Small Business Electronic Applications:
Annotated SF424 (R&R) Form Set

FORMS Included in SBIR and STTR applications:

Federal-wide Forms

- SF424 (R&R) Cover Component [Page 2]
- Project/Performance Site Location(s) [Page 4]
- R&R Other Project Information [Page 5]
- R&R Senior/Key Person Profile (Expanded) [Page 6]
- R&R Budget [Page 7]
- R&R Subaward Budget Attachment(s) Form [Page 11]
- SBIR/STTR Information [Page 12]

Agency-specific (PHS) Forms

- PHS Cover Letter [Page 14]
- PHS 398 Cover Page Supplement [Page 15]
- PHS 398 Research Plan [Page 17]
- PHS 398 Checklist [Page 18]

IMPORTANT NOTES:

- The announcement text for the target Funding Opportunity Announcement (FOA) and the Application Guide found at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_Verb.pdf remain the official documents for defining application requirements. The Application Guide provides detailed instructions for every form and form field. This resource is meant to complement, not replace, those documents.
- The light blue boxes throughout the document represent processing notes and eRA system validations.
- The yellow boxes with red outlines are required fields. The Application Guide and this resource describe NIH form field requirements above what is marked on the federal-wide forms.
- The eRA system checks submitted applications against many of the business rules defined in the Application Guide. Not all system validations are contained in this resource. For a complete list of eRA eSubmission Validations see: http://grants.nih.gov/grants/ElectronicReceipt/files/SF424RR_Validation.pdf.
- General tips:
  - Use simple PDF formatted files for all attachments
    - Do not use Portfolio or similar feature to bundle multiple files into a single PDF
    - Disable security features like password protection
  - Keep filenames to 50 characters or less and use only letters, numbers and underscore (_)
  - Follow guidelines for fonts, margins and avoid 2-column and “landscape” formats
  - Do not cut & paste from documents prepared using sophisticated word processors (e.g., Word) into form fields
    - Some word processors alter special characters (e.g., smart quotes)
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. * TYPE OF SUBMISSION
Pre-application
Application
Changed/Corrected Application

2. DATE SUBMITTED

3. DATE RECEIVED BY STATE

4. a. Federal Identifier

4. b. Agency Routing Identifier

5. APPLICANT INFORMATION

* Legal Name:

* Department:
Division:

* Street1:

* Street2:

* City:
County / Parish:

* State:
Country:

* Country:
USA: UNITED STATES

* ZIP / Postal Code:

* Phone Number:
Fax Number:

* Email:

Person to be contacted on matters involving this application

Prefix:

* First Name:

* Last Name:

* Phone Number:
Fax Number:

Email:

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

7. * TYPE OF APPLICANT:

Other (Specify):

Small Business Organization Type

Women Owned
Socially and Economically Disadvantaged

8. * TYPE OF APPLICATION:

□ New
□ Resubmission
□ Renewal
□ Continuation
□ Revision

□ Increase Award
□ Decrease Award
□ Increase Duration
□ Decrease Duration

* Is this application being submitted to other agencies?

Yes
No

What other Agencies?

9. * NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

National Institutes of Health

Pre-populated from opportunityinfo.

NIH will assign CFDA post-submission.

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

NIH only saves first 81 characters of Project Title. Phase II should have same title as awarded Phase I. If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant.

12. PROPOSED PROJECT:

* Start Date

* Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

Generally, SBIR Phase I awards do not exceed 6 months and STTR Phase I awards do not exceed one year. Generally, SBIR and STTR Phase II awards do not exceed two years.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix:

* First Name:

* Last Name:

* Phone Number:
Fax Number:

Email:

PD/PI first/last name should match name on file for Commons ID provided in the Credential field of the R&R Senior/Key Person Profile form.

** Footer not part of forms

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Updated May 2011 **
15. ESTIMATED PROJECT FUNDING
Manually enter Estimated Project Funding Amounts.

| a. Total Federal Funds Requested |
| b. Total Non-Federal Funds |
| c. Total Federal & Non-Federal Funds |
| d. Estimated Program Income |

Program Income is gross income earned by applicant organization that is directly generated by the proposed project.

16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

- a. YES
- b. NO

STTR and SBIR: Check "No-Program is not covered by E.O. 12372".

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

19. Authorized Representative

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

* Signature of Authorized Representative

Completed on submission to Grants.gov

* Date Signed

Completed on submission to Grants.gov

20. Pre-application

Do not use unless specifically noted in the opportunity.
**Project/Performance Site Location(s)**

**Project/Performance Site Primary Location**

- Organization Name: [Field]
- DUNS Number: [Field]
- **Street1**: [Field]
- Street2: [Field]
- * City: [Field]  County: [Field]
- * State: [Field]  Province: [Field]
- * Country: [USA: UNITED STATES]  * Project/Performance Site Congressional District: [Field]

**Project/Performance Site Location 1**

- I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.
- Organization Name: [Field]
- DUNS Number: [Field]
- * Street1: [Field]
- Street2: [Field]
- * City: [Field]  County: [Field]
- * State: [Field]  Province: [Field]
- * Country: [USA: UNITED STATES]  * Project/Performance Site Congressional District: [Field]

**Additional Location(s)**

- Form allows up to 30 Project/Performance locations prior to using attachments for additional locations. Next Site button appears once Site Location 1 is completed.

- Additional Location(s): [Field]  [Add Attachment]  [Delete Attachment]  [View Attachment]
RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved?  
   □ Yes □ No  
   If Human Subjects = Yes, additional attachments are required in the PHS 398 Research Plan.
   Is the Project Exempt from Federal regulations?  
   □ Yes □ No  
   If Yes, check appropriate exemption number.  
   1 □ 2 □ 3 □ 4 □ 5 □ 6
   If no, is the IRB review Pending?  
   □ Yes □ No  
   IRB Approval Date:  
   Human Subject Assurance Number:  
   IRB Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data.
   If Human Subjects = Yes, the Human Subject Assurance Number or the text ‘None’ must be provided.

2. * Are Vertebrate Animals Used?  
   □ Yes □ No  
   If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan.
   Is the IACUC review Pending?  
   □ Yes □ No  
   IACUC Approval Date:  
   Animal Welfare Assurance Number  
   IACUC Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data.
   If Vertebrate Animals = Yes, the Animal Welfare Assurance Number or the text ‘None’ must be provided.

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

4. * Does this project have an actual or potential impact on the environment?  
   □ Yes □ No  
   4.a. * Does this project have 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
   If yes, please explain:

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
   If yes, please explain:

4.d. If yes, please explain:

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

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

6.a. If yes, identify countries:  
   Generally, all SBIR and STTR work should be done in US.

6.b. Optional Explanation:

7. * Project Summary/Abstract  
   Succinct project summary of proposed work. Typically 30 lines or less; system error if over 1 page. Do not include proprietary or confidential information; if awarded this information becomes public.

8. * Project Narrative  
   Typically 2-3 sentences statement of public health relevance. Error if over 1 page.

9. Bibliography & References Cited  
   Required unless otherwise noted in opportunity. Not system enforced.

10. Facilities & Other Resources  
    Required unless otherwise noted in the opportunity. Not system enforced.

11. Equipment  

12. Other Attachments  
   Only provide Other Attachments when requested in the opportunity.
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Project Director/Principal Investigator**

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
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<tbody>
<tr>
<td>* Last Name:</td>
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<tr>
<td>Position/Title:</td>
<td>Department:</td>
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<tr>
<td>Organization Name:</td>
<td>Organization Name required by NIH. PD/PI Organization Name is pre-populated from SF424 (R&amp;R) cover.</td>
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<tr>
<td>* Street1:</td>
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<td>Street2:</td>
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<td>* Project Role: PD/PI</td>
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<td>Degree Type:</td>
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<td>Degree Year:</td>
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<tr>
<td>Attach Biographical Sketch</td>
<td>Attach Current &amp; Pending Support</td>
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</table>

**PROFILE - Senior/Key Person**

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
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<td>* Last Name:</td>
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<td>Position/Title:</td>
<td>Department:</td>
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<td>Organization Name:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts.</td>
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**PD/PI**

*Project Role will default to PD/PI and must remain PD/PI (do not edit).*

| Degree Type: | | |
| Degree Year: | | |
| *Attach Biographical Sketch | Attach Current & Pending Support | |

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

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**Footer not part of forms**

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Updated May 2011 **
** RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1 **

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>
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</table>

If more than 8 Sr/Key, use Attachment and enter total funds requested for additional Sr/Key persons.

Additional Senior Key Persons: [ ]

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>
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<td>Post Doctoral Associates</td>
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<td>Graduate Students</td>
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<td>Undergraduate Students</td>
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</table>

Aggregate information provided in section B. Detailed information should be provided in Budget Justification.

Total Number Other Personnel: [ ]

Total Salary, Wages and Fringe Benefits (A+B): [ ]

STTR: If the PD/PI is an employee of the Research Institution (RI) then their information should be entered on the RI subaward budget page and the amounts on the project budget can be blank or $0.

SBIR: There must be a Personnel entry with a role of PD/PI for each budget year of Project budget.

Base Salary can be left blank for submission, but is required prior to award.

SBIR and STTR: Commercial organizations usually treat fringe benefits as indirect costs, so in most cases the value will be $0.
RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 

* Budget Type:  

   - [ ] Project  
   - [ ] Subaward/Consortium  

Enter name of Organization: 

* Start Date:  * End Date:  

Budget Period 1

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

<table>
<thead>
<tr>
<th>Equipment item</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>9.</td>
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<td>10.</td>
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<tr>
<td>11. Total funds requested for all equipment listed in the attached file</td>
<td></td>
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<tr>
<td>Total Equipment</td>
<td></td>
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</tbody>
</table>

Additional Equipment:  

D. Travel

1. Domestic Travel Costs ( Incl. Canada, Mexico and U.S. Possessions)  
2. Foreign Travel Costs  
   - Generally, Foreign Travel Costs do not apply to SBIR and STTR applications.  
Total Travel Cost

E. Participant/Trainee Support Costs  

1. Tuition/Fees/Health Insurance  
2. Stipends  
3. Travel  
4. Subsistence  
5. Other  
Number of Participants/Trainees  Total Participant/Trainee Support Costs

RESEARCH & RELATED Budget (C-E) (Funds Requested)
**RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1**

* ORGANIZATIONAL DUNS: [Enter value]

* Budget Type: [ ] Project [ ] Subaward/Consortium

Enter name of Organization: [Enter name]

* Start Date: [Enter date] * End Date: [Enter date] Budget Period 1

**F. Other Direct Costs**

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8. [Blank]
9. [Blank]
10. [Blank]

Total Other Direct Costs [Enter value]

**G. Direct 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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<td>2.</td>
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<td>4.</td>
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</tbody>
</table>

Total Direct Costs (A thru F) [Enter value]

**H. Indirect Costs**

Applicants without a NIH-negotiated Indirect Cost Rate can request up to 40% in both Phase I and Phase II.

Total Indirect Costs [Enter value]

**Cognizant Federal Agency**

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

**I. Total Direct and Indirect Costs**

Total Direct and Indirect Institutional Costs (G + H) [Enter value]

**J. Fee**

A Fee cannot be entered for a Subaward/Consortium budget.

**K. * Budget Justification**

(Only attach one file.)

**RESEARCH & RELATED Budget (F-K) (Funds Requested)**
### RESEARCH & RELATED BUDGET - Cumulative Budget

<table>
<thead>
<tr>
<th>Section</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section A, Senior/Key Person</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Section B, Other Personnel</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total Number Other Personnel</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total Salary, Wages and Fringe Benefits (A+B)</strong></td>
<td></td>
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<tr>
<td><strong>Section C, Equipment</strong></td>
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<tr>
<td><strong>Section D, Travel</strong></td>
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<tr>
<td>1. Domestic</td>
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<td>2. Foreign</td>
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<td><strong>Section E, Participant/Trainee Support Costs</strong></td>
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<td>1. Tuition/Fees/Health Insurance</td>
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<td>2. Stipends</td>
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<td>3. Travel</td>
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<td>4. Subsistence</td>
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<td>5. Other</td>
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<tr>
<td>6. Number of Participants/Trainees</td>
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<td><strong>Section F, Other Direct Costs</strong></td>
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<tr>
<td>1. Materials and Supplies</td>
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<td>2. Publication Costs</td>
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<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<td>7. Alterations and Renovations</td>
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<td>8. Other 1</td>
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<td>9. Other 2</td>
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<td>10. Other 3</td>
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<td><strong>Section G, Direct Costs (A thru F)</strong></td>
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<td><strong>Section H, Indirect Costs</strong></td>
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<tr>
<td><strong>Section I, Total Direct and Indirect Costs (G + H)</strong></td>
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<tr>
<td><strong>Section J, Fee</strong></td>
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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 PDF document.

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

If submitting an application with >10 subaward budgets, budgets 11 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form.

The sum of all subaward budgets; e.g., those attached separately on this form and those provided as part of the budget justification, must be included in Line F.5 Subawards/Consortium/Contractual Costs of the project budget.

When submitting subaward budgets that are not active for all periods of the project, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period of the subaward should match the corresponding project budget period start/end dates.

Common use scenarios:
1. Applicant extracts and sends the R&R Budget form to the subaward organization for completion.
2. Subaward organization completes form and returns it to the applicant organization.
3. Applicant attaches the completed form within project application package.

OR

1. Applicant requests budget information from subaward organization, extracts R&R Budget form, completes it with provided information and attaches it to the project application package.
** SBIR/STTR Information **

** OMB Number: 4040-0001 **
** Expiration date: 06/30/2011 **

* 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:

1. ** 1a. 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? **
   - [ ] Yes
   - [ ] No
   ** Must meet SBIR/STTR eligibility requirements at time of award (not submission). **

2. ** 1b. Anticipated Number of personnel to be employed at your organization at the time of award. **
   - [ ]

3. ** 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? **
   - [ ] Yes
   - [ ] No
   ** Required if Yes. Cannot include if No. **

4. ** 3. 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: http://www.sba.gov **
   - [ ] Yes
   - [ ] No

5. ** 4. Will all research and development on the project be performed in its entirety in the United States? **
   - [ ] Yes
   - [ ] No
   ** Explanation: Required if No. Cannot include if Yes. Add Attachment Delete Attachment View Attachment **

6. ** 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? **
   - [ ] Yes
   - [ ] No
   ** If yes, insert the names of the other Federal agencies: Required if Yes. Cannot include if No. **

7. ** 6. 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

8. ** 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: Add Attachment Delete Attachment View Attachment
   ** Required for Phase II and Fast Track submissions. Limited to 12 pages. **
### SBIR/STTR Information

#### 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.*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
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</tr>
<tr>
<td>Attach File:</td>
<td>Add Attachment</td>
<td>Delete Attachment</td>
</tr>
</tbody>
</table>

#### 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.*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Please indicate whether the answer to BOTH of the following questions is TRUE:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(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</td>
<td></td>
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<tr>
<td>(2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?</td>
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<tr>
<td>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?</td>
<td></td>
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</tbody>
</table>
PHS Cover Letter

OMB Numbers: 0925-0001
0925-0002

*Mandatory Cover Letter Filename:

Add Cover Letter File    Delete Cover Letter File    View Cover Letter File

Cover letter is only for internal Agency use and will not be shared with peer reviewers.

Used to convey information to Receipt & Referral staff (e.g., request of assignment to a particular awarding component or Scientific Review Group, individuals/competitors that should not review application or reason for late submission.)

Required for any submission made after the submission deadline, including submissions to correct errors/warnings within the "error correction window" that follows the submission deadline.

If revising the cover letter for a Changed/Corrected application, include all previous submitted cover letter information. The system only retains the last cover letter submitted.

See Application Guide for suggested cover letter format.
### 1. Project Director / Principal Investigator (PD/PI)

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

Pre-populated from SF424 (R&R) cover.

### 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>
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</thead>
<tbody>
<tr>
<td>Middle Name:</td>
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<tr>
<td>* Last Name:</td>
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<tr>
<td>Suffix:</td>
<td></td>
</tr>
<tr>
<td>* Phone Number:</td>
<td>Fax Number:</td>
</tr>
</tbody>
</table>

This section is pre-populated from SF424 (R&R) cover.

| * Title: | |
|----------| |
| * Street1: | |
| Street2: | |
| * City: | |
| County/Parish: | |
| * State: | |
| Province: | |
| * Country: USA: UNITED STATES | * Zip / Postal Code: |

This section provides for the collection of additional Business Official contact information not included on SF424 (R&R) cover.
4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells?

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/research/registry/. 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.

If Yes, then "cannot be referenced" box must be checked or approved cell line entries must be included.

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission.
PHS 398 Research Plan

1. Application Type:

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

*Type of Application:

- New
- Resubmission
- Renewal
- Continuation
- Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application
   (for RESUBMISSION or REVISION only)

2. Specific Aims

3. *Research Strategy

4. Inclusion Enrollment Report

5. Progress Report Publication List

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table

9. Inclusion of Children

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan

13. Consortium/Contractual Arrangements

14. Letters of Support

15. Resource Sharing Plan(s)

16. Appendix

Phase I SBIR/STTR: do not include appendices unless specifically solicited by NIH.

DO NOT use Appendix attachments to circumvent page limits in other sections of the application. See NIH Guide notice NOT-OD-10-077.

Appendices are stored separately in eRA Grant Folder (not as part of application image) and are accessible to appropriate Agency staff and peer reviewers.

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.
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: 

This section is pre-populated from the Standard Form 424 (Research and Related) Cover Component form.

2. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

- [ ] Change of Investigator

- [ ] Change of Grantee Institution

* Name of former institution:

Used to specify change of PD/PI or change of institution.
Change of Investigator not allowed for Revision applications.

3. Inventions and Patents  (For renewal applications only)

* Inventions and Patents:  Yes [ ]  No [ ]

SBIR and STTR: Only applies to Phase II applications.

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

* Previously Reported:  Yes [ ]  No [ ]
### 4. *Program Income*

Program Income is gross income earned by applicant organization that is directly generated by the proposed project.

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

- ☐ Yes
- ☐ No

The number of program income budget periods must be less than or equal to the number of periods included in the budget form.

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><em>Budget Period</em></th>
<th><em>Anticipated Amount ($)</em></th>
<th><em>Source(s)</em></th>
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### 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