Public reporting burden for this collection of information is estimated to 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001). Do not send completed forms to this address.

Form Approved Through 8/31/2015 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.		
Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
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 *(Street, city, state, zip code)*

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3f. MAJOR SUBDIVISION

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: FAX:

E-MAIL ADDRESS:

4. HUMAN SUBJECTS RESEARCH ☐ No ☐ Yes	4a. Research Exempt ☐ No ☐ Yes	If "Yes," Exemption No.
4b. Federal-Wide Assurance No.	4c. Clinical Trial ☐ No ☐ Yes	4d. NIH-defined Phase III Clinical Trial ☐ No ☐ Yes

5. VERTEBRATE ANIMALS ☐ No ☐ Yes	5a. Animal Welfare Assurance No.

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		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: → ☐ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER

DUNS NO. Cong. District

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name
Title
Address

Tel: FAX:
E-Mail:

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name
Title
Address

Tel: FAX:
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. *(In ink. "Per" signature not acceptable.)*	DATE

Use only if preparing an application with Multiple PDs/PIs. See http://grants.nih.gov/grants/multi_pi/index.htm for details.

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

3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR

3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. NIH Commons User Name
3c. POSITION TITLE	3d. MAILING ADDRESS *(Street, city, state, zip code)*	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX *(Area code, number and extension)* TEL: FAX:	E-MAIL ADDRESS:	

3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR

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3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR

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3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX *(Area code, number and extension)* TEL: FAX:	E-MAIL ADDRESS:	

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:				

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

Number the *following* pages consecutively throughout

the application. Do not use suffixes such as 4a, 4b.

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

Page Numbers

Face Page........ 1

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells........ 2

Table of Contents........

Detailed Budget for Initial Budget Period........

Budget for Entire Proposed Period of Support........

Budgets Pertaining to Consortium/Contractual Arrangements........

Biographical Sketch – Program Director/Principal Investigator (*Not to exceed five pages each*)........

Other Biographical Sketches (*Not to exceed five pages each – See instructions*)........

Resources........

Checklist........

Research Plan........

1. Introduction to Resubmission Application, if applicable, or Introduction to Revision Application, if applicable * ....
2. Specific Aims * ....
3. Research Strategy * ....
4. Inclusion Enrollment Table (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)........

Appendix *(Five identical CDs.)*

☐ Check if Appendix is Included

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

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

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							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	

OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$**
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$**

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

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	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: *Salary and fringe benefits. Applicant organization only*.					
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES					
TRAVEL					
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES					
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*					
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS					
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					**$**

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

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 ADMINSTRATIVE 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 $ ______

*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

PHS Inclusion Enrollment Report

OMB Number: 0925-0001 and 0925-0002

This report format should not be used for collecting data from study participants

*Study Title:

*Delayed onset sudy? ☐ Yes ☐ No

If study is not delayed onset, the following selections are required:

Enrollment Type ☐ Planned ☐ Cumulative (Actual)

Using an Existing Dataset or Resource ☐ Yes ☐ No

Participants Location ☐ Domestic ☐ Foreign

Clinical Trial ☐ Yes ☐ No **NIH-Defined Phase III Clinical Trial?** ☐ Yes ☐ No **Trial Phase?** -- Select Phase--

Phase 0
Phase 1
Phase 1/2
Phase 2
Phase 2/3
Phase 3
Phase 4

Comments:

Ethnic Categories										
Racial 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 or 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

DELETE REPORT NEXT REPORT

To ensure proper performance, please save frequently

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 (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	DoB (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.