

Request for Application 2023-2024

Duke Clinical and Translational Science Institute (CTSI)

Community Engaged Research Initiative (CERI) Population Health Improvement Awards (PHI)

IMPORTANT DEADLINES:

Mandatory Letter of Intent (LOI): due Friday, January 27, 2023, 5:00 p.m. EST.

Full proposal by invitation: due Friday, March 31, 2023, 5:00 p.m. EST.

The Duke Clinical and Translational Science Institute (CTSI)'s Community Engaged Research Initiative (CERI) aims to support community-engaged research partnerships. Funds are available for eligible **NEW** community-academic partner investigator teams. During the 2023-2024 funding cycle, CTSI-CERI will fund two \$50,000 awards to stimulate community-engaged research through community-academic research-partnered projects to improve Durham County population health.

Duke CTSI facilitates translational research by providing funding, promoting community-academic collaborations, encouraging translational research innovation, and providing access to resources/services in a collaborative and service-oriented fashion.

This RFA will support the following type of work:

- Studies that address mechanisms and drivers of health contributing to human health and health inequities.
- Studies that contribute to improvements in population health or health equity by addressing barriers and opportunities to improve clinical care or healthy behaviors in community settings.
- Studies that contribute to improved population health outcomes or health equity through changes in clinical practice, community/environmental or systems changes, or health policy.
- Studies addressing barriers and facilitators to implement evidence-based practices promoting health and health equity in community settings.
- Studies and program evaluation studies to address the impact of existing interventions to improve population health.
- Studies evaluating the process and outcomes of the implementation of evidence-based interventions in community settings.

I. Purpose and instructions

These awards are intended to support equitable, bidirectional, and collaborative research proposals from community organizations/groups in partnership with Duke University researchers. Studies should address population health issues identified as priorities by the **Durham** community that will help close existing health inequities and improve population health. Funds may be used to generate formative or pilot data or evaluate existing programs to better position partnerships for external funding. **Applications supported by this RFA will only consider NEW partnerships.**

A consultation with CERI is encouraged before submitting the mandatory Letter of Intent (LOI). Submit your request [here](#). Research teams are highly encouraged to consider and incorporate the recommendations made during the consultation. Guidance may include (but is not limited to) partnership development, RFA alignment, study feasibility, or operational capacity. CERI can also connect applicants to other CTSI cores able to assist with project components (e.g. biostatistics, metrics and evaluation, project management, and emerging technologies). Some Core assistance is fee-based, and these costs should be included in the final budget.

If your application is funded, you should schedule a meeting as soon as possible with Duke Office of Clinical Research (DOCR), and Duke Office of Research Contracts (ORC) to ensure and review the necessary steps to comply with Duke research policies and to discuss your partnership agreements. Your research team should plan to attend (the Duke and Community Co-Investigators, key project staff, and any other department-level staff). Duke Investigators, taking fiduciary responsibility for the project, are responsible for contacting their Clinical Research Unit to ensure support for the implementation and execution of the proposed study. **Detailed PI responsibilities are listed in the [Duke faculty handbook](#).**

II. Key Dates

- **Mandatory Letter of Intent deadline: Friday, January 27, 2023 (5:00 PM ET)**
- Selected applicants will receive an invitation to submit a full proposal no later than the week of February 20, 2023
- Invited Applicant Submission Deadline: Friday, **March 31, 2023 (5:00 PM ET)**
- Selection of Awardees: by the week of **May 15, 2023**
- Funding Period: The budget period is for **12 months** beginning September 1, 2023, and ending no later than August 31, 2024. Awardees can use a 3-month start-up period (June-August 2023) to ensure the timely completion of any necessary agreements or other pre-award activities.

III. Priorities:

Duke CTSI and CERI are interested in projects that have been envisioned and co-created through a collaboration between the community and Duke partners. For this RFA, preference will be given to projects that utilize data from the [SEED \(Social, Environmental, and Equity Drivers\) Health Atlas](#) to identify communities within Durham facing unique health challenges and design projects to help move the needle toward improving the population health of these communities. The SEED Health Atlas is a resource for the community and researchers to learn about health and drivers of health in the Durham area, including education access and quality, health care access and quality, neighborhood and built environment, social and community context, and economic stability. The SEED Health Atlas data can inform:

- Research that **focuses on areas of disparity and health inequity** (Race or ethnicity, sex, sexual identity, age, disability, socioeconomic status, and geographic location)
- Pilot studies that **use previously gathered data** in selecting and tracking outcomes, including, but not limited to Patient or Community Reported Outcomes
- **Tests of innovative implementation strategies** to optimize uptake of solutions at the community level that show promise and support **sustainable solutions** geared toward improving local health and securing follow-on support for larger investigations of implementation
- **Evaluation of programs** that are currently ongoing, addressing unique challenges faced by communities identified using the SEED Health Atlas

In addition to the prioritization of proposals that are informed by SEED Health Atlas data, proposals will be evaluated based on the following:

- A problem-based or hypothesis-driven research or evaluation question. The project has a strong scientific premise, with well-constructed and clearly defined aims and approach, with the potential to advance health research and understanding of community, population health, and health disparity and inequities
- A plan to co-develop and test evidence-based practices, such as interventions in community settings
- A plan to achieve sustainability
- The ability to mobilize community assets and strengths to test the feasibility of implementation strategies for population health improvement
- An overall equity framework including partnership equity (shared leadership responsibilities, distribution of research activities, and financial resources)

IV. Eligibility

- Proposed research must include a team that is comprised of both Duke Faculty and community partner(s). Although a Co-Principal Investigator structure is recommended to support co-led community-academic partnerships, the Duke Faculty member must serve as the Principal Investigator of record as she/he/they will serve as the person with the fiduciary and overall responsibility for the sponsored project. **Duke PI must ensure they have the needed support and resources from their Department Clinical Research Unit to execute and complete the proposed project and that they follow Duke policies.** Detailed PI responsibilities are listed in the [Duke Faculty handbook](#).
- Applicants may be involved in more than one proposal but can only serve as the project lead or lead investigator in one application during the funding cycle. Submissions can be made by either the Duke or the community lead. However, only one application can be submitted by the team. As mentioned above, the lead Duke Faculty partner will serve as the Principal Investigator of record.
- Research must relate directly to health, and the objectives of the project should include an outcome that will benefit community/population health or patient care

- Nonprofits with 501(c) (3) IRS Status (Other than Institutions of Higher Education), particularly community organizations with a focus on public health, social services, caregiving, and patient advocacy) and members of practice-based research networks
- Eligible agencies of the state and local government
- Permanent, full-time Duke Faculty, including faculty in the **Faculty Career Track** and the **Faculty Tenure Track**
- While we encourage diverse engagement on projects, a rank of less than medical instructor (such as post-doctoral trainees, fellows, learners, and/or research coordinators and other staff) are not eligible to serve as a PI or as co-investigators.
- **Previously funded work via this mechanism will not be considered.**

V. Letter of Intent and Application Procedures

Letter of Intent (Mandatory)

- Research statement**, including research question and specific aims (No more than 1/2 page)
- Brief summary** of proposed research design: purpose, significance, innovation, approach (up to 1 page), **Arial 11 font, and single-spaced**. Be sure to answer the following:
 - What is your research question? How does the SEED Health Atlas inform your research? What problem are you trying to solve, and what do you anticipate is the long-term impact of your project?
 - What is innovative about your research study?
 - What is the general design of your study, and how will it be carried out?
 - How are you working together to determine roles and responsibilities?
 - How will you ensure an equity framework within your research through the design and conduct of the research project?
- Translation statement** – ¼ page:
 - How will success and impact be evaluated and measured?
 - What is the clinical/population health impact of the proposed work?
 - What are the translational research findings of the proposed work?
 - What is the potential for scalability and sustainability of the findings of the proposed work?
- Draft budget** for each research partner organization (e.g. percent salary and fringe costs support for staff, requested project support costs, etc.) Review allowable costs below. Example of budget structure (may be modified as needed):

Expenses	Community Partner (insert name)	Justification	Duke Partner	Justification	Combined costs
Salary					
Fringe					
Incentives					
Project expenses					
<i>Other</i>					
<i>Other</i>					
<i>Other</i>					
Total					

- Combine all documents into a single PDF and email to CeRi@dm.duke.edu by Friday, January 27, 2023 5:00 PM EST.**

Applicants invited to submit full applications will receive an email notification no later than the week of February 20, 2023. The following guidance is for full proposal submission which is by invitation. Unsolicited proposals will not be reviewed.

Sections will be uploaded into the **My Research Proposal (MRP) application system** as individual PDF or word document files. Application instructions will be provided to invited applicants in an email.

Application sections are:

- A. Abstract** (unstructured max of 250 words)
 - B. Specific aims** (one page)
 - C. Research plan:** The proposal research plan (5-page limit) should include the following:
 - **Purpose** – background, and rationale for the project. Approximately 1/2 page.
 - **Significance** - relevance and alignment with the community and population health priorities. Approximately 1/2 page.
 - **Innovation** - application design/research plan includes innovative elements. Approximately 1/2 page).
 - **Approach, Methods & Analysis** -include design, procedures, sample, recruitment, methods/measures, data management, and analysis plan. Also, include how the SEED Atlas informs the proposed project. Approximately 2 pages.
 - **Sustainability plan:** May include future grant submission plans- where and what kind of grant will be submitted using results from this pilot funding? When might this grant be submitted? Outline how the project is/will be translated – into the clinic/population. (Approximately 1/2 page)
 - **Translation Plan**– (approximately 1 page) applicants must demonstrate a strategy and plan for successful translation, and define what translation means in the context of the proposed project. Furthermore, applicants should clearly articulate the following for the proposed research:
 - its community partnership and engagement plan: the applicant must clearly outline relevant community partner(s); strategies to engage with them; delineate community partner (s)- relevant outcomes (i.e. outcomes relevant to patients, consumers, families, practitioners, administrators, and/or policymakers, etc); and plans to disseminate findings
 - its clinical/population health impact;
 - expected translational research findingsApplicants must choose a total of up to 5 [Indicators](#) of the [Translational Science Benefits Model](#) (TSBM) that are relevant to the proposal and specifically address how the proposed work will have an impact on the chosen TSBM Indicators.
 - **Timeline** (approximately 1/2 page)
- *Include where applicable clear evidence of how the proposal meets the review criteria in Section VII. (5-page limit, including tables and figures. References do not count toward the page limit; single line spacing, font no smaller than Arial 11, 1-inch margins.)
- D. Student Engagement Plan:** we encourage student engagement. However, students cannot assume the role of study coordinator or PI as mentioned above. If students are part of the research team, the applicant must outline the roles and responsibilities of the student.
 - E. Budgets** using [PHS398 form page 4](#) and **Budget Justifications** (please include in paragraph format on a separate page). Duke and community investigator partner budgets should be prepared individually, on separate form pages and uploaded as separate PDFs or word document. See below for guidelines for budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
 - [The FY23-24 Projected Non-Federal Fringe rates can be found here](#)

- F. Human and/or Animal Subjects Protections:** Institutional Review Board (IRB) approval is not required prior to submission **but will be required prior to funding**. Briefly describe any human and/or animal subject issues. If human subjects are involved, describe their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the Duke IRB and comply with HIPAA. If vertebrate animals are to be used, describe the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Studies must demonstrate compliance with the [NIH policy for the inclusion of women and minorities](#). In addition, if the research involves human subjects, all personnel named on the budget pages must have certification of training in the protection of human subjects before the start of the grant period.
- G. NIH Biosketch for faculty Investigators and Biosketch, resume (no format), or CV (no format) for Community Investigators** and for key members of the research team, as needed (combine and upload as a single PDF or word document) - [click here for NIH Biosketch details](#).

VI. Budget Guidelines

Note for Duke Investigators: This award is internally funded and does not need to be routed through the Office of Research Administration or Office of Research Support. However, include your grants team and your CRU in preparing this proposed budget.

Please note the following during budget preparation:

1. The budget period is for 12 months, beginning on September 1, 2023 and ending no later than August 31, 2024. Applicants may request \$50,000 in direct costs. Funding will not be available until applicable IRB documentation is provided to Duke CTSI.
2. Guidelines
 - A. Grant funds may be budgeted for:**
 - Support personnel
 - Use of CTSI's services, including salary support for CTSA UL1 faculty, such as biostatistics, metrics and evaluation, and emerging technologies
 - Travel that is necessary for conducting the research project
 - Travel expenses directly related to conducting research planning or implementation
 - Expenses related to conducting engagement activities with patients and other communities
 - Research supplies (not office supplies) and lab cost
 - Manuscript preparation and submission
 - B. Grant funds cannot be budgeted for:**
 - General consumable supplies
 - Meals or travel expenses incurred for personal or social purposes unrelated to the project.
 - Professional education or training
 - Computers or audiovisual equipment
 - Effort for post-doctoral trainees or fellows on training grant equivalents
 - Capital equipment (ex. heating and electric, cabinets, building renovations, etc.)
 - Print advertising
 - Office supplies or communication costs, including printing, postage and cell phones, or Foreign components, as defined in the [NIH Grants Policy Statement](#)
 - C. Awarded funds must be used to conduct the work proposed.** All direct charges to this award must adhere to federal regulations and requirements, as well as all Duke policies and procedures, regarding using CTSI School of Medicine funds. Duke CTSI reserves the right to revoke funding in the event it is determined that funds were not spent following the approved proposal.

VII. Selection Process and Review Criteria

Mandatory Letters of Intent (LOI) will be reviewed by a committee comprising of Duke CTSI faculty and staff. Full proposals will be reviewed by a committee of Duke CTSI faculty and staff, community members and/or representatives of community organizations, researchers, and experts in community and population health.

Review criteria will include:

- New partnerships
- Significance of the proposed research for clinical/population health
- Innovation of the research
- Use of the SEED Atlas to formulate the research question and proposed project
- Relevance and alignment with community and population health priorities (as stated above), and patient care
- Potential for the project to lead to future external funding, implementation, and sustainability
- Proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period & with the budget provided
- Level of community engagement in identifying the focus of the research and its purpose, design, conduct, and ownership.
- Translational potential as it pertains to the proposed area of research:
 - Has successful translation been defined?
 - Is there a description of how success and impact can be evaluated and measured?

VIII. Terms of the Award (if funded)

Duke CTSI will fund the research activities, **\$50,000** in direct costs per project proposal (no indirect costs will be awarded), covering expenditures for a maximum of 12- month period. The project will begin when applicable IRB documentation is provided to Duke's CTSI and the PI indicates everything is in place for the project to commence. If more than three months pass after notification of funding and the Project Lead is still not ready to start, Duke's CTSI reserves the right to retract the award. At the end of the 12-month project, any unexpended funds will be retained by the CTSI's grant program.

The primary source of funding is the Duke School of Medicine. **Awards are contingent upon funding from the School of Medicine.**

Requests for no-cost extensions will not be approved.

A. Approvals Required Before Funding Start Date

- Awardees are expected to finalize all regulatory requirements during a three-month study start-up period (June 1 – August 31, 2023).
- Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke IRB.
- Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to Duke CTSI prior to funds being released & work beginning on the project. Human subjects or animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period- <https://aboutctiprogram.org/en/homepage/>
- Fully executed appropriate legal agreement(s) between Duke and community partners must be in place prior to the start of work on the research project.
- Please submit documents in the requested timeframe to avoid cancellation of funding.

B. Project Execution

- A six-month interim progress report and a final progress report will be required. Duke CTSI expects Duke Investigators and community partners to report the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents over the lifetime of the work.
- The institutional funds used in our CTSI pilot funding programs take on the identity of federal funds in this award mechanism. They, therefore should be treated as such concerning IRB, and tech transfer office reporting.
- Any awardee who leaves or plans to leave their position should contact Duke CTSI **in advance** to discuss the future for the project.
- Awardees will be invited and are encouraged to serve as reviewers for future Duke CTSI funding opportunities.

C. Post-Award Reporting

Duke CTSI tracks significant events (“translational units”) that are required to translate a scientific discovery from laboratory, clinical or population studies into clinical or population-based applications to improve health by reducing disease incidence, morbidity and mortality. When requested, all awardees will be expected to provide updates on publications and other translational units that originated from the award. Examples include:

- All publications emerging from the work supported by this award are mandated to cite PHI as the funding source. (*Citation language below)
- Abstracts/presentations, manuscripts, published guidelines.
- Follow-on funding (e.g., grants, contracts, angel and venture capital investment)
- Regulatory meetings and filings (e.g., 510K, IDE, IND, BLA, NDA)
- Initiation of appropriate clinical studies
- Improved diagnosis or treatment of disease
- Implementation in clinical practice and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- Agreements with partners and strategic collaborators to translate more broadly
- Commercialization (e.g. new intellectual property, patent applications, license, commercial partnerships, start-up company)
- Direct-to-consumer interactions (e.g. apps)

* Citation language for Pilot Grant Awardees:

Cite the Duke CTSI for support provided to your project, including but not limited to, pilot consultation, educational training programs, and other support from Duke CTSI faculty or staff (e.g., to coordinate, facilitate, or plan meetings), as follows: *The project described herein was supported by the Duke Clinical and Translational Science Institute (CTSI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Duke CTSI.*

Awards Contingent Upon funding

CONTACT INFORMATION: For additional information on this funding opportunity, please contact daphne.lancaster@duke.edu.

Approved for release