

## 2024-2025 **CLINICAL RESEARCH** PILOT PROJECTS PROGRAM **Informational Webinar**



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## A Paradigm Shift



## Competitive Single-PI Silo Science



## **Collaborative Multi-Pl** Team Science

#### **Challenges and Barriers to Multi-institutional Research**

- Lack of trust
- Lack of scientist directory
- Lack of resource database
- Incomplete inventory of research projects and grants
- Limited IT infrastructure
- Dearth of RPG- and PPGfunded investigators
- Geographic separation and time-zone differences
- Deeply entrenched siloscience research culture
- Inadequate familiarity with clinical research
- Competing priorities and over-committed faculty





































## **Purpose**

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, the RCMI-CC is reissuing a Notice of Funding Opportunity for the Clinical Research Pilot Projects Program.

The Clinical Research 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.



## Clinical Research Pilot Projects Program

- Provides funding, on a competitive basis, for clinical research projects conducted by multiple principal investigators, comprising post-doctoral fellows, earlycareer faculty and/or early-stage investigators from two or more RCMI grantee institutions
- Maximizes utilization of RCMI core facilities
- Promotes mentoring and professional development across the RCMI Consortium
- Accelerates the achievement of research independence of RCMI investigators



## **Definitions**

Clinical Research = Human subjects research or research that involves an individual person or a group of people, or that studies materials from humans, such as their behavior or biological samples.

**Post-doctoral Fellows** = Individuals who have received a doctoral degree (or equivalent) and 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** = 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 PI for a substantial NIH independent research award (e.g., R01).

**Early-Career Faculty** = Assistant Professors (or equivalent).





## RCMI Pilot Projects Program Overview

#### **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

#### 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









































## **Applicant Eligibility**

- Post-doctoral fellows, early-career faculty and early-stage investigators at the 22 RCMI U54 Centers are eligible to apply as Multiple Principal Investigators.
- RCMI Investigators who are principal investigators of active NIH R03, R15, R16, R21, K01, K23, K99R00 and/or F32 grants are eligible.
- RCMI Investigators who are awardees of the Pilot Projects Program of their RCMI U54 Centers are eligible.
- Eligible RCMI Investigators may submit only one proposal as Multiple Principal Investigators.
- RCMI Investigators who hold affiliate or adjunct appointments should base their **eligibility** on the policies of their RCMI grantee institutions.



## **Multiple Principal Investigators**

Applications must propose <u>clinical research projects</u> that represent collaborations between postdoctoral fellows, early-career faculty and/or early-stage investigators from two or more RCMI U54 Centers.

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

Additional collaborators from other NIMHD programs (such as COE) and from non-RCMI programs (such as COBRE, INBRE, IDeA-CTR, CTSA, ISPCTN, RCMAR, ADRC, etc.) and the inclusion of community members are encouraged.

Applications that do not show such inter-institutional collaborative arrangements will be considered nonresponsive.





## **Applicant Ineligibility**

- RCMI Investigators who are principal investigators of active NIH R01, R35, R37, P01, P20, P60, U01, U19, U54, DP1, DP2, and/or DP5 grants are ineligible.
- RCMI Investigators who are awardees of the RCMI Coordinating Center Clinical Research Pilot Projects Program are ineligible.
- RCMI Investigators who are R01-type Research Project Leaders of their RCMI U54 Centers are ineligible.
- RCMI Investigators who are recipients of R01-equivalent awards from other federal agencies, such as AHRQ, CDC, DHS, DOD, DOE, HRSA, USDA, EPA, NSF, are ineligible.
- Graduate students are ineligible.



## **How to Find an MPI**

- Consult the Investigator Development Core Director(s) at your RCMI U54 Center
- Search the RCMI Profiles Researcher Networking Database by keywords to identify potential MPI (<a href="http://connect.rtrn.net/profiles/search/">http://connect.rtrn.net/profiles/search/</a>)
- Review the listing of pilot project awardees at other RCMI U54 Centers
- Register your name and research topic on the MPI Finder database (<a href="https://www.rcmi-cc.org/mpiprofile">https://www.rcmi-cc.org/mpiprofile</a>)



## **How to Find an MPI**

In addition to registering on MPI Finder, RCMI Scientific Webinars will be scheduled for you to interact with potential MPI, mentors and collaborators.

- Participate in an upcoming RCMI Scientific Webinar
- Obtain the three-slide presentation template from Pam Bullard (<u>pbullard@hawaii.edu</u>)
- Prepare a three-minute presentation of your research and your resource needs (e.g., types of clinical samples)
- Schedule a time for your presentation



## **Getting Extra Help with Your Proposal**

- Consult the Investigator Development Core Director(s) at your RCMI U54 Center
- Search the RCMI Profiles Researcher Networking Database by keywords to identify suitable mentors and collaborators (<a href="http://connect.rtrn.net/profiles/search/">http://connect.rtrn.net/profiles/search/</a>)

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☐ Study Design (including	power calculation,	sample
size. statistical analysis	plan)	

 $\square$  Other



## Investigator **Development** Core (IDC) **Directors at** the 22 RCMI **U54 Centers**

RCMI	IDC Directors	
CAU	Zhengxin Wang, PhD	
CDU	Yanyuan Wu, MD	Mohsen Bazargan, PhD
DSU	Brian McNaughton, PhD	
FAMU	Eun Sook Yu Lee, PhD	
FIU	Mary Jo Trepka, MD, MSPH	Jason Mitchell, PhD, MPH
HU	Georges Haddad, PhD	
JSU	TBN	
MMC	Chandravanu Dash, PhD	Zhenbang Chen, PhD
MSM	Jonathan K. Stiles, PhD	
MSU	Christine F. Hohmann, PhD	Shiva Mehravaran, MD
NAU	Hendrik De Heer, PhD	Nicolette Teufel-Shone, PhD
NCCU	Lorraine Graves, PhD	Vijay Sivaraman, PhD
PHSU	Richard J. Noel, Jr, PhD	
SDSU	Heather Corliss, PhD	Jennifer Thomas, PhD
TSU	Ivy Poon, PharmD	
TU	Temesgen Samuel, DVM, PhD	
UCR	Monica B. Carson, PhD	Bruce G. Link, PhD
UH	Ezemenari Obasi, PhD	
UHM	Kathryn L. Braun, DrPH	Eunjung Lim, PhD
UPR-MSC	Christian E. Bravo-Rivera, PhD	
UTEP	Marc B. Cox, PhD, MSPH	
XULA U24MD15970 trom t	Thomas E. Wiese, PhD the National Institute on Minority Health and H	ealth Disparities, National Institutes of Health





## **Mentors and Collaborators**

#### **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 in the Research Strategy.

#### **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 in the Research Strategy.



## **Application Process**

2024-2025 RCMI-CC Clinical Research Pilot Projects Program Application Link

All applicants must use the <u>online</u> Clinical Research Pilot Projects Program Template. All files must be converted to pdf for uploading.

- The Research Plan is limited to seven (7) pages:
   Specific Aims one (1) page
   Research Strategy six (6) pages
- Page limits include all tables, graphs, figures, diagrams, charts and other displays; also, a Mentoring Plan, a Communications Plan, and a project timetable and a plan to obtain extramural support are required.



## **Application Process: Page Limits**

The following items are **not counted** in the seven-page limit:

- Literature Cited or References
- Budget Itemization and Justification for each MPI
- Biosketches (5-page limit for each MPI, mentors, collaborators, and other significant contributors)
- Descriptions of Protection of Human Subjects from Research Risk; Inclusion of Women, Minorities and Children in Research
- Targeted/Planned Enrollment Table Format Page, if applicable



























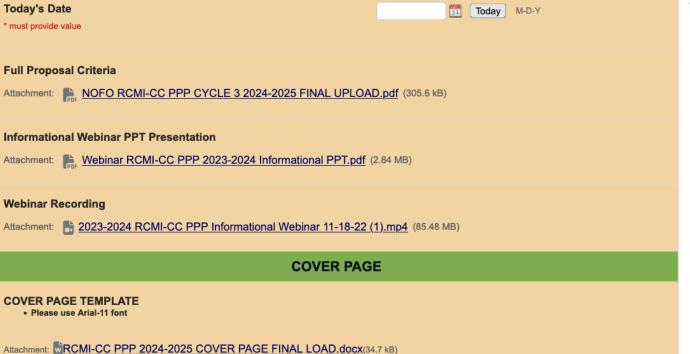




# REDCap online submission portal

2024-2025 RCMI-CC
Clinical Research Pilot
Projects Program
Application Link

#### 2024-2025 Clinical Research Pilot Projects Program





\* must provide value



Upload COVER PAGE in PDF

























Upload file

















## **Application Process: Cover Page**

1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces ar	nd nunctuation)
	as pariously
2. RESEARCH AREA (select one): □ Addiction & Drug Abuse □ Cance □ Digestive & Renal Diseases □ Environmental Health □ HIV/AIDS □ □ Neurological Disorders & Mental Health □ Obesity & Metabolic Syndro	☐ Infectious & Immunological Diseases
3. RESEARCHER CATEGORY (select one): ☐ Basic Biomedical + Basic ☐ Clinical + Basic Biomedical ☐ Clinical + Behavioral/Community ☐ Cli	
4. MULTIPLE PRINCIPAL INVESTIGATOR (CONTACT)	5. MULTIPLE PRINCIPAL INVESTIGATOR (select one)
(select one) □ CLINICAL RESEARCHER □ BASIC SCIENCE RESEARCHER □ BEHAVIORAL/COMMUNITY RESEARCHER	☐ CLINICAL RESEARCHER ☐ BASIC SCIENCE RESEARCHER ☐ BEHAVIORAL/COMMUNITY RESEARCHER
4a. NAME (Last, first, middle) and DEGREE(S)	5a. NAME (Last, first, middle) and DEGREE(S)
4b. CAREER STATUS (Post-Doc, Early Career, Early-Stage Investigator)	5b. CAREER STATUS (Post-Doc, Early Career, Early-Stage Investigator)
4c. AFFILIATION (RCMI Grantee Institution)	5c. AFFILIATION (RCMI Grantee Institution)
4d. TELEPHONE AND E-MAIL	5d. TELEPHONE AND E-MAIL
TEL: E-MAIL:	TEL: E-MAIL:
6. MENTOR (REQUIRED) (select one)  CUNICAL RESEARCHER   BASIC SCIENCE RESEARCHER  BEHAVIORAL/COMMUNITY RESEARCHER	7. COLLABORATOR (REQUIRED) (select one) CLINICAL RESEARCHER  BEHAVIORAL/COMMUNITY RESEARCHER
6a. NAME (Last, first, middle) and DEGREE(S)	7a. NAME (Last, first, middle) and DEGREE(S)
6b. ACADEMIC RANK (Associate or Full Professor)	7b. ACADEMIC RANK (Assistant, Associate or Full Professor)
6c. AFFILIATION (RCMI or non-RCMI Grantee Institution)	7c. AFFILIATION (RCMI or non-RCMI Grantee Institution)
6d. TELEPHONE AND E-MAIL	7d. TELEPHONE AND E-MAIL
TEL: E-MAIL:	TEL: E-MAIL:
8. ADDITIONAL TEAM MEMBER (OPTIONAL) (select one)	9. ADDITIONAL TEAM MEMBER (OPTIONAL) (select one)
Selections)  □ MENTOR □ COLLABORATOR  □ MULTIPLE PRINCIPAL INVESTIGATOR	□ MENTOR □ COLLABORATOR □ MULTIPLE PRINCIPAL INVESTIGATOR
(select one)  □ CLINICAL RESEARCHER □ BASIC SCIENCE RESEARCHER	(select one)  □ CLINICAL RESEARCHER □ BASIC SCIENCE RESEARCHER
☐ BEHAVIORAL/COMMUNITY RESEARCHER	☐ BEHAVIORAL/COMMUNITY RESEARCHER
8a. NAME (Last, first, middle) and DEGREE(S)	9a. NAME (Last, first, middle) and DEGREE(S)
8b. ACADEMIC RANK (if applicable)	9b. ACADEMIC RANK (if applicable)
8c. AFFILIATION (RCMI or non-RCMI Grantee Institution or Organization)	9c. AFFILIATION (RCMI or non-RCMI Grantee Institution or Organization)
8d. TELEPHONE AND E-MAIL	9d. TELEPHONE AND E-MAIL
TEL: E-MAIL:	TEL: E-MAIL:
10. OTHER KEY PERSONNEL AND OTHER SIGNIFICANT CONTRIBUT	,
11. RCMI CORE USAGE (select all that apply; include letters of support fro ☐ Investigator Development Core	om Core Directors):
☐ Community Engagement Core ☐ Research Infrastructure Core/Research Capacity Core ☐ Research Studio Program ☐ Collaboratory ☐ Collaboratory	
☐ Collaboratory 12. NON-RCMI CORE USAGE (specify name of core and program and inc	hada lattera of august from Core Directors):

#### Form-fillable Cover Page to be completed and uploaded online

- 1. Title of Project
- 2. Research Area
- 3. Researcher Category
- 4. Multiple Principal Investigator (contact)
- 5. Multiple Principal Investigator
- 6. Mentor (required)
- 7. Collaborator (required)
- 8. Additional Team Member (optional)
- 9. Additional Team Member (optional)
- 10. Other Key Personnel or Other Significant Contributors
- 11. RCMI Core Usage
- 12. Non-RCMI Core Usage

































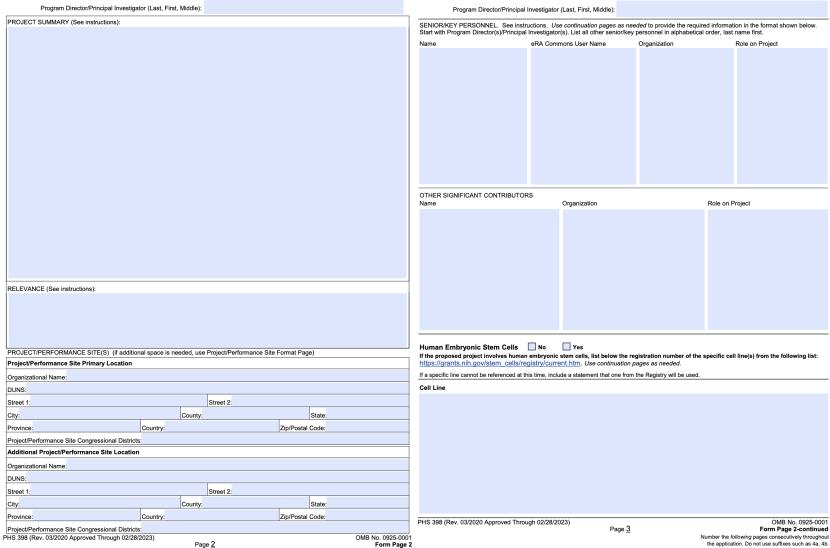








## **Application Process: Project Summary**











































## **Multiple Principal Investigator Plan**

An MPI Plan must be included as a separate uploaded file.

The MPI Plan must address the following:

- 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
- Procedures for resolving conflicts





























## **Application Process: Resources**

Principal Investigators (Last, First):	L
FACILITIES AND RESC	DURCES

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, using the Resources Format Page.

This document must also describe the services, if any, provided by RCMI and/or non-RCMI core facilities.



























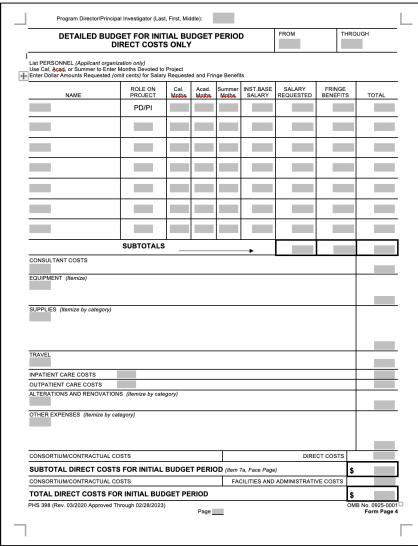


## **Application Process: Budgets**

- Non-modular itemized budget, with justification, for each MPI.
- Maximum request of \$150,000 per year.
- Funds may be requested for MPI and key personnel, small equipment (not to exceed \$5,000), supplies and travel.
- Project period: one year
- No provisions for indirect costs.
- No provisions for carryover requests.
- Funding will be provided through a subcontracting mechanism from the Morehouse School of Medicine to the MPI awardee institutions.



## **Application Process: NIH Budget Page**



#### <u>Download and use the Form Page 4</u>

- Budget for the Initial Budget Period of one year (Direct Costs Only)
- Separate budgets for each MPI
- List MPI and key personnel by name
- Indicate base salary and percent effort, with amounts of fringe benefit for each
- Consultant Costs
- Equipment
- Supplies
- Travel
- In-Patient Care Costs
- Out-Patient Care Costs
- Other Expenses

#### **Consult the Budget Justification** sample to prepare your justification





































## **Application Process: NIH Biosketch**

BIO	GRAPHICAL SKETCH		
Provide the following information for Follow this format for	or the Senior/key personnel and cleach person. DO NOT EXCEED		ibutors.
NAME:			
eRA COMMONS USER NAME (credential, e.ç	g., agency login):		
POSITION TITLE:			
EDUCATION/TRAINING (Begin with baccalau include postdoctoral training and residency tra			
INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY

- A. Personal Statement
- B. Positions, Scientific Appointments, and Honors
- C. Contributions to Science

#### Approved Through 01/31/2026

- Follow the sample format on the Biographical Sketch Format Page
- Figures, tables (other than that in the provided format page), or graphics are not allowed
- Do not embed or attach files (e.g., video, graphics, sound, data)
- The biosketch may not exceed five pages per MPI, mentor, collaborator, and other significant contributor
- A biosketch is required of all key personnel and other significant contributors

https://grants.nih.gov/grants/forms/biosketch.htm









































## **Application Process: Letters of Support**

- Letter(s) from RCMI and/or non-RCMI mentor(s), indicating willingness to meet and provide advice on project execution and career development
- Letter(s) from RCMI and/or non-RCMI collaborator(s), indicating willingness to provide needed expertise and clinical samples, if applicable
- Letter(s) from RCMI and/or non-RCMI Core Director(s), indicating willingness to provide consultation and/or core services
- Letters from RCMI PI/PD and IDC Directors of collaborating RCMI U54 Centers, indicating support and/or budgetary commitment to the proposed research



# Application Process: Protection of Human Subjects

- 1. Risks to Subjects
- 2. Adequacy of Protection Against Risks
- 3. Potential Benefits of the Proposed Research to Research Participants and Others
- 4. Importance of the Knowledge to be Gained
- 5. Eligibility Criteria
- 6. Inclusion of Individuals Across the Lifespan
- 7. Inclusion of Women and Minorities
- 8. Recruitment and Retention Plan
- 9. Study Team
- 10. Data and Safety Monitoring Plan



## **Application Process: IRB**

Also required from each MPI institution at the time of submission:

- Full approval from the Institutional Review Board (IRB)
- Alternatively, a copy of email correspondence of submission of an IRB application or reliance documentation request



## **Scientific Review**

- Established RCMI and non-RCMI investigators with subject-matter expertise and NIH study section experience will serve as reviewers.
- NIH-type review criteria: significance; innovation; approach; investigators; and environment.
- Non-NIH-type review criteria: research focus; collaborations and partnerships; core usage.
- The NIH-type 9-point scoring scale will be used.
- Reviewers will also assess the overall likelihood that pilot support will be leveraged into a competitive grant application to NIH or other funding agency.





## **NIH Review Criteria**

Significance: Does the proposed research address an important health problem? Does the proposed research address an ethnic or geographic disparity in health?

Innovation: Is the proposed research original and innovative? Does the research challenge existing paradigms? Does the research develop or employ novel tools or technologies? Does the research access a hard-to-reach underserved community?

Environment: Does the scientific environment contribute to the probability of success? Does the proposed research benefit from the scientific environment or subject populations? Is there evidence of institutional support, such as faculty-release time and/or matching funds?





### **NIH Review Criteria**

Approach: Are the clinical framework and study design appropriate to the aims of the proposed research? Do the MPI acknowledge potential problems and propose alternative strategies? Are the plans for the protection of human subjects from research risks, and the inclusion of minorities and members of both sexes/genders justified?

Investigators: Do the MPI show evidence of scientific productivity and 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 will be able to respond rapidly to unexpected problems or pitfalls?





## **Non-NIH Review Criteria**

Research Focus: Does the proposed research meet the definition of clinical research? Are health disparities of vulnerable groups addressed?

Collaborations and Partnerships: Does the proposed research represent a partnership between MPI from two or more RCMI U54 Centers? Do the collaborators and mentors have the appropriate qualifications and experience to ensure the successful execution 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 from core directors?





















## **Scientific Review**

## **NIH 9-Point Scoring Scale**

Impact	Score	Descriptor	Additional Guidance on Strengths and Weaknesses
High	1	Exceptional	Exceptional strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses



































## **Funding Priorities and Decisions**

- Funding priority will be given to clinical research projects that demonstrate a cross-disciplinary approach to improving minority health and/or reducing health disparities.
- Funding decisions will be based on priority scores, with direct oversight from the RCMI-CC MPI and ratification by the RCMI-CC Steering Committee. Final approval rests with NIMHD.



## **RCMI Scientific Webinar Series**

As a reminder, RCMI Scientific Webinars will be scheduled for prospective applicants to interact with potential MPI, mentors and collaborators.

- Scientific webinars will consist of three-minute presentations with time for questions
- The first webinar presentations will be held on October 24, 2023.
- A calendar link for signups, as well as a Zoom link, will be shared with RCMI investigators who are interested in presenting and/or attending one or more of the Scientific Webinars.



## RCMI Clinical Research Pilot Projects Program

#### **Key Dates:**

**RELEASE OF NOFO:** 

October 6, 2023

#### **APPLICATION DUE DATE:**

January 16, 2024 at 5:00 pm (Hawaii time)

#### SCIENTIFIC REVIEW PERIOD:

January to February 2024

#### FUNDING DECISION AND APPROVAL PERIOD:

February to March 2024

#### ANTICIPATED AWARD DATE:

May 1, 2024































## RCMI Clinical Research Pilot Projects Program

## **Contact Information**

We encourage your inquiries.

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# RCM Clinical Research Pilot Projects Program

