Request for Application 2022-2023

Duke Clinical Translational Science Institute (CTSI)

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

<mark>IMPORTANT DEADLINES:</mark>

Letter of Intent (LOI): due Wednesday January 26, 2022, 11:59 p.m.
Full proposal by invitation: due Friday, April 1, 2022, 11:59 p.m.

The Duke Clinical Translational Science Institute (CTSI)'s Community Engaged Research Initiative (CERI) aims to support community-engaged research partnerships. Funds are available for eligible **NEW and ADVANCED** community-academic partner investigator teams. During the 2022-2023 funding cycle, CTSI-CERI will fund two $50,000 awards to stimulate <u>community-engaged research through community-academic research partnered projects to improve population health.</u>

Duke CTSI facilitates translational research by providing funding, promoting investigator collaboration, encouraging innovation, providing project management assistance, and providing access to resources/services in a collaborative and service-oriented fashion.

Translational research includes:

- Studies that address mechanisms contributing to human health and health equity, regardless of whether the context of the discovery is the laboratory, individuals, or communities.
- Studies that contribute to improvements in health or health equity by addressing barriers to clinical care or healthy behaviors, access to care in community settings.
- Research that contributes to improved population health outcomes or health equity through changes in clinical practice, community/environmental or systems changes, or health policy.
- Research that studies barriers and facilitators to the implementation of evidence based practices promoting health and health equity. **Program evaluations or quality improvement projects (ex. satisfaction surveys) will not be funded by this mechanism.**

I. Purpose and Types of Award

These awards are intended to provide support for joint research proposals from community organizations/groups in partnership with Duke University researchers, who have either already developed <u>or</u> are ready to develop new partnerships to create innovations that address population health issues identified as priorities by the community. Funds may be used to generate formative or pilot data to better position partnerships for external funding to test or implement innovations in larger studies. **There are two types of applications supported by this RFA: 1) New Partnership Award and 2) Advanced Partnership Award. Below are the details pertaining to each type of award:**

Award Type	New Partnership Award	Advanced Partnership Award
Description:	Encourage submissions from **NEW and recently established** community-academic partnerships. Jointly prepared research proposals should seek to improve community and population health through health research that advances the science of stakeholder and community-engaged research.	Seeks joint research proposals from **ESTABLISHED** community-academic partner investigative teams aiming to improve community and population health through health research that advances the science of stakeholder and community-engaged research.

	1. Develop research innovations to address existing or emerging health problems identified by the community, and/or 2. Demonstrate readiness to pilot test solutions through a community-engaged research study, **3) describe your process of developing a bi-directional collaborative partnership and include a clear plan for the proposed collaboration** 3. Show how pilot research will lead to external funding.	1. Reference previous partnered projects, programs, grants, publications, etc. that demonstrate a strong and longstanding history of equitable and effective collaboration. 2. Develop research innovations to address existing or emerging health problems identified by the community, and/or 3. Demonstrate readiness to pilot test solutions through broader community-engaged research studies, and 4. Show how research will lead to external funding.
CERI Consultation:	**A consultation with CERI is recommended prior to submitting Letter of Intent (LOI). Submit your request here** CERI can connect applicants to other CTSI cores able to assist with projects (e.g. biostatistics, metrics and evaluation, project management, emerging technologies). Some Core assistance is fee-based and these costs should be included in the final budget.	
Notes:	Interested academic or community stakeholders that would like assistance in identifying collaborators to pursue a New Partnership Award are encouraged to **request a consultation** with CERI prior to establishing a research question. To request a consultation with CERI, please complete **this form.**	Past co-developed Awardee partnerships that are applying for an Advanced Partnership Award should describe the results from the previous award, how their new proposal is different, and how it advances previous work and /or addresses a new community health priority.

II. Key Dates
- **Mandatory Letter of Intent deadline: Wednesday, January 26, 2022 (11:59 PM ET).**
- Selected applicants will receive an invitation to submit a full application no later than the week of February 14, 2022.
- Invited Applicant Submission Deadline: Friday, **April 1, 2022 (11:59 PM ET)**
- Selection of Awardees: by Friday, **May 15, 2021**
- Funding Period: The budget period is for **12 months** beginning September 1, 2022 and ending no later than August 31, 2023. Awardees are encouraged to utilize a 3 month start-up period (June-August 2022) in which CTSI may provide staff support to help facilitate agreements and other pre-award activities.

III. Priorities:
Duke CTSI and CERI are interested in the following types of research projects that have been envisioned and co-created through a collaboration between community and Duke partners:
- Research that focuses on health care priorities identified in the community through community-level assessments such as the 2020 Durham County Community Health Assessment, including but not limited to diabetes, obesity or overweight, mental health, substance use, cold, flu and cough, violent crime, affordable housing, gentrification, public transportation improvement, police reform and crime reduction, physical activity infrastructure, access to care, and health programming and health education.
- Priorities identified by interdisciplinary and multisector community-level coalitions, including but not limited to Partnership for a Healthy Durham, Latinx Advocacy Team and Interdisciplinary Network for COVID-19 (Latin-19), the African American COVID Task Force (AACT+), Aging Well Durham, the Community Health Coalition, and others.
- Evidence-based strategies to strengthen the roles that Community Health Workers play in improving population health

- Research that **focuses on areas of disparity and health equity** (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 are committed to **developing solutions that are sustainable** that are geared toward improving local health and securing follow-on support for larger investigations of implementation
- **NOTE: This RFA does not fund program/project development or evaluations of existing programs/projects. Quality improvement projects are not funded through this mechanism.**

Preference will be given to research proposals that clearly demonstrate the following:
- A problem-based/ hypothesis-driven research 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 equity
- 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 that also includes partnership equity (shared leadership responsibilities, distribution of research activities, and financial resources).

IV. Eligibility

- **Submission of mandatory LOI (see below for submission instructions).**
- 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 responsibility
- 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 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 professional and non-tenure track
- While we encourage diverse engagement on projects, rank of less than medical instructors (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.

V. Letter of Intent and Application Procedures
Letter of Intent (Mandatory)
A. **Research statement**, including research question and specific aims (No more than 1/2 page)
B. **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:
    a. What is your research question?
    b. What is innovative about your research study?
    c. What is the general design of your study and how will it be carried out?

d. What is the history of your collaboration and how are you working together to determine roles and responsibilities?

e. How will you ensure an equity framework within your research through the design and conduct of the research project?

C. **Translation statement** – ¼ page:

a. How will success and impact be evaluated and measured?

b. What is the clinical/population health impact of the proposed work?

c. What are the translational research findings of the proposed work?

d. What is the potential for scalability and sustainability of the findings of the proposed work?

D. **Simple 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. Include a very brief budget justification for each entity. Example of simple budget structure (may be modified as needed):

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

E. ==**Combine all documents into a single PDF and email to CeRi@dm.duke.edu by midnight on Wednesday, January 26, 2022.**==

Applicants invited to submit full applications will receive email notification the week of February 14, 2022. **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 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 project. Approximately 1/2 page.
- **Significance** - relevance and alignment with 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. Approximately 2 pages. *If research was previously funded by CTSI/CERI, also explain how preliminary results contribute to this follow on proposal and how the research is different from what was previously funded.*
- **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 clearly 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:

- o its stakeholder engagement plan: the applicant must clearly outline relevant stakeholders; strategies to engage with them; delineate stakeholder-relevant outcomes (i.e. outcomes relevant to patients, consumers, families, practitioners, administrators, and/or policymakers); and plans to disseminate findings
- o its clinical/population health impact;
- o expected translational research findings

Applicants 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**
- 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.

C. **Student Engagement Plan**: The applicant must outline the roles and responsibilities of the mentor, mentoring activities, research areas of engagement, etc. if students are part of the research team.

D. **Budgets** using PHS 398 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. 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 FY22-23 Projected Non-Federal Fringe rates can be found here: https://resources.finance.duke.edu/resources/docs_sec/FbratesAnnounce_2122_March.pdf

E. **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, provide a description of 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, provide a description of 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 prior to the start of the grant period.

F. **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) - 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, we strongly recommend that you include your grants team in the preparation of this proposal budget.

Please note the following during budget preparation:

1. The budget period is for 12 months beginning on September 1, 2022 and ending no later than August 31, 2023. 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 conduct of the research planning or implementation
- Expenses related to conducting engagement activities with patients and other stakeholders
- Research supplies (not office supplies) and lab cost

    B. Grant funds **may not typically** be budgeted for:
- General consumable supplies
- Meals or travel expenses incurred for personal or social purposes not related to the project.
- Professional education or training
- Computers or audiovisual equipment
- Manuscript preparation and submission
- Effort for post-doctoral trainees or fellows on training grant equivalents
- Capital equipment
- 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 the use of CTSI School of Medicine funds. Duke CTSI reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal.

VII. Selection Process and Review Criteria

Mandatory Letters of Intent (LOI), and invited full Applications will be reviewed by a committee comprised of Duke CTSI faculty and staff, community members and/or community organizations, researchers, and experts in community and population health. Review criteria will include:

- Plans to advance and reinforce partnerships
- Significance of the proposed research for clinical/population health
- Innovation of the research
- 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
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period & with the budget provided
- Level of community or stakeholder 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) which will cover 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 period, 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 Prior to Funding Start Date**

- Awardees are expected to finalize all regulatory requirements during a three month study start-up period (June1 – August 31, 2022).
- 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.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. **Project Execution**

- Duke CTSI staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. Duke CTSI expects Duke Investigators and community partners to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
- Assistance from the Community Engaged Research Initiative (CERI) will be available to all awardees and includes a variety of engagement support services including capacity building, tools for sustainable and equitable partnerships, and ongoing feedback and input as needed.
- A Duke CTSI staff member will interact regularly with the awardees to help manage timelines, report progress relative to planned milestones, and serve as a resource to identify and fulfill unmet project needs via the Duke CTSI and other key resources.
- The institutional funds used in our CTSI pilot funding programs take on the identity of federal funds in this award mechanism and therefore should be treated as such with regards to IRB, and tech transfer office reporting.
- Any awardee who leaves or plans to leave their position should contact Duke CTSI **in advance** to discuss future plans 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 of publications and other translational units that originated from the award. Examples include:

- 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)

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

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