

Duke Clinical Translational Science Institute (CTSI)
Population Health Improvement Awards
Request for Application 2019-2020

IMPORTANT DEADLINES:

Mandatory Letter of Intent: 11:59 p.m. ET, January 24, 2019

Application (by invitation): 11:59 p.m. ET, March 19, 2019

The Duke Clinical Translational Science Institute (CTSI), Duke's home of the National Institutes of Health's Clinical and Translational Science Award, is interested in promoting community-engaged research partnerships. Funds are available for eligible new and advanced investigator teams. The CTSI will provide awards of up to \$25,000 to stimulate new community-engaged research partnerships, and to further advance and support community-engaged research proposals within established community-research partnerships.

I. Purpose and Types of Award

These awards are intended to assist joint research proposals from community organizations/groups in partnership with Duke researchers who have either already developed or are ready to establish new partnerships to co-develop solutions designed to address population health issues identified as priorities by the community and provide support for community-partnered studies to generate pilot data needed to develop larger scale proposals, awards, and projects. Funds may be used to develop formative or pilot data to better position partnerships for follow-on funding to test innovations in larger implementation studies.

There are two application types of population health improvement awards:

1) The **Co-Development Award** encourages and facilitates **new** investigative community-academic partnerships designed to improve community health and may also include health research that advances the science of stakeholder and community-engaged research. Successful research proposals focus on developing and pilot testing innovative solutions to translate evidence-based discoveries into community settings through broader community-engaged implementation research.

Interested academic or community stakeholders who need assistance in identifying collaborators to pursue a Co-Development Award are encouraged to [request a consultation](#) with Duke CTSI Community Engaged Research Initiative (CeRi).

2) The **Advanced Partnership Award** seeks to support joint research proposals from community organizations/groups and Duke researchers who have already developed innovations to address health problems and are ready to advance pilot testing these solutions through broader community-engaged implementation research studies.

II. Priority

Duke CTSI is interested in the following types of research projects:

- Research that focuses on **Health care priorities** identified in the community through community level assessments such as PCOR Town Halls on Outcomes that Matter, Partnership for a Healthy Durham, and the [Durham County Community Health Assessment](#).
- Research that utilizes the [Durham Neighborhood Compass](#).
- Research that **focuses on an area of disparity** (Race or ethnicity, sex, sexual identity, age, disability, socioeconomic status, and geographic location) related to diabetes, asthma, cardiovascular disease/hypertension, mental health, cancer, obesity, dementia, and kidney disease.
- Pilots studies that **use previously gathered data** in selecting and tracking outcomes.
- **Tests of innovative implementation strategies** to optimize uptake of solutions at the community level.
- Research proposals that show promise and are committed to **developing solutions that are sustainable**.

- Research proposals that are geared toward improving local health and securing follow-on support for larger investigations of implementation.

Preference will be given to proposals that have an explicit plan to:

- co-develop and test evidence-based practices in community settings
- achieve sustainability
- mobilize community assets and strengths to test feasibility of implementation strategies for population health improvement
- demonstrate an equitable partnership

The primary source of funding is from the National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award UL1TR002553.

III. Key Dates

- Mandatory Letter of Intent Deadline: **January 24, 2019**
- Selected applicants will receive an invitation to apply by February 15, 2019
- Invited Applicant Submission Deadline: **March 19, 2019**
- Selection of Awardees: by **April 30, 2019**
- Funding Period: The budget period is for **12 months** beginning July 1, 2019 and ending no later than June 30, 2020.

IV. Eligibility

- **Submission of mandatory LOI (see section VIII 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 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 health or patient care.
- Nonprofits with & without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Community organizations (especially those with a focus on public health, social services, caregiving, and patient advocacy) and members of practice-based research networks
- Eligible agencies of the federal, state, and local government
- Permanent, full-time, Duke faculty, including professional and non-tenure track.
- Rank of less than assistant professors such as post-doctoral trainees, medical instructors and/or fellows are not eligible to serve as a PI. However, they are eligible to serve as co-investigators and play a prominent role in conducting the research.

V. Funding

The research activities will be funded by Duke CTSI, **up to \$25,000** in direct costs per project proposal (no indirect costs will be awarded).

Duke CTSI's Population Health Improvement awards 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.

Requests for no-cost extensions will not be approved.

Note for Duke Investigators: This award is internally funded and does not need to be routed through the Office of Research Administration.

VI. Proposal Preparation

The CTSI strongly recommends involving the [Community Engaged Research Initiative](#) early in the development of your Letter of Intent. CeRI can connect applicants to other CTSI cores able to assist with their 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 budget: [Request a consultation](#)

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:

- Significance of the work
- 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
- Level of community or stakeholder engagement

VIII. Letter of Intent and Application Procedures

A **Mandatory Letter of Intent** will be submitted via email Duke's MyResearchProposal online submission system.

- To apply, go to <http://bit.ly/myresearchproposal>, click on "Create New User" (or log in if you already have an account). Proposals must be submitted under the Principal Investigator's name.
- A step-by-step user's guide for applying via the MyResearchProposal (MRP) software is available - Please review this [document](#).
- Enter Access Code '**CTSI**' then select the "Population Health Awards 2019" funding opportunity and follow the instructions.
- Select Co-Development **or** Advanced application type as applicable.
- For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or 919-668-4774.

Preliminary Information - Applicants will enter general project information via the MRP – (this information will be carried over into the application phase if applicants are invited to apply):

1. Project name (PI Last names, Project Title)
2. Duke & Community Co-Investigator Information (e.g. Name, Department /Community Organization, etc.)
3. Anticipated budget request (up to \$25K)
4. General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, etc.).
5. Is this a resubmission of a proposal submitted in a previous funding year?

Letter of Intent (Mandatory) –sections B & C are to be uploaded as individual PDF files

- A. Abstract / Specific aims (2500 characters / roughly one page)

- B. Summary of proposed research design: purpose, significance, innovation, approach. (Limited to 2 pages not including references, Arial 11 font, and single space.). Be sure to answer the following:
 - a. What is innovative about this project?
 - b. Expected significance and impact of the project from a community engaged research perspective.
- C. High level draft budgets for each research partner organization (e.g. percent salary support for staff, requested project support costs, etc.) Please include a draft budget for each partner including a Duke budget and community partner budget(s) along with a very brief budget justification for each entity. No format.

Note: Applicants invited to submit full applications will receive email notification when the full application is accessible in the MRP. Unsolicited full proposals submitted will not be reviewed.

Invited Applications for the Submission of Full Proposals – most sections will be uploaded as individual PDF files.

Application sections are:

- A. **Brief abstract/ Specific aims** (2500 characters / roughly one page)
- B. **Research Plan:** The proposal research plan (5 page limit) should include the following sections:
 - 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, and analysis plan – approximately 2 pages)
 - Timeline (approximately 1/2 page)
 - Stakeholder engagement plan including plan to disseminate findings (approximately 1/2 page)
 - Plans for sustainability: Future grant submission plans- where and what kind of grant will be submitted using results from this pilot funding? When will this grant be submitted? (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.)
- C. **Budgets and Budget Justifications** using PHS 398 form pages 4 and 5. Duke and community investigator partner budgets should be prepared on separate form pages and uploaded as separate PDFs. Section IX below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
- D. **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.
- E. **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](#).

IX. Budget Guidelines

Please note the following during budget preparation:

- 1. The budget period is for 12 months beginning on July 1, 2019 and ending no later than June 30, 2020. Applicants may request up to a total of \$25,000 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 core services, including salary support for core faculty, such as biostatistics, metrics and evaluation, and emerging technologies.
 - Local travel that is necessary for conducting the research project
 - Meals or travel expenses directly related to conduct of the research planning or implementation.
 - Expenses related to conducting engagement activities with patients and other stakeholders
 - Equipment, research supplies (not office supplies) and core lab costs
- 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 regarding the use of CTSA 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. "The general criteria for determining allowable direct costs on federally-sponsored projects is set forth in [2 CFR Part 200: Uniform Administrative Requirements](#), Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance). The [Duke General Accounting Procedure](#) (GAP) 200.320 is a resource to determine whether or not a particular cost item would be considered an allowable direct cost for budgeting and/or charging on a federally sponsored project."

X. Terms of the Award

A. Approvals Required Prior to Funding Start Date

- Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke CTSI 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. 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 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.
- Duke's CTSA grants UL1TR002553 notice of grant awards included both federal funding and our institutional commitment. The institutional funds used in our CTSA 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.
- All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR002553 and UL1TR002553. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Publications must also be registered in PubMed Central. After your publication is accepted, [click here](#) for a guide to complying with the NIH Public Access Policy.
- Any awardee who leaves his or her position should contact Duke CTSI 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 Eve Marion (eve.marion@duke.edu). 919-668-5969.