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NOTES:

- The Funding Opportunity Announcement (FOA) and associated application guide remain the official documents for defining application requirements. This resource is meant to complement, not replace, those documents.

- The actual display of the forms depends on your submission method (e.g., ASSIST). The same forms, form fields and guidance apply regardless of submission option even if the display is slightly different.

- This resource is for FORMS-F application packages, see Do I Have the Right Forms for My Application?

- Registration in multiple systems is needed prior to submission, see Get Registered! Can take 6 weeks – start early!

- Don’t forget to periodically check the Related Notices section of the FOA for any updates to instructions or policies since the opportunity was posted.

- The blue annotations throughout this resource represent tips for completing form fields and avoiding common errors/warnings.
APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

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

2. DATE SUBMITTED
   - Applicant Identifier

3. DATE RECEIVED BY STATE
   - State Application Identifier

4. a. Federal Identifier
   - Federal Identifier
   - Agency Routing Identifier

5. APPLICANT INFORMATION
   - Legal Name: Small business
   - Department: Division:
   - Street1: Street2:
   - City: County / Parish:
   - State: Province:
   - Country: USA: UNITED STATES
   - ZIP / Postal Code: Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.

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

7. TYPE OF APPLICANT:
   - Other (Specify):
   - Women Owned
   - Socially and Economically Disadvantaged
   - Small business must be in the U.S. or U.S. territory.

8. TYPE OF APPLICATION:
   - New
   - Resubmission
   - Renewal
   - Continuation
   - Revision
   - See application guide for definitions.
   - 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:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
   - NIH will assign CFDA post-submission.

11. DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:
   - Phase II should have the same title as awarded Phase I. If Revision (box 8), provide exact title (including punctuation and spacing) as seen in eRA Commons for awarded grant. Limited to 200 characters.

12. PROPOSED PROJECT:
   - Start Date: Ending Date
   - Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). See application guide for additional details.

13. CONGRESSIONAL DISTRICT OF APPLICANT
   - Generally, Phase 1: 6-12 months, Fast-Track: 2.5-3 yrs, Phase II: 2 yrs, Phase IIB: up to 3 yrs, Commercialization Readiness Pilot (CRP): up to 2 years.

Person to be contacted on matters involving this application
   - Prefix: First Name: Middle Name: Last Name: Suffix:
   - Position/Title:
   - Phone Number:
   - Fax Number:
   - Email: Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.

What other Agencies?

Please select one of the following

- NIH Office of Extramural Research

FORMS-F Series (Updated August 11, 2020)
Page 2

OMB Number: 4040-0001
Expiration Date: 12/31/2022
APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: First Name: Middle Name: Last Name: Middle Name: 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 (Expanded) form. Suffix: 
Position/Title: Organization Name: 
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 
Date Signed: 

15. ESTIMATED PROJECT FUNDING
Manually enter amounts.
16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES
This preapplication/application was made available to the state Executive Order 12372 process for review on: Date: 
SBIR/STTR: Check "No - Program is not covered by E.O. 12372; OR Program has not been selected by State for review."
b. NO
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) 
*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. 
I agree 

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation
Add Attachment Delete Attachment View Attachment 

19. Authorized Representative
Prefix: First Name: Middle Name: Last Name: Middle Name: Authorized Organization Representative (AOR) in Grants.gov must have signature authority for the organization. The electronic signature of the submitting AOR is recorded with submission. 
Position/Title: Organization: 
Department: Division: Street1: Street2: City: County / Parish: State: USA: UNITED STATES 
Province: ZIP / Postal Code: 
Phone Number: Fax Number: 
Email: 
Signature of Authorized Representative 
Date Signed: 

20. Pre-application
Cover letter is posted separately in eRA Commons, is not part of the assembled application image, and content is only available to select agency staff. If Phase 1 or Phase II was a contract or awarded from another agency, include contract/award number. If application proposes the use of human fetal tissue (HFT) from elective abortions, you must include a Cover Letter with a statement about HFT involvement. 

21. Cover Letter Attachment 

1. 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

Answer required if euthanasia is NOT consistent with AVMA guidelines. Up to 1000 characters.

2. 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)

Form accommodates up to 10 budget periods. The number of program income budget periods must be less than or equal to the number of periods included in the budget form.

3. 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, 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):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions?

☐ Yes  ☐ No

If "yes" then provide the HFT Compliance Assurance

Required if Yes. Cannot be included if No.

If "yes" then provide the HFT Sample IRB Consent Form

Required if Yes. Cannot be included if No.
5. Inventions and Patents Section (for Renewal applications)

*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: ____________________________

*If change of PD/PI box is checked, you must provide the last name of the former PD/PI.

☐ Change of Grantee Institution

*Name of former institution: ____________________________

*If change of Grantee Institution box is checked, you must provide the name of former institution.
1. Are Human Subjects Involved?
   - Yes ☐ No ☐

1.a. If YES to Human Subjects

   Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

   If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

   If no, is the IRB review Pending? ☐ Yes ☐ No

   IRB Approval Date: __________________________

   Human Subject Assurance Number: __________________________

   If Human Subjects = Yes, enter the text 'None' or the approved Federalwide Assurance (FWA) number on file with OHRP. Enter the 8-digit number only.

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: __________________________

   If Vertebrate Animals = Yes, enter the text 'None' or the Office of Laboratory Animal Welfare (OLAW)-approved 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 - positive or negative - on the environment? ☐ Yes ☐ No

   If yes, please explain: If 4a is Yes, then 4b is required. Up to 55 characters.

4.b. If yes, please explain: If 4b is Yes, then 4c is required. Up to 55 characters.

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: If 4c is Yes, then 4d is required. Up to 55 characters.

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

5.a. If yes, please explain: If 5a is Yes, then 5a is required. Up to 55 characters.

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

6.a. If yes, identify countries: If 6a is Yes, then a list of countries is required in 6a. Abbreviations can be used. Up to 55 characters.


7. Project Summary/Abstract

   Succinct project summary of proposed work. Typically 30 lines or less; system will give error if over 1 page. If awarded this information becomes public. Do not include proprietary or confidential information.

8. Project Narrative

   Typically 2-3 sentence statement of public health relevance; system will give 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 opportunity. Research must be performed in U.S. facilities. Foreign sites must be approved by the funding officer.

11. Equipment

    Required unless otherwise noted in opportunity. Limited system enforcement.

12. Other Attachments

    Only provide Other Attachments when requested in the funding opportunity announcement, notice of special interest or application guide. If provided, follow any guidance regarding attachment filenames.

    Field accommodates multiple attachments.
### Project/Performance Site Location(s)

#### Project/Performance Site Primary Location

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.

<table>
<thead>
<tr>
<th><strong>Organization Name:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DUNS Number:</strong></td>
<td>DO NOT check box. NIH only accepts applications from registered organizations.</td>
</tr>
<tr>
<td><strong>Street1:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Street2:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>City:</strong></td>
<td>County:</td>
</tr>
<tr>
<td><strong>State:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Province:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Country:</strong></td>
<td>USA: UNITED STATES</td>
</tr>
<tr>
<td><strong>ZIP / Postal Code:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Project/ Performance Site Congressional District:</strong></td>
<td></td>
</tr>
</tbody>
</table>

#### 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.

<table>
<thead>
<tr>
<th><strong>Organization Name:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DUNS Number:</strong></td>
<td>Optional for non-primary sites. Helps facilitate application processing, so include if you have it.</td>
</tr>
<tr>
<td><strong>Street1:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Street2:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>City:</strong></td>
<td>County:</td>
</tr>
<tr>
<td><strong>State:</strong></td>
<td></td>
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<tr>
<td><strong>Province:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Country:</strong></td>
<td>USA: UNITED STATES</td>
</tr>
<tr>
<td><strong>ZIP / Postal Code:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Project/ Performance Site Congressional District:</strong></td>
<td></td>
</tr>
</tbody>
</table>

#### Additional Location(s)

Form accommodates up to 300 sites. Use the Additional Locations attachment to include any sites over 300. See Additional Performance Site Format page at: https://grants.nih.gov/grants/forms/additional-performance-site.htm

Add Attachment  | Delete Attachment  | View Attachment
### 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>
</tr>
</thead>
<tbody>
<tr>
<td>* Last Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Division:</td>
<td></td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* City:</td>
<td>County/Parish:</td>
<td></td>
</tr>
<tr>
<td>* State:</td>
<td>Province:</td>
<td></td>
</tr>
<tr>
<td>* Country: USA: UNITED STATES</td>
<td>* Zip / Postal Code:</td>
<td></td>
</tr>
<tr>
<td>* Phone Number:</td>
<td>Fax Number:</td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Credential, e.g., agency login:** [VALID ERA COMMONS USERNAME MUST BE SUPPLIED. Contact PD/PI must be affiliated in Commons with applicant organization. Commons account designated on this form should not have both the PI and SO roles (if PD/PI also serves as SO, use a separate account for SO functions).]

| * Project Role: | PD/PI | Other Project Role Category: |

**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.**

#### PROFILE - Senior/Key Person 1

<table>
<thead>
<tr>
<th>Prefix:</th>
<th>* First Name:</th>
<th>Middle Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Last Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Position/Title:</td>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Organization Name:</td>
<td>Division:</td>
<td></td>
</tr>
<tr>
<td>* Street1:</td>
<td>Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.</td>
<td></td>
</tr>
<tr>
<td>Street2:</td>
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<tr>
<td>* City:</td>
<td>County/Parish:</td>
<td></td>
</tr>
<tr>
<td>* State:</td>
<td>Province:</td>
<td></td>
</tr>
<tr>
<td>* Country: USA: UNITED STATES</td>
<td>* Zip / Postal Code:</td>
<td></td>
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<tr>
<td>* Phone Number:</td>
<td>Fax Number:</td>
<td></td>
</tr>
<tr>
<td>* E-Mail:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Credential, e.g., agency login:**

*Project Role:*

*Other Project Role Category:*

**Degree Type:**

**Degree Year:**

*Attach Biographical Sketch*

*Attach Current & Pending Support*

**For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. If multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form is required.**

**Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm**

**Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm**

**Can collect data for 100 Sr/Key personnel (including PD/PI). Option to provide attachment for additional Sr/Key info is available after the 100 entries are made. See Additional Senior/Key Person Profiles format page at: https://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.**
RESEARCH & RELATED BUDGET - Budget Period 1

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

**Enter name of Organization:**

**Start Date:**

**End Date:**

**Budget Period:** 1

**Start Date:**

**End Date:**

**Project DUNS:**

**Subaward/Consortium Budget Period:** 1

**OMB Number:** 4040-0001

**Expiration Date:** 12/31/2022

---

### A. Senior/Key Person

**Prefix**

**First**

**Middle**

**Last**

**Suffix**

**Base Salary ($)**

**Requested Salary ($)**

**Fringe Benefits ($)**

**Funds Requested ($)**

- **Project Role:** PD/PI

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

**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 Sr/Key entry with a role of PD/PI for each budget year of the Project budget.

**Additional Senior Key Persons:**

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

- **Total Senior/Key Person**

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

---

### B. Other Personnel

**Aggregate information should be provided in section B and explained in Budget Justification.**

**Number of Personnel**

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

- **You can name up to 6 additional Project Role categories. Once data for the first user-defined Project Role is entered, you will have the option to add another. If you run out of additional categories combine categories in a single row and explain what was included in the Budget Justification.**

**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

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

Once equipment data is entered, you will be able to add up to 9 more rows to this section for a total of 10 equipment items.

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

Total funds requested for all equipment listed in the attached file

### 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/STTR applications.*

   Total Travel Cost

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance

   Only complete this section if requested to do so in the funding opportunity announcement.

2. Stipends

3. Travel

4. Subsistence

5. Other

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
</table>
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

Examples of possible uses: Tuition Remission; Technical Assistance; Patient Care Costs

8. If proposing the use of human fetal tissue from elective abortions, you must include a "Human Fetal Tissue Costs" item (if no cost incurred, enter 0). Type the string as requested (without quotation marks). Systems will only pick up an exact match to the letters and spacing of the string (not case specific). The line item cannot be combined with any "Other" costs.

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></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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

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)

J. Fee

A reasonable fee, not to exceed 7% of total costs for each Phase of the project is available with SBIR/STTR awards. A Fee cannot be entered for a Subaward/Consortium budget.

K. Total Costs and Fee

Total Costs and Fee (I + J)

L. Budget Justification

(Only attach one file.)

Budget Justification is required and must cover all budget periods.
## RESEARCH & RELATED BUDGET - Cumulative Budget

**Section A, Senior/Key Person**

**Section B, Other Personnel**

**Section C, Equipment**

**Section D, Travel**

1. Domestic
2. Foreign

**Section E, Participant/Trainee Support Costs**

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other
6. Number of Participants/Trainees

**Section 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. Other 1
9. Other 2
10. Other 3

**Section G, Direct Costs (A thru F)**

**Section H, Indirect Costs**

**Section I, Total Direct and Indirect Costs (G + H)**

**Section J, Fee**

**Section K, Total Costs and Fee (I + J)**

---

**Totals ($)**
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.

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 parent budget.

If submitting an application with >30 subaward budgets, budgets 31 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. This form should only be used in conjunction with the R&R Budget form.

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## Introduction

1. **Introduction to Application**  
   (for Resubmission and Revision applications)  
   - **Limited to 1 page. Required for Resubmission and Revision applications.**

## Research Plan Section

2. **Specific Aims**  
   - **Required. Limited to 1 page.**

3. **Research Strategy**  
   - **Required: Phase I SBIR/STTR: limited to 6 pages. Phase II: SBIR/STTR and Fast Track SBIR/STTR: limited to 12 pages.**

4. **Progress Report Publication List**

## Other Research Plan Section

5. **Vertebrate Animals**  
   - **Required if Vertebrate Animals is Yes on the Other Project Information form.**

6. **Select Agent Research**

7. **Multiple PD/PI Leadership Plan**  
   - **Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.**

8. **Consortium/Contractual Arrangements**

9. **Letters of Support**

10. **Resource Sharing Plan(s)**

11. **Authentication of Key Biological and/or Chemical Resources**  
    - **Required if project involves key biological and/or chemical resources. Recommend 1 page. No system validation enforcement.**

## Appendix

12. **Appendix**
SBIR/STTR Information

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

☐ DOE  ☐ HHS  ☐ USDA  ☐ Other:

Check HHS for all NIH, CDC, and FDA submissions.

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

The 9-digit code is included in the registry filename received from SBA upon registration (e.g., SBC_123456789.pdf.)

* Program Type (select only one)

☐ SBIR  ☐ STTR  Must select SBIR or STTR (not Both).

☐ 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  ☐ Phase IIC

SBIR only & only when allowed in FOA.  Not valid for HHS (NIH, CDC, FDA).

* Commercialization Readiness Program  (See agency-specific instructions to determine application type participation.)

Not valid for HHS (NIH, CDC, FDA).

Check opportunity for allowable Application Types.

* Agency Topic/Subtopic:  Optional.

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

* 1. 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?  Selection required. Must meet SBIR/STTR eligibility requirements at time of award (not submission).

* 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.

☐ Required.

* 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?  Selection required.

Yes  ☐ No  ☒

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

Required if Yes. Up to 250 characters. Cannot include if No.

* 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?

Yes  ☐ No  ☒

* If no, provide an explanation in an attached file.

Explanation:  Required if No. Cannot include if Yes.

* 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?  Selection required.

Yes  ☐ No  ☒

* If yes, insert the names of the other Federal agencies:

Required if Yes. Up to 250 characters. Cannot include if No.

* 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)?  Selection required.

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.

Yes  ☐ No  ☒

Required for Phase II, Direct Phase II, Phase IIB, Phase I/Phase II Fast-Track and Commercialization Readiness Program applications. Limited to 12 pages.

NIH Office of Extramural Research

FORMS-F Series (Updated August 11, 2020)
### SBIR/STTR Information

**SBIR-Specific Questions:** Answers only required for SBIR applications.

*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.*

- [ ] Yes
- [ ] No

* 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.

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

- [ ] Yes
- [ ] No

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

**STTR-Specific Questions:** Answers only required for STTR applications.

*Questions 10 - 12 apply only to STTR applications. If you are submitting **ONLY** an SBIR application, leave questions 10 - 12 blank.*

- [ ] 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.

[ ] Enter the DUNS or DUNS+4 number of the non-profit research partner for the STTR applicant.
Complete human subjects section of R&R Other Project Information form prior to completing this form.

**PHS Human Subjects and Clinical Trials Information**

OMB Number: 0925-0001
Expiration Date: 02/28/2023

*Does any of the proposed research in the application involve human specimens and/or data?*

- Yes
- No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Only include attachment if proposed research uses human specimens and/or data not considered to be human subjects research.

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

- Are Human Subjects Involved?
  - Yes
  - No

- Is the Project Exempt from Federal regulations?
  - Yes
  - No

- Exemption number: 
  - 1
  - 2
  - 3
  - 4
  - 5
  - 6
  - 7
  - 8

If No to Human Subjects

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).

Add a record for each proposed Human Subject Study by selecting “Add New Study” or “Add New Delayed Onset Study” as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.

**Other Requested Information**

Only provide an Other Requested Information attachment when specifically requested in the funding opportunity announcement text or application guide.

**Study Record(s)**

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

**Delayed Onset Study(ies)**

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.

**Study Title**

Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

1) Please attach Human Subject Study 1

**Anticipated Clinical Trial?**

**Justification**

Add Attachment  Delete Attachment  View Attachment

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**OMB Number:** 0925-0001  
**Expiration Date:** 02/28/2023

**Study Record: PHS Human Subjects and Clinical Trials Information**

---

**Section 1 - Basic Information**

1.1. *Study Title (each study title must be unique)*

- Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. *Is this Study Exempt from Federal Regulations?*

- Yes  
- No  

1.3. Exemption Number

- 1  
- 2  
- 3  
- 4  
- 5  
- 6  
- 7  
- 8

1.4. *Clinical Trial Questionnaire*

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?

- Yes  
- No

1.4.b. Are the participants prospectively assigned to an intervention?

- Yes  
- No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

- Yes  
- No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

- Yes  
- No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

---

**Section 2 - Study Population Characteristics**

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

2.1. Conditions or Focus of Study

- Required and system enforced unless exemption 4 is only exemption selected. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

- Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

- Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

2.3. Age Limits

- Minimum Age

- Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

- Required and system enforced unless exemption 4 is only exemption selected.

2.4. Inclusion of Women and Minorities

- Required and system enforced unless exemption 4 is only exemption selected.

2.5. Recruitment and Retention Plan

- Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.6. Recruitment Status

- Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.7. Study Timeline

- Required and system enforced for CT study unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.8. Enrollment of First Participant

- Dropdown list: Anticipated, Actual

- Date: MM/DD/YYYY

2.9. Inclusion Enrollment Report(s)

- Inclusion Enrollment Reports required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

- Add Inclusion Enrollment Report

- Up to 20 Inclusion Enrollment Reports can be added.
# Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

   Required. Up to 600 characters.

2. * Using an Existing Dataset or Resource

   - Yes
   - No

   Answer required and system enforced.

3. * Enrollment Location Type

   - Domestic
   - Foreign

   Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

4. Enrollment Country(ies)

   Multi-select from list of countries.

5. Enrollment Location(s)

6. Comments

   Up to 500 characters.
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Report 1 of 1
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

Add Attachment Delete Attachment View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

Answer required and system enforced. "N/A" is only a valid option if study is not exempt from federal regulations (i.e., Question 1.2 is No).

If yes, describe the single IRB plan

NIH: If Yes, not required. AHRQ: If Yes, required.

Add Attachment Delete Attachment View Attachment

3.3. Data and Safety Monitoring Plan

Required and system enforced for CT study. Optional for HS study.

Add Attachment Delete Attachment View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No

Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team

Optional.

Add Attachment Delete Attachment View Attachment

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

4.1.c. Interventions

Up to 20 Interventions allowed.

Intervention Type

Dropdown list: Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)

Name

Up to 200 characters.

Description

Up to 1,000 characters.

4.1.d. Study Phase

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and N/A

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

4.1.e. Intervention Model

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other

4.1.f. Masking

☐ Yes ☐ No

Participant Care Provider Investigator Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/Outcomes Assessor check boxes.

4.1.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized
4.2. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

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<tr>
<th>Name</th>
<th>Up to 255 characters.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Dropdown list: Primary; Secondary; and Other</td>
</tr>
<tr>
<td>Time Frame</td>
<td>Up to 255 characters.</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters.</td>
</tr>
</tbody>
</table>

4.3. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

4.4. Subject Participation Duration

Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.5. Will the study use an FDA-regulated intervention?

☐ Yes ☐ No

Answer required and system enforced for CT study unless otherwise noted in opportunity.

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

Required and system enforced if Yes.

4.6. Is this an applicable clinical trial under FDAAA?

☐ Yes ☐ No

4.7. Dissemination Plan

Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.
PHS Assignment Request Form

Funding Opportunity Number:  
Pre-populated from announcement information.

Funding Opportunity Title:  

Awarding Component Assignment Suggestions (optional)

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

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

Suggested Awarding Components: 

Study Section Assignment Suggestions (optional)

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

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

Suggested Study Sections: 
Only 20 characters allowed

Rationale for assignment suggestions (optional)  
Entry is limited to 1000 characters.
List individuals who should not review your application and why (optional)

Entry is limited to 1000 characters.

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual. Provide specific reason why an individual should not review your application. Information will be considered, but listing an individual does not guarantee they will not be on review panel.

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

Note: Do not provide names of individuals

Expertise:
Each entry is limited to 40 characters

Limit your answers to expertise. DO NOT enter the names of individuals you’d like to review your application.