Technical Assistance Webinar for RFA-MD-22-006, *"Limited Competition: Research Centers in Minority Institutions (RCMI) Clinical Research Network for Health Equity (UG3/UH3 - Clinical Trial Optional)"*

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National Institute on Minority Health and Health Disparities

Webinar Tips

Participants may ask questions using the chat feature. Questions will be answered during the Q&A session at the end of the webinar as time permits.

These slides and a recording of today's webinar will be available at https://www.nimhd.nih.gov/funding/nimhd-funding/webinars.html

Agenda

I. RFA background and objectives

II. Application information

III. Peer review of applications

IV. Timeline for application submission, review, and award

V. Questions

Part I

RFA Background and Objectives

Background

- A clinical research network (CRN) is a consortium of research institutions with affiliated or collaborating ambulatory care clinical practices that collaborate to investigate research questions related to improving the quality of primary care and chronic ambulatory health care, including implementation of best practices and use of multi-level approaches to address health care delivery challenges, and answer questions relevant to the clinicians in this setting.

- CRNs are uniquely positioned for:
  - ✓ Efficacy studies, dissemination and implementation research and comparative effectiveness research.
- CRNs are ideal for conducting a wide variety of physician and patient studies and are a rich source of medical data.

Funding Opportunity Purpose

- Establish a clinical research network that will transform the development, delivery, and sustainability of evidence-based health care practices and services
- Provide the infrastructure to leverage community-based clinicians and/or health care delivery systems
- Conduct research addressing health care for populations that experience health disparities including the diverse clinicians providing health services.

Eligible Institutions: Limited to recipients of RCMI U54 awards made under RFA-MD-17-003, RFA-MD-17-006, RFA-MD-18-012, or RFA-MD-20-006

Primary Goals of RFA MD-22-006

- Develop infrastructure to establish local or regional consortia of ambulatory primary care settings that serve patients from populations that experience health disparities
- Enable practices that serve populations that experience health disparities to be involved in all aspects of clinical research
- Draw on the experience and insight of practicing clinicians and local communities to identify and frame research questions
- Produce research findings that are immediately relevant to the clinician and more easily translated into everyday practice and integrated into health care systems

Program Objectives

Each consortium is required to have the capacity and infrastructure to:

- Efficiently and rapidly identify, recruit and enroll clinicians that serve diverse patient populations into health services and clinical research
- Harmonize electronic health record (EHR) data across multiple integrated systems for common analyses
- Develop, test, and deploy interventions, workflows, and decision support systems
- Develop and test strategies to address health care disparities within ambulatory primary care settings

Program Objectives (Cont'd)

- Facilitate research that addresses emergent health conditions and risk or protective factors that are relevant for populations that experience health disparities
- Enable local or regional primary care clinicians and health care systems to participate in research
- Provide support for two pilot studies
- Work with the Coordinating Center to implement data management practices
- Build and maintain established relationships with relevant constituent groups (e.g., payors, federal and state agencies, patient advisory boards)

Program Objectives (Cont'd)

- Maintain accessibility to relevant patient, clinician, and health system data, including the capacity for:
  - Electronic data capture in practices
  - Research participant follow-up independent of in-office visits
  - Collection of common data elements and data sharing
- Coordinate and facilitate the conduct of research including:
  - Training clinicians and office/clinic staff to enable them to recruit, enroll, and collect data on their patients in their offices/clinics
  - Developing systems to assist clinicians in maintaining high rates of patient enrollment and retention
- Develop and test strategies to encourage adoption, scale-up, and sustainability of new and existing best practices

Milestones and UG3/UH3 Transition

- **UG3 Start-up/Planning Phase** (1-2 years): Designed to support a project with specific milestones to be accomplished by the end of the first project period
  - The milestones should be robust and associated with clear, quantitative criteria for success that allow go/no-go decisions at the UG3/UH3 transition point
- **UH3 Project Execution Phase** (up to 3 years): Follows successful completion of the UG3 Phase
  - Proposed annual milestones
- **Milestone**: A scheduled event in the project timeline, signifying the completion of a major project stage or activity
  - UG3 projects that meet their milestones will be administratively considered by NIMHD and prioritized for transition to the UH3 phase

Milestones and UG3/UH3 Transition

- At the end of the UG3 phase, the applicant will submit a detailed UH3 transition request
- Transition to the UH3 phase will occur only if administrative review of the transition request concludes that the UG3 planning milestones have been successfully met
- Initial funding of the UG3 planning phase does not guarantee support of the UH3 project execution phase.
  - Continuation of the award is conditional upon satisfactory progress and subject to availability of funds

UG3 Phase: Planning

- **Objectives**
  - ✓ Development of resources needed for the proposed pilot projects
  - ✓ Further development and finalization of study partnerships including signed contracts with performing clinical sites
  - ✓ Single Institutional Review Board (IRB) approval of the study
  - ✓ Data and Safety Monitoring Plans
  - ✓ Finalization of the informed consent form(s), manual of operations, and proposed pilot project management plans
- The pilot project management plan must delineate how the study will monitor and evaluate critical processes impacting feasibility of launch, conduct, and completion, coupled with on-time and on-budget performance milestones
- All regulatory approvals for proposed pilot projects should be obtained prior to the end of the UG3 award

UH3 Phase: Project Execution

- **Objectives**
  - Conduct two pilot projects in accordance with activities planned in the UG3 phase
  - UH3 objectives will be fully described in the phase II application
- **General Goals**
  - Complete enrollment and follow-up of all study participants
  - Within 12 months of completion of the proposed examination and study visits
    - Complete, cleaned, and de-identified dataset
    - Any supporting documentation required for the data analyses

Part II

Application Information

Key Information

- This competition is limited to recipients of RCMI U54 awards made under RFA-MD-17-003, RFA-MD-17-006, RFA-MD-18-012, or RFA-MD-20-006
- To be eligible, the parent award must be active when the application is submitted
- Applicant organizations may submit more than one application, provided that each application is scientifically distinct
- Only New Applications can be submitted in response to this FOA

Application and Submission Information

Letter of Intent (LOI)

- A LOI is not required, is not binding, and does not enter into the review of a subsequent application. The information it contains helps NIMHD staff estimate potential review workload and plan the review meeting.
- To submit a LOI, prospective applicants are asked to include:
  - Descriptive title of proposed activity
  - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  - Names of other key personnel
  - Participating institution(s)
  - Number and title of this funding opportunity

  ✓ See FOA Part 2, Section IV.2 for instructions on submitting LOI

UG3/UH3 Application Components

R&R Budget

- All instructions in the SF424 (R&R) Application Guide must be followed.
- For the initial UG3/UH3 application, a complete detailed budget is required for both the UG3 phase and the UH3 phase.
- The applicant should estimate the costs for the UH3 implementation phase based on the scope of work described in the application for the UH3 phase
- Budget justifications must be included

RCMI CRNHE Consortium Research Strategy

- List separate specific aims for each phase and clearly label them as UG3 specific aims and UH3 specific aims
- Within the Research Strategy, describe the UG3 Phase first and then the UH3 Phase.
  - No need to repeat background info or methods details in the UH3 portion that were provided in the UG3 portion
  - UH3 Phase must be described in sufficient detail to permit reviewers to assess the significance and innovation of the proposed work
- Describe the organizational plan and management structure for providing leadership and administrative support.
  - Delineate roles and responsibilities
  - Propose the formation of a Patient/Community Advisory Board

RCMI CRNHE Consortium Research Strategy

- For the two pilot studies in Phase 2, describe plans to:
  - Solicit, review, and select pilot projects
  - Build capacity and infrastructure support
  - Enable primary care clinicians to participate in research
  - Work with the CC to implement data management practices
- Describe methods and design activities to support the pilot projects and collaboration with the CC
- Describe the approach to:
  - Develop collaborative agreements
  - Identify capacity needs within each participating practice and health care system
- Describe strategies to:
  - Inform research questions, recruit practices, implement studies
  - Disseminate practices and products developed through consortium studies

RCMI CRNHE Consortium Research Strategy

- For each practice and health care system identified as a potential member of the consortium, provide data about:
  - ✓ Geographic service areas
  - ✓ Key demographic characteristics of patients including race/ethnicity, age distribution, and insurance status
  - ✓ Characteristics of practice settings (e.g., in-hospital, ambulatory)
  - ✓ Demographic characteristics including race/ethnicity and gender of the clinicians providing care (MDs/DOs, PAs, or NPs)
- Describe the approach the consortium will take to develop a disease-agnostic research agenda that can include:
  - Observational studies, pragmatic clinical trials, efficacy trials, translational research, comparative effectiveness, and implementation science
  - Development and testing of feasible, scalable, and sustainable interventions and service delivery strategies that will ultimately improve health and health care services for populations that experience health disparities

RCMI CRNHE Consortium Research Strategy

- Describe activities designed to establish long-term relationships with communities and community organizations, including:
  - ✓ Tribal governments and agencies, grassroots organizations, public health departments, and community and faith-based organizations
- Projects should include well-defined milestones for the planning phase (UG3) and annual milestones for the implementation phase (UH3)
- Transition from the UG3 to the UH3 phase is contingent upon the successful completion of proposed milestones

RCMI CRNHE Consortium Letters of Support

- Applicants must provide letter(s) from practices that are potential members of the consortium
- Indicate the commitment of the practice(s) to
  - Participate in the RCMI CRNHE program
  - The RCMI CRNHE Consortium goals
- Specify any institutional support, e.g., financial support, dedicated space, salary support for professional or administrative staff, interface with other centers and initiatives
- Inclusion of Letters of Support in the application should adhere to the SF424 instructions and be combined into a single file attachment. The Letters of Support attachment should begin with a table of letter authors, their institutions, and the type of each letter (institutional commitment or resources; collaboration or role in the project; potential or current user of a resource or service provided in the application).

Award Information

- NIMHD intends to commit $3.0 million in FY 2022 to fund two awards
- Application budgets are limited to $1.0 million in direct costs annually
- Applicants may request no more than 5 years of support; the scope of the proposed project should determine the project period

Part III:

Peer Review of Applications

UG3/UH3 Program Peer Review

- Applications will be assessed for **completeness** by the Center for Scientific Review (**CSR**);

- NIMHD **program staff** will assess the applications for **responsiveness** based on the eligibility criteria in the RFA; and

- NIMHD scientific Review Officer (**SRO**) will assemble a panel of experts from the extramural community to **peer review** the applications.

Preparations for Peer Review

- RFA Specific Characteristics & Review Criteria
  - Overall program goals
  - Mechanism characteristics specific to this RFA
  - Review Criteria: Specific to this RFA in Section V
    - Additional Review Criteria/Considerations (e.g. Human Subjects/Budgets, etc.)
- Administrative Review of Applications
  - **RFA requirements**: whether the applications are **complete** as required by the RFA and have the appropriate sections to be able to be reviewed?
  - Which **personnel** are involved in each application and their institution affiliation?
  - The **specific aims** stated in each application and **expertise** needed.

SEP Reviewer Selection

- Scientific Expertise
  - As defined in RFA
  - Collective content of the applications
- Attention to Conflict of Interest
- Diverse representation of opinion:
  - gender
  - demographics
  - geography

Review Process

- Pre-Meeting: Reviewers submit the **written opinions/critiques**
- During Meeting: Reviewers discuss the applications and vote for **overall impact/final scores**
- After meeting: SRO write the **resume** and finalize the summary statements

Peer Review Criteria

- Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

- Reflects the likelihood for Project to exert a sustained, powerful influence on the research field(s).

5-Scored Review Criteria

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

Additional Review Criteria

(included in the determination of the overall score)

- Study Timeline (Specific to applications designated clinical trial on the electronic cover sheet)
- Protection for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards

Additional Review Considerations

(criteria not included in the determination of the overall score)

- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
  https://grants.nih.gov/policy/reproducibility/guidance.htm
- Budget and Period of Support

Award Budget

- UG3/UH3 Exploratory/Developmental Phased Award Cooperative Agreement involves 2 phases:
  - UG3 phase is to provide funding for up to 2 years,
  - UH3 phase is to provide funding up to 3 additional years
- Budgets limited to $1,000,000 in direct costs per year
- NIMHD intends to commit $3,000,000 in FY 2022 to fund 2 awards

UG3/UH3 Program Peer Review Meeting

- Some applications may be “streamlined” -- not discussed (ND)
  - Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

- Final Impact Score based on average of all voting reviewers multiplied by 10
  - Scores range from 10 (exceptional) to 90 (poor)

- A summary statement for all applications would be available approximately 30 days after the review meeting

❖ **Do not contact the members of the review panel!**

Videos on Peer Review Topics

The Center for Scientific Review (CSR) has produced videos with an inside look at peer review for scientific and technical merit and with tips for preparing applications.

https://public.csr.nih.gov/NewsAndPolicy/PeerReviewVideos

Resources for using eRA Commons

https://era.nih.gov/era-training/era-videos.htm?q=era_training/era_videos.cfm#iar1

Problems with Submission Processing

Always contact eRA Service Desk.

https://grants.nih.gov/support/index.html

In Doubt

Phone NIH

Peer Review, Program, and Grant Administration Contacts are included on the last slide of this presentation and in the RFA.

Part IV:

Timeline for Submission, Review, and Selection of Cooperative Agreements

Timeline

- Letter of Intent Due Date: May 01, 2022
- Application Due Date: May 31, 2022
- Peer Review Meeting: July 2022
- Council Review: August 2022
- Earliest Start Date: September 2022

Participant Questions

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