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IDeA Network of Biomedical Research Excellence

Developmental Research Projects Program (DRPP) **Informational Workshop** 2026-2027 Grant Cycle

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NIH/NIGMS P21GM103475-22

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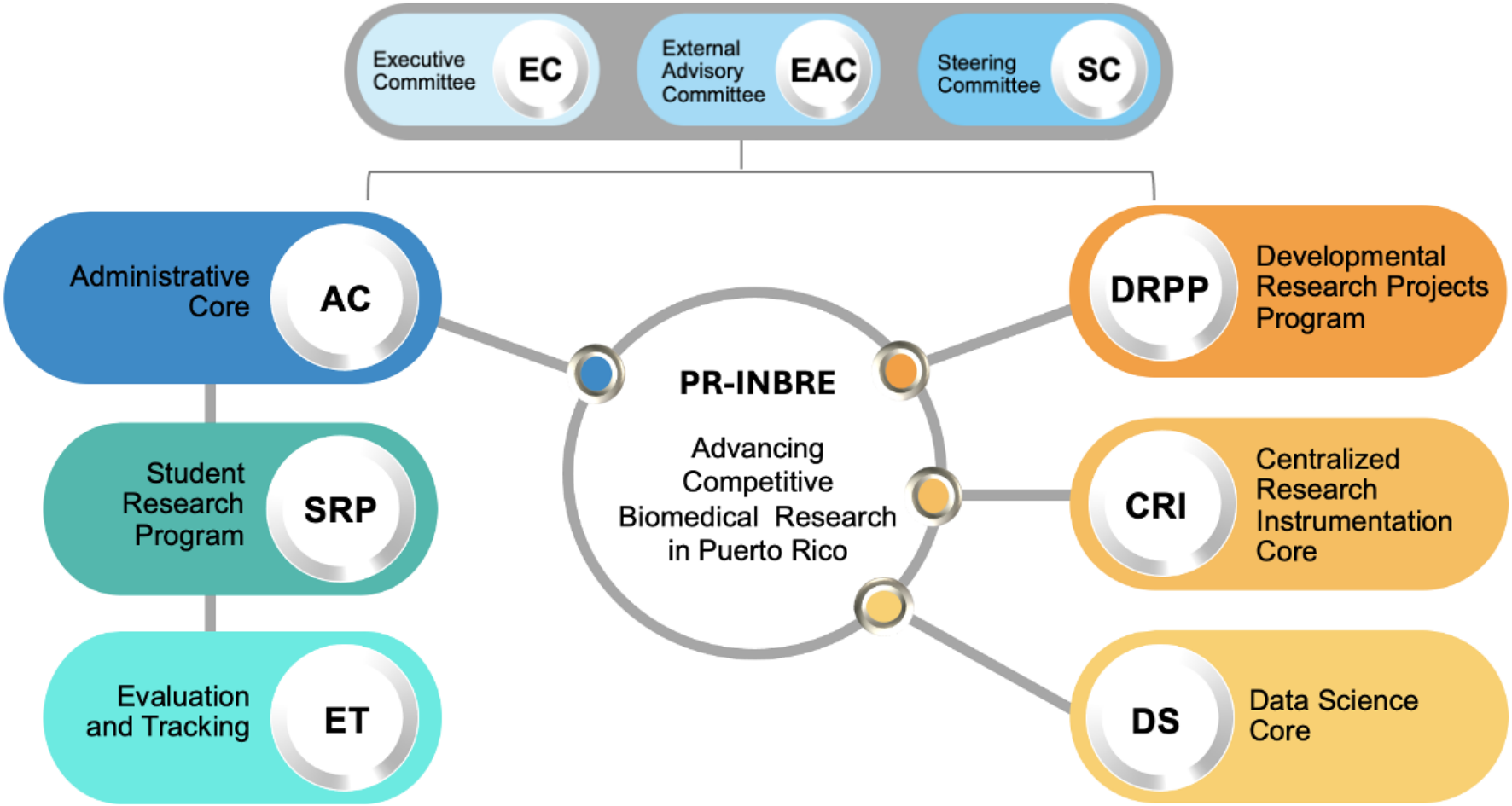
NIH NIGMS

Celebrating Over Twenty Years of Excellence in Development of Biomedical Research in Puerto Rico!

NIH/NIGMS 5P21GM103475

Background

PR INBRE has been active in Puerto Rico since **2001**



Program Officer-NIH

Principal Investigator

External Advisory Committee

Program Coordinator

Evaluation & Tracking

Administrative Core
Program Administrator
Administrative Assistant
Project Coordinator

Steering Committee

Mentoring Coordinator

Bioinformatics
Core Directors

Access to Biomedical Electronic Scientific Information

Data Visualization & Data Analysis

Centralized Research and Instrumentation
Core Director

Developmental Research Projects Program
Core Director
Coordinator

Science, Technology, and Competency Enhancement
Core Director

Community Based Research

DNA Sequencing & Genotyping
Facility Coordinator

Genetics
Facility Coordinator

Proteomics
Facility Coordinator

Metabolomics
Facility Coordinator

ChemTox
Facility Coordinator

Protein Dynamics
Facility Coordinator

PR-INBRE EAC Members

Drs. James Brown, Veronica Martinez, Reinhard Laubenbacher, Orestes Quesada (VP for Res), José Rodríguez-Medina (PI), Sanjay Malhotra, Stephen Cutler

External Advisory Committee

James R. Brown M.Sc., Ph.D.
Visiting Scholar
Ecological and Evolutionary Signal-processing and Informatics (EESI) Lab
Electrical and Computer Engineering, College of Engineering
Drexel University
Philadelphia, PA

Reinhard Laubenbacher, Ph.D.
Dean's Professor of Systems Medicine
Director, Laboratory for Systems Medicine
Division of Pulmonary, Critical Care, and Sleep Medicine
Department of Medicine
University of Florida

Sanjay V. Malhotra, Ph.D., FRSC
Professor & Endowed Chair in Cancer Research
Director, Center for Experimental Therapeutics
Oregon Health & Science University

Stephen J. Cutler, Ph.D.
Dean and Professor
College of Pharmacy
University of South Carolina

Veronica Martinez, Ph.D.
Associate Prof. in Residence
Pathology & Laboratory Medicine
University of California at Davis

INBRE EAC Expertise

- **EAC member Reinharad Laubenbenbacher, Ph.D., Professor, Jackson Laboratory Cancer Center**
  https://www.jax.org/research-and-faculty/faculty/reinhard-laubenbacher
  Bioinformatics

- **EAC Member Dr. James Brown, Director, Computational Biology & GlaxoSmithKline Senior Fellow**
  https://www.linkedin.com/in/james-brown-1b652a6/
  Drug development, Bioinformatics, and computational biology

- **EAC Member Dr. Sanjay Malhotra, Professor, Ohio Health Sciences University**
  https://www.ohsu.edu/school-of-medicine/malhotra-lab/people
  Experimental therapeutics for cancer

- **EAC Member Dr. Stephen Cutler, Dean, College of Pharmacy, University of South Carolina**
  https://www.sc.edu/study/colleges_schools/pharmacy/faculty-staff/cutler_stephen.php
  Natural products chemistry

- **EAC Member Dr. Verónica Martinez-Cedeño, Professor, University of California, Davis.**
  https://biology.ucdavis.edu/people/veronica-martinez-cerdeno
  Expertise in neuroscience, neurodegenerative diseases, autism

PR-INBRE Cores

Bioinformatics Resource Core

Dr. Humberto Ortiz

Dr.Filipa Godoy

Centralized Research Instrumentation Core

Dr. Carmen Cadilla

Dra. Beatriz Zayas

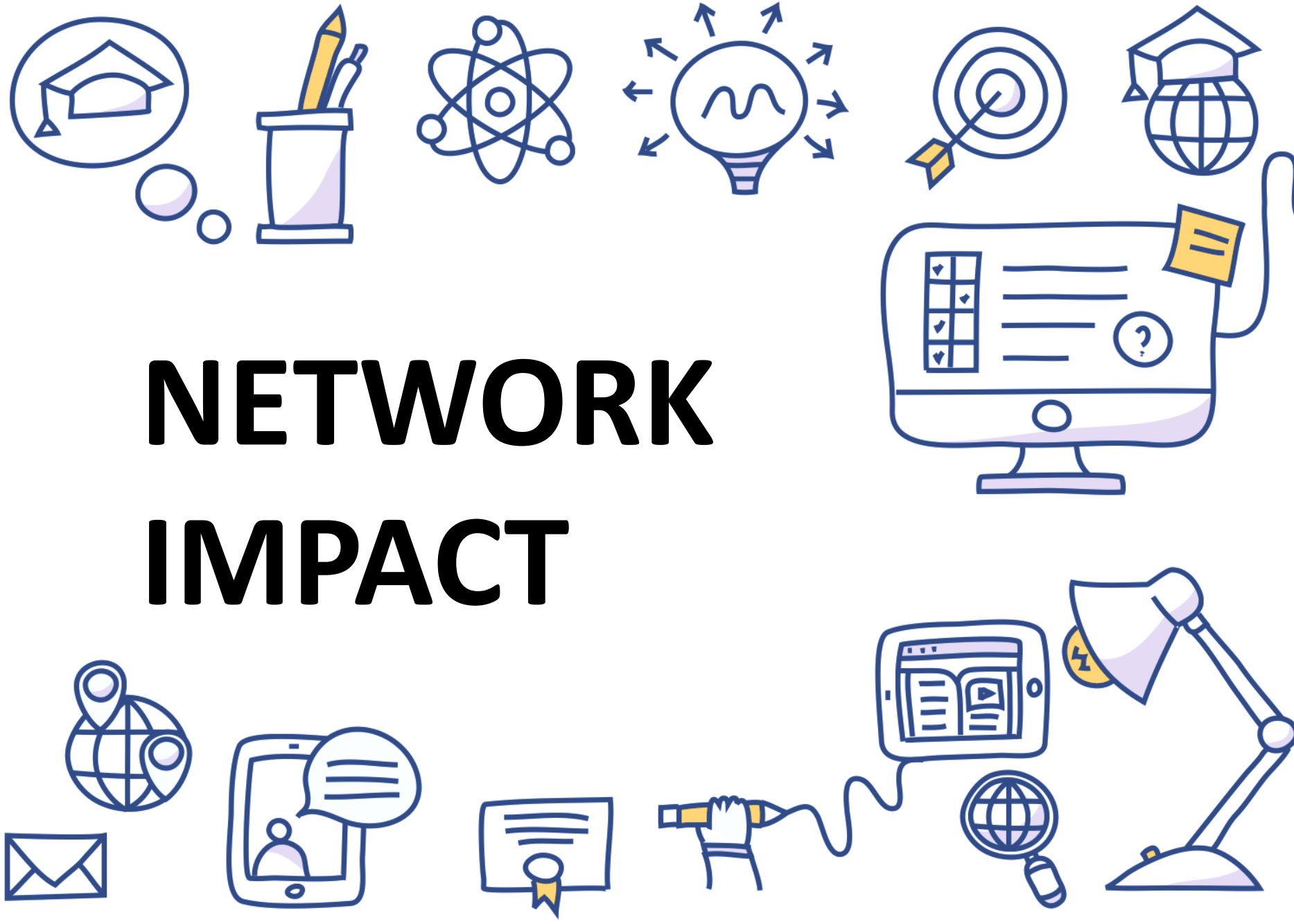
Dr. Luis Vázquez

Science and Technology Competency Enhancement (STCE) Core

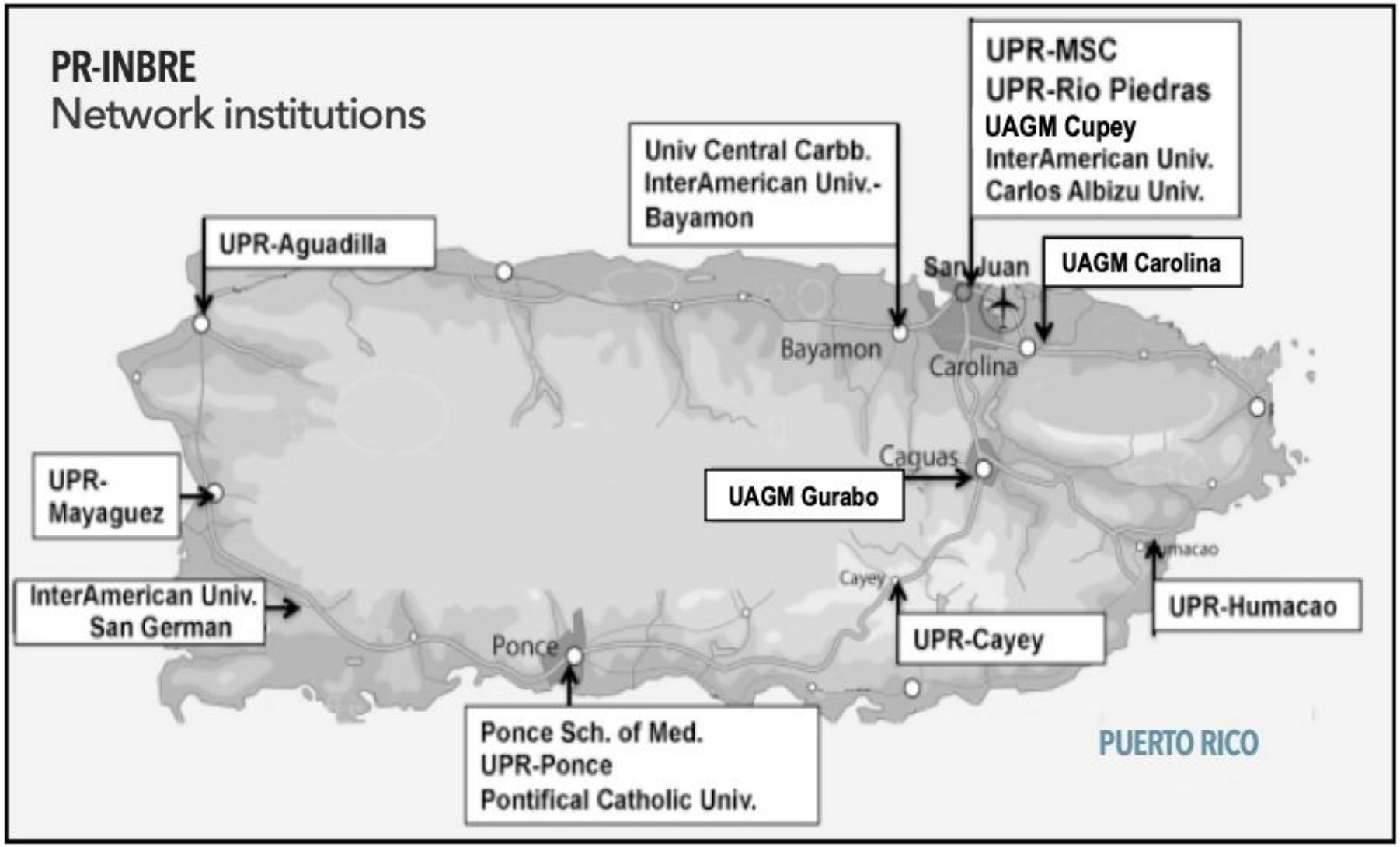
Dr. Loyda Mendez

Developmental Research Project Program (DRPP) Core

Dr. Suranganie Dharmawardhane



NETWORK IMPACT


PR-INBRE
Network institutions
UPR-MSC
UPR-Rio Piedras
UAGM Cupey
InterAmerican Univ.
Carlos Albizu Univ.
Univ Central Carbb.
InterAmerican Univ.-
Bayamon
UPR-Aguadilla
San Juan
UAGM Carolina
Bayamon
Carolina
Caguas
UPR-
Mayaguez
UAGM Gurabo
Cayey
UPR-Humacao
InterAmerican Univ.
San German
UPR-Cayey
Ponce
Ponce Sch. of Med.
UPR-Ponce
Pontifical Catholic Univ.
PUERTO RICO

Build on the established multi-disciplinary research network with a scientific focus to strengthen the lead and partner institutions' biomedical research expertise and infrastructure

Enhance the research capacity of network institutions so they can participate more fully in the competition for NIH awards

Collaborative partnerships
development of areas of potential research
support for faculty development
access to research resources

Provide hands-on research experiences, mentoring, and career development activities for students and faculty at primarily undergraduate institutions, community colleges, and minority serving institutions, and serve as a pipeline to health research careers

Follow the PR-INBRE Website for updates

http://inbre.hpcf.upr.edu/


Like us on
facebook
LinkedIn

Developmental Research Projects Program Core Team

Director: Suranganie Dharmawardhane, Ph.D.
Su.d@upr.edu

Coordinator: Jessyka Rosado
Jessyka.rosado@upr.edu

Core Specific Aims

Specific Aim 1: Provide research support to promising investigators

Specific Aim 2: Implement a structured mentoring program for the DRPP investigators

Specific Aim 3: Enhance the research infrastructure of the PUIs and reinforce access to core facilities

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OUTLINE

1. PR-INBRE Developmental Research Projects Program (DRPP) Funding Process Overview
2. New NIH Regulations
3. PHS 398 Forms- What We Expect
4. Composition of an Abstract/Summary
5. Specific Aims Page
6. Approach section
7. Additional attachments

Developmental Research Projects Program (DRPP)
2P20GM103475-22
Budget Requested: 1.5 million

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Aim 1:

- Full project funding ($125,000/yr)

  For 3-5 years

- Pilot projects $50,000/yr

  Renewable for 2 years based on merit

- 2 Summer Research positions from PUIs

Table 6. DRPP Measurable outcomes of success.
Research project grant applications (R15, R03, R21, R35, or R01) submitted by the end of the 2nd year of funding, using preliminary data from the RP or PP.
Peer-reviewed manuscripts in press, submitted, or ready for submission at the end of the 2nd year of funding.
Productive collaborations among DRPP investigators, mentors, and experienced investigators from institutions in the PR-INBRE network and other IDeA states.
Attendance and presentations (oral and poster) at national and international conferences.

New This Cycle!

Prioritize proposals with biomedical relevance regardless of the research focus or institution

- **Full project eligibility changed!**
  - ✓All network PUIs and OIs are eligible for full project funding
  - ✓Early-stage investigators (assistant professor rank and within 10 yrs of finishing PhD preferred)

    Not more than five years as an Assistant Professor!

  - ✓All network researchers for pilot project funding opportunities
  - ✓Full project grantees are expected to obtain independent R-type (R15, R16, R01, MIRA) funding after 5 years

- Fund and train **postdoctoral fellows** to perform research and teaching at PUIs and provide a conduit of junior faculty for future full projects.

- 2 **Summer Research positions** from PUIs ($25,000)

Specific Aim 3: **Enhance the research infrastructure of the PUIs and reinforce access to core facilities.**

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Aim 3A. Small instrumentation grants for PUIs.

- $25,000 each, non-renewable for small instrument needs

Aim 3B. Mini grants for feasibility studies.

- ~$5-10,000 each, nonrenewable for collaborative projects- grant or manuscript submission

To **use the INBRE core facilities.**

Stay tuned for FOAs!

Please, show how you would use the core services!

Contact CRI Director at carmen.cadilla@upr.edu

Dr. Beatriz Zayas

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Include letter of collaboration from the cognizant core director

ChEMTox Biotesting

Translational Proteomics

Dr. Loyda Melendez

Metabolomics

Dr. Nataliya Chorna

Centralized Research Instrumentation

Dr. Riccardo Papa

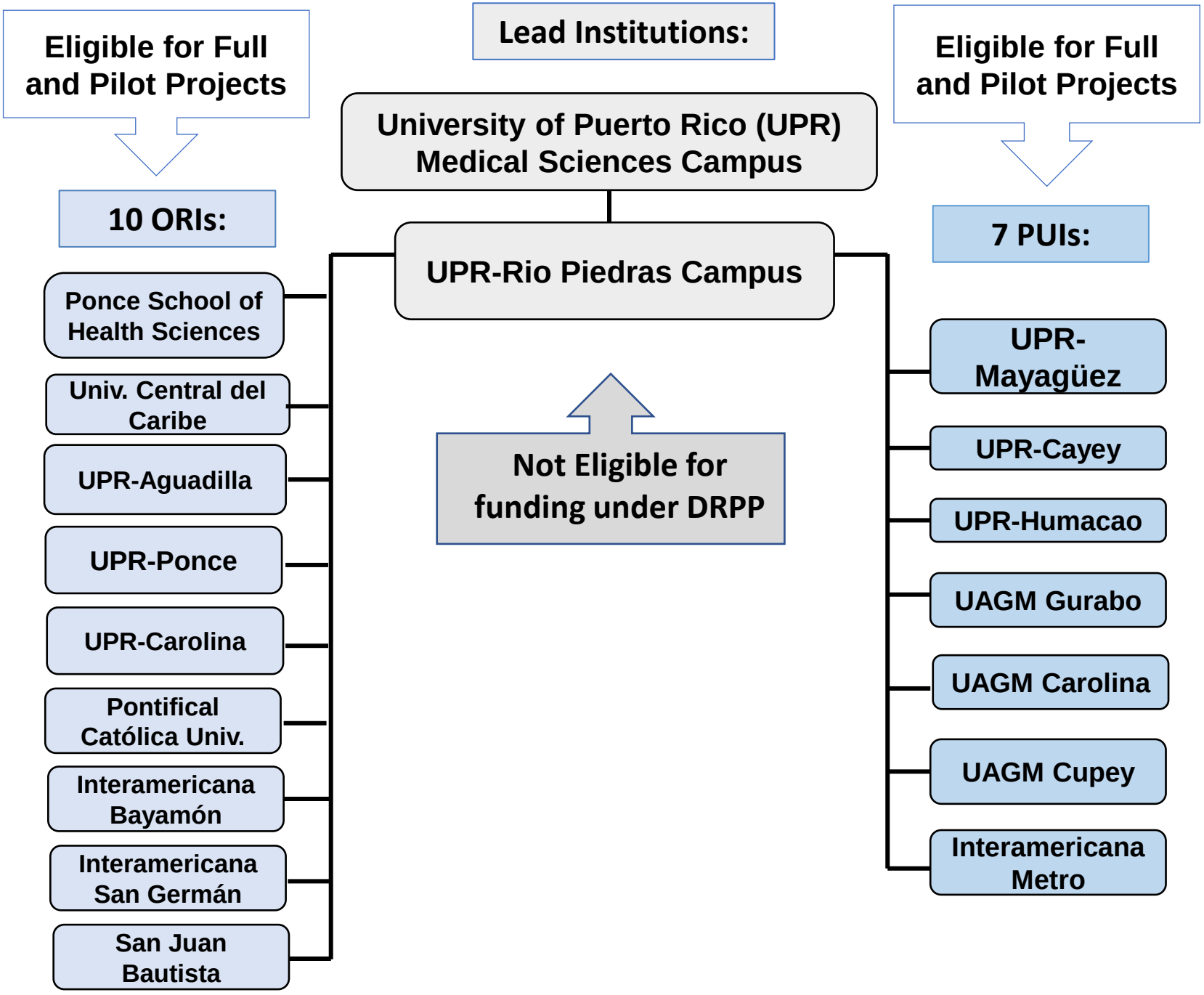
Sequencing Genomic Facility

Human Genetics and Genomics

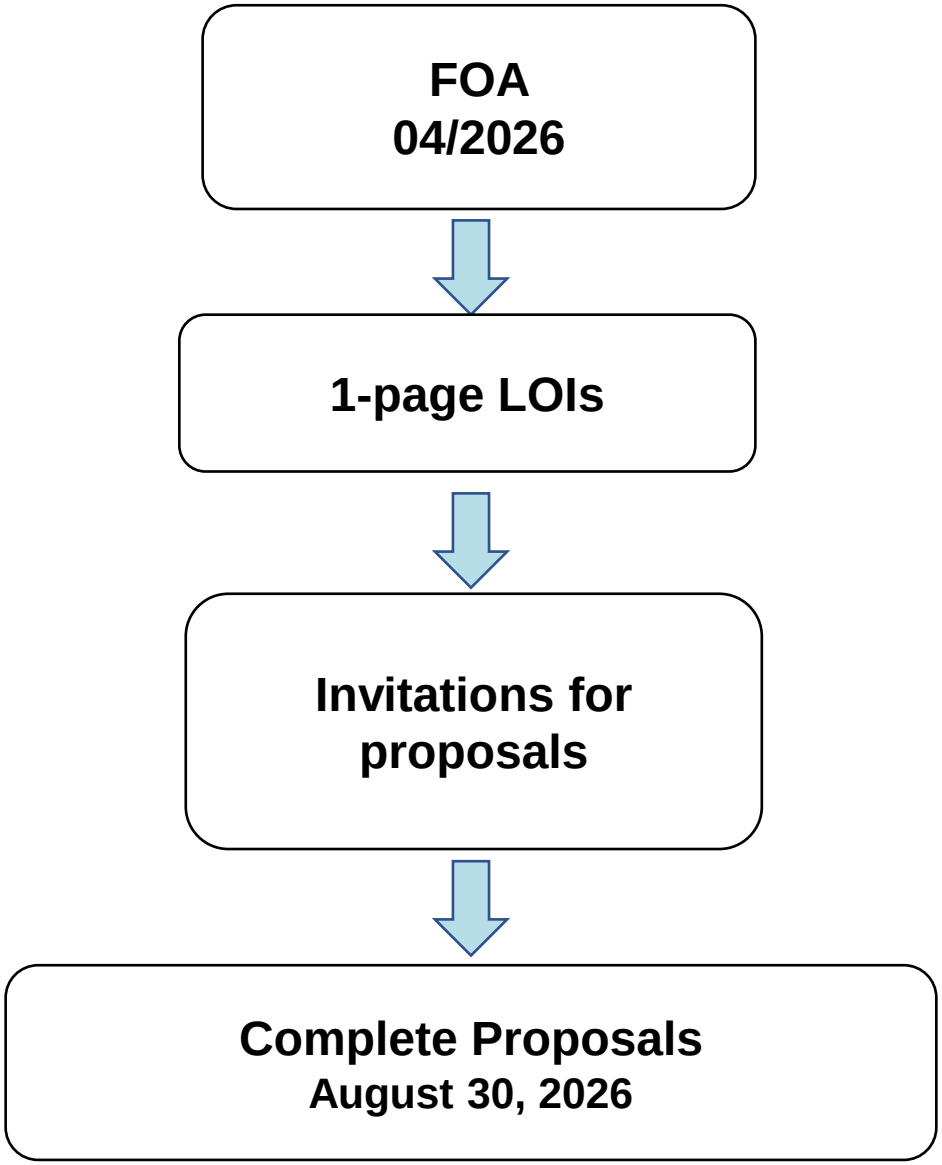
Dr. Carmen Cadilla

Microbiome

Dr. Filipa Godoy


Eligible for Full and Pilot Projects
Lead Institutions:
Eligible for Full and Pilot Projects
University of Puerto Rico (UPR) Medical Sciences Campus
10 ORIs:
UPR-Rio Piedras Campus
7 PUIs:
Ponce School of Health Sciences
Univ. Central del Caribe
UPR-Aguadilla
UPR-Ponce
UPR-Carolina
Pontifical Católica Univ.
Interamericana Bayamón
Interamericana San Germán
San Juan Bautista
Not Eligible for funding under DRPP
UPR-Mayagüez
UPR-Cayey
UPR-Humacao
UAGM Gurabo
UAGM Carolina
UAGM Cupey
Interamericana Metro

PR-INBRE DRPP Funding Cycle 1



What happens to your application?

Applications due August 30, 2026
Inbre_proposals@hpcf.upr.edu

September 2026: First Tier Review
1 Reviewer INBRE Administrative core
1 Reviewer in PR
1-2 Reviewers outside of PR

September 2026: Internal Review Committee:
Second Tier Review
Impact Factor ≤35 (pilot) and ≤30 (Full)
Technical merit, **S**cientific excellence, and **P**rogrammatic relevance.

September 2026: Third Tier Review
External Advisory Committee

Final Approval from NIH Program Office for Compliance
October 2026

Overall Impact:
The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

e.g. Applications are addressing a problem of high importance in the field. May have some or no weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment)

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

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Funding Opportunity Announcement (FOA)

- Please, use PHS398 forms (SF424 forms will not be accepted)!
- A developmental mentoring/collaboration plan is mandatory:

	Full Proposals	Pilot Proposals
Application page limit	**12**	**6**
Mentoring/Collaboration Plan	Should be included within the 12-page limit	Should be included within the 6-page limit
Required Support Letters	Letter or e-mail from the mentor and a letter of support from the Department chair detailing full-time employment as faculty with approval of at least 50% release time.	Letter or e-mail from the collaborator and a letter of support from the Department chair detailing full-time employment as faculty with approval of at least 25% release time.
IRB and IACUC Applications	Evidence required if applicable	Evidence required if applicable
Number of anticipated awards	6	6
Total Period Funding	$125,000	$50,000
Maximum Project period	5.0 yrs	2.0 yrs

If the project involves OMICS or statistics- please consult with PRINBRE Bioinformatics core! http://inbre.hpcf.upr.edu/bioinformatics-resource-core/

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

Grant Application PHS 398 (Revised 03/2020)

Form Page 1: Face Page
Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Biosketches 5 page), Other Significant Contributors, and Human Embryonic Stem Cells
Form Page 3: Research Grant Table of Contents
Form Page 4: Detailed Budget for Initial Budget Period
Form Page 5: Budget for Entire Proposed Project Period (Modular Budget Form, with budget justification)
Resources Format Page
Checklist Form
For Human subjects research:
Planned Enrollment Report
Cumulative Inclusion Enrollment Report

Please, do not scan your forms! Fill in Microsoft word, then convert to pdf!

Form Page 1

Form Approved Through 02/28/2023 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)* From	Through	7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs ($)	7b. Total Costs ($)	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. *(In ink. "Per" signature not acceptable.)*	DATE

PHS 398 (Rev. 03/2020) Face Page **Form Page 1**

Title of Project: 81 characters
Must be the same as your LOI, approved IACUC or human IRB protocol. *The title should capture the essence of project objectives*

Human subjects and animal research: Yes or NO
If Yes: add correct Federal-wide assurance number for human subjects research
If No to 4- do not fill out 4a-4d
Add animal welfare assurance No. only if you say yes to animal research

Dates of Proposal:
Initial: 01/11/26-08/30/27?
Pilot=$50,000
Total:
Pilot: 01/11/26-08/30/28
=$50,000+50,000=$100,000

Please include a signature

Form Page 2

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

PROJECT SUMMARY (See instructions):

Please, fill this space.
Do NOT give a separate attachment!

RELEVANCE (See instructions):

Why should NIH fund it?

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:		

Project Summary:

30 lines

Hypothesis-Driven Research

- Concise presentation of the project.
- Include the project's broad, long-term objectives and specific aims
- Include a description of the research design and methods for achieving the stated goals
- Write in plain language, so even a non-scientist can understand the importance of the project

What are you going to do, why you are doing it, what do you hope to find?

Project Relevance:

- Maximum 3 sentences on the biomedical relevance of the project.

Code Words in Project Summary

LONG TERM GOAL/S

CRITICAL NEED

GAP IN KNOWLEDGE

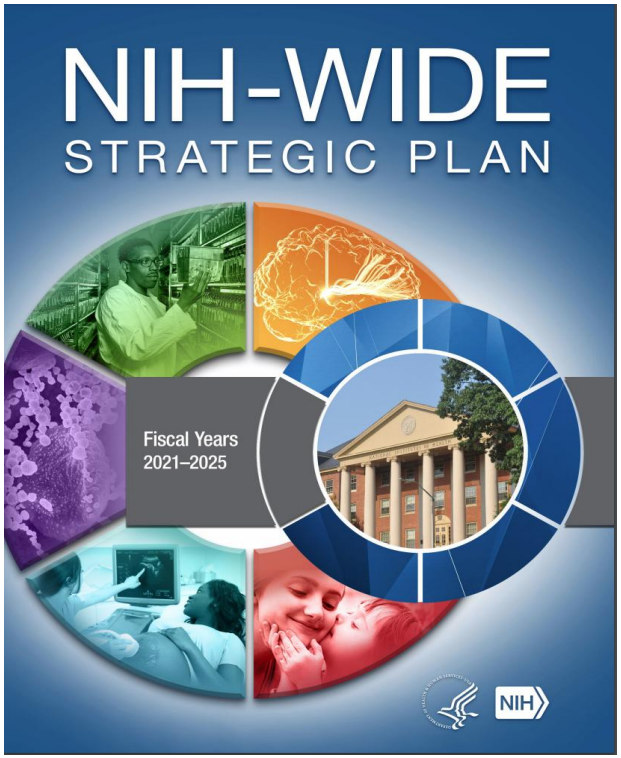
OBJECTIVE

RATIONALE

CENTRAL HYPOTHESIS SPECIFIC AIMS

IMPACT

RELEVANCE:
3 sentences on health relevance



PROJECT NARRATIVE

Genetically similar viruses can cause widely disparate diseases through manipulation of innate immune pathways. This project uses mammalian reovirus, a powerful experimental model for studies of virus pathogenesis, to identify mechanisms for strain-specific differences in cellular responses to infection that influence organ-specific disease. As other pathogenic microbes employ similar strategies, this research program will uncover conserved mechanisms of infectious disease pathogenesis.

Table of Contents

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

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

Please, note that the **Bibliography (References)** are included after the Research Strategy and is not constrained by page limits.

Who is doing the study?

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

Chose Wisely…..

Include NIH Biosketches and letters

Key personnel: Ph.D./MD

PI

Mentor

Collaborator

Post Doc

Biographical Sketch Common Form

Description

The Biographical Sketch Common Form is a standardized document used to summarize the qualifications, experience, and relevant contributions of key personnel for federally funded research projects.

It ensures consistency, transparency, and compliance with federal disclosure requirements, particularly those outlined in National Security Presidential Memorandum - 33 regarding foreign government-sponsored programs and talent recruitment activities.

NIH uses the Biographical Sketch Common Form together with the NIH Biographical Sketch Supplement.

How to Access

> **Use SciENcv**
> SciENcv must be used to prepare the form. There is not a blank template that can be downloaded and completed outside of SciENcv.

- SciENcv provides a single interface to complete both the Biographical Sketch Common form and the NIH Biographical Sketch Supplement and produces a combined PDF document to include in applications and progress reports.
- Investigators who transfer information from an existing SciENcv document (e.g., National Science Foundation Biographical Sketch, NIH Biosketch in different format) to the NIH Biographical Sketch Common Form format must carefully review the resulting document for accuracy and completeness
- Find additional tips about SciENcv in NOT-OD-26-018.

Biographical Sketch-NEW

https://grants.nih.gov/grants-process/write-application/forms-directory/biographical-sketch-common-form

https://grants.nih.gov/faqs#/common-forms-biographical-sketch-current-pending-support.htm

https://www.ncbi.nlm.nih.gov/sciencv/

A. Products

The new NIH Biographical Sketch Common Form splits research outputs into Section C: Products, allowing a maximum of 10 total entries divided into two distinct lists: up to 5 products closely related to the proposed project, and up to 5 other significant products highlighting broader scientific contributions

Accepted Product Types

Publications: Peer-reviewed papers, books, and manuscripts with proper identifiers (like PMC IDs when applicable).

Digital & Research Data: Datasets and digital archives.

Software & Code: Research software, code repositories, and tools.

Intellectual Property: Patents and licensed technologies.

Other Media: Presentations, websites, or established research-driven commercial products/businesses.

Management Rules

Products must be pulled directly from connected profile platforms like NCBI My Bibliography or an integrated ORCID account.

Full citations are confined strictly to this section; narrative sections (like the Supplement's contributions to science) cannot contain full citations but can reference these numbered products.

Biosketch Supplement

There is no page limit to the NIH Biosketch

The Biosketch Supplement has the following limitations:
Personal Statement (*3500 characters)*
Briefly describe why you are well-suited for your role(s) in this project. Relevant factors: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to.
No references! You may not include references in your contributions to science or the personal statement. You may refer to the references in your products section, but you cannot cite them.

Honors: 15 Maximum

Contributions to Science: Briefly describe **up to five** of your most significant contributions to science, but each contribution may not exceed 2000 characters.

You can only download a PDF document that is already formatted.
You cannot make formatting changes, but you can edit.

The National Institutes of Health (NIH) strictly prohibits individuals participating in NIH-supported research from being party to a Malign Foreign Talent Recruitment Program (MFTRP)

Applicant and Recipient Institution Responsibilities:

- Work with faculty and other staff to make sure that all applications, progress reports (Research Performance Progress Reports), and Just in Time submissions include an accurate and complete account of all sources of research support, and relevant affiliations for individuals named as senior/key personnel

- Ensure that all "Investigators" (42 CFR 50.603) who plan to participate in, or are participating in NIH-funded research, disclose their "significant financial interests" to the institution in accordance with regulation and institutional policy for the institution's determination and management of a financial conflict of interest

- Ensure that all reports and communications submitted to NIH are complete and accurate

The National Institutes of Health (NIH) strictly prohibits individuals participating in NIH-supported research from being party to a Malign Foreign Talent Recruitment Program (MFTRP)

Applicant and Recipient Institution Responsibilities:

•Protect proprietary information and sensitive and confidential data as part of the proper stewardship of federally funded research

•Take all reasonable and appropriate actions to prevent the inadvertent disclosure, release, or loss of sensitive personal information

• Immediately notify NIH of developments that have a significant impact on NIH-supported activities

•Disclose information throughout the grant process, from updating a senior/key personnel's biosketch and other support, submitting an application, progress reporting, and submitting final reports, or anytime there is a significant change that impacts the NIH award

• Obtain NIH prior approval for inclusion of any foreign components to an NIH award!

Do not include foreign collaborators in your publications!

NIH's Implementation of Common Forms for Biographical Sketch and Current and Pending (Other) Support for Due Dates on or after January 25, 2026
Notice Number: NOT-OD-26-018

Malign Foreign Talent Recruitment Program Certification:

- NIH will require MFTRP certifications from applicants and individuals identified as senior/key personnel with the implementation of the Common Forms for Biographical Sketch and Current/Pending (Other) Support.
- **Institutional Certification:** In accordance with Section 10632 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19232), the AOR must certify, via their signature on the face page of the application, that all individuals identified by the applicant as senior/key personnel have been made aware of and have complied with their responsibility under that section to certify that the individual is not a party to a malign foreign talent recruitment program.
- **Individual Certification at the time of the application**: In accordance with Section 10632 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19232), each individual identified by the applicant as a senior/key person must certify on their Common Form for Biographical Sketch, attached on the R&R Senior/Key Person Profile (Expanded) Form, that **they are not a party to a malign foreign talent recruitment program.**
- **Annual Certification at the time of the RPPR**: For NIH awards with RPPRs submitted on or after January 25, 2026, individuals serving as senior/key personnel must certify annually to their participation or non-participation in an MFTRP by uploading a certification statement in Section G.1.

New! NIH Training Mandate for Senior/Key Personnel

*The National Institutes of Health (NIH) strictly prohibits individuals participating in NIH-supported research from being party to a **Malign Foreign Talent Recruitment Program***

Effective October 2025, NIH requires institutions to provide formal training to all faculty and researchers identified as senior/key personnel: **NOT-OD-25-133**
Training: https://www.secure-center.org/ctm

Certificate of Completion

This certificate is presented to

Suranganee Dharmawardhane

For successfully completing

Research Security Training (Federal Modules 1-4 Condensed and Combined)

Date Completed: 4/22/2026

Other Support: New! Also in SciENCV

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

PHS OTHER SUPPORT
For All Application Types – DO NOT SUBMIT UNLESS REQUESTED

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual:
Commons ID:

Other Support – Project/Proposal

*Title:

*Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

Other support includes all resources made available to researchers or senior key personnel in support of, and/or related to, all of their research endeavors, regardless of whether they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

This includes resources and/or financial support from all foreign and domestic entities available to the researcher. This includes, but is not limited to, financial support for laboratory personnel and the provision of high-value materials that are not freely available (e.g., biologics, chemicals, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

Name of Individual:
Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##.##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

*Estimated Dollar Value of In-Kind Information:

***Overlap** (summarized for each individual):

I, PD/PI or other senior/key personnel, 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: _____

Date: _____

If in-kind contributions **are intended for use on the project being proposed** to NIH in this application, the information must be included as part of the Facilities and Other Resources or Equipment section of the application and need not be replicated on this form.

In-kind contributions **not intended for use on the project/proposal being proposed** in this application must be reported. If the time commitment or dollar value is not readily ascertainable, reasonable estimates should be provided.

Other Support has to be Certified!

Certification:

I understand that I have been designated as a covered individual by the Federal funding agency.

I certify to the best of my knowledge and belief that the information contained in this Current and Pending (Other) Support Form is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729-3733 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to DOE's funding decision, and (2) I have a responsibility to update the disclosures during the project period of the award should circumstances change which impact the responses provided above.

I also certify that, at the time of submission, I am not a party in a malign foreign talent recruitment program. I further understand should I take action to involve myself with a Malign Foreign Talent Recruitment Program during the period of performance of the award, I must notify the recipient's Authorized Agent immediately, but no later than five business days of taking such action and immediately recuse myself from all DOE awards.

If this is an R&D proposal/award, I also certify to the following statement:

Within the past 12 months I have completed research security training meeting the requirements in SEC. 10634(b) of 42 USC 19234.

Certified by Dharmawardhane, Surangaie in SciENcv on 2026-08-12 05:52:41

Contents of a Research Plan

Page:32, PHS398 instructions

1. Introduction to Application (Resubmission or Revision Applications only)
2. Specific Aims
3. Research Strategy (Significance, Innovation, and Approach)
4. Bibliography and References Cited/Progress Report Publication List
5. Vertebrate Animals
6. Select Agent Research
7. Multiple PD/PI Leadership Plan
8. Consortium/Contractual Arrangements
9. Letters of Support (e.g., Consultants)
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources
12. PHS Human Subjects and Clinical Trials Information

SPECIFIC AIMS

One Page (not included in 6 or 12 page limit)

- The single most important section in the grant
  - ✓It's the master plan for the rest of the proposal
  - ✓You engage or lose the Reviewer on this page
- It's the most difficult section to write
  - ✓The logic of each aim must be compelling
  - ✓The answers must be important to the field
- Write Aims that you are excited about!
  - ✓Think about the research plan before you start writing

Specific Aims

- Provides an overview of the details - tells what your proposal is about, and how you will get there
  - ✓ start with 1 - 2 paragraph general overview
  - ✓ then list AIMS, each clearly defined
  - ✓ end with a brief statement of what you will learn if successful
- The reader must finish this section convinced that the proposed research is significant and that you have a feasible approach
- The aims should be clearly and concisely stated; many also include sub-aims
- Typically 2 - 4 related aims. Later aims should NOT depend on the success of previous aims

Specific Aims

- Whenever possible – test a hypothesis in the specific aim title
  - ✓You want the Reviewer to know that your work is hypothesis-driven
  - ✓Don't make the Reviewer work to figure out what the hypothesis is
- The goal of the aim should be to understand the mechanism, even if the experiments are largely descriptive
- 1-2 Specific Aims for a 2-year grant – each aim is a manuscript, or is a significant part of a publication
- The Specific Aims should be detailed but far-reaching – the Aims should not be a list of experiments

Specific Aims: Don’ts

- Write your Aims early – some may fall apart as you design a plan to test them or discuss them with colleagues.
- Try to limit this section to one page – it’s a roadmap to the rest of the proposal, and it must include the logic behind your aims.
- Don’t assume your Reviewer is an expert in your particular area – so write Aims for a non-expert.
- Don’t state a hypothesis that you cannot actually test with the experiments you are proposing.
- Avoid using phrases like: To correlate… To describe… To develop, these help get your grant pegged as “too descriptive”.
- Avoid wishy-washy, passive tense, or flowery language – instead write your aims in active form with strong, meaningful verbs.

Criteria for scoring the approach section

NIH New Guidelines after January 25, 2025: Changes to Review Policy

1. **Enabling peer reviewers to better focus on answering the key questions necessary to assess the scientific and technical merit of proposed research projects:**
   - ✓ Should the proposed research project be conducted?
   - ✓ Can the proposed research project be conducted?
2. **Mitigating the effect of reputational bias** by refocusing the evaluation of investigator/environment to within the context of the proposed research.

Enhancing Reproducibility in NIH Applications: Resource Chart

NIH Grants Policy Website: http://grants.nih.gov/reproducibility/index.htm

NIH Website: https://www.nih.gov/research-training/rigor-reproducibility

4 AREAS OF FOCUS	WHAT DOES IT MEAN?	WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?
Rigor of the Prior Research	A careful assessment of the **rigor of the prior research** that serves as the key support for a proposed project will help applicants identify any weaknesses or gaps in the line of research. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project *See related FAQs, blog post	**Research Strategy** ➢ Significance ➢ Approach
Scientific Rigor (Design)	**Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. *See related FAQs, blog post, examples from pilots	**Research Strategy** ➢ Approach
Biological Variables	**Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. *See related FAQs, blog posts, article	**Research Strategy** ➢ Approach
Authentication	**Key biological and/or chemical resources** include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not have been generated with NIH funds and: • may differ from laboratory to laboratory or over time; • may have qualities and/or qualifications that could influence the research data; • are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan. *See related FAQs, blog post, examples	**Other Research Plan Section** ➢ Include as an attachment ➢ Do not include in the Research Strategy.

****This chart is based on general instructions for research grant applications submitted for January 25, 2019 due dates and beyond. It should only be used as a guide. For all applications, please read the applicable Funding Opportunity Announcement (FOA) & Application Guide for specific instructions.**

Five regulatory criteria reorganized into three factors

For due dates before Jan 25, 2025

(all considered in overall impact score)

- **Significance** - scored
- **Investigator(s)** - scored
- **Innovation** - scored
- **Approach** - scored
- **Environment** - scored

For due dates on/after Jan 25, 2025

- **Factor 1 : Importance of the Research**
  - Significance, Innovation
  - Scored 1 - 9
- **Factor 2 : Rigor and Feasibility**
  - Approach (also includes Inclusion and Clinical Trial (CT) Study Timeline)
  - Scored 1 - 9
- **Factor 3 : Expertise and Resources**
  - Investigators, Environment
  - Evaluated as appropriate or gaps identified; gaps require explanation
  - Considered in overall impact; no individual score

NIH New Guidelines

Factor 1. Importance of the Research
Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field or more broadly. Assess whether the application addresses an important gap in knowledge in the field, solves a critical problem, or creates a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data), and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods, or technologies or uses existing concepts, methods, or technologies in novel ways to enhance the overall impact of the project.

APPROACH: 6-page pilot proposals, 12-page full proposals
Significance and Innovation

0.5-1 pages **SIGNIFICANCE**

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Should lead the reader to each question or hypothesis that you're testing in each aim
- State this explicitly
- This section must explain why the Study Section should fund your proposal rather than the next one

What is the "value added" to your field if you're able to do the work?

Scored Review Criteria 1-9: Significance

- Does the project address an important health problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Common Problems with Significance and Innovation**
  - ✓ Not significant, exciting, or new research
  - ✓ Lack of compelling rationale for experiments
  - ✓ Incremental or low-impact research
  - ✓ Weak or little biological, biomedical, or behavioral relevance

INNOVATION (PHS 398: page 34)

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches, or methodologies, instrumentation, or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches, methodologies, instrumentation, or interventions.
- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches, or methodologies, instrumentation, or interventions?
- Are the concepts, approaches, or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is it a refinement, improvement, or new application of theoretical concepts, approaches, methodologies, instrumentation, or interventions proposed?

Factor 2. Rigor and Feasibility
Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).
- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.

Factor 2. Rigor and Feasibility
Approach

- For applications involving human subjects or vertebrate animals, also evaluate:
  - the rigor of the intervention or study manipulation (if applicable to the study design).
  - whether outcome variables are justified.
  - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
  - whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Scientific Premise/Rigor of prior research

In the ***Significance section of your Research Strategy, describe*** the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

The ***scientific premise*** for an application is the research that is used to form the basis for the proposed research question(s). NIH expects applicants to describe the general strengths and weaknesses of prior research they cite as crucial to supporting the application. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.

Preliminary Studies
(can be in Significance or in Research Strategy)

- In order of Specific Aims
- You don't have to know the outcome of each experiment before the grant is submitted
- You DO have to:
  - ✓Show that you can perform all the necessary techniques and methods (Letters of Collaboration)
  - ✓You are committed to this area of research and are off and running
  - ✓New techniques are feasible, reliable, and yield interpretable data
  - ✓**Show that the preliminary data has scientific rigor**

RESEARCH STRATEGY

Specific Aims are fleshed out with the actual experimental approach

- ✓ **Rationale** (1 paragraph) -- logic
- ✓ **Experiments** – How? Abbreviated Methods
  CONTROLS (positive and negative)
- ✓ **Analysis and Interpretation** – what will the results mean?
- ✓ **Pitfalls and Alternative Approaches**

Your research strategy needs to answer 4 essential questions:

- What do you intend to do?
- Why is the work important?
- What has already been done?
- How are you going to do the work?

Scored Review Criteria: 1-9

Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?
- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- If the project involves Human Subjects Research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Approach: page 34: PHS398 guidelines:

I. Describe the **overall strategy, methodology** and analyses to be used to accomplish the specific aims of the project.

- Describe the experimental design and methods proposed, and how they will achieve robust and unbiased results?
- Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.

II. Discuss **potential problems, alternative strategies**, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stages of development, describ e any strategy to establish feasibility, and address the man agement of any high-risk aspects of the proposed work.

Approach:

III. Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.
For example, strong justification from the scientific literature, prelim inary data, or other relevant considerations
must be provided for applications proposing to study only one sex.

IV. If your study(s) involve **human subjects**, you are expected to expl ain how relevant biological variables are important to the proposed experimental design and analyses.

V. The sections on the ***Inclusion of Women and Minorities*** and ***Inclusi on of Children*** can be used to expand your discussion on inclusion a nd justify the proposed proportions of individuals (such as males and f emales) in the sample.

*Please refer to **NOT-OD-15-102** for further consideration of NIH expectations about sex as a biological variable.*

Common problems with experimental approach

- Lack of a clear, strong hypothesis or questions
- Too ambitious, too much work proposed
- Unfocused or unrelated aims, unclear goals, not integrated
- Limited or narrow aims
- Too many unnecessary experimental details
- Not enough detail on approaches being developed
- Not enough preliminary data to show rationale or significance of project
- Unconvincing preliminary data
- Lack of appropriate controls
- Not directly testing the hypothesis
- Correlative or descriptive data
- Experiments not directed towards mechanisms
- No discussion of alternative models or hypotheses
- No discussion of potential pitfalls
- No discussion of data interpretation or future directions

Factor 3. Expertise and Resources

Investigator(s)

- Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work.
- For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

- Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

Developmental Plan

Mandatory Training/Developmental Plan:

- Include a detailed training and Individual Development Plan (IDP). Identify weaknesses and indicate how collaborators and mentors can address them. Discuss how mentors and collaborators will specifically help the proposed research and your IDP.
- Indicate plans for training, conferences, publications, and grant applications.
- Explain how you would use this mechanism to leverage independent federal funding.

The INBRE Leadership and the EAC can help you!

INVESTIGATORS

- Are the PD(s)/PI(s), collaborators, and other researchers properly trained and well-suited to the project?
- Are the collaborators essential for the successful completion of the proposed aims?
- If Early-Stage Investigators (≤10 yrs from Ph.D.) or New (No R01) Investigators, or in the early stages of independent careers, do they have appropriate experience and training?
- Do early/new investigators have a tenure-track or equivalent position with a firm institutional commitment to space, salary, startup funds, etc.
- If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- Does the mentor have adequate expertise and commitment to mentor the PI?
- Is the Training Plan well developed?

Common Problems with reviewers concerning the investigators

- No demonstration of expertise or publications in the approach section.
- Low productivity, few recent or few primary author papers.
- Needed collaborators not recruited; letters from collaborators missing.
- The collaborator does not complement the research proposed.

Mentors:

- Does the mentor have publications and demonstrated expertise in the field?
- Is the mentor committed to the professional development of the applicant?

Mentor Expectations

- Assist with the outline of an individual development plan (IDP) and ensure that the investigator adheres to the guidelines of the IDP and the INBRE expectations.
- Provide guidance to Developmental project investigators in the logical flow of experiment and hypothesis testing.
- Advise Developmental project investigators on specific deadlines for experimental protocols.
- Advise Developmental project investigators in developing strategies and deadlines for publications.
- Advise Developmental project investigators in the development of specific aims for grant proposals and set specific deadlines for each section of a grant proposal.

Mentor Expectations

- Advise Developmental project investigators with summaries of reviewer critiques from unfunded/unscored applications on strategies for resubmission. Assist with generating the necessary preliminary data to improve resubmissions.
- Serve as an initial reviewer of proposals planned for submission.
- Assist Developmental project investigators in the evaluation of candidate technical staff and research fellows.
- Provide guidance on mentoring of the Developmental project investigator’s fellows and students.
- Facilitate access to successful senior investigators through introductions.

Mentor Expectations

- Act as an advocate for the Developmental project investigators with administration and ensure they have “protected time” for research and career development.
- Train Developmental project investigators on the preparation of presentations for national meetings.
- Assist with evaluations from the external evaluator team (EET) and external advisory committee.
- Mentor participation will also be evaluated by the EET, the RC, PC, and PI from the biannual progress reports and questionnaires to the Developmental project investigators.

Full proposal mentors are required to meet the DRPP director and the grantee for progress reports twice a year!

Unscored Review Criteria

Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?

  Do not assume! Give details in the Facilities and Resources

- Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed?

  Include a letter of institutional commitment for release time and position: 50% for full projects and 25% for pilot projects

- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

  Include strong letters of commitment from mentors and collaborators!

Consideration of relevant biological variables

- ***Biological variables***, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease.
- In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes, and treatment response.
- NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. http://orwh.od.nih.gov

Additional considerations

Additional Review Considerations (no effect on overall score)

Additional Review Considerations Before Jan 25, 2025

- Applications from Foreign Organizations**
- Select Agent Research**
- Resource Sharing Plans**
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

**Review shifting to NIH staff

Authentication of key biological and/or chemical resources

Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Key biological and/or chemical resources:

1. may differ from laboratory to laboratory or over time
2. may have qualities and/or qualifications that could influence the data
3. are integral to the proposed research
4. are not limited to resources generated with NIH funds

Standard laboratory reagents (e.g., buffers) that are not expected to vary do not need to be included in the plan.

Authentication of key biological and/or chemical resources

Briefly describe how you plan to authenticate resources.

- How will you ensure the identity and validity of key biological and/or chemical resources used in the proposed studies?
- The quality of the resources used to conduct research is critical to reproducing the results. Each investigator will have to determine which resources used in their research fit these criteria and are therefore key to the proposed research.

Other Attachments
(Page 36, PHS398 Guide)

- **Vertebrate Animals**

If live vertebrate animals are involved in the project, address each of the following criteria:

1. **Description of Procedures**: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

Other Attachments
(Page 36, PHS398 Guide)

2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).

3. Minimization of Pain and Distress: Describe the interventions, including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

Other Attachments

- **Select agents research**

  Select Agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents.

- **Multiple PI/PD Leadership plan**
- **Consortium/contractual arrangements**
- **Letters of support**
- **Resource sharing plan**
- **Authentication of Key Resources Plan**
- e.g., cell lines, specialty chemicals, antibodies, and other biologics.

Human Subjects Research

https://humansubjects.nih.gov/nih-human-subjects-policies-guidance

View Burden Statement

PHS Inclusion Enrollment Report

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

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title (must be unique):**

* 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

Enrollment Location ☐ Domestic ☐ Foreign

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

Comments:

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	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

Report 1 of 1

< Previous Report | Delete Report | Next Report >

To ensure proper performance, please save frequently.

FORMATTING

Text in PDF attachments must follow these minimum requirements:

Don’t scan- convert to PDF file!

- Font size: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%).
- Type density: must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: must be no more than six lines per vertical inch.

Text Color: must be black (colored text in figures, graphs, diagrams, charts, tables, footnotes, and headings is acceptable as long as it is legible).

FORMATTING

Text in PDF attachments must follow these minimum requirements:

Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font requirements.

- The following fonts are recommended, although other fonts (both serif and non-serif) are acceptable if they meet the above requirements.

Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana

- Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

Other Important Issues

Don't annoy the reviewer!

- Page requirements: 6 (pilot) or 12 (full) pages
- Font size and line spacing
- SPACING OF TEXT SECTIONS
- Embed figures into the text. Include a brief, clear legend.
- Figure must be absolutely clear/visible to the Reviewer.
- Learn how to use MS Word
- Spelling and grammar – ZERO TOLERANCE for sloppy mistakes.

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		$

PHS 398 (Rev. 6/09) Page ___ **Form Page 4**

Budget

First year of the project

Key Personnel & Role:
- **PI- CO PI- Graduate students, etc.**

Time & Effort:
- **Full project – 50% calendar year (6 months)**
- **Pilot project – 25 % calendar year (3 months)**
- **Include base salary**

Consultants ‘ cost is not personnel:
- **Vendor**
- **Subcontract**

If a Subcontract exists, you must include the information with the proposal

- **Include all expenses to be incurred in this first period**

Budget

For the entire period

- **Submit each line of expenses by project year**
- **You need to include the justification of the budget in accordance with the information that is present on this page**
- **The budget justification is the explanation of what you are going to use and its cost.**

Consult with Ms. Jessyka Rosado for all your budgeting needs!

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.

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 ADMINSTRATIVE 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 _____ % = 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 $ _____

Enter Rate above as a decimal (e.g., 0.25 for 25%, 0.495 for 49.5%) 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.):*

- Please include a **checklist** at the end of your application.
- Your institution must have an **FHA agreement** with the Department of Human Health.
- The indirect costs (FHA costs) have to be included in the proposal.

DRPP Activities

- Monthly peer-review meetings, quarterly writing club.
- Review of grant applications and manuscripts.
- Published manuscripts need to have PMCID numbers from my bibliography (NIH Era Commons)
- Annual PRINBRE retreat and EAC meeting.
- Workshops, seminars, mentoring.
- Annual progress reports

Welcome to the PRINBRE Family!