



***Center for Collaborative Research
in Health Disparities***

RCMI Grant U54-MD007600

PILOT PROJECT PROGRAM

APPLICATION GUIDELINES

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Director, Investigator Research Core

APPLICATION GUIDELINES

RCMI Program Goal

The major goal of the RCMI Program is to develop a more efficient and competitive research infrastructure at the University of Puerto Rico Medical Sciences Campus (UPR_MSC) to conduct **basic, behavioral, clinical and population studies on health disparities** affecting the Puerto Rican population.

RCMI Program Objectives

The specific aims of the current cycle are to: **(1)** target specific minority health and health disparities areas for development and provide initial funding for research activities to support them; **(2)** promote the professional development of new faculty, early-stage investigators and senior postdocs working on these areas **(3)** develop an efficient and agile research structure to provide services that will facilitate the conduct of collaborative research in minority health and health disparities and **(4)** develop long-lasting partnerships with community-based organizations.

The Pilot Project Program

Scope and Priorities

The overall goals of the Pilot Project Program (PPP) are three-fold: 1) to fund innovative research using targeted technologies focusing on health disparities and/or global health; 2) to mentor early career investigators as they transition to independent funding, 3) to involve RCMI faculty and outside collaborators/mentors in order to strengthen collaborative networks.

High priority will be given to pilot projects from junior/early stage investigators and senior post-docs focusing on basic, behavioural, clinical and community-based participatory research **in areas related to health disparities** (i.e. cancer, neurological disorders, infectious diseases, diabetes, obesity, etc.), which will utilize CCRHD-RCMI core services and resources available at the RCMI Translational Research Network (RTRN). The PPP will support the collection of preliminary data that can be used to advance these areas. Collaborations with investigators outside Puerto Rico and in other RCMI institutions are also encouraged. This approach is consistent with the scope of the RCMI Program, the vision and mission of the National Institute on Minority Health and Health Disparities (NIMHD), and the Strategic Plan of the UPR Medical Sciences Campus.

Specific Requirements

A. Eligibility

- The PPP Small Grants Initiative **targets** junior/early stage investigators (less than 10 years after receiving a doctoral degree) and senior post docs, whose unique skills or expertise and innovative ideas could contribute to on-going and/or new translational (basic, behavioral and clinical) research in the targeted areas of health disparities. These applicants are required to identify a scientific mentor.
- Applications from post-doctoral students (students who finalized their doctoral degrees) and medical fellows will not be considered.

B. Collaborative Requirement

A Scientific Mentor is required who is an active participation in career development activities sponsored and/or promoted by the CCRHD. During previous cycles, the Program has developed a strong information and communication infrastructure leading to the Integrated Information Core. These efforts have provided the necessary resources to develop long distance collaborations, as well as continuous interactions with consultants and advisors minimizing the geographical isolation highlighted as an obstacle by many of our investigators.

High priority will be given to proposals involving basic, behavioural, clinical and community-based collaborations that will utilize the information and communication infrastructure developed by the CCRHD at the Medical Sciences Campus or at the RCMI Translational Research Network (RTRN). All collaborative activities must provide a Plan for Handling Intellectual Property and Sharing of Research Resources.

C. Areas of Interest

The objective of the RCMI Program at UPR-RCM is to stimulate translational research on health disparities. Research addressing health disparities should address at least one of the following areas:

- Diseases of higher prevalence in the local population or unique to the community such as cancer, infectious diseases, cardiovascular and metabolic syndrome (diabetes, obesity), rare genetic disorders, and mental health.
- Research involving basic, behavioral, clinical and community collaborations, or multidisciplinary approaches that could lead to a fully-independent project.
- Novel applications of molecular genetics, pharmacogenomics, proteomics, information technology, and/or bioimaging in translational studies.

Award Information

Funds Available/Project: \$30-40,000/year maximum

Expected Number of Awards: 3-4 awards

Maximum support period: 2 years*- not renewable

Initial Budget Period: 1 year

*Note: Two-year proposals are strongly encouraged. As with any federal award, the second year of funding is contingent on availability of funds and project progress.

Submission Instructions and Forms:

Specific instructions and forms for the preparation of an RCMI proposal are included in **Appendix A**. Incomplete proposals will not be considered. Special attention should be given to inclusion of biographical sketches, all budget justifications, review protocols for the use of human subjects and vertebrate animals, and conflict of interest. Please refer to the instructions provided for these and other areas.

Technical Requirements:

To be eligible for initial consideration under this announcement, applicants must:

1. Meet the eligibility criteria as defined above
2. Submit a **Letter of Intent**:

A letter of intent **is required** to help organize the review process and avoid conflict of interest in the review. The letter should include a descriptive title of the proposed activity, a brief description of the activity (200-300 words) and preliminary specific aims, 3-4 keywords, the name, address, telephone number and e-mail of the Investigator as well as the name and institutions of the scientific mentor/collaborator(s). Approval (Vo/Bo) by the Department Chair is required. The letter should be delivered to the RCMI Office or sent by email not later than **April 25, 2018** to the attention of:

Gregory J. Quirk, Ph.D.
Key Activity Director
Pilot Project Program
RCMI Office B621-A
Medical Sciences Campus
Tel: (787) 763-9401,
(787) 758-2525 Ext. 1620/1621
E-mail: rcmi.rcm@upr.edu

3. Be responsive to at least one of the areas of interest as outlined in Section C of the Specific Requirements.

4. Provide evidence of assurances (IACUC/ IRB) and certificates (Biosafety, Responsible Conduct in Research, Financial Conflict of Interest). Submissions of proposals to IACUC, IRB, or others are accepted.

5. Abide by the page limit (6 pages, R03 type application) and formatting requirements described in these Guidelines.

6. Use PHS 398 forms and formats, as described in Appendices A and B.

7. Submit electronically the completed application by the receipt deadline to: rcmi.rcm@upr.edu

Because of time limitations we will not be able to send any application forward to review that does not meet these technical requirements.

Allowable Costs:

Allowable direct costs include small scientific equipment, laboratory supplies, scientific editing, partial -work for graduate students, consultant fees (i.e. mentors/collaborators), training, as well as travel related to the scientific work performed. Salaries as well as office and computer supplies, and indirect costs are not allowed. A complete budget and budget justification must be included.

Oversight and Evaluation:

Progress of awardees will be monitored on a regular basis by the Key Activity Director, Dr. Gregory Quirk, with the assistance of the external evaluator. As part of this oversight, grantees will be required to submit a progress report every 6 months and make an oral presentation to the External Advisory Committee. Questionnaires and interviews will be utilized to determine if the project is achieving the desired outcomes. Junior/early stage investigators must participate in mentoring activities associated with the Pilot Project Program.

Review Process

Upon receipt, applications will be sent for external scientific and technical review. Selection will be made by the RCMI Pilot Project Program Review Committee based on external scientific reviews, program impact and priorities, potential for leading to a fully-funded independent project, collaborations, and the availability of funds. **Appendix B** includes the criteria to be considered in the evaluation of pilot projects. After evaluation, applications will be submitted by the RCMI Program to NIMHD for final approval.

RECEIPT AND REVIEW SCHEDULE

| | |
|---|------------------------------|
| Letter of Intent | <u>April 25, 2018</u> |
| Application Receipt Deadline: (Late applications will not be considered) | <u>May 15, 2018</u> |
| Completion of Peer and Internal Review: | <u>May 28, 2018</u> |
| Announcement of Selected Pilot Projects: | <u>May 31, 2018</u> |
| Earliest Start Date: | <u>August 1, 2018</u> |

Contact Information:

Dr. Gregory Quirk
Key Activity Director
Pilot Project Program
RCMI Program
Ext. 1303 / 1620
E-mail: rcmi.rcm@upr.edu

General Information for Submission of Proposals:

<http://rcmi.rcm.upr.edu/rcmi-ppp>

APPENDIX A.

1. FORMS FOR PILOT PROJECT APPLICATION

The Pilot Project Application must be complete in order to be accepted. A faculty member may not submit more than one project in response to this announcement.

Each application should include the following sub-sections and should use the most recent NIH format: (<https://grants.nih.gov/grants/funding/phs398/phs398.html>)

- Face page** (Form Page 1)
- Cover page with abstract** (Form Page 2)
- Budget** (Form Page 4) and detailed budget justification (2-3 pages).
- Biographical Sketch(s)**, (BS) (latest version, not exceed 5 pages for each person). All BS for key personnel and collaborators should follow the NIH format (<https://grants.nih.gov/grants/forms/biosketch.htm>). Current Other Support needs to be included.

- Research Plan (6 pages)**

Specific Aims (1 page) - Should include a brief description of the knowledge gap to be filled with the proposed project, list the goals and the specific research outcomes it intends to accomplish, state the hypothesis to be tested. State the relevance the proposed project has to health disparities in Hispanics.

Significance and Innovation (1 page) - This page should include one paragraph regarding the significance of the proposed study and its relevance to health disparities; and a paragraph explaining why the proposed project is innovative.

Approach, Research Design and Research Timetable (2½ pages) – Describe the experimental approach for each aim proposed including the methods (data collection) and statistical analysis (including interpretation). Include a section of pitfalls and alternative strategies. A timetable for the proposed project is required and should include the proposed methods, plans for abstract and/or peer-reviewed manuscript submission, and possible external funding.

- Structured Career Development Plan (1½ pages)** – Describe the career development activities to be performed including methods and evaluation of outcomes. Also include a justification regarding the plan and the objectives of the proposed pilot project and future directions.

2. COMPLIANCE WITH INSTITUTIONAL AND FEDERAL REGULATIONS

Human Subjects Section: All projects using human subjects must address the **6 points of Human Subjects** as outlined in PHS 398. Also, for each protocol, the investigator must address the inclusion of women, minorities and children. Plans for recruitment and retention of subjects should also be addressed. Complete the “Planned Enrollment Report” form PHS 398. Completion of this form alone does not satisfy the need to address the inclusion of women, minorities and children.

(<https://humansubjects.nih.gov/nih-human-subjects-policies-guidance>)

Include the Targeted/Planned Enrollment Table, if applicable.

(<https://grants.nih.gov/grants/funding/phs398/enrollment.doc>)

Vertebrate Animals: All projects utilizing vertebrate animals must address the **5 points on the utilization and care of these animals** as outlined in the PHS 398.

Provide copy of the IRB or IACUC, Institutional Biosafety Committee, and Good Clinical Practice (if applicable) approval letter, or submit evidence of having initiated the review process of the committee that applies. If working with animals, please submit copy of IACUC training certifications. **Proposals submitted to this Call and to the IRB/IACUC must be the same title.**

Provide Training Certifications that apply for all participants:

Biosafety Certification that apply...

Certification of education in “Responsible Conduct in Research”

http://ori.dhhs.gov/education/products/montana_round1/research_ethics.html

Certification of education in “Financial Conflict of Interest (FCOI)”

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Certification of education in [Human Subject Protection](#), [HIPAA](#) & [GCP](#)

Resource Sharing Plans (including data sharing, model organism sharing, and genome-wide association study [GWAS], if applicable).

Letters of Support of Mentors, Key Personnel and Consultants.

The Application should be submitted as one PDF electronic file to:

rcmi.rcm@upr.edu

IMPORTANT NOTE:

Proposals will NOT be processed unless applicant provides evidence of having submitted his/her protocol to the corresponding regulatory office for approval.

Proposals will NOT be submitted to NIMHD for approval until applicant provides evidence of compliance with all assurances and certifications that apply for his/her project.

3. References

National Institutes of Health (NIH), Public Health Service (PHS) 398 webpage:

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

Within this webpage you will find PHS 398 Instructions and Forms.

Research Plan

Refer to page 43 (I-43) of the Grant Application Instructions.

6 points of Human Subjects

Refer to page 44 (III-16) of the Supplemental Grant Application Instructions.

5 points on the Utilization and Care of Animals

Refer to page 48 (III-20) of the Supplemental Grant Application Instructions.

APPENDIX B

REVIEW CRITERIA. Reviewers will consider the following criteria in determining priority scores:

1. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Is there a logical flow to the application? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators: Are the investigators productive, appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the mentor/advisor bring complementary and integrated expertise to the project?

5. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

6. CCRHD-RCMI Relevance: Will the research make a contribution to the development of **translational studies in health disparities** at the UPR Medical Sciences Campus? Does the project utilize **CCRHD-RCMI** and/or **RTRN** resources? Do the proposed studies have the potential to lead to a fully-independent project?