Technical Assistance Webinar: DECIPHER U24 FOA RFA-HL-20-004

Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHER) Research Coordinating Center

(RCC - U24 Clinical Trial Not Allowed)

April 15, 2019, 3 pm EST

Center for Translation Research and Implementation Science (CTRIS)





Webinar Logistics

Event password: decipher

Number (US/Canada): 1-650-479-3208

Meeting Number/Access code: 622 207 914

Event address for attendees:

https://nih.webex.com/nih/onstage/g.php?MTID=e9e353bd1b608347 3f01a9abf4db575d1

Please, mute your phones and computers



Webinar Agenda

Introductions

- CTRIS Personnel and Overview

Overview of DECIPHeR Research Coordinating Center (RCC) (U24 Clinical Trial Not Allowed)

- Purpose and Background
- Scope of RCC Activities
- Structure
- Award Information and Review Process
- Important Dates

Question & Answer Session

FAQs posted at https://www.nhlbi.nih.gov/grants-and-training/funding-opportunity-announcements-2908.



Questions

You may send questions now and subsequently to Melissa.greenparker@nih.gov



Introductions

Dr. George A. Mensah

Director, Center for Translation Research and Implementation Science (CTRIS), NHLBI

Dr. LeShawndra Price

Chief, Health Inequities and Global Health Branch, CTRIS

Dr. Melissa Green Parker

Program Official, CTRIS

Dr. Kathleen Fenton

Health Scientist, CTRIS

Ms. Tammi L. Simpson

Sr. Grants Management Specialist, NHLBI



Center for Translation Research and Implementation Science (CTRIS)

 CTRIS plans, fosters, and supports research to identify the best strategies for ensuring successful integration of evidence-based interventions within clinical and public health settings, such as health centers, worksites, communities, and schools in the United States and abroad.

 CTRIS supports late-stage T4 translation research to help turn discoveries into improved health.

https://www.nhlbi.nih.gov/about/divisions/center-translation-research-and-implementation-science

@NHLBI_TRANSLATE



Why Focus on T4 Translation Research

Biomedical Model

Bench Research

- Fundamental Discovery Science
 - Animal Studies

Bedside

- 1st Human Studies
- Controlled Observations
- Phase I Clinical Trials

Patients

 Phase II and III Clinical Trials

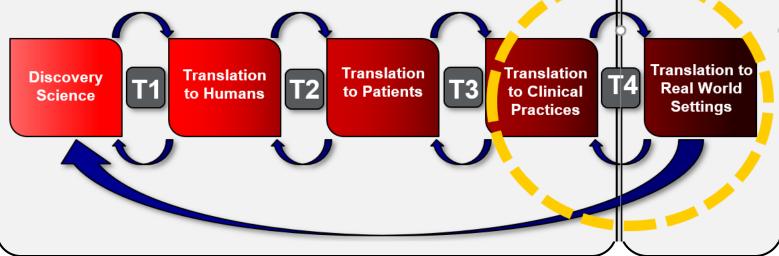
Clinical Practices*

- Phase IV Clinical Trials;
- Comparative Effectiveness Research;
- D&I Research

Biomedical and Socioecological Model

Real World Settings

- Implementation Trials
- D&I Research with Implementation Research Outcomes
- Research Training and Career Development





NIH National Heart, Lung, and Blood Institute

Reducing Health Disparities through Translation Research

Objective 3: Population
Differences





JAMA. 2017;317(19):1955-1957.

Cardiovascular Mortality
Differences —
Place Matters

George A. Mensah, David C. Goff, Gary H. Gibbons



Circulation Research



Reducing Cardiovascular Disparities Through Community-Engaged Implementation Research: A National Heart, Lung, and Blood Institute Workshop Report George A. Mensala, Richard S. Cooper, Anna Maria Siega-Riz, Lisa A. Cooper, Justin D. Smith, C. Hendricks Brown, John M. Westfall, Elizabeth O. Ofili, LeShawndra N. Price, Sonia Arteaga, Melissa C. Green Parker, Cheryl R. Nelson, Bradley J. Newsome, Nicole Redmond, Rebecca A. Roper, Bettina M. Beech, Jada L. Brooks, Debra Furr-Holden, Samson Y. Gebreab, Wayne H. Giles, Regina Smith James, Tené T. Lewis, Ali H. Mokdadt, Kari D. Moore, Joseph E. Ravenell, Al Richmond, Nancy E. Schoenberg, Mario Sims, Gopal K. Singh, Anne E. Sumner, Roberto P. Treviño, Karriem S. Watson, M. Larissa Avilés-Santa, Jared P. Reis, Charlotte A. Pratt, Michael M. Engelgau, David C. Goff, Ir and Eliseo J. Pérez-Stable

DECIPHER: Community-engaged participatory research to reduce disparities in heart, lung, blood, and sleep disorders.



DECIPHER U24 FOA's Purpose

Invites applications for a Research Coordinating Center (RCC) to support projects from DECIPHER UG3/UH3 projects, which will test late-stage (T4) implementation strategies for optimally and sustainably delivering proven-effective, evidence-based, multi-level interventions to reduce or eliminate cardiovascular and/or pulmonary health disparities, and promote and improve population health in high-burden communities.

Scope of Activities for RCC

- The DECIPHER RCC will be responsible for enabling collaboration and communication among DECIPHER investigators and the broader research community; for facilitating network outreach; and for harmonizing research projects conducted across awardees..
- Specific activities of the DECIPHER RCC will include, but are not limited to,:
 - 1. Organization and Management
 - 2. Research Coordination and Data Analysis
 - 3. Research Skills Development and Capacity Building
- While the U24 mechanism is not phased, the RCC's work is dependent on the performance of the associated DECIPHeR UG3/UH3 projects.

Structure

- The RCC U24 will play a central role in organization, management, and data analysis which will require collaboration with the UG3/UH3 awardees.
- This FOA will utilize a resources-related cooperative agreement mechanism and will be performance-based to ensure that the RCC's contributions to the effective and efficient conduct of the DECIPHeR UG3/UH3 projects and analysis of data are on time and on budget.
- Applicants are strongly encouraged to employ project management principles as appropriate.

Cooperative Agreement Terms and Conditions of Award

- Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities.
- Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.
- Specific tasks and activities shared among the awardees and the NIH are defined in <u>Section VI. Award Administration Information</u>

DECIPHER U24 Award Information

- NHLBI intends to fund up to one U24 award.
- Application budgets are limited to \$750,000 total costs in FY 2020, and \$625,000 total costs per year in FY 2021 FY 2025, and \$750,000 in FY 2026.
- Application budgets may not exceed direct costs of up to \$485,000 in FY 2020, \$405,000 per year in FY 2021 - FY 2025, and \$485,000 in FY 2026.
- The scope of the proposed project should determine the project period.
- The maximum project period is up to 7 years.



Required Budget Information

 All instructions in the <u>SF424 (R&R) Application Guide</u> must be followed.

Start Up Meeting

Budgets must include funds for the PD/PI and two additional key personnel to participate in a two-day start-up meeting in Bethesda, Maryland at the NIH during the first year of the award (within the UG3 phase).

Annual Meetings

• Budgets must include funds for the PD/PI and two additional key personnel to attend annual 3 day meetings of key staff of each award, appropriate NHLBI staff, RCC key personnel, and selected experts in year 2 through the end of the award period and should include costs for hosting one of these annual meetings at the activity site of one of the awardee projects on a rotating basis.

Required Budget Information, cont'd

Community Engagement

- In order to equitably engage the community of interest in the research activities under the award, applications should budget for local community meetings or other appropriate activities.
- If parts of the costs are to be provided by sources other than NHLBI, these contributions must be presented in detail in the budget justification.

DSMB

- Include all costs associated with DSMB activities. This includes:
 - costs for preparing reports for the DSMB and meeting requirements for the DSMB members;
 - liability insurance for DSMB members, if applicable;
 - costs associated with assessing DSMB member conflict of interest
 - coordination of support for at least one DSMB meeting per year (by teleconference or videoconference) if the DSMB is convened by NHLBI.
- Include budget support for publication, data sharing, and broad dissemination of results.

Review and Selection Process

- Applications will be evaluated for scientific and technical merit convened by NHLBI, in accordance with <u>NIH peer review policy and</u> procedures, using the stated review criteria.
- As part of the scientific peer review, all applications:
 - May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score.
 - Will receive a written critique.



Anticipated Announcement and Award Dates

 After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Letters of Intent (optional) Due Date	Application Receipt Date	Special Emphasis Panel Review	Earliest Start Date
April 17, 2019	May 17, 2019	October 2019	April 2020
April 17, 2019 - Sept. 1, 2019	Oct 1, 2019	March 2020	July 2020

Letter of Intent (LOI)

- Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.
- Prospective applicants are asked to submit a LOI that includes the following information:
 - 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
- The LOI should be sent to:

Director, Office of Scientific Review

Division of Extramural Research Activities

Telephone: 301-435-0279

Email: nhlbichiefreviewbranch@nhlbi.nih.gov



Questions and Answers

Send Questions to:Melissa.greenparker@nih.gov

FAQs for DECIPHER U24:

https://www.nhlbi.nih.gov/grants-andtraining/funding-opportunities-and-contacts/allfunding-opportunity-announcements-2908

Thank You

