

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  <b>Grant Application</b>  <i>Do not exceed character length restrictions indicated.</i>		<b>LEAVE BLANK—FOR PHS USE ONLY.</b>			
		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: _____					
<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>					
TEL: _____ FAX: _____		E-MAIL ADDRESS:			
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes		4a. Research Exempt <input type="checkbox"/> No <input type="checkbox"/> Yes		If "Yes," Exemption No.	
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 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. <i>(In ink. "Per" signature not acceptable.)</i>	
				DATE	



3f. MAJOR SUBDIVISION		E-MAIL ADDRESS:
3g. TELEPHONE AND FAX ( <i>Area code, number and extension</i> ) TEL: _____ FAX: _____		
<b>3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR</b>		
3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. NIH 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:		

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: <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.

Number the following pages consecutively throughout the application. Do not use suffixes such as 4a, 4b.

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

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 – Program Director/Principal Investigator (Not to exceed five pages each)</b> .....	_____
<b>Other Biographical Sketches (Not to exceed five pages each – See instructions)</b> .....	_____
<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 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).....	_____



OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>	
OTHER EXPENSES <i>(Itemize by category)</i>	

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

PHS 398 (Rev. 06/15 Approved Through 8/31/2015)

Page \_\_\_\_

OMB No. 0925-0001  
Form Page 4

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					
<b>SUBTOTAL DIRECT COSTS</b> <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>					\$

---

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

---

PHS 398 (Rev. 06/15 Approved Through 8/31/2015)

Page \_\_\_\_

OMB No. 0925-0001  
**Form Page 5**

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 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				\$ <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

# 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 study?  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
<b>Total</b>	0	0	0	0	0	0	0	0	0	0

DELETE REPORT

NEXT REPORT

To ensure proper performance, please save frequently

**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.