th>Opportunity Title:</th>
<th>NIH SBIR Omnibus Solicitation (SAMPLE ONLY)</th>
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<tr>
<td>Offering Agency:</td>
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<td>83.867</td>
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<td>CFDA Description:</td>
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<td>SBIR/STTR Program Coordinator</td>
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<tr>
<td></td>
<td>Email: *********@mail.nih.gov</td>
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<td></td>
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This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

* Application Filing Name: __________________________

**Mandatory Documents**

- SF424 (R&R)
- SBIR/STTR Information
- PHS 398 Research Plan
- PHS 398 Checklist
- PHS 398 Cover Page Supplement
- Research & Related Budget

Optional Documents

- R&R Subaward Budget Attachment Form
- PHS 398 Cover Letter File

Instructions
Application Submission Verification and Signature

Opportunity Title: NIH SBIR Omnibus Solicitation (SAMPLE ONLY)
Offering Agency: NIH
CFDA Number: 83.887
CFDA Description: Vision Research
Opportunity Number: PA-06-SBIR
Competition ID:
Opportunity Open Date: 10/15/2006
Opportunity Close Date: 01/01/2008
Application Filing Name:

Do you wish to sign and submit this Application?

Please review the summary provided to ensure that the information listed is correct and that you are submitting an application to the opportunity for which you want to apply.

If you want to submit the application package for the listed funding opportunity, click on the "Sign and Submit Application" button below to complete the process. You will then see a screen prompting you to enter your user ID and password.

If you do not want to submit the application at this time, click the "Exit Application" button. You will then be returned to the previous page where you can make changes to the required forms and documents or exit the process.

If this is not the application for the funding opportunity for which you wish to apply, you must exit this application package and then download and complete the correct application package.

Sign and Submit Application  Exit Application
Component: SF424 (R&R): An Application Cover Component

- Similar to the PHS398 Face Page
- Provides general information about the applicant organization, contact information for the PD/PI and Authorized Organizational Representative
- Provides application-specific information (type, title etc)
**SF424 (R&R)**  
**Cover Component**  
**Page 1**

<table>
<thead>
<tr>
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<th>2. DATE SUBMITTED</th>
<th>Applicant Identifier</th>
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<tr>
<td>SF 424 (R&amp;R)</td>
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1. **TYPE OF SUBMISSION**

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<th>Application</th>
<th>Corrected Application</th>
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2. **APPLICANT INFORMATION**

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Person to be contacted on matters involving this application

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

* Phone Number:  Fax Number:  Email:  

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

7. **TYPE OF APPLICANT:**

- Please select one of the following

8. **TYPE OF APPLICATION:**

- New
- Resubmission
- Renewal
- Continuation
- Revision

If Revision, mark appropriate box(es).

- A. Increase Award
- B. Decrease Award
- C. Increase Duration
- D. Decrease Duration
- E. Other (specify)

9. **NAME OF FEDERAL AGENCY:**

- National Institutes of Health

10. **CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**

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11. **DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:**

12. **AREAS AFFECTED BY PROJECT**

(city, counties, states, etc.)

13. **PROPOSED PROJECT:**

* Start Date:  * Ending Date:  

14. **CONGRESSIONAL DISTRICTS OF:**

a. * Applicant  
   b. * Project  

15. **PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

| Prefix: * First Name:  Middle Name:  * Last Name:  Suffix: |
|---|-------------------|----------------------|
| Position/Title:  * Organization Name: |
| Department:  Division: |
| * Street1:  Street2: |
| * City:  County:  * State:  * ZIP Code: |
| * Country: USA |
| * Phone Number:  Fax Number:  * Email: |

OMB Number: 4040-0001  
Expiration Date: 04/30/2008
## SF 424 (R&R) Cover Component

### Page 2

#### 16. ESTIMATED PROJECT FUNDING

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<tr>
<td>a. * Total Estimated Project Funding</td>
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<tr>
<td>b. * Total Federal &amp; Non-Federal Funds</td>
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<tr>
<td>c. * Estimated Program Income</td>
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#### 17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

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<tr>
<td>a. YES</td>
<td>THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:</td>
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<td>DATE:</td>
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<tr>
<td>b. NO</td>
<td>PROGRAM IS NOT COVERED BY E.O. 12372; OR</td>
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<td></td>
<td>PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</td>
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#### 18. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

* 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.

#### 19. Authorized Representative

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* Signature of Authorized Representative

Completed on submission to Grants.gov

* Date Signed

Completed on submission to Grants.gov

20. Pre-application

Add Attachment  Delete Attachment  View Attachment

OMB Number: 4040-0001
Expiration Date: 04/30/2008
Component: SF424 (R&R): An Application Cover Component (cont.) A Few Data Issues

- **Item 1, Type of Submission**
  - Pre-application—instructed not to use unless specifically noted in FOA
  - Changed/Corrected Application—To be used only when correcting an application that failed system validations. This is NOT a resubmission (amendment)

- **Item 5, Applicant Information**: This is for the applicant *organization*
Item 8, Type of Application--New Terminology

- New is the same
- Resubmission is equivalent to a Revision (*a revised or amended application*)
- Renewal is equivalent to a Competing Continuation
- Continuation is equivalent to a Progress Report. For the purposes of NIH and other PHS agencies, the box for Continuation will **not** be used and should **not** be checked.
- Revision is somewhat equivalent to a Competing Supplement

Terminology cross-walk provided in instructions
Component: SF424 (R&R): An Application Cover Component (cont.) A Few Data Issues (cont.)

- **Item 10, CFDA Number & Title**
  - *CFDA = Catalog of Federal Domestic Assistance*
  - Fields are pre-filled based on the specific announcement
  - Fields will be blank for applications in response to a FOA that include multiple CFDAs
  - When multiple CFDAs are listed in an announcement, a CFDA will be assigned by the eRA system once a specific Institute assignment is made
Component: Research and Related Project/Performance Site Locations

- Equivalent to the PHS398 Form Page 2 Performance Site section
- Collects individual data for up to 8 locations
- > 8 locations information is provided in an attachment (not structured data, just text)
Project/Performance Site Locations

RESEARCH &RELATED Project/Performance Site Location(s)

Project/Performance Site Primary Location

Organization Name: [Blank]

* Street1: [Blank]  Street2: [Blank]


Project/Performance Site Location 1

Organization Name: [Blank]

* Street1: [Blank]  Street2: [Blank]


Additional Location(s) [Blank]  [Add Attachment]  [Delete Attachment]  [View Attachment]

Reset Entry  Next Site

OMB Number: 4040-0001
Expiration Date: 04/30/2008
Component: Research and Related Other Project Information

- Includes information on involvement of Human Subjects, Vertebrate Animals, Environmental Impact, Foreign Involvement

- Includes separate PDF attachments for
  - Project Summary/Abstract
  - Project Narrative
    - NIH will use this upload for the “Relevance” section of the Abstract
    - Separate component developed for Research Plan
  - Bibliography & References (previously section G. Literature cited)
  - Facilities & Other Resources
  - Equipment resources

Equivalent to PHS 398 Resources Format Page
RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved?  □ Yes  □ No
   1.a If YES to Human Subjects
      Is the IRB review Pending?  □ Yes  □ No
      IRB Approval Date:
      Exemption Number: □ 1 □ 2 □ 3 □ 4 □ 5 □ 6
      Human Subject Assurance Number:

2. * Are Vertebrate Animals Used?  □ Yes  □ No
   2.a If YES to Vertebrate Animals
      Is the IACUC review Pending?  □ Yes  □ No
      IACUC Approval Date:
      Animal Welfare Assurance Number:

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

4.a * Does this project have an actual or potential impact on the environment?  □ Yes  □ No
   4.b If yes, please explain:
   4.c If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?  □ Yes  □ No
   4.d If yes, please explain:

5.a * Does this project involve activities outside the U.S. or partnership with International Collaborators?  □ Yes  □ No
   5.b If yes, identify countries:
   5.c Optional Explanation:

6. * Project Summary/Abstract

7. * Project Narrative

8. Bibliography & References Cited

9. Facilities & Other Resources

10. Equipment

11. Other Attachments

OMB Number: 4040-0001
Expiration Date: 04/30/2008
Component: Research and Related Senior/Key Person

- Captures personal profile information on the PD/PI, Key Personnel, and Other Significant Contributors
- Captures structured data **for 8 individuals (PI and 7 others)**
- > 8 information is provided in an attachment (not structured data, just text)
- Biosketch is attached for each person
  - Same data requirement; however, page limits slightly change to just 4 pages
  - Eliminating the 2 page limit for subsections
- Note, Attachment for Current & Pending Support (a.k.a. Other Support) will **not** be used
**Senior/Key Person Profile**

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### RESEARCH & RELATED Senior/Key Person Profile

#### PROFILE - Project Director/Principal Investigator

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Credential, e.g., agency login:  

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**Attach Biographical Sketch**  
**Attach Current & Pending Support**

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### PROFILE - Senior/Key Person 1

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</table>

<table>
<thead>
<tr>
<th>* City:</th>
<th>County:</th>
<th>* State:</th>
<th>* Zip Code:</th>
<th>* Country:</th>
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<table>
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<tr>
<th>* Phone Number</th>
<th>Fax Number</th>
<th>* E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Credential, e.g., agency login:  

<table>
<thead>
<tr>
<th>* Project Role:</th>
<th>Other Project Role Category:</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Attach Biographical Sketch**  
**Attach Current & Pending Support**

---

### ADDITIONAL SENIOR/KEY PERSON PROFILE(S)

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

**Additional Current and Pending Support(s)**
Component: Research and Related Budget, Sections A & B

- Personnel separated into 2 sections
  - A. Senior/Key Person
    - Allows 8 as named individuals & structured data
    - > 8 information is provided in an attachment (*not structured data, just text*)
  - B. Other Personnel
    - Postdocs, Grad Students, Undergrads: captures # only
    - NIH will request more detail in Budget Justification

- Business Process Change from Percent Effort to Person Months
# R&R Budget

**Sections A & B**

## A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>* First Name</th>
<th>Middle Name</th>
<th>* Last Name</th>
<th>Suffix</th>
<th>* Project Role</th>
<th>Base Salary ($)</th>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Months</th>
<th>* Requested Salary ($)</th>
<th>* Fringe Benefits ($)</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>PC/PI</td>
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</tbody>
</table>

9. Total Funds requested for all Senior Key Persons in the attached file:

Additional Senior Key Persons: XXXX

## B. Other Personnel

<table>
<thead>
<tr>
<th>* Number of Personnel</th>
<th>* Project Role</th>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Months</th>
<th>* Requested Salary ($)</th>
<th>* Fringe Benefits ($)</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
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<td></td>
<td>Graduate Students</td>
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<td></td>
<td>Undergraduate Students</td>
<td></td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
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</tr>
</tbody>
</table>

Total Number Other Personnel: XXXX

Total Salary, Wages and Fringe Benefits (A+B): XXXX
Component: Research and Related Budget, Sections C - E

■ C. Equipment
  □ *Allows itemization of up to 10*
  □ > 10 total dollars are inserted in line 11; however, the details are provided in an attachment

■ D. Travel
  □ R&R separates out Domestic & Foreign
  □ This *will not change* any NIH policy/practice. We will continue to award as a single category

■ E. Participant/Trainee Support Costs
  □ *Will not be used* by NIH *unless* specifically noted in an announcement
  □ Tuition Remission will continue to included in section F. Other Direct Costs
RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 

* Budget Type: □ Project □ Subaward/Consortium

Enter name of Organization: 

Reset Entries □ Start Date: □ End Date: □ Budget Period: 1

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

C. Equipment Description
List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

11. Total funds requested for all equipment listed in the attached file

<table>
<thead>
<tr>
<th>Total Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Additional Equipment: [ ] Add Attachment [ ] Delete Attachment [ ] View Attachment

D. Travel
1. Domestic Travel Costs (incl. Canada, Mexico and U.S. Possessions)
2. Foreign Travel Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Total Travel Cost

E. Participant/Trainee Support Costs
1. Tuition/FEES/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

Number of Participants/Trainees Total Participant/Trainee Support Costs
Component: Research and Related Budget, Sections F - K

- F. Other Direct Costs
  - Itemizes Supplies, Publication Costs, Consultants, ADP/Computer Services, Consortium Costs, Equipment or Facility Rental/User Fees, Alterations & Renovations
  - Includes agency-specific instructions; can include costs such as patient care, tuition remission, etc.,.

- G. Total Direct Costs (A – F)
- H. Indirect Costs
- I. Total Costs
- J. Fee
- K. Budget Justification—a PDF text attachment
## R&R Budget

### Sections F - K

**F. Other Direct Costs**

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td></td>
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<tr>
<td>10.</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

**G. Direct Costs**

**Total Direct Costs (A thru F)**

**H. Indirect Costs**

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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</tr>
</tbody>
</table>

**Total Indirect Costs**: 0.00

**Cognizant Federal Agency**

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

**I. Total Direct and Indirect Costs**

**Total Direct and Indirect Institutional Costs (G + H)**: 0.00

**J. Fee**

**Funds Requested ($)**

**K. * Budget Justification**

(Only attach one file.)
Component: Research and Related Budget, General Notes

- Applicant prepares a detailed budget for every budget period
- There is no summary budget page like the PHS398 Form Page 5
- A detailed Cumulative budget is system-generated
Component: R&R Subaward Budget Attachment Form

- Used for detailed budget from any consortium grantee

- *Allows up to 10 separate budget attachments*; one for each consortium grantee

- Applicant sends the R&R budget component to the consortium grantee for completion; it is returned to the applicant; applicant attaches it in this component

- Applicant still needs to include the total costs for all consortiums in their own detailed budget, Section F.5
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a Pure Edge document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1
2) Please attach Attachment 2
3) Please attach Attachment 3
4) Please attach Attachment 4
5) Please attach Attachment 5
6) Please attach Attachment 6
7) Please attach Attachment 7
8) Please attach Attachment 8
9) Please attach Attachment 9
10) Please attach Attachment 10

Add Attachment | Delete Attachment | View Attachment

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

Information

- Includes eligibility questions answered by both SBIR & STTR applicants as well as separate sections for SBIR & STTR-specific questions
- Includes Commercialization Plan as PDF Attachment
**Program Type (select only one)**
- [ ] SBIR
- [ ] STTR
- [ ] Both  
  (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)

**SBIR/STTR Type (select only one)**
- [ ] Phase I
- [ ] Phase II
- [ ] Fast-Track  
  (See agency-specific instructions to determine whether a particular agency participates in Fast-Track)

### Questions 1-7 must be completed by all SBIR and STTR Applicants:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td><strong>1.</strong> Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
</table>
| ![ ] | ![ ] | **2.** Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?  
  * If yes, insert the names of the Federal laboratories/agencies: |

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td><strong>3.</strong> Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: <a href="http://www.sba.gov">http://www.sba.gov</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
</table>
| ![ ] | ![ ] | **4.** Will all research and development on the project be performed in its entirety in the United States?  
  If no, provide an explanation in an attached file.  
  * Explanation: |

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
</table>
| ![ ] | ![ ] | **5.** Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?  
  * If yes, insert the names of the other Federal agencies: |

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>![ ]</td>
<td>![ ]</td>
<td><strong>6.</strong> 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)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
</table>
| ![ ] | ![ ] | **7.** Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.  
  * Attach File: |
### SBIR-Specific Questions:

**Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.**

**8.** Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td></td>
<td><img src="attachment" alt="Attach File:" /> Add Attachment Delete Attachment View Attachment</td>
</tr>
</tbody>
</table>

**9.** Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

| Yes | No |

### STTR-Specific Questions:

**Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.**

**10.** Please indicate whether the answer to BOTH of the following questions is TRUE:

- (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND
- (2) Has the Project Director/Principal Investigator devoted at least 10% effort to the proposed project?

| Yes | No |

**11.** In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

| Yes | No |
Agency-specific Components (a.k.a. PHS 398 Components)

- PHS398 Cover Letter File
- PSH398 Cover Page Supplement
  \textit{(supplements the R&R Cover)}
- PHS 398 Modular Budget
- PHS 398 Research Plan
- PHS 398 Checklist
Component: PHS 398 Cover Letter

- Provides a text attachment for a cover letter
- Instructions to applicant remain the same as in the PHS398
- Will be stored separately in the eRA Grant Folder, not as a part of the main application grant image
- Will be seen only by appropriate NIH staff; not peer reviewers
PHS 398 Cover Letter

*Mandatory Cover Letter Filename: 

Add Cover Letter File  Delete Cover Letter File  View Cover Letter File
Component: PHS 398 Cover Page Supplement

- Companion form to the (R&R) Cover Component
- For the PI, includes New Investigator Code & Degree fields (Note, PD/PI info at the top is pre-filled. Provided here for reference only)
- Includes Clinical Trial & Phase-III defined clinical trial indicators
- For the Business Official Contact, includes complete contact information (title & mailing address missing from section 5 of the R&R Cover)
- Includes Human Embryonic Stem Cells section
1. Project Director / Principal Investigator (PD/PI)

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Name:</td>
<td></td>
</tr>
<tr>
<td>* Last Name:</td>
<td></td>
</tr>
<tr>
<td>Suffix:</td>
<td></td>
</tr>
</tbody>
</table>

* New Investigator? □ No □ Yes

Degrees: ______________________  ______________________  ______________________

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

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Name:</td>
<td></td>
</tr>
<tr>
<td>* Last Name:</td>
<td></td>
</tr>
<tr>
<td>Suffix:</td>
<td></td>
</tr>
</tbody>
</table>

* Phone Number: ______________________ Fax Number: ______________________

Email: ______________________

* Title: ______________________

* Street1: ______________________

Street2: ______________________

* City: ______________________

County: ______________________

* State: ______________________

* Zip Code: ______________________  * Country: USA
4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells?  □ No  □ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/registrar/index.asp. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s):  □ Specific stem cell line cannot be referenced at this time. One from the registry will be used.
Component: PHS 398 Modular Budget

- Provides data entry for each budget period for
  - A. Direct Costs
    - DC less consortium F&A
    - Consortium F&A
    - Total DC
  - B. Indirect Costs Calculation section
  - C. Total Costs (A + B)

- Cumulative Budget is system-generated
- Budget Justification PDF text attachments for Personnel, Consortium and Other
# PHS 398 Modular Budget, Periods 1 and 2

### Budget Period: 1

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
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</thead>
<tbody>
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</tbody>
</table>

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

Indirect Cost Rate Agreement Date

**Total Indirect Costs**

### Budget Period: 2

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
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</table>

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

Indirect Cost Rate Agreement Date

**Total Indirect Costs**

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

Funds Requested ($)
Component: PHS 398 Research Plan

- Separate PDF attachments for each section *(designed to maximize benefits of system validations)*
- Same formatting requirements in the PHS398 continue here—margins, page limits, etc
- Appendix Material
  - Allows up to 10 separate attachments
  - Will be stored separately in the NIH eRA Grant Folder, **not as a part of the main application grant image**
  - Will be accessible to appropriate NIH staff and peer reviewers
# PHS 398 Research Plan

## 1. Application Type:
From SF 424 (R&R) Cover Page and PHS98 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**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

   *(for RESUBMISSION or REVISION only)*

2. **Specific Aims**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

3. **Background and Significance**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

4. **Preliminary Studies / Progress Report**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

5. **Research Design and Methods**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

### Human Subjects Sections
Attachments 6-10 apply only when you have answered "yes" to the question "are human subjects involved" on the R&R Other Project Information Form. In this case, attachments 6-10 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.

6. **Protection of Human Subjects**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

7. **Inclusion of Women and Minorities**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

8. **Targeted/Planned Enrollment Table**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

9. **Inclusion of Children**
   - [ ] Add Attachment
   - [ ] Delete Attachment
   - [ ] View Attachment

10. **Data and Safety Monitoring Plan**
    - [ ] Add Attachment
    - [ ] Delete Attachment
    - [ ] View Attachment

### Other Research Plan Sections

11. **Vertebrate Animals**
    - [ ] Add Attachment
    - [ ] Delete Attachment
    - [ ] View Attachment

12. **Consortium/Contractual Arrangements**
    - [ ] Add Attachment
    - [ ] Delete Attachment
    - [ ] View Attachment

13. **Letters of Support**
    - [ ] Add Attachment
    - [ ] Delete Attachment
    - [ ] View Attachment

14. **Resource Sharing Plan(s)**
    - [ ] Add Attachment
    - [ ] Delete Attachment
    - [ ] View Attachment

15. **Appendix**
    - [ ] Add Attachments
    - [ ] Remove Attachments
    - [ ] View Attachments
Component: PHS 398 Checklist

- Captures additional information currently captured in the PHS398 Checklist
  - Change of PI
  - Change of Grantee Institution
  - Inventions & Patents
  - Program Income
  - PDF Text Upload for and Assurances/Certifications explanation
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.

<table>
<thead>
<tr>
<th>*Budget Period</th>
<th>*Anticipated Amount ($)</th>
<th>*Source(s)</th>
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5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided at: http://grants.nih.gov/grants/guide/appendix/table_02.html

*Human Subjects; *Research Using Human Embryonic Stem Cells; *Research on Transplantation of Human Fetal Tissue; *Women and Minority Inclusion Policy; *Inclusion of Children Policy; *Vertebrate Animals; *Debarment and Suspension; *Drug- Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only); *Lobbying; *Non-Delinquency on Federal Debt; *Research Misconduct; *Civil Rights (Form HHS 441 or HHS 690); *Handicapped Individuals (Form HHS 641 or HHS 690); *Sex Discrimination (Form HHS 639-A or HHS 690); *Age Discrimination (Form HHS 660 or HHS 690); *Recombinant DNA and Human Gene Transfer Research; *Financial Conflict of Interest (except Phase I SBIR/STTR); *Prohibited Research; *Select Agents; *Smoke-Free Workplace; *STTR ONLY: Certification of Research Institution Participation.

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

Explanation:  

Add Attachment  
Delete Attachment  
View Attachment
What will a completed application look like?

- After submission, the NIH eRA system will:
  - Assemble the grant image
  - Generate a Table of Contents
  - Include headers (PI name) & footers (page numbers) on all pages

- “eRA Assembly of Grant Application” is found at:

(A document providing a sample Table of Contents & a chart cross-referencing the location in the forms components for each piece of the grant image)
Next Steps

- Review E-Application website:

- Familiarize yourself with the forms and application guide(s)
  - Preview versions of application packages and application guides are available at:
  - Must have PureEdge Viewer installed in order to manipulate the sample application packages. *Check with your IT folks for permission and assistance in downloading this software.*
Finding Help: Application Preparation

- Review application instruction guide(s)
- Contact Grants Info:
  
  Grants Info
  Phone: 301-435-0714
  301-451-0088 (TTY)
  Email GrantsInfo@nih.gov

- All these help resources are found at:
  
  http://era.nih.gov/ElectronicReceipt/support.htm