

CLINICAL RESEARCH PILOT PROJECTS PROGRAM, CYCLE 3

RELEASE DATE: October 6, 2023

The RCMI Coordinating Center Clinical Research Pilot Projects Program is intended to provide funding, on a competitive basis, for hypothesis-driven clinical research projects conducted by collaborative teams of Multiple Principal Investigators (MPI), comprising post-doctoral fellows, early-career faculty and/or early-stage investigators from two or more RCMI U54 Centers, along with their RCMI and/or non-RCMI Mentor(s) and Collaborator(s). A Mentoring Plan, a Communications Plan, and a timetable for seeking extramural funding are required, as are letters of support from Mentor(s), Collaborator(s), core directors, and MPI/PI and Investigator Development Core (IDC) Directors of partnering RCMI U54 Centers.

MPI from two or more RCMI U54 Centers are limited to submit only one application. Applications must be submitted online ([2024-2025 RCMI-CC Clinical Research Pilot Projects Program Application Link](#)) and must be received no later 5:00 PM Hawaii standard time. E-mail applications will not be accepted.

APPLICATION DUE DATE: Tuesday, January 16, 2024

SCIENTIFIC REVIEW PERIOD: January to February 2024

EARLIEST ANTICIPATED AWARD DATE: Wednesday, May 1, 2024

Summary of Requirements

Applicant and Institutional Eligibility

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

MPI Plan

Mentoring Plan

Research Category

- Clinical Research proposed by clinical, basic biomedical and 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

Research Plan 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
- Investigator
- Environment
- Communications plan
- Future NIH applications

Budget and Justification

- Non-modular budget
- One-year project
- \$150,000 direct cost

NIH Biosketches

- MPI applicants
- Mentors and collaborators
- Other key personnel

Other Documents

- IRB submission/approval
- Letters of support

PURPOSE OF THE NOFO

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 reissuing a Notice of Funding Opportunity for the 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 between post-doctoral fellows, early-career faculty (Assistant Professor) and/or early-stage investigators from **two or more RCMI U54 Centers** for clinical research projects that utilize the infrastructure of the Investigator Development Core (IDC), Community Engagement Core (CEC) and Research Capacity Core (RCC) 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 and data science, 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>

Post-doctoral fellows are defined as individuals who have received a doctoral degree (or equivalent) and who are engaged in a temporary and defined period of mentored advanced training to enhance their professional skills and research independence needed to pursue a chosen career path.

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

Early-career faculty are defined as Assistant Professors (or equivalent).

Applicant Eligibility

Post-doctoral fellows, early-career faculty (Associate Professors) and early-stage investigators at RCMI grantee institutions, who hold a doctoral degree (MD, PhD, ScD, DrPH, PharmD, EdD, DSW, etc.) and who possess the skills, knowledge and resources necessary to conduct the proposed research, are **eligible** to submit an application. Each application must be led by Multiple Principal Investigators (MPI) from two or more RCMI U54 Centers. MPI are limited to submitting only one application. MPI, as well as their mentors and collaborators, will be listed in the RCMI Profiles database. RCMI Investigators who are PI of active NIH R03, R15, R16, R21, K01, K23, K99R00 and/or F32 grants are **eligible**, as are RCMI Investigators who are current or former Pilot Projects Program awardees of their RCMI U54 Centers. The table below shows the acceptable types of MPI teams for the clinical research projects. Neither MPI has to be a clinical researcher. However, the proposed project must meet the definition of clinical research.

RCMI MPI #1 (Contact)	RCMI MPI #2
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

Applicant Ineligibility

RCMI Investigators who are PI of active NIH R01, R35, R37, P01, P20, P60, U01, U19, U54, DP1, DP2, DP5 are **ineligible** to apply. Also, those who are awardees of the Clinical Research Pilot Projects Program

or who are R01-type Research Project Leaders of their RCMI U54 Centers or who are recipients of R01-equivalent awards from other federal agencies, such as AHRQ, CDC, DHS, DOD, DOE, HRSA, USDA, EPA, NSF, are **ineligible**, as are graduate students.

Finding an MPI

Prospective applicants should consult the IDC Directors at their RCMI U54 Center to identify post-doctoral fellows, early-career faculty and early-stage investigators at another RCMI U54 Center, who may serve as MPI on their research project. In addition, prospective applicants can search the RCMI Profiles Researcher Networking Database by keywords to identify a potential MPI (<http://connect.rtrn.net/profiles/search/>) and can register on the MPI Finder database (<https://www.rcmi-cc.org/mpiprofile>). Finally, prospective applicants can present their research and resource needs (e.g., types of clinical samples) at an upcoming RCMI Scientific Webinar by contacting their IDC Director.

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. Prospective applicants should consult the IDC Directors at their RCMI U54 Center to identify suitable mentors. In addition, prospective applicants can search the RCMI Profiles Researcher Networking Database by keywords to identify a mentor (<http://connect.rtrn.net/profiles/search/>). A brief Mentoring Plan is required. The Mentoring Plan should mention the frequency of meetings and what will be discussed or monitored, as well as how leadership and presentation skills will be acquired by the MPI.

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. Prospective applicants should consult the IDC Directors at their RCMI U54 Center to identify suitable collaborators. In addition, prospective applicants can search the RCMI Profiles Researcher Networking Database by keywords to identify a collaborator (<http://connect.rtrn.net/profiles/search/>). A brief Communications Plan is required.

Application Process

MPI applicants must use the Pilot Projects Program Templates available on the REDCap-based online grant submission system ([2024-2025 RCMI-CC Clinical Research Pilot Projects Program Application Link](#)). The Research Plan 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 application must include a Mentoring Plan, specifying the designated mentor(s); a Communications Plan, specifying the designated collaborator(s); and a timetable for seeking subsequent or supplemental 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 Research Plan page limits are the cover page; project summary; biosketches for the MPI, collaborator(s), mentor(s) and other significant contributors; MPI Plan; Facilities and Resources; cited references; itemized budget with justification; Protection of Human Subjects from Research Risk; Inclusion of Women, Minorities and Children in Research; and a Targeted/Planned Enrollment Table.

Cover Page

A form-fillable application cover page must be included, as a separate uploaded file. Information must be provided for the following: Title of Project; Research Area; Researcher Category; Multiple Principal Investigator (contact); Multiple Principal Investigator; Mentor (required); Collaborator (required); Additional Team Member (optional); Other Key Personnel or Other Significant Contributors; RCMI Core Usage; and Non-RCMI Core Usage.

Project Summary

A project summary must be included, as a separate uploaded file, using PHS398 Form Page 2. Key personnel and other significant contributors should be listed on Form Page 2-continued.

NIH Biosketches

An NIH Biosketch of each MPI applicant must be included, as a separate uploaded file. In addition, an NIH Biosketch of each mentor, collaborator, and other significant contributor is required. Each NIH Biosketch **may not exceed five pages**.

Multiple Principal Investigator Plan

An MPI Plan must be included, as a separate uploaded file. The MPI Plan must address the following points: Qualifications of each MPI; Responsibilities and contributions of each MPI; Procedures for fiscal and project management coordination; Data sharing and communications policies; Publications and intellectual property policies; and Procedures for resolving conflicts. There are no page limits to this section.

Facilities and Resources

A list and description of relevant facilities and resources available to the MPI applicants for the proposed research must be included, as a separate uploaded file. If RCMI and/or non-RCMI Cores are being used, the names of the Core Directors should be provided. There are no page limits to this section.

Literature Cited or References

A list of references must be included, as a separate uploaded file. Ideally, references should be numbered in the order in which the corresponding citations appear in the text, rather than listed alphabetically by author. There are no page limits to this section. However, the references cited are not meant to constitute a comprehensive review of the literature.

Budgets

A non-modular itemized budget, with detailed justification, is required for each MPI applicant, using the form pages. Grant support through the Clinical Research Pilot Projects Program may be used for costs associated with personnel salaries, small equipment (not to exceed \$5,000), supplies, travel and in-patient and/or out-patient care. There are no page limits to this section.

Protection of Human Subjects

Clear and concise information must be included about the following 10 items, as a separate uploaded file: Risks to Subjects; Adequacy of Protection Against Risks; Potential Benefits of the Proposed Research to Research Participants and Others; Importance of the Knowledge to be Gained; Eligibility Criteria; Inclusion of Individuals Across the Lifespan; Inclusion of Women and Minorities; Recruitment and Retention Plan; Study Team; and Data and Safety Monitoring Plan. There are no page limits to this section.

Targeted/Planned Enrollment Table

A Targeted/Planned Enrollment Table must be included for projects proposing the enrollment of human subjects, as a separate uploaded file, using the Targeted/Planned Enrollment Table Format Page.

Institutional Review Board

Full approval from the Institutional Review Board (IRB) of each partnering MPI institution must be included, as a separate uploaded file. Alternatively, the application must include a copy of email correspondence of submission of an IRB application or reliance documentation request from each partnering MPI institution.

Letters of Support

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

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 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.

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 for a project period of one year. **No provisions for indirect costs will be allowed.**

Scientific Review

RCMI faculty with subject-matter expertise and NIH study section experience, as well as established investigators of non-RCMI programs, will serve as reviewers. All applications will be evaluated using a REDCap-based online review system by three subject-matter experts. In all cases, individuals with conflicts of interest, either real or perceived, will not be assigned as reviewers. NIH-type review criteria and a 9-point scoring scale will be used (ranging from 1: exceptional to 9: poor)

<https://www.niaid.nih.gov/grants-contracts/scoring-summary-statements>. 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 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? Is the sample size calculation methodology appropriate for the study design? Is the sample size sufficient to answer the primary research question(s)? Are the statistical methods appropriate for the analysis of the data that will be collected? 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? Have the MPI previously worked with the mentor(s) and/or collaborator(s)? 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 tenure-track position, faculty-release time and/or matching funds, in the form of commitment letters from departmental chair(s) or dean(s) and/or designated high-ranking official(s)?

Research Focus: Is the proposed research meet the definition of clinical research? Does the proposed research align with the mission of NIMHD and RCMI-CC? Does the proposed research address health disparities of ethnic minorities or other vulnerable populations?

Collaborations and Partnerships: Does the proposed research represent a partnership between post-doctoral fellows, early-stage investigators and/or early-career MPI applicants from two or more RCMI U54

Centers? Do the collaborator(s) and mentor(s) 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 or more RCMI grantee institutions and their RCMI and/or non-RCMI collaborator(s) and mentor(s) will be considered highly responsive to this NOFO. 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 Clinical Research 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.

INQUIRIES

Inquiries concerning this NOFO are encouraged. An informational webinar for prospective applicants, mentors and collaborators, as well as IDC Directors, will be held on October 12, 2023. A Zoom link will be sent to all who register for the webinar. Please use the hyperlink to register for the informational webinar.

Informational Webinar Registration Link:

[Informational Webinar Registration Link](#)

Vivek R. Nerurkar, Ph.D.
Multiple Principal Investigator
RCMI Coordinating Center
John A. Burns School of Medicine
University of Hawaii at Manoa
651 Ilalo Street, BSB320
Honolulu, Hawaii 96813
Telephone: (808) 692-1668
Email: nerurkar@hawaii.edu

Pamela L. Bullard, B.A.
Administrative Coordinator
RCMI Coordinating Center
John A. Burns School of Medicine
University of Hawaii at Manoa
651 Ilalo Street
Honolulu, Hawaii 96813
Telephone: (808) 692-1475
Email: pbullard@hawaii.edu