Preview of FORMS-E Grant Application Form Changes

FORMS-E application forms required for NIH & AHRQ due dates on or after January 25, 2018
New PHS Human Subjects and Clinical Trials Information Form
PHS Human Subjects and Clinical Trials Information Form

Disclaimer

This resource is:

- A representation of the data items collected in the new PHS Human Subjects and Clinical Trials Information form
- Continuously evolving as we work through implementation details

This resource is NOT:

- A representation of the final look and feel of the form based on a pre-implementation form mock-up

Goals

- Consolidate human subjects information currently scattered across multiple PHS forms within an application package
- Expand clinical trial data collection
  - Provide information needed for peer review
  - Position us for future data exchange with ClinicalTrials.gov

Getting Acclimated to New Form

- New form included in all applications (whether or not human subjects or clinical trials are involved)
- Collects study level information
- NIH will continue to collect some application level Human Subjects information on the Research & Related Other Project Information form
  - Used federal-wide, not within NIH control to remove Human Subjects questions from this form to our new PHS Human Subjects and Clinical Trials Information form
- When HS= Yes on Research & Related Other Project Information form applications must include one of the following on the new PHS Human Subjects and Clinical Trials Information Form
  - 1 or more full study records, OR
  - 1 or more delayed onset study records, OR
  - A combination of full and delayed onset study records
- Required form fields vary based on a number of factors, including:
  - Whether study is delayed onset
  - Announcement-specific instructions
  - Human subject exemptions
  - Whether study involves a clinical trial
Data Collection for Delayed Onset Study

Delayed Onset Study

* Required field(s)

* Study Title
Enter title of delayed onset study

* Anticipated Clinical Trial?  ○ Yes  ○ No

* Justification Attachment  Add Attachment  Delete Attachment  View Attachment

Save  Cancel
Full study records are comprised of 5 sections.

Although feature may not be available for initial rollout, we hope to be able to pull data from ClinicalTrials.gov into ASSIST to reduce data entry.

If all questions in Clinical Trials Questionnaire are Yes, then study will be flagged as a clinical trial.
### Inclusion Enrollment Report

**Human Subjects Study** 🔗

1. * Using an Existing Dataset or Resource
   - Yes
   - No

2. * Enrollment Location Type
   - Domestic
   - Foreign

3. Enrollment Country(ies)
   - UNITED STATES OF AMERICA

4. Enrollment Location(s)

5. Comments
   - Enter up to 500 characters
   - Characters Remaining: 500

#### Planned

*Used when Existing Data Source or Resource = No*

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#### Cumulative (Actual)

*Used when Existing Data Source or Resource = Yes*

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<tr>
<td>More than One Race</td>
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<td>Total</td>
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4.3. Outcomes or Measures

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Time Frame</th>
<th>Brief Description</th>
</tr>
</thead>
</table>

Add New Outcome

4.4. Statistical Design and Power

Add Attachment

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention?
   - Yes
   - No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Add Attachment

4.7. Dissemination Plan

Add Attachment

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

<table>
<thead>
<tr>
<th>Attachment File Name</th>
<th>Delete On Save</th>
<th>Update Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment 1.pdf</td>
<td></td>
<td>Update</td>
<td>View</td>
</tr>
<tr>
<td>Attachment 2.pdf</td>
<td></td>
<td>Update</td>
<td>View</td>
</tr>
</tbody>
</table>
FORMS-E Changes in Agency-specific (PHS) Forms

PHS forms not included in this resource have not been changed except to update the form expiration date.
**Introduction**

1. Introduction to Application  
*(RESUBMISSION)*

**Candidate Section**

2. Candidate Information and Goals for Career Development

**Research Plan Section**

3. Specific Aims

4. * Research Strategy

5. Progress Report Publication List  
*(for RENEWAL applications only)*

6. Training in the Responsible Conduct of Research

**Other Candidate Information Section**

7. Candidate's Plan to Provide Mentoring

**Mentor, Co-Mentor, Consultant, Collaborators Section**

8. Plans and Statements of Mentor and Co-Mentor(s)

9. Letters of Support from Collaborators, Contributors, and Consultants

**Environment and Institutional Commitment to Candidate Section**

10. Description of Institutional Environment

11. Institutional Commitment to Candidate's Research Career Development

**Human Subject Sections**

12. Protection of Human Subjects

13. Data Safety Monitoring Plan

14. Inclusion of Women and Minorities

15. Inclusion of Children

---

*Replace parenthetical text with "(for Resubmission and Revision applications)."

*Replace parenthetical text with "(for Renewal applications)."

*Remove this section (attachments 12-15) and renumber remaining form fields.*
PHS 398 Career Development Award Supplemental Form

Other Research Plan Sections

16. Vertebrate Animals
   Add Attachment  Delete Attachment  View Attachment

17. Select Agent Research
   Add Attachment  Delete Attachment  View Attachment

18. Consortium/Contractual Arrangements
   Add Attachment  Delete Attachment  View Attachment

19. Resource Sharing
   Add Attachment  Delete Attachment  View Attachment

20. Authentication of Key Biological and/or Chemical Resources
   Add Attachment  Delete Attachment  View Attachment

Appendix

21. Appendix
   Add Attachments  Delete Attachments  View Attachments

* Citizenship

* U.S. Citizen or Non-Citizen National?
   Yes  No

If no, select most appropriate Non-U.S. Citizen option

☐ With a Permanent U.S. Resident Visa
☐ With a Temporary U.S. Visa
☐ Not Residing in the U.S.

If with a temporary U.S. visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, also check here:

Replace sentence with "If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:"

NIH Office of Extramural Research 11 Updated: April 27, 2017
1. Human Subjects Section

Clinical Trial?

- Yes
- No

*Agency-Defined Phase III Clinical Trial?

- Yes
- No

2. Vertebrate Animals Section

Are vertebrate animals euthanized?

- Yes
- No

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines?

- Yes
- No

If "No" to AVMA guidelines, describe method and provide scientific justification

3. Program Income Section

*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)

4. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells?

- Yes
- No

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:

- Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):
5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents:  Yes ☐  No ☐

If “Yes” then answer the following:

*Previously Reported:  Yes ☐  No ☐

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director/Principal Investigator:

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

☐ Change of Grantee Institution

*Name of former institution:
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</tbody>
</table>

*Replace parenthetical text with "(for Resubmission and Revision applications)".*

*Remove this section (attachments 5-8) and renumber remaining form fields.*

---

**Introduction**

1. Introduction to Application (Resubmission and Revision)

**Research Plan Section**

2. Specific Aims

3. *Research Strategy

4. Progress Report Publication List

**Human Subjects Section**

5. Protection of Human Subjects

6. Data Safety Monitoring Plan

7. Inclusion of Women and Minorities

8. Inclusion of Children

**Other Research Plan Section**

9. Vertebrate Animals

10. Select Agent Research

11. Multiple PD/PI Leadership Plan

12. Consortium/Contractual Arrangements

13. Letters of Support

14. Resource Sharing Plan(s)

15. Authentication of Key Biological and/or Chemical Resources

**Appendix**

16. Appendix
# PHS 398 Research Training Program Plan

## Introduction
1. Introduction to Application (for Resubmission and Revision)

## Training Program Section
2. * Program Plan
3. Plan for Instruction in the Responsible Conduct of Research
4. Plan for Instruction in Methods for Enhancing Reproducibility
5. Multiple PD/PI Leadership Plan (if applicable)
6. Progress Report (for RENEWAL applications only)

## Faculty, Trainees and Training Record Section
7. Participating Faculty Biosketches
8. Letters of Support
9. Data Tables

## Other Training Program Section
10. **Human Subjects**
11. **Data Safety Monitoring Plan**
12. Vertebrate Animals
13. Select Agent Research
14. Consortium/Contractual Arrangements

## Appendix
15. Appendix
PHS Assignment Request Form

Funding Opportunity Number: 
Funding Opportunity Title: 

Awarding Component Assignment Request (optional)
If you have a preference for an Awarding Component (e.g., NIH Institute/Center), enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign" below. Requests will be considered; however, loci of review is predetermined for some applications and assignment requests cannot always be honored.

Awarding Components can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Assign to Awarding Component: 
Do Not Assign to Awarding Component: 

Study Section Assignment Request (optional)
If you have a preference for a study section assignment, use the link below to identify the most appropriate study section, then enter the short abbreviation for that study section in "Assign to/Do Not Assign to Study Section" below. Requests will be considered; however, assignment requests cannot always be honored.

Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Assign to Study Section: 
Do Not Assign to Study Section: 

Updated: April 27, 2017
### PHS Assignment Request Form

**List Individuals who should not review your application and why (optional)**

Only 1000 characters allowed

**Identify Scientific areas of expertise needed to review your application (optional)**

*Note: Please do not provide names of individuals*

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<th>Expertise:</th>
<th>Only 40 characters allowed</th>
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<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Make sure applicants can provide 1000 characters of text, even if it extends past 8 lines.
**PHS Fellowship Supplemental Form**

### Introduction
1. Introduction
   - *RESUBMISSION*
   - Change to "Introduction to Application".
   - Change parenthetical text to "(for Resubmission applications)".

### Fellowship Applicant Section
2. * Applicant's Background and Goals for Fellowship Training
3. * Specific Aims
4. * Research Strategy
5. * Respective Contributions
6. * Selection of Sponsor and Institution
7. Progress Report Publication List
   - *RENEWAL*
   - Change parenthetical text to "(for Renewal applications)".
8. * Training in the Responsible Conduct of Research

### Research Training Plan Section
9. Sponsor and Co-Sponsor Statements
10. Letters of Support from Collaborators, Contributors, and Consultants

### Sponsor(s), Collaborator(s), and Consultant(s) Section
9. Sponsor and Co-Sponsor Statements
10. Letters of Support from Collaborators, Contributors, and Consultants

### Institutional Environment and Commitment to Training Section
11. Description of Institutional Environment and Commitment to Training

### Other Research Training Plan Section
12. Human Subjects Involvement Indefinite?
13. Clinical Trial?
14. Agency-Defined Phase III Clinical Trial?
15. Protection of Human Subjects
16. Data Safety Monitoring Plan
17. Inclusion of Women and Minorities
18. Inclusion of Children

---

**Human-Subjects**

Remove this sub-section (attachments 12-18) and renumber remaining form fields.

**Other Research Training Plan Section**

Keep section heading to encompass Vertebrate Animals and Other Research Training Plan Information sub-sections.

---

**Request form changes.**
Vertebrate Animals

The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

Are Vertebrate Animals Used?

- Yes
- No

19. Vertebrate Animals Use Indefinite?

- Yes
- No

20. Are vertebrate animals euthanized?

- Yes
- No

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines?

- Yes
- No

If "No" to AVMA guidelines, describe method and provide scientific justification

21. Vertebrate Animals

Other Research Training Plan Information

22. Select Agent Research

23. Resource Sharing Plan

24. Authentication of Key Biological and/or Chemical Resources

Additional Information Section

25. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells?

- Yes
- No

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/](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:

- Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s):

26. Alternate Phone Number:

27. Degree Sought During Proposed Award:

Degree:

If "other", please indicate degree type:

Expected Completion Date (month/year):

- Reset Entry

28. * Field of Training for Current Proposal:
### PHS Fellowship Supplemental Form

#### 29. Current Or Prior Kirschstein-NRSA Support?

- * Level
- * Type
- Start Date *(if known)*
- End Date *(if known)*
- Grant Number *(if known)*

If yes, identify current and prior Kirschstein-NRSA support below:

- [ ] Yes
- [ ] No

#### 30. Applications for Concurrent Support

If yes, please describe in an attached file:

- [ ] Yes
- [ ] No

#### 31. Citizenship:

- [ ] U.S. Citizen
- [ ] U.S. Citizen or Non-Citizen National?
- [ ] Non-U.S. Citizen

- [ ] With a Permanent U.S. Resident Visa
- [ ] With a Temporary U.S. Visa

If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, please also check here.

#### 32. Change of Sponsoring Institution

Name of Former Institution:

#### Budget Section

**All Fellowship Applicants:**

1. * Tuition and Fees:

   - [ ] None Requested
   - [ ] Funds Requested

   **Year 1**
   **Year 2**
   **Year 3**
   **Year 4**
   **Year 5**
   **Year 6 (when applicable)**

   **Total Funds Requested:**

**Senior Fellowship Applicants Only:**

2. Present Institutional Base Salary:

   **Amount**
   **Academic Period**
   **Number of Months**

3. Stipends/Salary During First Year of Proposed Fellowship:

   a. Federal Stipend Requested:
      **Amount**
      **Number of Months**

   b. Supplementation from other sources:
      **Type** *(sabbatical leave, salary, etc.)*
      **Amount**
      **Number of Months**
      **Source** *(e.g., sabbatical leave, salary)*
Add "Appendix" section header in bold text.

Number and remove bold formatting from "28. Appendix" field name.
FORMS-E Changes in Federal-wide (Research & Related) Forms

Federal-wide Research & Related forms not included in this resource have not been changed except to update the form expiration date.
## A. Senior/Key Person

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<thead>
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<th>Middle</th>
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<th>Months</th>
<th>Cal. Acad. Sum.</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
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</thead>
</table>

**Project Role:** PD/PI

**Additional Senior Key Persons:**

**Total Senior/Key Person**

## B. Other Personnel

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<th>Project Role</th>
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<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
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**Total Number Other Personnel**

**Total Other Personnel**

**Total Salary, Wages and Fringe Benefits (A+B)**
### C. Equipment Description

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

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<thead>
<tr>
<th>Equipment item</th>
<th>Funds Requested ($)</th>
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Additional Equipment: [Add Attachment] [Delete Attachment] [View Attachment]

Total funds requested for all equipment listed in the attached file

<table>
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<tr>
<th>Total Equipment</th>
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</table>

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### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost

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

---

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant/Trainee Support Costs</th>
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### F. Other Direct Costs

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<tr>
<td>2. Publication Costs</td>
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<tr>
<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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<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
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<tr>
<td>7. Alterations and Renovations</td>
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<td>8.</td>
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<td>9.</td>
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**Total Other Direct Costs**

### G. Direct Costs

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

### H. Indirect Costs

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</tbody>
</table>

**Total Indirect Costs**

### I. Total Direct and Indirect Costs

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

### J. Fee

**Funds Requested ($)**

### K. Total Costs and Fee

**Total Costs and Fee (I + J)**

### L. Budget Justification

(Only attach one file.)

[Add Attachment] [Delete Attachment] [View Attachment]

**New Total Costs and Fees Calculation**
## RESEARCH & RELATED BUDGET - Cumulative Budget

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<td>Section C, Equipment</td>
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<td>Section D, Travel</td>
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<td>1. Domestic</td>
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<tr>
<td>Section E, Participant/Trainee Support Costs</td>
<td></td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
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<tr>
<td>2. Stipends</td>
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<tr>
<td>3. Travel</td>
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<tr>
<td>4. Subsistence</td>
<td></td>
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<tr>
<td>5. Other</td>
<td></td>
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<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
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<tr>
<td>Section F, Other Direct Costs</td>
<td></td>
</tr>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
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<tr>
<td>2. Publication Costs</td>
<td></td>
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<tr>
<td>3. Consultant Services</td>
<td></td>
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<tr>
<td>4. ADP/Computer Services</td>
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<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
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<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
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<tr>
<td>7. Alterations and Renovations</td>
<td></td>
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<tr>
<td>8. Other 1</td>
<td></td>
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<td>9. Other 2</td>
<td></td>
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<tr>
<td>10. Other 3</td>
<td></td>
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<tr>
<td>Section G, Direct Costs (A thru F)</td>
<td></td>
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<tr>
<td>Section H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
<td></td>
</tr>
<tr>
<td>Section J, Fee</td>
<td></td>
</tr>
<tr>
<td>Section K, Total Costs and Fee (I + J)</td>
<td>New Total Costs and Fees Calculation</td>
</tr>
</tbody>
</table>
SBIR/STTR Information

* Agency to which you are applying (select only one)

[ ] DOE [ ] HHS [ ] USDA [ ] Other: New field.

* SBC Control ID: (This 9 digit code is obtained from the Small Business Administration)

* 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)

* Application Type (select only one)

[ ] Phase I [ ] Phase II [ ] Fast-Track [ ] Direct Phase II [ ] Phase IIA [ ] Phase IIB [ ] Commercialization Readiness Program (See agency-specific instructions to determine application type participation.)

Phase I Letter of Intent Number: New field.


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

* 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

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

* 1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms? 

[ ] Yes [ ] No

* 1d. Is your small business a Faculty or Student-Owned entity? 

[ ] Yes [ ] No

* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? 

[ ] Yes [ ] No

* If yes, insert the names of the Federal laboratories/agencies:

* 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

* 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:

[ ] Yes [ ] No

* 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:

* 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 email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

[ ] Yes [ ] No

* 7. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase III Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.

* Attach File:

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### SBIR/STTR Information

#### SBIR-Specific Questions:

* 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.

- [ ] Yes
- [ ] No

* Attach File: [Add Attachment] [Delete Attachment] [View Attachment]

#### STTR-Specific Questions:

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

- [ ] Yes
- [ ] No

* 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. Will the Project Director/Principal Investigator devote 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

* 12. Provide DUNS Number of non-profit research partner for STTR.

[New field]