Duke CTSI Population Health Improvement Co-Development Award ($15K – 25K)
Request for Applications 2018-2019
Application Deadline: 11:59 p.m. ET, February 22 2018

Duke Clinical Translational Science Institute (CTSI), Duke’s home of the National Institutes of Health’s Clinical and Translational Science Award, will provide awards of up to $25,000 to stimulate new community-engaged research. The Duke CTSI is interested in promoting community-engaged research partnerships and pilot funds are now available for eligible new investigator teams.

I. Purpose

Funding will be provided to assist collaborations of community organizations and Duke researchers who are ready to co-develop and test innovative solutions focused on improving community health that addresses Durham County health priorities. 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. The co-development awards may also include health research that advances the science of stakeholder and community-engaged research. Preference will be given to proposals which have an explicit plan for co-developing and testing innovative practices in community settings, plan for sustainability, and mobilize community assets and strengths to test feasibility of strategies for population health improvement.

This pilot program is designed to encourage and facilitate new investigative community-academic partnerships designed to improve community health. Successful research proposals focus on developing and testing innovative solutions to translate evidence-based discoveries into community settings through broader community-engaged implementation research. Duke CTSI is interested in the following types of research projects:

- **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 **focuses on an area of disparity** including diabetes, asthma, cardiovascular disease/hypertension, mental health, cancer, obesity, dementia, and kidney disease.
- Pilot studies that **use previously gathered data** in selection and tracking of outcomes
- **Testing 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**.

Emphasis is placed on improving local health and the ability to secure follow-on support for larger investigations of implementation.

**Interested academic or community stakeholders who need assistance in identifying collaborators are encouraged to contact Eve Marion eve.marion@duke.edu (919-668-5969) with the Duke CTSI Community Engagement Core to arrange a consultation.**

**Technical Assistance** is 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.
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 UL1TR001117.

II. Key Dates

- Optional Letter of Intent: 1/10/2017
- Application Submission Deadline: 2/22/2018
- Selection of Awardees: March-April 2018
- Funding Period: The budget period is for 12 months beginning between May 1 and July 1, 2018 and ending no later than June 30, 2019.

III. Eligibility

- Proposed research must involve investigator teams comprised of a Duke faculty investigator and at least one community partner investigator. Although a Co-PI structure is recommended to support co-led community-academic partnerships, the Duke faculty member will serve as the PI 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. Either the Duke or the Community lead can submit the application. However, only one application can be submitted by the team.
- The 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 practiced-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. A mentoring plan will be requested for the trainees if selected for funding.

IV. Funding

The research activities will be funded by Duke CTSI, and will fund up to $25,000 direct costs (plus 10% indirect cost for community partners only) per project

Duke CTSI’s Population Health Improvement awards cover expenditures for a maximum of 12-month period. The budget period will begin when applicable IRB/IACUC documentation is provided to Duke’s CTSI and the PI indicates everything is in place for the project to begin.

If more than six months passes 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 ORA (Duke).
V. Proposal Preparation

The CTSI strongly recommends involving the Community Engagement Core https://www.ctsi.duke.edu/what-we-do/community-engagement which can connect applicants to other CTSI cores able to assist with their projects (e.g. biostatistics, metrics and evaluation, project management, emerging technologies). Any projected assistance from these cores must be included in the budget.

VI. Selection Process and Review Criteria

1. Applications will be reviewed by a study section committee comprised of Duke CTSI, community members, community organizations, researchers, and experts in community and population health. Review criteria will include:

   • Significance of the work
   • Novelty/innovation of the research
   • Relevance of the proposed study to translational research
   • Potential for the project to lead to future external funding or to a commercialization opportunity
   • Soundness of the proposed methods
   • Feasibility of accomplishing the stated project goals within the one-year project period
   • Level of community or stakeholder engagement

VII. Application Procedure

An optional Letter of Intent may be submitted via email to Eve Marion (eve.marion@duke.edu) no later than 1/10/18. “Population Health Awards” should be included in the subject line.

Proposal is submitted via Duke’s MyResearchProposal online submission system.

   • To apply, go to [http://bit.ly/myresearchproposal](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 software is available - Please review this [document](#).
   • Enter Access Code ‘CTSI’ then select the “Duke CTSI Population Health Improvement Co-Development Award2018” funding opportunity and follow the instructions.
   • For questions concerning MyResearchProposal passwords or system issues, please contact Anita Grissom or Kara McKelvey at myresearchproposal@duke.edu

Applicants will enter general project information via the web-based form:

1. Brief Description, and Amount Requested
2. Duke & Community Investigator Information (e.g. Name, Department /Community Organization, etc.)
3. General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).

Proposal sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

A. Proposal Overview: The proposal overview should include; Background, Proposed Solution to the Problem, Objectives, Activities, Patient and stakeholder engagement plan and Impact on the community. Include where applicable clear evidence of how the proposal meets the review criteria. (5-
page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, 1-inch margins.)

B  Budget with Budget Justification using the provided form (combined into a single PDF without a page limit). Section VI below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. **Duke and community partner budgets should be prepared on separate form pages but submitted together as a single PDF.**

C. Human and/or Animal Subjects: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) 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. Projects involving animal subjects must be reviewed and approved by a Duke and/or IACUC. (no page limit).

D. Resume (no format) (Community Investigators) and NIH Biosketch (Faculty Investigators) and for key members of the research team (as a single PDF) - [click here for NIH Biosketch details](#).

**VIII. Budget Guidelines**

Please note the following during budget preparation:

1. The budget period is for 12 months beginning between May 1 and July 1, 2018 and ending no later than June 30, 2019. Up to a total of $25,000 in direct costs (10% indirect costs, community partners) between the Duke and community partner may be requested and the amount requested. Funding will not available until applicable IRB/IACUC documentation is provided to Duke CTSI.

2. **Budget 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
      - Indirect costs capped at 10% (Community Partner only)

   B. Grant funds may **not** be budgeted for:
      
      - Office supplies or communication costs
      - 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
• 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.”

VIII. 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. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project’s start date. 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.
• Research involving human subjects must also be approved by the National Center for Advancing Translational Sciences (NCATS) prior to receiving funds. The Duke CTSI will request required documents from the PIs and submit a regulatory package for each institution to NCATS for review and approval.
• 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.
• A Duke CTSI Project Leader will be assigned to each funded project. The investigators will interact regularly with the Duke CTSI Project Leader, who will work with the investigators to manage projects, 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 UL1TR001117 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, IACUC, and tech transfer office reporting. NCATS approval is required prior to initiating research involving human subjects, and inventions resulting from pilot awards must be reported in iEdison and include UL1TR001117 as the source of federal funding.

• 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 UL1TR001117 and UL1TR001111. 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.

C. Post-Award Reporting

Duke CTSI tracks significant events (“translational units”) 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. The Duke CTSI will contact investigators annually to determine if any translational units have been achieved as a result of this award. Examples include:

• Abstracts/presentations, manuscripts, published guidelines
• Follow-on funding (e.g., grants, contracts, angel and venture capital investment)
• Milestones achieved in animal models, manufacturing and toxicity campaigns
• 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)

When requested, all awardees will be expected to provide updates of publications and other translational units that originated from the award.

Awardees and applicants are expected to serve as reviewers for future Duke CTSI funding opportunities.

CONTACT INFORMATION

For additional information on this funding opportunity, please contact Eve Marion (eve.marion@duke.edu).