

Johns Hopkins University - University of Maryland
DIABETES RESEARCH CENTER

PILOT AND FEASIBILITY GRANT PROGRAM

INSTRUCTIONS AND APPLICATION MATERIALS

OVERVIEW

The JHU-UMD-DRC **Pilot and Feasibility (P&F) Program** provides limited funding support towards the development of preliminary data sufficient for the application of a research grant or towards the testing of an innovative hypothesis, which might have important implications or yield significant results for diabetes-related research.

The **P&F Program Steering Committee** oversees and administers the P&F grant peer review and funding decisions.

P&F grant applications are peer reviewed by at least two reviewers according to NIH review guidelines. Generally, one reviewer is from an outside institute and one is from either JHU or UMD.

Up to four P&F awards are granted each year, depending on available funds. A second year of support may be awarded after review of progress in the first year and application for continued support.

The P&F program is announced at the beginning of each year. Applications are due at the end of February. Awardees are contacted and informed in April.

Awardees are required to present their proposed work during the Annual Diabetes Research Center Symposium in May. The 12-month funding period starts in July.

Please **submit your application via email** by end of day, on **Friday, February 17, 2017** according to the instructions in the application material.

ELIGIBILITY AND SUBMISSION REQUIREMENTS

ELIGIBILITY

Faculty members at the Johns Hopkins University, University of Maryland or Howard University who are:

- 1) New investigators without current or past NIH support as principal investigators
- 2) Established investigators who have not previously worked in diabetes-related areas
- 3) Established investigators in diabetes-related areas with a proposal for testing the feasibility of a new or innovative idea that is both diabetes-related and represents a clear and distinct departure from his/her ongoing research interests, are encouraged to submit to the P&F Program.

Applications for collaborative projects and translational studies are strongly encouraged.

REQUIREMENTS

- 1) Pilot and Feasibility (P & F) Program Submission Form (see below)
- 2) NIH PHS 398 Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
- 3) NIH PHS 398 Form Page 4: Detailed Budget for Initial Budget Period (July 1st to June 30th of the requested funding period)*
- 4) NIH PHS 398 Form Page 5: Budget for Entire Proposed Project Period (Includes Budget Justification)*
- 5) Biographical Sketch in NIH PHS 398 format (new format).
- 6) Research Plan on NIH PHS 398 Continuation Pages (see section PHS 398: Part I I-42 of PHS 398 Instructions for details; follow all instructions) **Please limit your research plan to 5 pages (letter)**, not including references
- 7) A Brief Candidate Background Description, **limited to 350 words**, on NIH PHS 398 Continuation Page*
- 8) A Brief Description how the JHU-UMD-DRC core services (see JHU-UMD-DRC website) may support the proposed work **limited to 250 words**, on NIH PHS 398 Continuation Page*

Visit the NIH site for further details

<http://grants.nih.gov/grants/funding/424/index.htm#format>

All forms can be downloaded at this link:

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

Please submit completed applications via email to:

Cheikh Seye, MBA

Senior Financial Analyst
Administrative Manager
Department of Pediatrics
Johns Hopkins University
pseye1@jhmi.edu

TIMELINE

Announcement of P&F Grant Application – December/January

Application Deadline –Friday 17. February 2017

Applications Reviewed – March 31. 2017

1st and 2nd Year Awardees Notified – April 20. 2017

Awardees Announced – DRC Annual Symposium, May 3. 2017

After receiving the submissions, the P & F Steering Committee will review the applications for compliance with administrative guidelines. The proposals will be sent for peer review to two reviewers, with at least one reviewer from outside the institutions, We plan to award up to **4** applications this year depending on the number of fundable applications and the availability of funds.

*The proposed budget for each award may be up to **\$50,000 a year in direct costs** (indirect costs will be provided to the budget of the principal investigator/applicant's institute; sub-awards will not be covered by additional indirect costs). One year of funding will be awarded. A second year of funding will be possible if productivity is demonstrated in a written progress report to the Steering Committee, a brief research plan for the second year of funding and presentation of accomplished work at the Diabetes Research Center Symposium.

CONTACT

Cheikh Seye, MBA

Administrative Manager
Johns Hopkins University School of Medicine
Department of Pediatrics
pseye1@jhmi.edu

Andrew Wolfe, PhD

Director, P&F Program
Associate Professor
Johns Hopkins University
awolfe3@jhmi.edu

PILOT AND FEASIBILITY PROGRAM STEERING COMMITTEE

Andrew Wolfe, PhD

Johns Hopkins University
awolfe3@jhmi.edu

Mehboob A. Hussain, MD

Johns Hopkins University
mhussai4@jhmi.edu

Braxton N. Mitchell, PhD

University of Maryland
bmitchel@medicine.umaryland.edu

Hsin-Chieh (Jessica) Yeh, PhD

Johns Hopkins University
hyeh1@jhmi.edu

Johns Hopkins University - University of Maryland
DIABETES RESEARCH CENTER

PILOT & FEASIBILITY PROGRAM

PROJECT AND CANDIDATE DESCRIPTION
(Please include this page with your submission)

Submission Date:

Title of Proposal:

Category: ☐ Basic ☐ Clinical/Translational ☐ Epidemiology/Outcome

Program Director/Principal Investigator/Degree(s):

Position Title and Faculty Rank:

Division and Department:

Institute/University:

Mailing Address:

E-Mail Address:

Phone:

My application meets the following eligibility requirement for a P&F program application (check the appropriate category)

- ☐ New investigators without current or past NIH support as principal investigators
- ☐ Established investigators who have not previously worked in diabetes-related areas
- ☐ Established investigators in diabetes-related areas with a proposal for testing the feasibility of a new or innovative idea that is both diabetes-related and represents a clear and distinct departure from his/her ongoing research interests, are encouraged to submit to the P&F Program.

Department of Health and Human Services Public Health Services <h2 style="text-align: center;">Grant Application</h2> <p style="text-align: center;"><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 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 (<i>Street, city, state, zip code</i>) E-MAIL ADDRESS:			
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT					
3f. MAJOR SUBDIVISION					
3g. TELEPHONE AND FAX (<i>Area code, number and extension</i>) TEL: _____ FAX: _____					
4. HUMAN SUBJECTS RESEARCH No Yes		4a. Research Exempt If "Yes," Exemption No. No Yes			
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 (<i>month, day, year—MM/DD/YY</i>) From _____ Through _____		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) _____		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 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. (<i>In ink. "Per" signature not acceptable.</i>)		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 (<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:		
3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR		
3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. NIH Commons User Name
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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:		
3. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR		
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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):

SCIENTIFIC/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 key personnel in alphabetical order, last name first.

Name	eRA Commons User Name	Organization	Role on Project
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OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Role on Project
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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>
Face Page	<u>1</u>
Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells	_____
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 (<i>Not to exceed four pages each</i>).....	_____
Other Biographical Sketches (<i>Not to exceed four pages each – See instructions</i>).....	_____
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 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)	_____
Appendix (<i>Five identical CDs.</i>)	<div style="text-align: center;"> <input type="checkbox"/> Check if Appendix is Included </div>

* 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

\$

**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: <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 (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.

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

RESOURCES

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

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				\$	<div style="border: 1px solid black; width: 100px; height: 20px;"></div>

*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

Planned Enrollment Report

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

Study Title:

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total	
	Not Hispanic or Latino		Hispanic or Latino			
	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 Inclusion Enrollment Report

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

Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	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										

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