APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

1. TYPE OF SUBMISSION
   - Check "Application"

2. DATE SUBMITTED
   - Applicant Identifier
   - Applicant Identifier

5. APPLICANT INFORMATION
   - Legal Name:
   - Department:
   - Street1:
   - Street2:
   - City:
   - State:
   - Country:
   - Person to be contacted on matters involving this application

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

7. TYPE OF APPLICANT:
   - Institutional information will populate automatically

8. TYPE OF APPLICATION:
   - New
   - Renewal
   - Continuation
   - Revision

9. NAME OF FEDERAL AGENCY:
   - Institutional information will populate automatically

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
   - Will populate automatically

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
   - Enter formal project title; limited to 200 characters

12. PROPOSED PROJECT:
   - Start Date
   - Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT
   - UT-002 will populate in this field

See Key Dates section of announcement; start date may be an estimate, typically at least nine months after submission; project period should not exceed what is allowed in announcement.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: ___________________________ First Name: ___________________________ Middle Name: ___________________________ Suffix: ___________________________
Last Name: ___________________________ Position/Title: ___________________________
Organization Name: ___________________________ Department: ___________________________
Street1: ___________________________ Street2: ___________________________
City: ___________________________ County / Parish: ___________________________ Province: ___________________________
State: ___________________________ Country: USA: UNITED STATES ZIP / Postal Code: ___________________________
Phone Number: ___________________________ Fax Number: ___________________________
Email: ___________________________
PI information will autofill from the PI's profile in Cayuse

15. ESTIMATED PROJECT FUNDING
a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

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

a. YES
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)

I agree
Must check this box

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

19. Authorized Representative
Prefix: ___________________________ First Name: ___________________________ Middle Name: ___________________________ Suffix: ___________________________
Last Name: ___________________________ Position/Title: ___________________________
Organization: ___________________________ Department: ___________________________
Street1: ___________________________ Street2: ___________________________
City: ___________________________ County / Parish: ___________________________ Province: ___________________________
State: ___________________________ Country: USA: UNITED STATES ZIP / Postal Code: ___________________________
Phone Number: ___________________________ Fax Number: ___________________________
Email: ___________________________

The AOR is always Brent Brown (Director, Office of Sponsored Projects); use the pen icon to autofill his information into this section

Signature of Authorized Representative: ___________________________ Date Signed: ___________________________

Application is signed and dated electronically when it is submitted by OSP to Grants.gov

20. Pre-application

21. Cover Letter Attachment

See NIH's application instructions for when a cover letter is suggested or required
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.

Organization Name: ____________________________

DUNS Number: ____________________________

* Street1: ____________________________

Street2: ____________________________

* City: ____________________________ County: ____________________________

* State: ____________________________

Province: ____________________________

* Country: USA: UNITED STATES

* ZIP / Postal Code: ____________________________

* Project/ Performance Site Congressional District: ____________________________

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: ____________________________

DUNS Number: ____________________________

* Street1: ____________________________

Street2: ____________________________

* City: ____________________________ County: ____________________________

* State: ____________________________

Province: ____________________________

* Country: USA: UNITED STATES

* ZIP / Postal Code: ____________________________

* Project/ Performance Site Congressional District: ____________________________

Additional Location(s) ____________________________ Add Attachment Delete Attachment View Attachment
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Project Director/Principal Investigator**

- **Prefix:**
- **First Name:**
- **Middle Name:**
- **Last Name:**
- **Suffix:**
- **Organization Name:**
- **Division:**
- **Position/Title:**
- **Department:**
- **Street1:**
- **Street2:**
- **City:**
- **County/Parish:**
- **State:**
- **Country:**
- **ZIP / Postal Code:**
- **Phone Number:**
- **Fax Number:**
- **E-Mail:**
- **Credential, e.g., agency login:**
- **Project Role:**
- **Other Project Role Category:**
- **Degree Type:**
- **Degree Year:**

**VALID ERA COMMONS USERNAME MUST BE ENTERED IF the Commons ID has been entered into the PI's Cayuse Profile, it will automatically populate; if not, must hand enter; not validated by Cayuse, so double check to make sure entry is correct**

**Attach Biographical Sketch**

**Attach Current & Pending Support**

- **Required; limited to 5 pages**
- **Add Attachment**
- **Delete Attachment**
- **View Attachment**

### PROFILE - Senior/Key Person 1

- **Prefix:**
- **First Name:**
- **Middle Name:**
- **Last Name:**
- **Suffix:**
- **Organization Name:**
- **Division:**
- **Street1:**
- **Street2:**
- **City:**
- **County/Parish:**
- **State:**
- **Country:**
- **ZIP / Postal Code:**
- **Phone Number:**
- **Fax Number:**
- **E-Mail:**
- **Credential, e.g., agency login:**
- **Project Role:**
- **Other Project Role Category:**
- **Degree Type:**
- **Degree Year:**
- **Attach Biographical Sketch**
- **Attach Current & Pending Support**

- **Required; limited to 5 pages**
- **Add Attachment**
- **Delete Attachment**
- **View Attachment**

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.
### Cayuse Form: RR Budget

**RESEARCH & RELATED BUDGET - Budget Period 1**

**OMB Number:** 4040-0001  
Expiration Date: 12/31/2022

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

**Budget Period:** 1  
**Start Date:**  
**End Date:**  
Dates will autopopulate from the cover page

#### A. Senior/Key Person

Prefix: [Add Attachment]  
First  
Middle  
Last  
Suffix  
Base Salary ($)  
Cal. Acad. Sum.  
Requested Salary ($)  
Fringe Benefits ($)  
Funds Requested ($)

Project Role:  
PD/PI  
Role must be PD/PI for the PD/PI

Every Sr/Key listed must have measurable effort in either Calendar Months or a combination of Academic and Summer Months; effort may be entered as a percentage (Cayuse will convert to CM/AM/SM equivalent)

Additional Senior Key Persons:  
Add Attachment  
Delete Attachment  
View Attachment

Form will expand to up to 44 Senior/Key People

Total Senior/Key Person in the attached file

Total Senior/Key Person

#### B. Other Personnel

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

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

Cayuse includes 6 free text Project Role categories; form does not expand beyond 10 total rows so if you have more personnel roles than rows you must combine categories in a single row and explain in the Budget Justification

Total Number Other Personnel

Total Other Personnel

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

For each major section (A, B, C...), Cayuse has an Indirect Cost Type selector, where you can choose whether costs in that section are to be included in the Indirect Cost Base or excluded (if the costs are exempt from F&A)
### 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>Add Attachment</td>
<td>Delete Attachment</td>
</tr>
</tbody>
</table>

**Additional Equipment:**

Total funds requested for all equipment listed in the attached file

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

---

### D. Travel

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

2. Foreign Travel Costs

<table>
<thead>
<tr>
<th>Total Travel Cost</th>
</tr>
</thead>
</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>
</tr>
</thead>
</table>
## F. Other Direct Costs

<table>
<thead>
<tr>
<th>1. Materials and Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Publication Costs</td>
</tr>
<tr>
<td>3. Consultant Services</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
</tr>
<tr>
<td>8. These 3 free text categories (8, 9, 10) can be used for any direct cost categories that do not fit into the above categories; be sure to check the Indirect Cost Type to include F&amp;A for eligible direct cost items and exclude it where required (e.g., tuition, patient care)</td>
</tr>
</tbody>
</table>

### Total Other Direct Costs

### G. Direct Costs

### Total Direct Costs (A thru F)

### H. Indirect Costs

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

Rate type and amount chosen when application was created will prepopulate

### Total Indirect Costs

### I. Total Direct and Indirect Costs

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

### J. Fee

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

### L. Budget Justification

(Only attach one file.)

Budget Justification is required and must cover all budget periods

Subaward/Consortium/Contractual Costs will be pre-populated from the RR Subaward budget page

If FOA has a direct cost or total cost limit, verify cost limit manually

Indirect Cost Base will exclude any cost categories where the Indirect Cost Type "excluded" was selected
# RESEARCH & RELATED BUDGET - Cumulative Budget

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

NIH Office of Extramural Research

FORMS-F Series (Updated May 13, 2020)
**Use of Human Specimens and/or Data**

* 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.

<table>
<thead>
<tr>
<th>Are Human Subjects Involved?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Project Exempt from Federal regulations?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Exemption number:</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**If No to Human Subjects**

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

**If Yes to Human Subjects**

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**

- Required and system enforced for each delayed onset study; up to 600 characters; 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; 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.
**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
- [x] No

1.3. Exemption Number

- 1 2 3 4 5 6 7 8

1.4. *Clinical Trial Questionnaire*

- [ ] Yes
- [x] No

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.

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?

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

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

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

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.

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

**Section 2 - Study Population Characteristics**

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.

2.3. Age Limits

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 4 is the only exemption selected or otherwise noted in opportunity

2.8. Enrollment of First Participant

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

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

2.10. Anticipated, Actual

- [ ] Dropdown list: Anticipated, Actual

- [ ] Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset

- [ ] Add Inclusion Enrollment Report

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/P; however, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged; answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial; these studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.
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
<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
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</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<td>Black or African American</td>
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<tr>
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<td>Unknown/Not Reported</td>
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</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>Female</td>
<td>0</td>
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<td></td>
<td>Male</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<td>Black or African American</td>
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<td>Female</td>
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<td></td>
<td>Male</td>
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</tr>
<tr>
<td>More than One Race</td>
<td>Female</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>Female</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>Female</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Report 1 of 1
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

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

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?
- [ ] Yes
- [ ] No

3.5. Overall Structure of the Study Team

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

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Up to 200 characters</td>
</tr>
<tr>
<td>Description</td>
<td>Up to 1,000 characters</td>
</tr>
</tbody>
</table>

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)

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

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

4.1.f. Masking

- [ ] Yes
- [ ] No

- [ ] Participant
- [ ] Care Provider
- [ ] Investigator
- [ ] Outcomes Assessor

4.1.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

NIH Office of Extramural Research

FORMS-F Series (Updated May 13, 2020)
4.2. Outcome Measures

<table>
<thead>
<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 398 Modular Budget

**Expiration Date:** 02/28/2023

### A. Direct Costs

<table>
<thead>
<tr>
<th>Direct Cost less Consortium Indirect (F&amp;A)</th>
<th>0.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consortium Indirect (F&amp;A)</td>
<td></td>
</tr>
<tr>
<td><strong>Total Direct Costs</strong></td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Direct costs requested must be $250K or less per period to use Modular Budget form; request in "modules" of $25K.**

**Dates will autopopulate from the cover page.**

### B. Indirect (F&A) Costs

<table>
<thead>
<tr>
<th>Indirect (F&amp;A) Type</th>
<th>Indirect (F&amp;A) Rate (%)</th>
<th>Indirect (F&amp;A) Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Form allows for up to four F&A entries.**

**If you completed the RR Budget, Cayuse will autofill the modular equivalents in these fields; you can over-write Cayuse’s entries if needed.**

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

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
<th>0.00</th>
</tr>
</thead>
</table>

**Cumulative Budget Information**

1. **Total Costs, Entire Project Period**

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A, Total Direct Cost less Consortium Indirect (F&amp;A) for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section A, Total Consortium Indirect (F&amp;A) for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section A, Total Direct Costs for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section B, Total Indirect (F&amp;A) Costs for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section C, Total Direct and Indirect (F&amp;A) Costs (A+B) for Entire Project Period</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Budget Justifications**

- **Personnel Justification required**
- **Consortium Justification required if you have subcontractors**

**Personnel Justification**

**Consortium Justification**

**Additional Narrative Justification**

*Not needed for FOAs with direct cost limits that do not spread evenly across budget periods (e.g., R21 FOAs that allow $275,000 in direct costs over two years).**
## 1. Vertebrate Animals Section

Are vertebrate animals euthanized?  

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If "Yes" to euthanasia

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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?*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 150 characters</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

## 3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells?*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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 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?*

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If "yes" then provide the HFT Compliance Assurance

Add Attachment  

Delete Attachment  

View Attachment

Required if Yes; cannot be included if No

If "yes", you may not use a modular budget regardless of the direct cost total; a detailed budget is required; see general instructions for further guidance

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

Add Attachment  

Delete Attachment  

View Attachment

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

<table>
<thead>
<tr>
<th>Change of Project Director/Principal Investigator</th>
<th>Change of PD/PI is not allowed for Revision or Career Development (K) applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of former Project Director/Principal Investigator:</td>
<td></td>
</tr>
<tr>
<td>Prefix:</td>
<td></td>
</tr>
<tr>
<td>*First Name:</td>
<td></td>
</tr>
<tr>
<td>Middle Name:</td>
<td></td>
</tr>
<tr>
<td>*Last Name:  If change of PD/PI box is checked, you must provide the last name of the former PD/PI</td>
<td></td>
</tr>
<tr>
<td>Suffix:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change of Grantee Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Name of former institution:  If change of Grantee Institution box is checked, you must provide the name of former institution</td>
</tr>
</tbody>
</table>
# PHS 398 Research Plan

**Introduction**

1. **Introduction to Application** (for Resubmission and Revision applications)
   - Limited to 1 page (except R25 Resubmission can be 3 pages); required for Resubmission and Revision applications

**Research Plan Section**

2. **Specific Aims**
   - Required (except DP1, DP2, DP4, R35, R50 and X02; limited to 1 page)

3. **Research Strategy**
   - Adhere to page limits specified in FOA or Application Guide (FOA takes precedence)

4. **Progress Report Publication List**
   - Only allowed for Renewals and Resubmissions of renewals

**Other Research Plan Section**

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

6. **Select Agent Research**
   - Required if applicable

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**
   - If there are subcontractors, upload Letters of Intent or equivalent

9. **Letters of Support**
   - Cayuse will concatenate multiple letters of support into one PDF; be sure that letters are not larger than 8.5 x 11.0

10. **Resource Sharing Plan(s)**
    - Required if applicable, review FOA

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**
    - DO NOT use Appendix attachments to circumvent page limits in other sections of the application; applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required

    Allows for up to 10 appendices; see Application Guide and announcement for restrictions

    Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers
**PHS Assignment Request Form**

<table>
<thead>
<tr>
<th>Funding Opportunity Number:</th>
<th>Pre-populated from announcement information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Opportunity Title:</td>
<td></td>
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</tbody>
</table>

**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](https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents)

<table>
<thead>
<tr>
<th>Suggested Awarding Components:</th>
<th></th>
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</table>

**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](https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection)

<table>
<thead>
<tr>
<th>Suggested Study Sections:</th>
<th></th>
</tr>
</thead>
</table>

**Rationale for assignment suggestions** *(optional)*

*Entry is limited to 1000 characters.*

**Up to 1000 characters**
List individuals who should not review your application and why (optional)

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
This is a Cayuse-only form (not in the Grants.gov standard form set) used to indicate that the application is complete and ready for submission; please work with your OSP officer to coordinate application submission.

Routing Chain

Begin

TESTPI, SAM - University of Utah: DERMA

End

OSP, Routing - University of Utah

An AOR is on the routing chain, but has not yet approved this proposal. The proposal will not be submittable until an AOR has approved the proposal.

Routing History

<table>
<thead>
<tr>
<th>username</th>
<th>person</th>
<th>type</th>
<th>date/time</th>
<th>comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>u0363733</td>
<td></td>
<td>Modify</td>
<td>2020-01-29 14:10</td>
<td>Auto-built chain at copy time from PI</td>
</tr>
</tbody>
</table>

PI (or PI delegate assigned in the PI's profile) must click the Approval box next to his/her name to indicate approval of the application; an Approval dialog box will open; click the Approval button (comments are optional).

OSP is notified when the application is approved, but communicate with your OSP officer as normal to ensure the application is submitted.