Clinical and Translational Science Institute
Request for Applications
Community-Engaged Cooperative Agreement Award

PURPOSE

The Program in Community-Engaged Research (PCER) is seeking applications for pilot community-engaged research projects.

The Community-Engaged Cooperative Agreement supports research partnerships with representatives from community organizations and to all faculty with a rank of instructor or higher across the Atrium Health Enterprise including Atrium Health, Wake Forest Baptist Health, and Wake Forest School of Medicine who are interested in conducting community-engaged research. Wake Forest University faculty are also invited to apply. 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**. The mechanism being used is a cooperative agreement, which facilitates ongoing support from the PCER. The awardee team will have meetings with the PCER tem at least monthly and attend Core Working Group meetings 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:

- Address health equity within underserved communities and/or communities of color, broadly defined.
- Be responsive to community partners' needs and priorities.
- Delineate how community-engaged research (CEnR), community-based participatory research (CBPR), and/or citizen science best practices will be applied.
- Describe engagement and roles of community partners within the research process.
- Outline how teams will resolve conflicts and challenges that may arise.
- Explain how the project aligns with principles/characteristics of an academic learning health system.
- Detail dissemination plans for the pilot project findings.
- Specify how this pilot funding and project findings will facilitate extramural research funding.

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 an investigator.

The academic investigator must:

- Hold a faculty rank of instructor or higher
- Become a member of the WF CTSI Program in Community-Engaged Research Affinity Group
    - Contact Keena Moore, Administrator, Program in Community-Engaged Research at krmoore@wakehealth.edu

The community-representative investigator must:

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

KEY DATES

Date	Details
10/14/22	LOI Deadline
11/15/22	Invite for Full Applications
12/14/22, 11:59pm	Full Applications Due (if invited)
03/08/23	Selection of Awardees
07/01/23	Project Start Date
06/30/24	Project End Date

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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: 12/14/22, 11:59 pm

Investigators are to submit a full application by 12/15/21. 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 research plan, including translational importance, design and methods, dissemination plans, and next steps
- Study milestones and anticipated outcomes with timeline
- Contribution and summary of qualifications of each contributing investigator

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 Individuals Across the Lifespan, as applicable
- Targeted Enrollment Table, if applicable (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
    - 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 budget template form 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 07/01/22 and ending no later than 06/30/23. 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. Research projects that align with principles of the Academic Learning Health System;
7. A dissemination plan regardless of whether the study yields positive or negative results; and
8. The likelihood that the research will lead to external funding.

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Program Expectations

Prior to funding, awardees will be assigned to a PCER team member 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 monthly with PCER 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. Information on documents needed for NCATS approval can be found in **Appendix II**. 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 PIs are 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 Isaiah Randall irandall@wakehealth.edu.

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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

Wallerstein N, Duran B, Oetzel J, Minkler M (eds.) (2018). *Community-Based Participatory Research for Health.* Ed. 3. San Francisco, CA: Jossey-Bass.

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*. Ed. 2. 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.

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Appendix II: NCATS Approval

Projects that meet the definition of human subjects research will require prior approval from the National Center for Advancing Translational Sciences (NCATS), the funding source of the CTSA grant. This means that no funds will be released to the award recipient until NCATS has provided approval.

The following items are needed for the NCATS submission by 05/10/23:

- Project Information (i.e. submitting investigator, project title)
- IRB Approval
    - We do not require an initiated IRB application/approval by the Full Application Deadline; however, in order to submit for NCATS approval, certification of IRB approval is required. Therefore, we encourage draft protocols/consent documents be created as far in advance as possible. Notifications of funding will be sent by 3/08/22.

- Project Abstract
- IRB Approved Protocol
- IRB Approved Consent/Assent/waiver
- Protection of Human Subjects
- Inclusion of Individuals Across the Lifespan
- Inclusion of women, minorities, and children
- Recruitment and Retention Plan
- Targeted Enrollment Table
- Bio sketches (PI and Key Personnel)
- Documentation of CITI certification
- Data and Safety Monitoring Plan
- IND/IDE Documentation, if applicable
- Budget and Budget Justification

Please note: additional documentation will be required if project is classified as a Clinical Trial.