Cayuse Form: SF424 RR

Enter DSS

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

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

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**

Consult with OSP before using "Change/Corrected"

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:

Institutional information will populate automatically

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Person to be contacted on matters involving this application

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

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

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Phone Number: Fax Number:

Email:

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

Institutional information will populate automatically

7. TYPE OF APPLICANT: Please select one of the following

Other (Specify):

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:

See application guide for definitions

☐ New ☐ Resubmission

☐ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).

☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration

☐ E. Other (specify):

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:

Will populate automatically

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

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

Cayuse Form: SF424 RR

PPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

Organization Name:

Department:

PI information will autofill from the PI's profile in Cayuse

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Phone Number: Fax Number:

Email:

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

15. E

a. Total Federal Funds Requested *

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds *

d. Estimated Program Income

Enter "0" unless income will be generated from the grant

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:

Answer is normally "b. No", "Not Covered" for research applications, but review FOA for each application

b. NO ☐ 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 con erein 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

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

Organization:

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

Department:

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**

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

20. Pre-application Attachment

21. Cover Letter Attachment Attachment

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

Cayuse Form: RR Performance Sites

OMB Number: 4040-0010
Expiration Date: 12/31/2022

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:

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)

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:

Used for non-University of Utah sites; each non-UofU Performance Site requires an entry; if a site does not have a DUNS, enter 000000000

Additional Location(s) Add Attachment Delete Attachment View Attachment

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:

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

Animal Welfare Assurance Number:

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

Cayuse Form: RR Key Persons

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

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: Division:
* Street1:
Street2:
* City: County/ Parish:
* State: Province:
* Country: USA: UNITED STATES * Zip / Postal Code:
* Phone Number:
* E-Mail:
Credential, e.g., agency login:
*** Project Role:** PD/PI **Other Project Role Category:**
Degree Type:
Degree Year:
***Attach Biographical Sketch** Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

PI information will autofill from the PI's Profile in Cayuse

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

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

Required; limited to 5 pages

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: USA: UNITED STATES * 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 Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

Use Pen icon (in Cayuse appears in the upper right corner) to autofill each key person's information from his/her Cayuse Profile

Required; limited to 5 pages

Delete Entry

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

Next Person

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

Cayuse Form: RR Budget

RESEARCH & RELATED BUDGET - Budget Period 1

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

ORGANIZATIONAL DUNS: DUNS will prepopulate

Enter Name of 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

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)

PD/PI must have measurable effort in every budget period

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

Project Role: PD/PI

Role must be PD/PI for the PD/PI

Cayuse also has fields for Calendar salary, Academic salary, and Summer salary, salary is entered in 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

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

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 Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	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 ($)

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

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

		Funds Requested ($)
1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2.	Foreign Travel Costs	
	Total Travel Cost	

E. Participant/Trainee Support Costs

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

		Funds Requested ($)
1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Total Participant/Trainee Support Costs	

Number of Participants/Trainees

Cayuse Form: RR Budget

F. Other Direct Costs

		Funds Requested ($)
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.		
9.		
10.		
	Total Other Direct Costs	

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

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)

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	

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

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

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

J. Fee

Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	

L. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

Budget Justification is required and must cover all budget periods

Cayuse Form: RR Budget

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)		

Cayuse Form: PHS Human Subjects and Clinical Trials Information

PHS Human Subjects and Clinical Trials Information

Complete human subjects section of R&R Other Project Information form prior to completing this form

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

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

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

Information populated from R&R Other Project Information form

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

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 [ ] 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

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	Anticipated Clinical Trial?	Justification
		☐	[ ] Add Attachment | Delete Attachment | View Attachment

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.

Cayuse Form: PHS Human Subjects and Clinical Trials Information

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

* Always req — Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form — 2/28/2023

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 defaults to Yes and is not editable

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

2.3. Age Limits — **Minimum Age** — **Maximum Age**

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

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

If "N/A (No Limit)" selected, do not provide numerical min/max 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

Attachment | View Attachment

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)

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

Racial Categories	Ethnic Categories									
	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
Asian	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
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	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 — 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 — 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

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	Up to 255 characters
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters
Brief Description	Up to 999 characters

4.3. Statistical Design and Power ☐ Required and system enforced for CT study unless otherwise noted in opportunity [ttachment] [Delete Attachment] [View Attachment]

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

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

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Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments [Add Attachments] [Delete Attachments] [View Attachments]

Form supports up to 10 attachments; attachments only allowed for CT studies; only include attachments requested in opportunity

Cayuse Form: PHS 398 Modular Budget

Use this budget form for NIH applications that request = or <$250K in direct costs in all budget periods; **this form is only used by NIH**

PHS 398 Modular Budget

OMB Number: 0925-0001
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

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

	Funds Requested ($)
Direct Cost less Consortium Indirect (F&A)	0.00
Consortium Indirect (F&A)	
Total Direct Costs	0.00

B. Indirect (F&A) Costs

Form allows for up to for four F&A entries

Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base ($)	Funds Requested ($)

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

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 ($) 0.00

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	$	0.00
Section A, Total Consortium Indirect (F&A) for Entire Project Period	$	
Section A, Total Direct Costs for Entire Project Period	$	0.00
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	$	0.00

2. Budget Justifications

Personnel Justification required

Consortium Justification required if you have subcontractors

Personnel Justification		Add Attachment	Delete Attachment	View Attachment
Consortium Justification		Add Attachment	Delete Attachment	View Attachment
Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment

Additional Narrative Justification is required if there are any variations in the number of modules requested annually*; also, this section should describe any direct costs that were excluded from the total direct costs (such as equipment, tuition remission) and any work being conducted off-site, especially if it involves a foreign study site or an off-site F&A rate

*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)

Cayuse Form: PHS 398 Cover Page Supplement

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 | D

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

Cayuse Form: PHS 398 Cover Page Supplement

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

Cayuse Form: PHS 398 Research Plan

PHS 398 Research Plan

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

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 — View Attachment

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 — Attachment

Other Research Plan Section

5. Vertebrate Animals — Required for all applications if Vertebrate Animals is Yes on the Other Project Information form — View Attachment

6. Select Agent Research — Required if applicable — Add Attachment — Delete Attachment — View Attachment

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 — View Attachment

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

10. Resource Sharing Plan(s) — Required if applicable, review FOA — Delete Attachment — View Attachment

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 — View Attachment

Appendix

12. Appendix — Add Attachments — Delete Attachments — 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

Cayuse Form: PHS Assignment Request Form

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

Cayuse Form: PHS Assignment Request Form

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: DERMAT

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