

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

Enter DSS

3. DATE RECEIVED BY STATE State Application Identifier

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

4. a. Federal Identifier
b. Agency Routing Identifier

Use only for Revision/ Resubmission/ Renewals (box 8); enter institute and serial # of previous application # (e.g., CA987654 from 1R01CA987654-01)

2. DATE SUBMITTED Applicant Identifier

c. Previous Grants.gov tracking ID

For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX)

5. APPLICANT INFORMATION Organizational DUNS: If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678)

Legal Name: Department: Division: Street1: Street2: City: County / Parish: State: Province: Country: USA: UNITED STATES ZIP / Postal Code:

Institutional information will populate automatically

Person to be contacted on matters involving this application
Prefix: First Name: Middle Name: Last Name: Suffix: Position/Title: Street1: Street2: City: County / Parish: State: Province: Country: USA: UNITED STATES ZIP / Postal Code: Phone Number: Fax Number: Email:

Use pen icon to autofill the OSP Officer for this application into this section

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

Institutional information will populate automatically

7. TYPE OF APPLICANT: Other (Specify): Small Business Organization Type Women Owned Socially and Economically Disadvantaged

8. TYPE OF APPLICATION: New Resubmission Renewal Continuation Revision A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other (specify):

See application guide for definitions

Is this application being submitted to other agencies? Yes No What other Agencies? If Yes, please discuss with your OSP officer

9. NAME OF FEDERAL AGENCY: 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: [redacted] First Name: [redacted] Middle Name: [redacted]
Last Name: [redacted] Suffix: [redacted]
Position/Title: [redacted]
Organization Name: [redacted]
Department: [redacted]
Street1: [redacted]
Street2: [redacted]
City: [redacted] County / Parish: [redacted]
State: [redacted] Province: [redacted]
Country: USA: UNITED STATES ZIP / Postal Code: [redacted]
Phone Number: [redacted] Fax Number: [redacted]
Email: [redacted]

*For applications with a separate budget form, totals will normally populate from that budget form

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

a. Total Federal Funds Requested [redacted]
b. Total Non-Federal Funds [redacted]
c. Total Federal & Non-Federal Funds [redacted]
d. Estimated Program Income [redacted]

a. YES [] THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE: [redacted]
b. NO [x] PROGRAM IS NOT COVERED BY E.O. 12372; OR [] PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

*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.

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

[redacted] Add Attachment Delete Attachment View Attachment

19. Authorized Representative

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

Signature of Authorized Representative

Date Signed

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

20. Pre-application

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

21. Cover Letter Attachment

View Attachment

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: First performance site location will autofill from the PI's profile in Cayuse; can be manually updated; only one UU site is required, even if there are multiple UU investigators participating in the application (one site per campus/DUNS)

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: Used for non-University of Utah sites; each non-UofU Performance Site requires an entry; if a site does not have a DUNS, enter 00000000

Street2:

* City: County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Additional Location(s)

Cayuse Form: RR Other Project Information

RESEARCH & RELATED Other Project Information

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

If Human Subjects = Yes, additional information will be required on the PHS Human Subjects and Clinical Trials Information form

1. Are Human Subjects Involved?

Yes No

Answer Yes if all the proposed research human subject studies are exempt

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If multiple study records are included, enter all exemptions selected across all study records

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 is not required at time of submission; date cannot be in the future

IRB Approval Date: _____

Human Subject Assurance Number: _____

If Human Subjects = Yes, the UU HSA/FWA Number will populate automatically

2. Are Vertebrate Animals Used?

Yes No

If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan or equivalent form

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? Yes No

IACUC Approval Date is not required at time of submission; date cannot be in the future

IACUC Approval Date: _____

Animal Welfare Assurance Number: _____

If Vertebrate Animals = Yes, the UU Animal Welfare Assurance Number will populate automatically

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

If Yes, check with your OSP officer

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? Yes No

4.b. If yes, please explain: _____
If 4a is Yes, then 4b 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 5 is Yes, then 5a is required; up to 55 characters; normally should be marked "No" for UofU applications

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 6 is Yes, then a list of countries is required in 6a; abbreviations can be used; up to 55 characters

6.b. Optional Explanation: _____
Up to 55 characters; or upload a PDF in 12 titled "Foreign Justification"

7. Project Summary/Abstract

PDF normally required; 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

PDF normally required; typically 2-3 sentences; system will give error if over 1 page

9. Bibliography & References Cited

PDF normally required unless otherwise noted in opportunity; not system enforced

10. Facilities & Other Resources

PDF normally required unless otherwise noted in opportunity; limited system enforcement

11. Equipment

PDF normally required unless otherwise noted in opportunity; limited system enforcement

12. Other Attachments

Add Attachments

Delete Attachments

View Attachments

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

Field accommodates multiple attachments

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
 * Last Name: Suffix:
 Position/Title: Department:
 Organization Name: PI information will autofill from the PI's Profile in Cayuse
 * Street1:
 Street2:
 * City: County/ Parish:
 * State: Province:
 * Country: * Zip / Postal Code:
 * Phone Number:
 * E-Mail:
 Credential, e.g., agency login:
 * Project Role: **Other Project Role Category:**
Project Role will default to PD/PI and must remain PD/PI (do not edit)
 Degree Type:
 Degree Year: Required; limited to 5 pages
 *Attach Biographical Sketch
 Attach Current & Pending Support Only provide Current & Pending Support if specifically requested in FOA

PROFILE - Senior/Key Person 1

Prefix: * First Name: Middle Name:
 * Last Name: Suffix:
 Position/Title: Department:
 Organization Name: Division:
 * Street1:
 Street2:
 * City: County/ Parish:
 * State: Province:
 * 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: Required; limited to 5 pages
 Attach Biographical Sketch
 Attach Current & Pending Support

Cayuse form expands to include up to 40 Senior/Key People

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.

Other names for the Research and Related Budget are "Standard Budget", "Detailed Budget", or "Categorical Budget"; use this budget form if direct costs are >\$250K in any budget period, proposes the use of human fetal tissue from elective abortions, or if Agency or FOA does not allow the PHS Modular Budget

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

RESEARCH & RELATED BUDGET - Budget Period 1

Cayuse Form: RR Budget

ORGANIZATIONAL DUNS: DUNS will prepopulate organization:

Dates will autopopulate from the cover page

Budget Type: Project Subaward/Consortium
Cayuse will autocomplete

Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

PD/PI must have measurable effort in every budget period

| Prefix | First | Middle | Last | Suffix | Base Salary (\$) | Cal. | Acad. | Sum. | Requested Salary (\$) | Fringe Benefits (\$) | Funds Requested (\$) |
|--------|-------|--------|------|--------|------------------|------|-------|------|-----------------------|----------------------|----------------------|
| | | | | | | | | | | | |

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

those fields (and not in the Base Salary field), and they are used to autocalculate salary amounts; total salary will populate in the Base Salary field

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

Form will expand to up to 44 Senior/Key People

Total Senior/Key Person

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

| Number of Personnel | Project Role | Months | | | Requested Salary (\$) | Fringe Benefits (\$) | Funds Requested (\$) |
|--|--------------------------|--------|-------|------|-----------------------|----------------------|----------------------|
| | | Cal. | Acad. | Sum. | | | |
| <input type="text"/> | Post Doctoral Associates | | | | | | |
| <input type="text"/> | Graduate Students | | | | | | |
| <input type="text"/> | Undergraduate Students | | | | | | |
| <input type="text"/> | Secretarial/Clerical | | | | | | |
| 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)

Cayuse Form: RR Budget

C. Equipment Description

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

| Equipment item | Funds Requested (\$) |
|---|----------------------|
| <input type="text"/> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> Click green plus icon to create an equipment line; you can add up to 9 more rows to this section; change Indirect Cost Type to "excluded", so Cayuse does not calculate F&A on equipment > \$5,000 </div> | <input type="text"/> |
| Additional Equipment: <input type="text"/> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> Add Attachment Delete Attachment View Attachment </div> | <input type="text"/> |
| Total Equipment | |

Total funds requested for all equipment listed in the attached file

D. Travel

| | Funds Requested (\$) |
|---|----------------------|
| 1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions) | <input type="text"/> |
| 2. Foreign Travel Costs | <input type="text"/> |
| Total Travel Cost | |

E. Participant/Trainee Support Costs

| | Funds Requested (\$) |
|--|----------------------|
| 1. Tuition/Fees/Health Insurance | <input type="text"/> |
| 2. Stipends | <input type="text"/> |
| 3. Travel | <input type="text"/> |
| 4. Subsistence | <input type="text"/> |
| 5. Other | <input type="text"/> |
| Total Participant/Trainee Support Costs | |

Not normally used; only complete this section if indicated in the FOA

Cayuse Form: RR Budget

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. 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&A for eligible direct cost items and exclude it where required (e.g., tuition, patient care)

9.

10.

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

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |

Total Other Direct Costs

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

Total Direct Costs (A thru F)

G. Direct Costs

H. Indirect Costs

Indirect Cost Type

| | | | | |
|----------------------|------------------------|----------------------|-------------------------|----------------------|
| <input type="text"/> | Indirect Cost Rate (%) | <input type="text"/> | Indirect Cost Base (\$) | <input type="text"/> |
|----------------------|------------------------|----------------------|-------------------------|----------------------|

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

Rate type and amount chosen when application was created will prepopulate

Indirect Cost Base will exclude any cost categories where the Indirect Cost Type "excluded" was selected

Total Indirect Costs

Cognizant Federal Agency

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

Information will prepopulate

I. Total Direct and Indirect Costs

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

Total Direct and Indirect Institutional Costs (G + H)

J. Fee

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

K. Total Costs and Fee

Funds Requested (\$)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

Total Costs and Fee (I + J)

L. Budget Justification

(Only attach one file.)

| |
|----------------------|
| <input type="text"/> |
|----------------------|

Budget Justification is required and must cover all budget periods

Add Attachment

Delete Attachment

View Attachment

RESEARCH & RELATED BUDGET - Cumulative Budget

| | Totals (\$) |
|---|-------------|
| Section A, Senior/Key Person | |
| Section B, Other Personnel | |
| Total Number Other Personnel | |
| Total Salary, Wages and Fringe Benefits (A+B) | |
| 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) | |

PHS Human Subjects and Clinical Trials Information

[Redacted]

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

Use of Human Specimens and/or Data

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

Yes No

Answer required for all applications

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

Information populated from R&R Other Project Information form

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

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

[Redacted]

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Add as many Studies as needed

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

[Redacted]

Add Attachment

Delete Attachment

View Attachment

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

| | Study Title | Anticipated Clinical Trial? | Justification |
|--|-------------|-----------------------------|---|
| | [Redacted] | <input type="checkbox"/> | <p>[Redacted]</p> <p>Add Attachment Delete Attachment View Attachment</p> |

[Redacted]

[Redacted]

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form

* Always required field

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

Answer required and system enforced

1.3. Exemption Number

1 2 3 4 5 6 7 8

If Study Exempt is Yes, must provide exemption number; exemption must also be selected on Other Project Information form

1.4. * Clinical Trial Questionnaire

Answers to questionnaire required and system enforced

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

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

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

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

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)

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 4 is the only exemption selected or otherwise noted in opportunity

2.8. Enrollment of First Participant

Date: MM/DD/YYYY

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

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

* 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

Cayuse Form: PHS Human Subjects and Clinical Trials Information
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

Cayuse Form: PHS Human Subjects and Clinical Trials Information

Planned Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No; system enforcement relaxed if Comment is provided

| Racial Categories | Ethnic Categories | | | | | |
|--|------------------------|------|--------------------|------|-------|--|
| | Not Hispanic or Latino | | Hispanic or Latino | | Total | |
| | Female | Male | Female | Male | | |
| American Indian/ Alaska Native | 0 | 0 | 0 | 0 | 0 | |
| Asian | 0 | 0 | 0 | 0 | 0 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 | |
| Black or African American | 0 | 0 | 0 | 0 | 0 | |
| White | 0 | 0 | 0 | 0 | 0 | |
| More than One Race | 0 | 0 | 0 | 0 | 0 | |
| Total | 0 | 0 | 0 | 0 | 0 | |

Cayuse Form: PHS Human Subjects and Clinical Trials Information

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes; system enforcement relaxed if Comment is provided

Cumulative (Actual)

| Racial Categories | Ethnic Categories | | | | | | | | | | Total |
|---|------------------------|------|----------------------|--------------------|------|----------------------|--------------------------------|------|----------------------|-------|-------|
| | Not Hispanic or Latino | | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | Total | |
| | Female | Male | Unknown/Not Reported | Female | Male | Unknown/Not Reported | Female | Male | Unknown/Not Reported | | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| White | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| More than One Race | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Report 1 of 1

Cayuse Form: PHS Human Subjects and Clinical Trials Information

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

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

3.3. Data and Safety Monitoring Plan

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

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

4.1.b. Primary Purpose

4.1.c. Interventions

| | | |
|-------------------|---|---|
| Intervention Type | | 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 | <input type="text" value="Up to 200 characters"/> | |
| Description | <input type="text" value="Up to 1,000 characters"/> | |

4.1.d. Study Phase

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

4.1.e. Intervention Model

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

Cayuse Form: PHS Human Subjects and Clinical Trials Information

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

| | |
|--------------------------|--|
| Name | |
| Type | |
| Time Frame | |
| Brief Description | |

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

OMB Number: 0525-0067
Expiration Date: 02/28/2023

Form allows for up to 5 Budget Periods **Budget Period: 1** **Dates will autopopulate from the cover page**

Start Date: End Date:

A. Direct Costs Funds Requested (\$)

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

Direct Cost less Consortium Indirect (F&A)

Consortium Indirect (F&A)

Total Direct Costs

B. Indirect (F&A) Costs

| Indirect (F&A) Type | Indirect (F&A) Rate (%) | Indirect (F&A) Base (\$) | Funds Requested (\$) |
|---|-------------------------|--------------------------|----------------------|
| Form allows for up to four F&A entries | <input type="text"/> | <input type="text"/> | <input type="text"/> |

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

Indirect (F&A) Rate Agreement Date

Total Indirect (F&A) Costs

C. Total Direct and Indirect (F&A) Costs (A + B) Funds Requested (\$)

Cumulative Budget Information **System calculated**

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period \$

Section A, Total Consortium Indirect (F&A) for Entire Project Period \$

Section A, Total Direct Costs for Entire Project Period \$

Section B, Total Indirect (F&A) Costs for Entire Project Period \$

Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period \$

2. Budget Justifications

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

Personnel Justification

Consortium Justification

Additional Narrative Justification



PHS 398 Cover Page Supplement

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

1. Vertebrate Animals Section

Are vertebrate animals euthanized? Yes No

Answer required if Vertebrate Animals Used is Yes on the R&R Other Project Information form

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

Program income is income earned by a recipient, a consortium participant, or a contractor under a grant that was directly generated by the grant-supported activity or earned as a result of the award

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)

Up to 150 characters

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

Add Attachment

Delete Attachment

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

Required if Yes; cannot be included if No

Add Attachment

Delete Attachment

View Attachment

PHS 398 Cover Page Supplement

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

Change of PD/PI is not allowed for Revision or Career Development (K) applications

Name of former Project Director/Principal Investigator:

Prefix:

*First Name:

Middle Name:

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

Suffix:

Change of Grantee Institution

*Name of former institution:

If change of Grantee Institution box is checked, you must provide the name of former institution

PHS 398 Research Plan

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

| | |
|---|---|
| Introduction | |
| 1. Introduction to Application (for Resubmission and Revision applications) | <input type="checkbox"/> Limited to 1 page (except R25 Resubmission can be 3 pages); required for Resubmission and Revision applications <input type="button" value="View Attachment"/> |
| Research Plan Section | |
| 2. Specific Aims | <input type="checkbox"/> Required (except DP1, DP2, DP4, R35, R50 and X02; limited to 1 page) |
| 3. *Research Strategy | <input checked="" type="checkbox"/> Adhere to page limits specified in FOA or Application Guide (FOA takes precedence) |
| 4. Progress Report Publication List | <input type="checkbox"/> Only allowed for Renewals and Resubmissions of renewals <input type="button" value="Attachment"/> |
| Other Research Plan Section | |
| 5. Vertebrate Animals | <input type="checkbox"/> Required for all applications if Vertebrate Animals is Yes on the Other Project Information form <input type="button" value="View Attachment"/> |
| 6. Select Agent Research | <input type="checkbox"/> Required if applicable <input type="button" value="Add Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/> |
| 7. Multiple PD/PI Leadership Plan | <input type="checkbox"/> Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form |
| 8. Consortium/Contractual Arrangements | <input type="checkbox"/> If there are subcontractors, upload Letters of Intent or equivalent <input type="button" value="View Attachment"/> |
| 9. Letters of Support | <input type="checkbox"/> |
| 10. Resource Sharing Plan(s) | <input type="checkbox"/> Required if applicable, review FOA <input type="button" value="Attachment"/> <input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/> |
| 11. Authentication of Key Biological and/or Chemical Resources | <input type="checkbox"/> Required if project involves key biological and/or chemical resources; recommend 1 page; no system validation enforcement <input type="button" value="View Attachment"/> |
| Appendix | |
| 12. Appendix | <input type="button" value="Add Attachments"/> <input type="button" value="Delete Attachments"/> <input type="button" value="View Attachments"/> |

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

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

Funding Opportunity Number:

Funding Opportunity Title:

Pre-populated from announcement information

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:

NIH considers our requests with other assignment factors; suggestions are not automatically honored

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

NIH considers our requests with other assignment factors; suggestions are not automatically honored

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters.

Up to 1000 characters

PHS Assignment Request Form

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

1

2

3

4

5

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

Cayuse Form: Routing & Approval

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 & Approval

Routing Chain

   ... **Edit Chain?**

- Begin**
- TESTPI, SAM - University of Utah: DERMA
 -  OSP, Routing - University of Utah
- End**

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

 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

| username | person | type | date/time | comments |
|----------|--------|--------|------------------|---------------------------------------|
| u0363733 | | Modify | 2020-01-29 14:10 | Auto-built chain at copy time from PI |