

|  |          |  |  |      |          |        |              |  |          |                             |  |               |
|--|----------|--|--|------|----------|--------|--------------|--|----------|-----------------------------|--|---------------|
| Department of Health and Human Services<br>Public Health Services<br><h2 style="margin: 0;">Grant Application</h2> <p style="margin: 0;"><i>Do not exceed character length restrictions indicated.</i></p> |          | <b>LEAVE BLANK—FOR PHS USE ONLY.</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Type</td> <td style="width: 33%;">Activity</td> <td style="width: 34%;">Number</td> </tr> <tr> <td>Review Group</td> <td></td> <td>Formerly</td> </tr> <tr> <td>Council/Board (Month, Year)</td> <td></td> <td>Date Received</td> </tr> </table>   |  | Type | Activity | Number | Review Group |  | Formerly | Council/Board (Month, Year) |  | Date Received |
| 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<br>( <i>If "Yes," state number and title</i> )           |          |  |  |      |          |        |              |  |          |                             |  |               |
| Number:  |          | Title:   |  |      |          |        |              |  |          |                             |  |               |
| <b>3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR</b>  |          |  |  |      |          |        |              |  |          |                             |  |               |
| 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> )   |          | E-MAIL ADDRESS:  |  |      |          |        |              |  |          |                             |  |               |
| TEL:   |          | FAX:   |  |      |          |        |              |  |          |                             |  |               |
| 4. HUMAN SUBJECTS RESEARCH<br><input type="checkbox"/> No <input type="checkbox"/> Yes   |          | 4a. Research Exempt If "Yes," Exemption No.<br><input type="checkbox"/> No <input type="checkbox"/> Yes  |  |      |          |        |              |  |          |                             |  |               |
| 4b. Federal-Wide Assurance No.   |          | 4c. Clinical Trial<br><input type="checkbox"/> No <input type="checkbox"/> Yes   | 4d. NIH-defined Phase III Clinical Trial<br><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<br>Name<br><br>Address   |          | 10. TYPE OF ORGANIZATION<br>Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local<br>Private: → <input type="checkbox"/> Private Nonprofit<br><br>For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business<br><input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged   |  |      |          |        |              |  |          |                             |  |               |
|  |          | 11. ENTITY IDENTIFICATION NUMBER<br><br>DUNS NO. _____ Cong. District _____  |  |      |          |        |              |  |          |                             |  |               |
| 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE<br>Name<br><br>Title<br><br>Address<br><br><br>Tel: _____ FAX: _____<br>E-Mail: _____  |          | 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION<br>Name<br><br>Title<br><br>Address<br><br><br>Tel: _____ FAX: _____<br>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.<br>( <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)

|   |          |           |                  |
|---|----------|-----------|------------------|
| <b>Project/Performance Site Primary Location</b>    |          |           |                  |
| Organizational Name:                                |          |           |                  |
| DUNS:   |          |           |                  |
| Street 1:   |          | Street 2: |                  |
| City:   |          | County:   | State:           |
| Province:   | Country: |           | Zip/Postal Code: |
| Project/Performance Site Congressional Districts:   |          |           |                  |
| <b>Additional Project/Performance Site Location</b> |          |           |                  |
| 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: <http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp>. *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**

The name of the program director/principal investigator must be provided at the top of each printed page and each continuation page.

**RESEARCH GRANT  
TABLE OF CONTENTS**

|   | <i>Page Numbers</i>                                    |
|---|--|
| <b>Face Page</b> .....  | <u>1</u>   |
| <b>Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells</b> ..... | <u>2</u>   |
| <b>Table of Contents</b> .....  | _____  |
| <b>Detailed Budget for Initial Budget Period</b> .....  | _____  |
| <b>Budget for Entire Proposed Period of Support</b> .....   | _____  |
| <b>Budgets Pertaining to Consortium/Contractual Arrangements</b> .....  | _____  |
| <b>Biographical Sketch</b> – Program Director/Principal Investigator ( <i>Not to exceed four pages each</i> ).....                        | _____  |
| <b>Other Biographical Sketches</b> ( <i>Not to exceed four pages each – See instructions</i> ).....                                       | _____  |
| <b>Resources</b> .....  | _____  |
| <b>Checklist</b> .....  | _____  |
| <b>Research Plan</b> .....  | _____  |
| 1. Introduction to Resubmission Application, if applicable, or Introduction to Revision Application, if applicable * .....                | _____  |
| 2. Specific Aims * .....  | _____  |
| 3. Research Strategy * .....  | _____  |
| 4. Inclusion Enrollment Report (Renewal or Revision applications only).....   | _____  |
| 5. Bibliography and References Cited/Progress Report Publication List.....  | _____  |
| 6. Protection of Human Subjects.....  | _____  |
| 7. Inclusion of Women and Minorities.....   | _____  |
| 8. Targeted/Planned Enrollment Table.....   | _____  |
| 9. Inclusion of Children.....   | _____  |
| 10. Vertebrate Animals.....   | _____  |
| 11. Select Agent Research.....  | _____  |
| 12. Multiple PD/PI Leadership Plan.....   | _____  |
| 13. Consortium/Contractual Arrangements.....  | _____  |
| 14. Letters of Support (e.g., Consultants).....   | _____  |
| 15. Resource Sharing Plan (s).....  | _____  |
| <b>Appendix</b> ( <i>Five identical CDs.</i> )  | <input type="checkbox"/> Check if Appendix is Included |

\* Follow the page limits for these sections indicated in the application instructions, unless the Funding Opportunity Announcement specifies otherwise.



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

| BUDGET CATEGORY TOTALS   | INITIAL BUDGET PERIOD<br><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                                       |  |  |  |  |  |
| <b>SUBTOTAL DIRECT COSTS</b><br><i>(Sum = Item 8a, Face Page)</i>          |  |  |  |  |  |
| F&A CONSORTIUM/ CONTRACTUAL COSTS  |  |  |  |  |  |
| <b>TOTAL DIRECT COSTS</b>  |  |  |  |  |  |
| <b>TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD</b>               |  |  |  |  | <b>\$</b>                                |

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

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

---

## RESOURCES

---

Follow the 398 application instructions in Part I, 4.7 Resources.



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 Part III and listed in Part I, 4.1 under Item 14. 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.

DHHS Agreement dated: \_\_\_\_\_

No Facilities And Administrative Costs Requested.

DHHS Agreement being negotiated with \_\_\_\_\_

Regional Office.

No DHHS 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 \_\_\_\_\_ % = F&A costs \$ \_\_\_\_\_

b. 02 year Amount of base \$ \_\_\_\_\_ x Rate applied \_\_\_\_\_ % = F&A costs \$ \_\_\_\_\_

|            |                   |       |                |       |               |                 |  |
|------------|-------------------|-------|----------------|-------|---------------|-----------------|--|
| c. 03 year | Amount of base \$ | _____ | x Rate applied | _____ | % = F&A costs | \$              | _____  |
| d. 04 year | Amount of base \$ | _____ | x Rate applied | _____ | % = F&A costs | \$              | _____  |
| e. 05 year | Amount of base \$ | _____ | x Rate applied | _____ | % = F&A costs | \$              | _____  |
|            |                   |       |                |       |               | TOTAL F&A Costs | \$ <span style="border: 2px solid black; display: inline-block; width: 100px; height: 20px; vertical-align: middle;"></span> |

\*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.):*

---

**4. DISCLOSURE PERMISSION STATEMENT:** If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?  Yes  No

## Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

**Study Title:**

**Total Planned Enrollment:**

| <b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b> |                |              |              |
|--|----------------|--------------|--------------|
| <b>Ethnic Category</b>                                 | <b>Females</b> | <b>Males</b> | <b>Total</b> |
| Hispanic or Latino                                     |                |              |              |
| Not Hispanic or Latino                                 |                |              |              |
| <b>Ethnic Category: Total of All Subjects *</b>        |                |              |              |
| <b>Racial Categories</b>                               |                |              |              |
| American Indian/Alaska Native                          |                |              |              |
| Asian  |                |              |              |
| Native Hawaiian or Other Pacific Islander              |                |              |              |
| Black or African American                              |                |              |              |
| White  |                |              |              |
| More Than One Race                                     |                |              |              |
| <b>Racial Categories: Total of All Subjects *</b>      |                |              |              |

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

## Inclusion Enrollment Report

**This report format should NOT be used for data collection from study participants.**

**Study Title:** \_\_\_\_\_

**Total Enrollment:** \_\_\_\_\_ **Protocol Number:** \_\_\_\_\_

**Grant Number:** \_\_\_\_\_

| <b>PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)<br/>by Ethnicity and Race</b> |         |       |                                    |       |
|--|---------|-------|------------------------------------|-------|
| Ethnic Category  | Females | Males | Sex/Gender Unknown or Not Reported | Total |
| Hispanic or Latino   |         |       |                                    | **    |
| Not Hispanic or Latino   |         |       |                                    |       |
| Unknown (individuals not reporting ethnicity)  |         |       |                                    |       |
| <b>Ethnic Category: Total of All Subjects*</b>   |         |       |                                    | *     |
| <b>Racial Categories</b>   |         |       |                                    |       |
| American Indian/Alaska Native  |         |       |                                    |       |
| Asian  |         |       |                                    |       |
| Native Hawaiian or Other Pacific Islander  |         |       |                                    |       |
| Black or African American  |         |       |                                    |       |
| White  |         |       |                                    |       |
| More Than One Race   |         |       |                                    |       |
| Unknown or Not Reported  |         |       |                                    |       |
| <b>Racial Categories: Total of All Subjects*</b>   |         |       |                                    | *     |
|  |         |       |                                    |       |
| <b>PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)</b>            |         |       |                                    |       |
| Racial Categories  | Females | Males | Sex/Gender Unknown or Not Reported | Total |
| American Indian or Alaska Native   |         |       |                                    |       |
| Asian  |         |       |                                    |       |
| Native Hawaiian or Other Pacific Islander  |         |       |                                    |       |
| Black or African American  |         |       |                                    |       |
| White  |         |       |                                    |       |
| More Than One Race   |         |       |                                    |       |
| Unknown or Not Reported  |         |       |                                    |       |
| <b>Racial Categories: Total of Hispanics or Latinos**</b>  |         |       |                                    | **    |

\* These totals must agree.

\*\* These totals must agree.

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

**DO NOT SUBMIT UNLESS REQUESTED**  
**Renewal Applications Only**  
**ALL PERSONNEL REPORT**

Always list the PD/PI(s). In addition, list all other personnel who participated in the project during the current budget period for at least one person month or more, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort). Use Cal, Acad, or Summer to Enter Months Devoted to Project.

| Commons ID | Name | Degree(s) | SSN<br>(last 4<br>digits) | Role on Project<br>(e.g. PD/PI, Res. Assoc.) | DoB<br>(MM /YY) | Cal | Acad | Summer |
|------------|------|-----------|---------------------------|--|-----------------|-----|------|--------|
|            |      |           |                           |  |                 |     |      |        |

# ***Mailing address for application***

*Use this label or a facsimile*

All applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the United States Postal Service (USPS.) Applications delivered by individuals to the Center for Scientific Review will not be accepted.

Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:

**CENTER FOR SCIENTIFIC REVIEW  
NATIONAL INSTITUTES OF HEALTH  
6701 ROCKLEDGE DRIVE  
ROOM 1040 – MSC 7710  
BETHESDA, MD 20892-7710**

NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817

The telephone number is 301-435-0715. C.O.D. applications will *not* be accepted.

---

A special label for responding to RFAs is not required.

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

Use only if additional space is needed to list additional project/performance sites.

**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:

**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:

**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:

**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:

**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):

---

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

---

| NAME   | POSITION TITLE                   |       |                |
|--|----------------------------------|-------|----------------|
| eRA COMMONS USER NAME (credential, e.g., agency login)   |                                  |       |                |
| EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i> |                                  |       |                |
| INSTITUTION AND LOCATION   | DEGREE<br><i>(if applicable)</i> | MM/YY | FIELD OF STUDY |
|  |                                  |       |                |

---

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.



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