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)
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=e9e353bd1b6083473f01a9abf4db575d1

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**

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

**T1** Discovery Science → **T2** Translation to Patients → **T3** Translation to Clinical Practices → **T4** Translation to Real World Settings

---

Reducing Health Disparities through Translation Research

**Objective 3: Population Differences**

**JAMA** The Journal of the American Medical Association


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


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

---

Mensah et al., *Circ Res* 2018 Jan 19; 19; 122(2); 213-230.
Roth, et al. *JAMA*, May 16, 2017
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.
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.
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.
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 Section VI. Award Administration 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.
All instructions in the **SF424 (R&R) Application Guide** 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.
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.
Applications will be evaluated for scientific and technical merit convened by NHLBI, in accordance with NIH peer review policy and 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.

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](https://eracommons.org).

<table>
<thead>
<tr>
<th>Letters of Intent (optional) Due Date</th>
<th>Application Receipt Date</th>
<th>Special Emphasis Panel Review</th>
<th>Earliest Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 17, 2019</td>
<td>May 17, 2019</td>
<td>October 2019</td>
<td>April 2020</td>
</tr>
<tr>
<td>April 17, 2019 – Sept. 1, 2019</td>
<td>Oct 1, 2019</td>
<td>March 2020</td>
<td>July 2020</td>
</tr>
</tbody>
</table>
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
