

| | | | | |
|--|--|--|----------------------------------|--|
| Department of Health and Human Services Public Health Services <h2 style="margin: 0;">Grant Application</h2> <p style="margin: 0;"><i>Do not exceed character length restrictions indicated.</i></p> | | LEAVE BLANK—FOR PHS USE ONLY. | | |
| | | Type | Activity | Number |
| | | Review Group | | Formerly |
| | | Council/Board (Month, Year) | | Date Received |
| 1. TITLE OF PROJECT <i>(Do not exceed 81 characters, including spaces and punctuation.)</i> | | | | |
| 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> YES <i>(If "Yes," state number and title)</i> | | | | |
| Number: _____ Title: _____ | | | | |
| 3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR | | | | |
| 3a. NAME (Last, first, middle) | | 3b. DEGREE(S) | | 3h. eRA Commons User Name |
| 3c. POSITION TITLE | | 3d. MAILING ADDRESS <i>(Street, city, state, zip code)</i> | | |
| 3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT | | | | |
| 3f. MAJOR SUBDIVISION | | | | |
| 3g. TELEPHONE AND FAX <i>(Area code, number and extension)</i> | | | | |
| TEL: _____ FAX: _____ | | E-MAIL ADDRESS: _____ | | |
| 4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes | | 4a. Research Exempt If "Yes," Exemption No. <input type="checkbox"/> No <input type="checkbox"/> Yes | | |
| 4b. Federal-Wide Assurance No. | | 4c. Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes | | 4d. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes |
| 5. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes | | | 5a. Animal Welfare Assurance No. | |
| 6. DATES OF PROPOSED PERIOD OF SUPPORT <i>(month, day, year—MM/DD/YY)</i> | | 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD | | 8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT |
| From _____ Through _____ | | 7a. Direct Costs (\$) | 7b. Total Costs (\$) | 8a. Direct Costs (\$) |
| | | | | 8b. Total Costs (\$) |
| 9. APPLICANT ORGANIZATION Name Address | | 10. TYPE OF ORGANIZATION | | |
| | | Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged | | |
| | | 11. ENTITY IDENTIFICATION NUMBER | | |
| | | DUNS NO. | | Cong. District |
| 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE | | 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION | | |
| Name | | Name | | |
| Title | | Title | | |
| Address | | Address | | |
| Tel: _____ FAX: _____ | | Tel: _____ FAX: _____ | | |
| E-Mail: _____ | | E-Mail: _____ | | |
| 14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. | | SIGNATURE OF OFFICIAL NAMED IN 13. <i>(In ink. "Per" signature not acceptable.)</i> | | DATE |

Program Director/Principal Investigator (Last, First, Middle):

PROJECT SUMMARY (See instructions):

RELEVANCE (See instructions):

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

| | | | |
|---|----------|-----------|------------------|
| Project/Performance Site Primary Location | | | |
| Organizational Name: | | | |
| DUNS: | | | |
| Street 1: | | Street 2: | |
| City: | | County: | State: |
| Province: | Country: | | Zip/Postal Code: |
| Project/Performance Site Congressional Districts: | | | |
| Additional Project/Performance Site Location | | | |
| Organizational Name: | | | |
| DUNS: | | | |
| Street 1: | | Street 2: | |
| City: | | County: | State: |
| Province: | Country: | | Zip/Postal Code: |
| Project/Performance Site Congressional Districts: | | | |

Program Director/Principal Investigator (Last, First, Middle):

SENIOR/KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

| Name | eRA Commons User Name | Organization | Role on Project |
|------|-----------------------|--------------|-----------------|
|------|-----------------------|--------------|-----------------|

OTHER SIGNIFICANT CONTRIBUTORS

| Name | Organization | Role on Project |
|------|--------------|-----------------|
|------|--------------|-----------------|

Human Embryonic Stem Cells No Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: https://grants.nih.gov/stem_cells/registry/current.htm. *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

Cell Line

| | | |
|--|------|---------|
| DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY | FROM | THROUGH |
|--|------|---------|

List PERSONNEL (*Applicant organization only*)
 Use Cal, Acad, or Summer to Enter Months Devoted to Project
 Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

| NAME | ROLE ON PROJECT | Cal. Mnths | Acad. Mnths | Summer Mnths | INST.BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
|--------------------|-----------------|------------|-------------|--------------|------------------|------------------|-----------------|-------|
| | PD/PI | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| SUBTOTALS → | | | | | | 0 | 0 | 0 |

| | |
|--|--|
| CONSULTANT COSTS | |
| EQUIPMENT (<i>Itemize</i>) | |
| SUPPLIES (<i>Itemize by category</i>) | |
| TRAVEL | |
| INPATIENT CARE COSTS | |
| OUTPATIENT CARE COSTS | |
| ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>) | |
| OTHER EXPENSES (<i>Itemize by category</i>) | |

| | | |
|--|-------------------------------------|-------------|
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS | |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (<i>Item 7a, Face Page</i>) | | \$ 0 |
| CONSORTIUM/CONTRACTUAL COSTS | FACILITIES AND ADMINISTRATIVE COSTS | |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | | \$ 0 |

Program Director/Principal Investigator (Last, First, Middle):

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

| BUDGET CATEGORY TOTALS | INITIAL BUDGET PERIOD <i>(from Form Page 4)</i> | 2nd ADDITIONAL YEAR OF SUPPORT REQUESTED | 3rd ADDITIONAL YEAR OF SUPPORT REQUESTED | 4th ADDITIONAL YEAR OF SUPPORT REQUESTED | 5th ADDITIONAL YEAR OF SUPPORT REQUESTED |
|--|--|--|--|--|--|
| PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i> | | | | | |
| CONSULTANT COSTS | | | | | |
| EQUIPMENT | | | | | |
| SUPPLIES | | | | | |
| TRAVEL | | | | | |
| INPATIENT CARE COSTS | | | | | |
| OUTPATIENT CARE COSTS | | | | | |
| ALTERATIONS AND RENOVATIONS | | | | | |
| OTHER EXPENSES | | | | | |
| DIRECT CONSORTIUM/ CONTRACTUAL COSTS | | | | | |
| SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i> | 0 | 0 | 0 | 0 | 0 |
| F&A CONSORTIUM/ CONTRACTUAL COSTS | | | | | |
| TOTAL DIRECT COSTS | 0 | 0 | 0 | 0 | 0 |
| TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD | | | | | \$ 0 |

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

| INSTITUTION AND LOCATION | DEGREE (if applicable) | Completion Date MM/YYYY | FIELD OF STUDY |
|--------------------------|---------------------------|----------------------------|----------------|
| | | | |

A. Personal Statement**B. Positions, Scientific Appointments, and Honors****C. Contributions to Science**

Name of Applicant (Last, First, Middle):

RESEARCH PLAN

INTRODUCTION (RESPONSE TO REVIEWER) (1 page)

SPECIFIC AIMS (1 page)

SIGNIFICANCE (0.5 page)

INNOVATION (0.5 page)

RESEARCH STRATEGY (maximum 2 pages for Introduction to Research awards, 6 pages for all others)

BIBLIOGRAPHY AND REFERENCES CITED

Name of Applicant (Last, First, Middle):

VERTEBRATE ANIMALS SECTION

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

LETTER OF SUPPORT

- from Department Head and/or Clinical Unit Chief and any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the application
- from each DaCCoTA Core following core meetings

LETTER OF APPROVAL FROM EXTERNAL ADVISORY COMMITTEE

IACUC/IRB/IBC APPROVAL LETTERS

RESOURCE SHARING PLAN

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES



Completion Date
Expiration Date
Record ID

This is to certify that:

PI/Co-I/Key Personnel Name

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Applicable Trainings

Under requirements set by:

Institution Name



This GCP training contains all of the attested CITI Program modules from the **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) Version 2**. This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Verify at www.citiprogram.org/verify/?w86ff1e6b-fdec-4b36-a15d-0aafaaa3300a-40708901

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name:
- Institution Affiliation:
- Institution Email:
- Phone:

- Curriculum Group:
- Course Learner Group:
- Stage:

- Record ID:
- Completion Date:
- Expiration Date:
- Minimum Passing:
- Reported Score*:

REQUIRED AND ELECTIVE MODULES ONLY

DATE COMPLETED SCORE

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at:

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- Name:
- Institution Affiliation:
- Institution Email:
- Phone:

- Curriculum Group:
- Course Learner Group:
- Stage:
- Description:

- Record ID:
- Report Date:
- Current Score**:

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

MOST RECENT SCORE

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at:

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

Check Form for Errors

Save

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number:

Expiration Date:

* Always required field

Section 1 - Basic Information

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

1.2. * Is this Study Exempt from Federal Regulations? Yes No

1.3. Exemption Number 1 2 3 4 5 6 7 8

1.4. * Clinical Trial Questionnaire

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

1.4.a. Does the study involve human participants? Yes No

1.4.b. Are the participants prospectively assigned to an intervention? Yes No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? Yes No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes No

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

| | |
|---|--|
| X | |
| X | |
| X | |

Add New Condition

2.2. Eligibility Criteria

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

2.3.a. Inclusion of Individuals Across the Lifespan

2.4. Inclusion of Women and Minorities

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

2. * Using an Existing Dataset or Resource

Yes No

3. * Enrollment Location Type

Domestic Foreign

4. Enrollment Country(ies)

X

Add New Country

5. Enrollment Location(s)

6. Comments

Planned

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

Cumulative (Actual)

| 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 | | | | | | | | | | |
| Asian | | | | | | | | | | |
| Native Hawaiian or Other Pacific Islander | | | | | | | | | | |
| Black or African American | | | | | | | | | | |
| White | | | | | | | | | | |
| More than One Race | | | | | | | | | | |
| Unknown or Not Reported | | | | | | | | | | |
| Total | | | | | | | | | | |

< Previous Report

Report 1 of 1

Next Report >

|<< First Report

Delete Report

Last Report >>|

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

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

| x | Intervention Type |
|---|--------------------|
| | Name |
| | Description |

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

4.1.g. Allocation

4.2. Outcome Measures

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

Add New Outcome

4.3. Statistical Design and Power

4.4. Subject Participation Duration

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

Yes No

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

4.6. Is this an applicable clinical trial under FDAAA?

Yes No

4.7. Dissemination Plan

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

2.3.a Inclusion of Individuals Across the Lifespan

[This is an expansion of the attachment]

2.4 - Inclusion of Women and Minorities

[This is an expansion of the attachment]

2.5 - Recruitment and Retention Plan

[This is an expansion of the attachment]

2.7 - Study Timeline

[This is an expansion of the attachment]

3.1 - Protection of Human Subjects

[This is an expansion of the attachment]

3.3 - Data and Safety Monitoring Plan

[This is an expansion of the attachment]

3.5 - Overall Structure of the Study Team

[This is an expansion of the attachment]



Community Engagement Relevance Survey for DaCCoTA Applications

Directions: The Community Engagement Relevance Survey is required for all DaCCoTA applications. The purpose of this survey is to identify relevant community engagement in prospective applications.

Applicant Name:

Core and Grant Funding Mechanism:

Project Name:

This identification is required for all DaCCoTA (AICoRN, BERDC, PDC, PPP) applications:

As part of your application, please identify which of the following communities is most relevant to your Community Engagement Scholars application (select all that apply):

- American Indian (both rural and urban) communities
- Rural communities
- New American, Foreign-born, and Immigrant (NFI) communities
- Lesbian, Gay, Bisexual, Transgender, & Queer + (LGBTQ+) communities

For PDC Community Engagement Scholars Applications Only!

As part of your application, please identify which of the following research priorities is most relevant to your Community Engagement Scholars application (select all that apply):

- Behavioral health (including substance use disorder, mental health, suicidality, and overall wellness)
- Food insecurity, nutrition, and food deserts
- Chronic disease (including diabetes, cancer, hypertension, obesity, and pain)
- Culturally-safe and trauma-informed healthcare and research (including integrative therapies such as traditional healing, and innovative prenatal and natal, and postnatal care)
- Unresolved trauma (including health impacts of trauma and toxic stress, adverse childhood experiences, and disproportionate foster care experiences)

Program Director/Principal Investigator (Last, First, Middle): _____

CHECKLIST

TYPE OF APPLICATION (Check all that apply.)

- NEW application. (This application is being submitted to the PHS for the first time.)
- RESUBMISSION of application number: _____
(This application replaces a prior unfunded version of a new, renewal, or revision application.)
- RENEWAL of grant number: _____
(This application is to extend a funded grant beyond its current project period.)
- REVISION to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)
- CHANGE of program director/principal investigator.
Name of former program director/principal investigator: _____
- CHANGE of Grantee Institution. Name of former institution: _____
- FOREIGN application Domestic Grant with foreign involvement List Country(ies) Involved: _____

INVENTIONS AND PATENTS (Renewal appl. only) No Yes
 If "Yes," Previously reported Not previously reported

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

| Budget Period | Anticipated Amount | Source(s) |
|---------------|--------------------|-----------|
| | | |

2. ASSURANCES/CERTIFICATIONS (See instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in the [NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates](#). If unable to certify compliance, where applicable, provide an explanation and place it after this page.

3. FACILITIES AND ADMINISTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

- HHS Agreement dated: _____ No Facilities And Administrative Costs Requested.
- HHS Agreement being negotiated with _____ Regional Office.
- No HHS Agreement, but rate established with _____ Date _____

CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

| | | | | | |
|--|--|-------|---------------|----|----------------|
| a. Initial budget period: | Amount of base \$ _____ x Rate applied | 0.00% | % = F&A costs | \$ | 0.00 |
| b. 02 year | Amount of base \$ _____ x Rate applied | 0.00% | % = F&A costs | \$ | 0.00 |
| c. 03 year | Amount of base \$ _____ x Rate applied | 0.00% | % = F&A costs | \$ | 0.00 |
| d. 04 year | Amount of base \$ _____ x Rate applied | 0.00% | % = F&A costs | \$ | 0.00 |
| e. 05 year | Amount of base \$ _____ x Rate applied | 0.00% | % = F&A costs | \$ | 0.00 |
| Enter Rate above as a decimal (e.g., 0.25 for 25%, 0.495 for 49.5%) TOTAL F&A Costs | | | | | \$ 0.00 |

*Check appropriate box(es):

- Salary and wages base Modified total direct cost base Other base (Explain)
- Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.): _____