



## **CLINICAL RESEARCH PILOT PROJECTS PROGRAM. 2022–2023**

RELEASE DATE: October 7, 2022

The RCMI Coordinating Center Clinical Research Pilot Projects Program is intended to provide funding, on a competitive basis, for hypothesis-driven clinical research projects led by inter-institutional collaborative teams of multiple principal investigators (MPI), along with their Mentor(s) and Collaborator(s) from RCMI and/or non-RCMI grantee institutions. A Mentoring Plan, a Communications Plan, and a timetable for seeking extramural funding are required, as are letters of support from the Mentor(s), Collaborator(s) and Principal Investigators of the partnering RCMI U54 Centers.

**Post-doctoral fellows, early-career faculty and early-stage investigators from RCMI U54 Centers are limited to submitting only one application as multiple principal investigators (MPI). Applications must be submitted on-line ([RCMI-CC Clinical Research Pilot Projects Program Application](#)) and must be received no later 5:00 PM Hawaii standard time. E-mail applications will not be accepted.**

APPLICATION DUE DATE: Monday, January 23, 2023

SCIENTIFIC REVIEW PERIOD: January to February 2023

ANTICIPATED AWARD DATE: Monday, April 3, 2023

### **Summary of Requirements**

#### **Applicant and Institutional Eligibility**

- Post-doctoral fellows and early-stage investigators in Profiles database
- Multiple principal investigators (MPI)
- An RCMI investigator is limited to one application as MPI
- Applications must include MPI from two RCMI U54 Centers
- An RCMI U54 Center may be involved in more than one application
- Applications must include at least one mentor and collaborator from RCMI and/or non-RCMI grantee institutions

#### **MPI Plan**

#### **Research Category**

- Clinical Research proposed by clinical, basic biomedical and/or behavioral/ community researchers

#### **Research Area (aligned with NIH IC)**

- Addiction & Drug Abuse
- Cancer
- Cardiovascular & Pulmonary Diseases
- Digestive & Renal Diseases
- Environmental Health
- HIV/AIDS
- Infectious & Immunological Diseases
- Neurological Disorders & Mental Health
- Obesity & Metabolic Syndromes
- Women's Health

#### **Page Limits**

- Specific Aims (1 page)
- Research Strategy (6 pages)

#### **Specific Aims**

- Research question
- Central hypothesis
- Rationale
- Objective and Specific Aims

#### **Research Strategy**

- Significance
- Innovation
- Approach
- Mentoring Plan
- Communications Plan
- Timetable and Plan for Future NIH Applications

#### **Budget and Justification**

- Non-modular budgets
- One-year project
- \$100k–\$150k per year

#### **NIH Biosketches**

- MPI applicants
- Mentors and collaborators
- Other key personnel

#### **Other Documents**

- IRB submission/approval
- Letters of support

## **PURPOSE OF THE FOA**

A primary strategic goal of the RCMI Coordinating Center (RCMI-CC) is to improve minority health and to reduce ethnic and geographic disparities in health by coordinating the development and facilitating the implementation of clinical research across the RCMI Consortium. To more effectively engage RCMI investigators and to spur inter-institutional collaborative research, the RCMI-CC is launching a Clinical Research Pilot Projects Program.

The Pilot Projects Program is intended to foster inter-institutional collaborations and mentoring by providing funding for hypothesis-driven **clinical research projects** on the science of minority health and health disparities. In particular, this Pilot Projects Program solicits applications that involve *inter-*

*institutional collaborations* and mentoring between post-doctoral fellows and/or early-stage investigators from **two RCMI U54 Centers** in clinical research projects that utilize the infrastructure of the Investigator Development Core, Community Engagement Core and Research Capacity Core and that link the basic sciences and clinical medicine, integrate research discoveries with innovative medical applications, and develop improved patient-care practices through community engagement. Examples include, but are not limited to, collaborations across the life sciences, public health, clinical medicine, epidemiology, biostatistics, pharmacology, biomedical informatics, computational biology, ethics, social and behavioral sciences, biomedical imaging and bioengineering, law and health economics that advance our understanding about the social, economic, behavioral, cultural, environmental, and genetic and epigenetic determinants of health disparities and that improve our knowledge about biological systems to reduce the burden of disease and improve human health. The expectation is that data generated from the Clinical Research Pilot Projects Program will be successfully leveraged into full-fledged, competitive NIH grant applications.

**Definitions**

For the purpose of this funding opportunity, **clinical research** is defined as human subjects research or research that involves an individual person or a group of people, or research that studies materials from humans, such as their behavior or biological samples. <https://www.nih.gov/health-information/nih-clinical-research-trials-you/what-is-clinical-research>

A **post-doctoral fellow** is defined as an individual who has received a doctoral degree (or equivalent) and who is engaged in a temporary and defined period of mentored advanced training to enhance his or her professional skills and research independence needed to pursue a chosen career path.

An **early-stage investigator** is defined as a Principal Investigator (PI) who has completed their terminal research degree or post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as a PI for a substantial NIH independent research award (e.g., R01). <https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm>

An **early-career faculty** is defined as an Assistant Professor.

**Applicant Eligibility**

Any *post-doctoral fellow, or early-career faculty or early-stage investigator* at an RCMI grantee institution, who holds a doctoral degree (MD, PhD, ScD, DrPH, PharmD, EdD, DSW, etc.) and who possesses the skills, knowledge and resources necessary to carry out the proposed research, is invited to form a collaborative partnership with another eligible RCMI faculty to submit an application. Each application must be led by Multiple Principal Investigators (MPI) from two RCMI grantee institutions. Both MPI must meet the eligibility criteria. MPI are limited to submitting only one application. MPI must be listed in the RCMI Profiles database. Individuals from racial and ethnic minority groups, as well as individuals with disabilities and those from backgrounds underrepresented in the biomedical research workforce, are encouraged to apply.

The table below shows the acceptable types of MPI teams for the clinical research projects. To be clear, neither MPI has to be a clinical researcher. However, the proposed project must meet the definition of clinical research, as provided above.

<b>RCMI MPI #1 (Contact)</b>	<b>RCMI MPI #2</b>
Clinical Researcher	Clinical Researcher Behavioral/Community Researcher Basic Biomedical Researcher
Behavioral/Community Researcher	Behavioral/Community Researcher Basic Biomedical Researcher Clinical Researcher
Basic Biomedical Researcher	Behavioral/Community Researcher Basic Biomedical Researcher Clinical Researcher

An individual who currently serves as the principal investigator on an active NIH research project grant (R01) or program project grant (P01) or R35, P20, P60, U01, U19, U54, DP1, DP2, DP5 is **ineligible** to apply. Also, those with R01-equivalent awards from the National Science Foundation, Department of Defense and national societies and foundations, such as the American Heart Association, are ineligible, as are graduate students.

### **Mentors**

All MPI must designate at least one investigator from an RCMI or non-RCMI grantee institution as a *mentor*. Additional mentors may be from RCMI or non-RCMI grantee institutions or community-based organizations. A brief but sufficiently detailed Mentoring Plan is required.

### **Collaborators**

All MPI must designate at least one investigator from an RCMI or non-RCMI grantee institution as a *collaborator*. Additional collaborators may be from RCMI or non-RCMI grantee institutions or community-based organizations. A brief but sufficiently detailed Communications Plan is required.

### **Application Process**

The application must use the Pilot Projects Program Templates available on the REDCap-based online grant submission system ([RCMI-CC Clinical Research Pilot Projects Program Application](#)). The research proposal is limited to seven pages: the Specific Aims page is limited to one (1) page and the Research Strategy may not exceed six (6) pages (typed single-spaced using 11-pt Arial on one side of the page with 0.5-inch margins). All tables, graphs, figures, diagrams, charts and other displays must be included within the page limits. Also, the Research Strategy section must include a Mentoring Plan, specifying the designated mentor(s); a Communications Plan, specifying the designated collaborator(s); and a project timetable and plan for seeking subsequent extramural support, as well as a description of the services being requested from individual RCMI and non-RCMI Cores. **Preliminary data are not required.**

Not counted in the page limits are the MPI Plan, NIH biosketches and other support information for the MPI, collaborator(s) and mentor(s); cited references; itemized budget with justification; and full descriptions of Protection of Human Subjects from Research Risk; Inclusion of Women, Minorities and Children in Research. A Targeted/Planned Enrollment Table Format Page must also be included. Finally, evidence of IRB application (or approval) is required at the time of submission.

### **MPI Plan**

A detailed MPI Plan must be included as a separate uploaded file. The following must be covered: qualifications of each MPI; responsibilities and contributions of each MPI; procedures for fiscal and management coordination; data sharing and communications policies; publications and intellectual property policies; and procedures for resolving conflicts.

### **Facilities and Resources**

The facilities and other resources available for use in the proposed research at each of the partnering RCMI U54 Centers should be described, and uploaded as a separate file. In addition, available RCMI and/or non-RCMI core facilities should be listed and described.

### **Letters of Support**

Applications must include letters of support from the mentor(s) and collaborator(s). Such letters must outline their commitment and contribution to the proposed research and their involvement in the preparation of the application. In addition, letters of support are required from the principal investigators of both partnering RCMI U54 Centers. Finally, letters of support from the Directors of specific RCMI and/or non-RCMI Cores must be included, indicating the types of services being provided and costs, if applicable.

### **Budgets**

Non-modular itemized budgets, with justification, are required for each MPI. Each MPI must dedicate a minimum of 10% effort at cost. Grant support may be used for costs associated with other personnel salaries, small equipment (not to exceed \$5,000), participant incentives, supplies and domestic travel.

## **Available Funds and Anticipated Number of Awards**

A \$1,000,000 commitment will fund six or more inter-institutional collaborative clinical research pilot projects. Awards are expected to range from \$100,000 to \$150,000 in direct costs per year for a project period of one year. **No provisions for indirect costs will be allowed.**

## **Mechanism of Support**

Support from the Clinical Research Pilot Projects Program will be provided through a subcontracting mechanism from the Morehouse School of Medicine to each of the awardee institutions. The MPI will be solely responsible for planning, directing, and executing the research, but the RCMI-CC infrastructure will be available throughout the course of the pilot project.

## **Scientific Review**

RCMI faculty with subject-matter expertise and NIH study section experience, as well as principal investigators of non-RCMI programs, have agreed to serve as reviewers. All applications will be evaluated using a REDCap-based online review system by two RCMI investigators and one non-RCMI investigator. In all cases, individuals with conflicts of interest, either real or perceived, will not be assigned as reviewers. NIH-type review criteria and the NIH 9-point scoring scale will be used. Specifically, applications will be reviewed on the following criteria: significance, innovation, approach, investigators, and environment, as well as research focus, collaborations and partnerships, and core usage. In addition, the overall likelihood that support will be leveraged into a competitive MPI NIH grant application will be assessed.

*Significance:* Does the proposed research address an important health problem? Does the proposed research address an ethnic or geographic disparity in health? If the aims of the research are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of the study on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?

*Innovation:* Is the proposed research original and innovative? For example: Does the research challenge existing paradigms or current clinical practices or propose an innovative hypothesis to address a critical barrier that prevents progress in the field? Does the research develop or employ novel concepts, approaches, methodologies, tools or technologies? Does the research access a hard-to-reach underserved community?

*Approach:* Are the conceptual or clinical framework, study design, investigative methods and analytical tools adequately developed, well-integrated, well-reasoned and appropriate to the aims of the proposed research? Do the MPI acknowledge potential problems or pitfalls and consider alternative strategies? Does the research employ a team science approach? Are the plans for the protection of human subjects from research risks, and the inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the proposed scientific goals?

*Investigators:* Are the MPI applicants and collaborator(s) appropriately trained and well suited to conduct the proposed research? Is the proposed research appropriate to the experience level of the MPI and collaborator(s)? Does the investigative team bring complementary skills or experience to the project? Do the MPI applicants show evidence of scientific productivity and scientific achievement, as measured by the number and quality of publications and extramural funding record? Is the Mentoring Plan sufficiently detailed to ensure a beneficial outcome for the MPI? Is the Communications Plan sufficiently detailed to ensure that the MPI and collaborative team is sufficiently agile to respond rapidly to unexpected problems or pitfalls?

*Environment:* Does the scientific environment in which the proposed research will be performed contribute to the probability of success? Does the proposed study benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support, such as faculty-release time and/or matching funds?

*Research Focus:* Does the proposed research meet the definition of clinical research? Does the proposed research align with the mission of the NIMHD and RCMI-CC? Are health disparities of vulnerable groups addressed?

*Collaborations and Partnerships:* Does the proposed research represent a partnership between post-doctoral fellows, early-career faculty and/or other early-stage investigators from two RCMI U54 Centers? Do the collaborators and mentors have the appropriate academic qualifications, research experience, and productivity to contribute to the success of the proposed research? Does the project include non-RCMI mentors and/or collaborators?

*Core Usage:* Does the proposed research make use of RCMI and/or non-RCMI core facilities? Are letters of support provided by core directors?

### **Funding Recommendations and Decisions**

Applications that demonstrate a team-science approach to reducing health disparities and show convergence of expertise between MPI from two RCMI grantee institutions and their RCMI and non-RCMI collaborator(s) and mentor(s) will be considered highly responsive to this FOA. Funding recommendations will be based on priority scores, with direct oversight by the RCMI-CC MPI and ratification by the RCMI-CC Steering Committee, with final approval by NIMHD. Awards will be distributed across as many RCMI U54 Centers as possible, provided the proposed research is meritorious. Each Pilot Projects Program awardee will be required to submit a written summary of research productivity and progress, which will be included in the Research Performance Progress Report.

### **Informational Webinar**

An informational webinar for prospective applicants, mentors and collaborators, as well as IDC Directors and RCMI PI/PDs, will be held on October 14, 2022. A Zoom link will be sent to all who register for the webinar. Please use the hyperlink or QR code to register for the Informational Webinar.

**Informational Webinar Registration:** [RCMI-CC Pilot Projects Program Informational Webinar](#)

QR Code:



### **INQUIRIES**

Inquiries concerning this FOA are encouraged.

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