Clinical and Translational Science Institute (CTSI) Request for Applications Program in Community-Engaged Research Community-Engaged Cooperative Agreement Award - Rapid Response

Purpose

The Program in Community-Engaged Research (PCER) is seeking applications for pilot projects through the Translational Pilot Program. The goal of the community-engaged cooperative agreement is to test generalizable solutions to translational research challenges using **community-engaged research**. Successful pilot projects will have potential for extramural funding with clearly articulated next steps. Research projects that align with principles of the Academic Learning Health System are encouraged and will be considered responsive.

The primary focus of this award is the development of community-engaged research, community-based participatory research (CBPR), or citizen science projects. Definitions of community-engaged research, CBPR, and citizen science, as well as useful references can be found in Appendix I.

This award is designed as a cooperative agreement. The awardee team will have meetings with PCER directors and staff at least monthly and attend Core Working Group meetings at least monthly to discuss progress and study-related benchmarks, trouble shoot roadblocks, and harness broad PCER experiences and expertise in community-engaged research and other PCER resources.

One project will be funded. Successful pilots will receive up to \$30,000, to be spent within a **one year project period.**

Successful proposals will:

- Provide a rationale for the project's relevance for improving health
- Provide a rationale for the project's relevance and potential for generalizability (i.e., how can the results of this project be used to improve community/population health through translational science)
- Identify translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them
- Lay out a reasonable project plan that is feasible to complete in the one-year project period as there will be no opportunity to request carry-over
- Commit to using project results to develop a subsequent, larger community-engaged research/CBPR/citizen science extramural grant application

Eligibility

Applications must include a team with at least one investigator from Wake Forest and at least one representative of a community organization or local government agency serving as a project co-investigator.

The Wake Forest faculty member investigator must:

- Hold a faculty rank of instructor or higher
- Become a member of the WF CTSI Program in Community-Engaged Research Affinity Group

The community-representative investigator must:

 Work for a non-profit community organization or local government agency that serves community within Northwest North Carolina

Faculty members interested in CTSI Community Engagement Affinity Group membership should contact Keena Moore, Administrator, Program in Community-Engaged Research at krmoore@wakehealthe.edu.

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Date	Detail
06/04/21, 11:59 pm	Full Application Deadline
06/08/21	Selection of Awardees
06/11//21	If applicable, completed submission materials sent to NCATS for approval

07/01/21	Project Start Date
06/30/22	Project End Date

Funding

The CTSI will fund up to \$30,000 in direct costs per project. See section on Budget Guidelines for more details on allowable and non-allowable budget items. Since CTSA funds cannot be carried over from one budget period to the next, requests for no-cost extensions will not be approved.

Application Procedure

Full Application Deadline: 06/04/21, 11:59 pm

Investigators are to submit a full application by 06/04/21. Application instructions are included in the ePilot system and summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information

- Project Title
- Submitting Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (30 lines max)

Specific Aims (1 page max)

Research Plan (6 pages max)

- Significance, innovation, and approach, including translational importance, experimental design and methods, dissemination plans, and next steps
- Study milestones and anticipated outcomes with timeline
- Contribution and summary of qualifications of each contributing investigator (1 page max)

References (no page limit)

Information Regarding Human Subjects

Address the following if the project involves human subjects.

- IRB Approval Status (please note: IRB approval is not required for full application submission)
- Clinical Trial Classification
- Protection of Human Subjects
 - Needs to clearly describe risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
- Inclusion Plans for Women, Minorities, and Children, as applicable
- Targeted Enrollment Table, if applicable (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
 - o If you need assistance determining the level of safety monitoring your study will need, please contact the CTSI DSMB Administrator, Issis Kelly Pumarol at ikellypu@wakehealth.edu.

Budget and Justification (budget template plus 1 page justification)

Complete the <u>budget template form</u> provided along with a brief justification for the funds requested
for this RFA. Please include explanation of other resources that may be leveraged to support the
project. If the proposed research is to be carried out on more than one campus/institution, please
include details in the justification.

Sub-awards to other institutions to carry out work on a project are permissible provided the majority
of activity occurs within Wake Forest or one of its affiliates.

NIH-style biographical sketch for all Key Personnel

Budget Guidelines

The budget period is for 12 months beginning 07/01/21 and ending no later than 06/30/22. Up to \$30,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Travel necessary to perform the research
- Small equipment, research supplies and core lab costs, or
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may **not** be budgeted for:

- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Capital equipment
- Manuscript and grant application preparation and submission, or
- Indirect costs

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. The CTSI reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol. 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).

Review Criteria and Process

CTSI proposals are competitive and peer reviewed. Experts in community-engaged research, including those representing the community, will review proposals received and serve on the WF CTSI Council. Proposals will be evaluated based on NIH review criteria and scoring. Final award approval will be at the recommendation of CTSI PCER Leadership.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the CTSI Community-Engaged Cooperative Agreement Award Program. Any IRB or IACUC protocols must be approved prior to funding of the approved pilot.

Reviewers will score applications from 1 to 5 based on:

- 1. Significance of the problem to be addressed;
- 2. Innovation;
- 3. Strength of the investigative team;
- 4. Approach;
- 5. Likelihood the innovation will be broadly applicable and have impact on translational research:
- 6. A dissemination plan regardless of whether the study yields positive or negative results; and
- 7. The likelihood that the research will lead to external funding.

Program Expectations

Prior to funding, awardees will be assigned to a PCER staff to: (1) assist with study initiation; (2) convene an initial meeting with the project PI, CTSI administrative personnel, and a senior CTSI leader to discuss the project and how CTSI resources can be optimized to the planned study; (3) meet biweekly with Program in Community-Engaged Research leadership; and (4) provide project management and monitor progress

throughout the life of the study. If any significant issues arise, the study team will be required to work with the CTSI to define a strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:

- Participation in the study initiation meeting
- A formal update on progress to the CTSI Cabinet as requested
- Upon completion of the project:
 - Close-out report with plans for dissemination
 - Presentation of findings at Community Stakeholder's Advisory Committee meeting and CTSI Seminar Series
- Disclosure of implementation/dissemination results and efforts to seek extramural funding beyond the
 pilot grant and subsequent notification of any funds obtained and/or related publications or significant
 collaborations from the project for a minimum of 4 years.

Other Guidelines

- 1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB and NCATS. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CTSI prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
- 2. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the CTSI prior to funds being released.
- 3. CTSI staff will work closely with funded teams throughout the grant period to monitor progress and provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs 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.
- 4. 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 Number UL1TR001420. 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.
- 5. Any awardee who leaves his or her position should contact the CTSI to discuss future plans for the project.

Grant Administration

The PI is responsible for the administration of grant funds. Projects will be for a one year period of time.

Contacts

Questions about your research project or the electronic submission system should be directed to Keena Moore krmoore@wakehealth.edu.

Appendix I

Definition: Community-engagement

According to the CDC, community-engagement is the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being. In practice community engagement is a blend of science and art.

For further detail, see: https://www.atsdr.cdc.gov/communityengagement/pdf/PCE Report 508 FINAL.pdf

Definition: Community-based participatory research (CBPR)

Community-based participatory research is: An applied collaborative approach that enables community residents to more actively participate in the full spectrum of research (from conception – design – conduct – analysis – interpretation – conclusions – communication of results) with a goal of influencing change in community health, systems, programs or policies. Community members and researchers partner to combine

knowledge and action for social change to improve community health and often reduce health disparities. Academic/research and community partners join to develop models and approaches to building communication, trust and capacity, with the final goal of increasing community participation in the research process. It is an orientation to research, which equitably involves all partners in the research process and recognizes the unique strengths that each brings. For further detail, see: https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf

Other useful references for CBPR

Rhodes SD (ed). (2014). Innovations in HIV Prevention Research through Community Engagement. New York: Springer.

Israel B, Eng E, Schulz A, et al., (eds). (2013). *Methods in Community-based Participatory Research for Health*. (2nd edition)San Francisco, CA: Jossey-Bass.

Minkler M and Wallerstein N. (eds). (2008). *Community-Based Participatory Research for Health: From Process to Outcomes*. (2nd edition). San Francisco, CA: Jossey-Bass.

Viswanathan M, Ammerman A, Eng E, et al., (eds). (2004). *Community-Based Participatory Research:* Assessing the Evidence. Rockville, MD: Agency for Healthcare Research and Quality.

Definition: Citizen Science

Citizen science is scientific work undertaken by members of the general public, often in collaboration with or under the direction of professional scientists and scientific institutions, and citizen scientists, in the modern sense, are defined as a scientist whose work is characterized by a sense of responsibility to serve the best interests of the wider community or a member of the general public who engages in scientific work, often in collaboration with or under the direction of professional scientists and scientific institutions. For further detail, see http://scistarter.com/page/Citizen%20Science.html.