

CCTSI Community Engagement Pilot Grant Program (CE-Pilot) 2023 Award Cycle for Clinical Translational Science (CTS) Pilots- Request for Applications

Table Of Contents

1.	Funding Opportunity Summary	Page 2
2.	Key Information	Page 2
3.	Important Dates	Page 3
4.	Background	Page 3
5.	Funding Priorities and Requirements	Page 4
6.	Award Categories	Page 5
7.	Available Funding	Page 6
8.	Definitions	Page 7
9.	Eligibility	Page 8
10.	Exclusions/Restrictions.	. <u>Page 9</u>
11.	Application Process.	Page 10
12.	Review Process.	. <u>Page 11</u>
13.	Review Criteria	. <u>Page 11</u>
14.	Award Requirements	. <u>Page 12</u>
15.	Questions	<u>Page 13</u>
16.	Partnership Development Application	<u>Page 14</u>
17.	Joint Pilot Project Application	<u>Page 18</u>

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the sixteenth consecutive year. The CCTSI Community Engagement Pilot Grant Program (CE-Pilot) supports 9- to 12month awards to support community-academic research partnerships to perform pilot studies that will strengthen relationships and produce preliminary data for future competitive grant applications for community members and faculty of CCTSI Affiliated Institutions. Funded projects may encompass partnership development, project planning, capacity building as well as T3/T4 translational research projects which will readily enhance translational science, and also provide insights that could be generalizable to other health-related areas (such as health disparities, cardiovascular disease, childhood chronic conditions, social emotional health, and COVID-19 effects on the community or others). This includes research evaluating the translation of evidencebased interventions or practices into real world, clinical and community settings. Projects designed to demonstrate that a health disparity exists are not appropriate for this grant program; rather, we are interested in funding projects focused on reducing health disparities or designed to understand how to decrease health disparities. Projects that do not involve Community Engagement within the affected community and/or patient population throughout the research project will not be considered. Research that is not directly or indirectly related to improving human health is not supported. Revisions of unfunded applications from prior years are encouraged as long as they address new NCATS requirements in addressing translational roadblocks (see below) and all revised proposals are considered new applications, rather than resubmissions.

Community-Academic partnerships may apply for either a Partnership Development Award or a Joint Pilot Award:

- a) **Partnership Development Awards** provide seed funding to support activities related to the development of new or emerging community-academic research partnerships.
- b) <u>Joint Pilot Awards</u> are open to established community-academic partnerships who seek funds for a well-defined translational research project that may produce preliminary data for future competitive grant applications.

Please note: for any Academic and/or Community co-Principal Investigators who have been previously funded by a CCTSI Community Engagement pilot grant, prior adherence to program requirements will be taken into consideration in the grant review process.

II. Key Information

<u>Award Categories</u>: Partnership Development \$8,000/award

Joint Pilot Project \$25,000/award (increased award amount this

year!)

<u>Award Period</u>: Partnership Development 9 months, May 2023–January 2024

Joint Pilot Project 12 months, May 2023–April 2024

Contacts: Yuliza Hernandez Kaylee Rivera Gordon

760-963-7818

III. Important Dates

08/22/2022: RFA Release Date

09/09/2022: Applicants Webinar/Conference Call

10/03/2022: Mandatory Intent to Apply Form Deadline for both CE Pilot Grants

11/01/2022: Application Submission Deadline for both CE Pilot Grants

03/01/2023: Anticipated Notice of Selection

April 2023 Mandatory Community Engagement Training

05/01/2023: Award Start Date

01/31/2024: Partnership Development Award End Date

04/30/2024: Joint Pilot Award End Date

Applicants Webinar / Conference Call: Specific questions not addressed in the RFA or website FAQs may be asked during the applicants' webinar/conference call. Specific information about partnerships, funding allocations, community partner fiscal relationship with Trailhead Institute, etc. will be covered during the webinar. Details and Zoom links are located on the left sidebar of the CCE-Pilot) webpage. The webinar includes a presentation about the program, application and review criteria, and resources plus an open Q&A session with the program managers. Participation in the applicant's webinar is highly encouraged but not required.

IV. Background

The CCTSI Pilot Grant Program was initiated in 2009 and is supported by the National Center for Advancing Translational Science (NCATS), the University of Colorado School of Medicine Dean's Office, and the <u>Traystman Fund</u>. The <u>Partnership of Academicians and Communities for Translation (PACT)</u> with the CCTSI Community Engagement & Research (CE&R) Core is dedicated to advancing community engagement in research as a critical step in narrowing the gap between what we know based on research discoveries and what we actually do to improve health and healthcare. Accordingly, the funding referred to in this RFA is intended to build capacity in community-academic partnerships, using community-based participatory research (CBPR) principles to translate evidence-based interventions or practices from efficacy studies into effective implementation at the community or clinic level. Through this program, community members and researchers participate in a collaborative journey that begins with partnership development, advances to the identification of shared health and research interests and culminates in a pilot research project. View our current and past awardees on the <u>Past CE-Awards</u> webpage.

What is Translation?

The National Center for Advancing Translational Sciences (NCATS) defines <u>translation</u> as: the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

There is a significant gap between the health and healthcare interventions generated through research and the everyday application of those interventions in communities and clinical practice. Often, scientific discoveries are generated through research practices that fail to consider how discoveries will reach and be utilized by real people within the context of their busy and complicated lives, resulting in inefficiencies that delay the translation of discoveries into every-day practice. **These inefficiencies are called 'translational gaps', or 'roadblocks'**.

In recent years, we have been able to address some of these 'translational roadblocks' by developing and conducting research in full partnership with the people who are most affected by the issues being studied. Including patients and community members in the research design, implementation, and dissemination of research findings back into the community has emerged as a reliable method of generating research discoveries that matter to communities, meet the needs of patients, are applicable in routine clinical practice, and improve health outcomes. The translation of a basic discovery to an improvement in public health requires cross-

disciplinary teams of scientists, clinicians, patients, communities, and other stakeholders with wide-ranging expertise and perspectives. **Health research is evolving beyond the practice of including patients and communities as research subjects, to including them as research partner.**

V. Funding Priorities and Requirements

- Applicants must propose work conducted within a partnership between academic researchers and community organizations or individuals (please see definition of community in Section IX). Projects must employ a community-based participatory approach that involves key stakeholders, including persons most affected by the research being proposed, as <u>full partners</u>, from conception to the research design; implementation, analysis, interpretation, and dissemination of research results.
- Special consideration will be given to applications that address issues of health equity and fully engage patients, stakeholders, and community members who are disproportionately impacted by health disparities.
- We encourage applications that target one or more of the following health disparity priority areas:

 (1) Childhood chronic conditions;
 (2) Social-emotional health;
 and (3) Cardiovascular disease;
 and 4) The disproportionate impact of COVID-19 on marginalized and underserved communities. Applications addressing other topic areas will also be accepted.
- All Joint Pilot Project applications must also address a <u>translational science roadblock</u> (see Section VI.B. below). This requirement does not apply to Partnership Development grants, though applicants are encouraged to think about how the partnership might eventually result in a research project that addresses a translational roadblock.
- Applications should focus on T3/T4 Translational Research:

T3 research explores ways of applying evidence-based recommendations or guidelines in general practice. T3 research yields knowledge about how interventions work in real-world settings.

Approaches include:

- Phase IV Clinical Trials: Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
- Health Services Research
 - Dissemination
 - Communication
 - Implementation
- Clinical Outcomes Research

T4 research studies factors and interventions that influence the health of populations. **T4** research ultimately results in improved global health. **Approaches include:**

- Population-level Outcome Studies
- Social Determinants of Health
- Proposed projects may be clinical, and/or focused on health promotion and disease prevention strategies
 (e.g., is intervention or treatment X more effective than intervention or treatment Y when translated into
 real-world settings? What are the barriers to using a particular intervention or treatment?); or more policyoriented (e.g., what is the effectiveness of different community-based dissemination modalities or policies
 on the use of interventions or practices?).
- Projects must be completed within the time period outlined in this RFA, no-cost extensions (NCE) will not be allowed for the 2023 award cycle. Activities for Partnership Development and Joint Pilot Projects are outlined in Award Categories (Section VII).

If you are unsure whether your topic falls within the scope of this RFA, please contact Yuliza Hernandez or Kaylee Gordon (emails above) for consultation.

VI. Award Categories

The Community Engagement & Research Core expects to award up to a total of \$115,000 to fund pilot projects in two categories. Applicants may apply for **one** of the two funding categories (not both):

A – Partnership Development (PD) Projects are intended to support new or developing partnerships over a nine-month period dedicated to relationship building, exploration of shared areas of interest, creation of a partnership structure, identification of a specific research collaboration, and the development of a research plan for future submission as a one-year Joint Pilot Project. While successfully funded Partnership Development projects are expected to have time and effort allocated to develop a Joint Pilot research plan, this deliverable is flexible based on the wants and needs identified by the partnership throughout the Partnership Development project. The partnership may use this time to apply for alternative extramural funding that best fits its short- and long-terms goals. Applicants for Partnership Development Projects may request up to \$8,000 (total budget for Community and Academic co-Principal Investigators combined). Applications exceeding \$8,000 will not be considered. Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the Community co-Principal Investigator.

Activities for Partnership Development Awards may include, but are not limited to:

- Building relationships between partners (e.g., facilitating formal and informal meetings for partners to learn more about each other, to explore the involvement of other potential partners, and to discuss how the partners will adopt and use equitable collaborative principles and operating norms).
- Exploring shared research interests and identifying capacity building needs (e.g., identifying partnership research priorities, determining nature of collaborative research approach that will be used, delineating capacity-building needs, participating in trainings and/or ongoing mentoring opportunities).
- Developing an Advisory Committee and/or other appropriate partnership infrastructure mechanisms (e.g., defining roles and responsibilities, developing communication and decision-making mechanisms, policies and procedures; developing a set of collaborative participatory research principles to guide decisions regarding various aspects of the research process).
- Evaluating the partnership process (e.g., collecting data to assess how and to what extent the partnership is achieving its goals, and the challenges and facilitating factors associated with developing, maintaining and sustaining the partnership).
- Developing a research plan for a Joint Pilot Project.

B – Joint Pilot (JP) Projects are appropriate for experienced researchers or junior investigators who demonstrate appropriate mentorship and who have an **established community-academic partnership** in place and seek funds over a one-year period for a well-defined joint research project that may produce preliminary data for future competitive grant applications and is addressing a translational science roadblock. Applicants for Joint Pilot Projects are funded at **\$25,000** (total budget for Community and Academic co-Principal Investigators combined). Applications exceeding \$25,000 will not be accepted. Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the Community co-Principal Investigator. Please note that renewals or follow-on funding requests from previously funded CE&R **Joint Pilot Awards** will not be considered. However, revisions of previously unfunded applications from earlier cycles are welcome, as long as they address new NCATS requirements in addressing translational roadblocks (see below). All revised proposals are considered new applications rather than resubmissions.

Activities for Joint Pilot Projects may include, but are not limited to:

- T3/T4 translational activities described in Section V
- Data collection and/or analysis of community-specific information or other quantitative and qualitative data.

- Disseminating and translating research findings (e.g., development and implementation of appropriate dissemination tools, such as, fact sheets and policy briefs, to community and academic audiences and to policymakers).
- Studies of the community translation process, including studies of dissemination methods.

Translational Science Roadblocks

All Joint Pilot proposals must describe (in "Project Significance") the "translational science roadblock" that your project will be address and how the results from this project could potentially be generalized to improve other areas of translational science (e.g., processes used to make research more efficient) and address translational science roadblocks, such as:

- Developing or testing novel methods, processes or study designs to address health disparities
- Developing and testing new tools for engagement of communities and underserved populations
- Developing or testing processes to improve enrollment of diverse populations in a hypothesis-driven research pilot study
- Developing or testing models that better predict a person's response to treatment
- Using novel methods to translate findings from the laboratory, clinic, or community into treatments and interventions
- Developing data acquisition methods or post-processing that will facilitate use of complex technologies and datasets in clinical research
- Novel use of informatics or big data to answer important clinical questions
- Developing or testing novel methods in early stage (Phase 1-2) clinical trials to make the trial more efficient
- Enhancing the design and conduct of clinical trials so the results more accurately reflect the patient population generally affected by a disease (to enhance clinical relevance)

It should be noted that in most small clinical research projects there are specific "<u>translational science</u> <u>roadblocks</u>" that need to be overcome:

- improved study design by improving rigor and transparency in major generalizable areas of translational discovery
- technical execution of complex mechanistic studies in humans or animal models
- challenges to data acquisition, integrity and analysis
- translational barrier from animal models to human trials; or between adult and pediatric patient populations
- timely participant recruitment and retention
- enhanced recruitments and engagement of underserved populations

The Pilot Grant team is available to assist you in designating a translational science roadblock for your study.

VII. Available Funding

All CE Pilot awards are contingent upon funding made available to the CCTSI from the NCATS, and the CU SOM Office.

The CE Core expects to award a total of \$115,000 to fund pilot projects in two categories:

- A. Partnership Development Projects at \$8,000 total cost per 9-month project
- B. Joint Pilot Projects at \$25,000 total cost per 12-month project

Partnerships may only submit an application for **one** of the two funding categories (not both). **Indirect costs are not permitted.** The number of awards in each category varies each year depending on the merit of applications in each category. The funding rate for CCTSI Pilot Grant Awards has averaged 19-27% over the past three years, similar to or better than NIH funding rates.

<u>CCTSI Affiliated Institutions</u>: University of Colorado Denver, University of Colorado Anschutz Medical Campus, University of Colorado Boulder, Colorado State University, University of Colorado Hospital, Children's Hospital Colorado, National Jewish Health, Denver Health and Hospital Authority, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.

<u>Academic co-Principal Investigator</u>: Any researcher who holds a faculty appointment with a CCTSI affiliated institution. See above for a list of CCTSI Affiliated Institutions. See below for definition of Junior Investigator.

<u>Clinical Trial</u>: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Trial Phases 1-4: The stage of a clinical trial studying a drug or biological product, based on <u>definitions</u> developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions. **NO TRIAL BEYOND PHASE IIB CAN BE SUPPORTED BY CCTSI PILLOT GRANT FUNDS.**

<u>Community and/or Community Partners</u>: We define community and/or community partners broadly as a group of people linked by characteristics such as geographic location, race, ethnicity, gender, age, occupation, social and/or cultural ties; those who share common perspectives (or a common cause); and/or those who engage in joint action in geographical or virtual settings. Please consult with us if you have any uncertainty about whether a partner qualifies as a Community Partner.

<u>Community-Based Participatory Research (CBPR)</u>: A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community health and eliminate health disparities.

<u>Community Engagement</u>: Community engagement is a collaborative process through which communities and researchers work together to solve mutually recognized problems and build on strengths that each party brings to the collaboration. Community engagement involves engagement of the affected populations and/or patients within the community. CBPR is a method for community engagement. Other methods include community service, service-learning, training and technical assistance, coalition-building, capacity-building, and economic development.

Efficacy: An intervention's ability to do more good than harm among the target population in an ideal setting (e.g., randomized clinical control trial or community-level trial).

Effectiveness: An intervention's ability to do more good than harm for the target population in a real world setting.

Evidence-based: An intervention has undergone sufficient scientific evaluation to be proven to be efficacious or effective (e.g., intervention is considered valid or "proven" because it is strongly linked to desirable outcome).

<u>Health Disparities</u>: Simply stated, a disparity in health or health care is an avoidable and UNWANTED difference or gap—among individuals and groups. This definition of health disparities includes differences in health status, the presence of disease, health outcomes, as well as quality of and access to health care. Health disparities can affect many different populations including those with lower socioeconomic status, racial and ethnic minorities, residents in rural areas, women, children, the elderly, and persons with disabilities.

<u>Human Subject Research (HSR)</u>: Research involving direct and/or indirect interaction with human participants, biospecimen, samples, existing data sets, etc. (including exempt studies). In some cases, this

may include identifiable and deidentified data, and may include analysis of specimen that may have been collected for another study.

<u>Intervention</u>: An intentional action (singular or constellation) designed for an individual, a community, or a region that alters a behavior, reduces risk, or improves outcome. Interventions can be a medical or behavioral therapy, modification to the natural or built environment, including engineering controls, public health policy, public health program, health communication, or public health law.

<u>Junior Investigator</u>: An investigator within the first 2 years of completion of a degree with a full-time faculty appointment at one or more CCTSI-affiliated institution(s). Junior Investigators will be required to enter into a Mentor/Mentee Relationship throughout the CCTSI project period. A letter from the Mentor must be included in the application materials. See http://accelerate.ucsf.edu/training/mdp-materials for Mentor Development Course materials, including mentorship plans and agreements.

<u>Key Roles</u>: Individuals who accept primary responsibility for the research design and/or execution, including Academic co-Principal Investigator, Community co-Principal Investigator.

<u>Mentor</u>: Mentors should have adequate knowledge, skills and training to guide mentees to successful community-engaged research projects and future funding. Competency areas for mentors of junior clinical and translational science investigators are divided into six thematic areas: (1) Communication and managing the relationship, (2) Psychosocial support, (3) Career and professional development, (4) Professional enculturation and scientific integrity, (5) Research development, and (6) Clinical and translational investigator development (Abedin, Biskup, Silet, et al, 2012). See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3476465/ for guidance and additional information.

Non-Key Roles: Individuals who may offer support for the research study (with or without salary) but who do not have responsibility for the research design and/or execution may include: Professional Research Assistants (with or without salary), lab staff, graduate students, undergraduate students, tech support, fellows, consultants and directors of institutional core facilities, individuals offering fee-based services or supplying biobank biospecimen.

IX. Eligibility

- 1. Applications must be developed and submitted jointly by the academic and community partners. Both the community and academic will be considered co-Principal Investigators on the grant.
- 2. Academic co-Principal Investigators must have a full-time faculty appointment at one or more CCTSI Affiliated Institution(s).
 - a. Academic co-Principal Investigators must be eligible according to the PI Eligibility by Academic Rank table. If you have eligibility question for atypical ranks, please contact CCTSI.
 - b. Volunteer Faculty positions are not eligible to apply for awards.
 - c. Graduate students, undergraduate students, and PRAs are encouraged to participate in Non-Key Roles.
 - d. Post-doctoral trainees are not eligible to serve as the co-Principal Investigator for CE Pilots.
 - e. Investigators who are not with a CCTSI Affiliated Institution are not eligible to be in a Key Role but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.
- 3. An individual may be included in a Key Role on only one application in an award year between the Colorado (CO-Pilot), Child and Maternal Health (CMH-Pilot), and Community Engagement (CE-Pilot) Pilot Grant Programs. This restriction is not applicable to the Translational Methods (TM-Pilot) Pilot Grant Program, nor to Non-Key Roles. Key Roles are defined in each program's RFA. Please refer to **Definitions** (Section IX) of this RFA.

- 4. Researchers who are housed at or working on behalf of CCTSI Affiliated Institutions (University of Colorado Denver, University of Colorado Anschutz Medical Campus, University of Colorado Boulder, Colorado State University, University of Colorado Hospital, Children's Hospital Colorado, National Jewish Health, Denver Health and Hospital Authority, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center) are considered academic researchers.
- 5. Academic researchers who are submitting/listed on pilot grant applications must become members of the CCTSI in order to submit the application. A simple membership application can be found at the following Web site and entitles you to access various CCTSI resources but does not obligate you to participate in any studies or activities: https://cctsi.cuanschutz.edu/funding/membership. Community applicants also are encouraged to become CCTSI members, but membership is not required prior to submitting applications.
- 6. All awarded projects which include Human Subject Research are subject to Institutional Review Board (IRB) policy, and some projects may require NIH/NCATS prior-approval before award funds can be spent on research activities involving human subjects.
- 7. Please refer to Exclusions (Section XI) and Definitions (Section IX) for details on Community co-Principal Investigator eligibility.

X. Exclusions/Restrictions

The following exclusions/restrictions apply to all CCTSI Pilot Grant Awards:

- An individual may apply in a Key Role on only one application in an award year between Colorado (<u>CO-Pilot</u>), Child and Maternal Health (<u>CMH-Pilot</u>), and Community Engagement (<u>CE-Pilot</u>) Pilot Grant Programs. This restriction is not applicable to the Translational Methods (<u>TM-Pilot</u>) Pilot Grant Program, nor to Non-Key Roles. Key Roles are defined in each program's RFA. Please refer to **Definitions** (**Section IX**) of this RFA.
- Projects designed to demonstrate that a health disparity exists are not appropriate for this grant program; rather, we are interested in funding projects focused on reducing health disparities or designed to understand how to decrease health disparities.
- Projects that do not involve community engagement within the affected community and/or patient population throughout the research project will not be considered.
- Renewals or follow-on funding requests from previously funded Partnership Development or Joint Pilot projects will not be considered. However, revisions of previously *unfunded* applications from earlier cycles are welcome.
- Key Role individuals on a no-cost extension (NCE) Pilot award are not allowed to apply for the new cycle.
- Projects with primary research sites that are outside of the state of Colorado (or outside of the United States) will not be considered.
- Academic Junior Investigators who have not identified a mentor and included a letter of support in the
 application will not be considered. Please refer to **Definitions (Section IX)** for details on what is
 required of the junior investigator, or mentee, and the mentor.
- Any clinical trials proposed in CCTSI Pilot Grant Applications are restricted to Phase I or Phase IIB.
 Phase III or Phase IV clinical trials will not be supported. Please refer to **Definitions (Section IX)** of this RFA.
- Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include indirect costs (F&A) in the application.

XI. Application Process

There are two steps to applying for CCTSI Pilot Grant Funding. All submissions are time stamped upon submission. Items received after the 5 pm deadline will not be accepted. **Early submission is strongly encouraged.**

Step 1) Intent to Apply Form (LOI)

This online form collects minimal information about the proposal for development of review panels and takes 10-20 minutes to complete. The Intent to Apply Form is <u>not</u> used to determine inclusion or exclusion of applicants for full application. While submission of the Intent to Apply Form (LOI) is <u>mandatory</u>, the information collected is not binding and minor changes may be made at the time of application. The "Save and Return Later" button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click "Submit." Applicants who do not submit an Intent to Apply Form by the deadline stated above will not be eligible to submit a full application. Upon submission, both co-Principal Investigators should receive an immediate confirmation email, which includes a unique link to the online Application Form.

There are no restrictions on the number of Intent to Apply Forms submitted by an individual investigator; however, the investigator and other individuals listed in Key Roles may apply for only one project across the current Colorado (CO-Pilot), Child and Maternal Health (CMH-Pilot), and Community Engagement (CE-Pilot) Pilot Grant Program award cycle (see XI. Exclusions/Restrictions).

Access the Intent to Apply Form (LOI) by clicking the "Intent to Apply (LOI)" button on the Community Engagement Pilot Grant Program (CE-Pilot) webpage. Due by 5pm Mountain Time on October 3, 2022.

Step 2) Application Form

Individuals who submit the mandatory Intent to Apply Form (LOI) will immediately receive a unique link to the proposal's Application Form via email. The "Save and Return Later" button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click "Submit." Upon submission, both co-Principal Investigators should receive an immediate email confirmation, including a PDF of the full application submission. Once submitted, applications are considered final and cannot be modified – no exceptions. If you have any questions about using the CCTSI online submission system, please contact Kristen House (Kristen.House@cuanschutz.edu) for assistance.

Access the **Application Form** using the unique link that is emailed to the PI after submitting the LOI. Due by 5pm Mountain Time on November 1, 2022.

Application Guidelines: Refer to the Application Guidelines posted on the Community Engagement webpage (https://cctsi.cuanschutz.edu/community/ce-pilot) for information and documentation that is collected in the online Intent to Apply Form and Application Form.

A. Formatting Guidelines

- 1. Applications must be submitted online (using the unique application link sent to you in your Intent to Apply Form confirmation email) as a **single document** in Adobe PDF format.
- 2. Applications will require some information to be completed online (contact information, a 250-word maximum abstract, and a summary of the funding request) and some will be completed offline and uploaded in PDF format.
- 3. Offline portions of the applications must be written in Arial, 11- point font.
- 4. Offline portions of the applications must be single-spaced with one-inch margins.

- 5. Applications may include up to two letters of support/commitment, up to two Memos of Understanding (MOUs) and a one-page bibliography as a single appendix (which means they must be merged into one, PDF document with the application).
- 6. Academic co-Principal Investigators will be required to submit a current Biosketch.
- 7. Junior Investigators must submit a letter from a Mentor outlining the support the Junior Investigator will receive from the Mentor. See **Definitions** (Section IX) for the definition of a Junior Investigator.
- 8. Applications must adhere to the page limits and other instructions outlined in the application forms.

XII. Review Process

A Review Committee composed of academic and community reviewers experienced in community engaged research and community-based participatory research will review all grant applications, giving preference to those that have the potential to meaningfully engage community partners in the research process, improve research translation at clinic or community level, and decrease health disparities while meeting the criteria outlined in this RFA. Applications should be well written, precise, succinct, and should answer all applicable questions **in the order in which they are presented** in the application. All applications will be evaluated by community *and* academic reviewers.

XIV. Review Criteria

Scoring criteria will include: potential for building strong working partnerships, general responsiveness to the RFA requirements, a well-demonstrated conceptual understanding of the principles of community engaged research, project focus, project outcomes related to community-engagement, partnership development, translational research and health disparities. For Joint Pilot Projects, scoring criteria will include quality of the study design and measurement methods within the framework of CBPR collaboration and probability of extramural funding, if successful. Additionally, two new scoring criteria for Joint Pilot Projects will be introduced this cycle:

- **Significance** to the CCTSI Vision to "Accelerate and catalyze the translation of innovative science into improved health and patient care."
- **Translational Science Roadblock:** does the Pilot proposal address a <u>translational science</u> roadblock that could be generalizable to other research studies?

Funding recommendations will be based on an assessment of the merits and potential impact of each application and a comparison of the budget request to the proposed work plan, which will be reflected in a numerical score by which applications will be ranked. Previous adherence to CCTSI CE pilot grant program requirement will also be considered, if applicable. Applications will be funded in order of rank until funding is exhausted. The Review Committee will present funding recommendations to the PACT Council and the CCTSI Executive Committee for approval. All funding decisions are final. Brief, written feedback will be provided to unfunded applicants.

All CCTSI Pilot Grant awards are distributed after CCTSI, institutional, and federal pre-approval requirements have been met:

- A. Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals upon Notice of Award Selection (March) to avoid delays in releasing award funds (May).
- B. **Institutional Approvals:** Awardees must obtain research approval from appropriate institutional review bodies, such as COMIRB, IACUC, Biosafety, IBC, Children's Hospital Research Institute, CSU IRB or any other regulatory group relevant to their project. If a funded project will use <u>Clinical and Translational Research Center (CTRC) Services</u>, Principal Investigators must obtain Scientific Advisory and Review Committee (SARC) approval. CTRC resources include inpatient/outpatient research facilities, clinical research nursing support, nutrition research support, exercise research laboratory, and CTRC Core Lab support.
- C. **NIH/NCATS Prior-Approvals:** Some pilot projects involving Human Subject Research (HSR) may require additional review by the National Center for Advancing Translational Sciences (NCATS) prior to initiating research activities. Contact Kristen House (Kristen.House@cuanschutz.edu), for details.
- D. Funded Community and Academic co-Principal Investigators must attend any specified mandatory workshops or trainings as defined by the CCTSI Community Engagement & Research Core and agree to participate in project-specific Facilitated Coaching Session(s). A mandatory training session will be held in April 2023. Attendance by both the Academic and Community co-Principal Investigators is required.
- E. Funded Community co-Principal Investigators and Academic co-Principal Investigators <u>must</u> attend a mandatory finance and administration webinar ahead of the award start date.
- F. All funded grantees are required to submit a mid-project progress report and a final progress report at the end of the project that evaluates the community-academic partnership, the community engagement process, project implementation, project results, and lessons learned.
- G. An additional report is required one year later, detailing progress to date and all submitted publications and grant applications (pending or funded) relating to the pilot project.
- H. Grantees agree by their acceptance of this funding to identify, and budget for, an opportunity for the partnership to disseminate project outcomes back to the community and prepare a short presentation at a PACT Council Meeting. Awardees also are strongly encouraged to accept invitations to networking events designed to disseminate project outcomes.
- I. Awardees are expected to publish their findings in scholarly peer-reviewed journals, present at professional meetings, and share findings with relevant communities through established communication channels (i.e., newsletters, local news publications, etc.). Investigators are responsible for submitting any peer-reviewed journal articles resulting from research funded by this award to PubMed Central, the NIH digital archive of biomedical and life sciences journal literature. Investigators must cite the CCTSI NIH grant numbers on all publications.
- J. **Spending Account Setup:** CCTSI will coordinate the spending account setup for each project at the Academic co-Principal Investigator's institution, including speedtypes. Funding account number(s) are included in the official Notice of Award. Community Co-Principal Investigators funds will be administered via reimbursement through Trailhead Institute.
- K. Intellectual Property and Products: Applicants are reminded to avoid public disclosure (text or verbal) of results without first determining if intellectual property exists, as this may result in a lost opportunity to protect and commercialize any invention. Pls are encouraged to contact Paul Tabor at CU Innovations Office (303-724-0221) to discuss the possibility of intellectual property (including patents), publications, and presentations prior to receiving CCTSI Pilot Grant Award funds. In the event that publications, patents, or other tangible outcomes do arise from a CCTSI funded project, it is imperative that CCTSI support is acknowledged.
- L. **Citing CCTSI Funding:** All publications, grants, and presentations resulting from research funded by the CCTSI or using CCTSI resources should cite the CCTSI UL1 TR002535 Grant Number as a contributing

source of support. Please refer to the <u>How to Cite our CCTSI Grant</u> for all publications, patents, or other tangible outcomes from this project during and after project completion.

XVI. Questions

A. Please visit the Community Engagement Pilot Program website to find our Frequently Asked Questions (FAQ's): https://www.cuanschutz.edu/cctsi/funding/cepilot

B. Community Engagement Pilot Grant Applicants' Webinar:

The purpose of the webinar is to explain the application requirements and to address questions from potential applicants. We will post the recording on the website after the webinar.

DATE: SEPTEMBER 9, 2022, 12:00-1:00PM MDT.

To join the webinar please use the information below:

Join from PC, Mac, Linux, iOS or Android: https://zoom.us/j/220561396

Or join by phone: 1-646-558-8656

Meeting ID: 220 561 396

C. Ongoing Technical Assistance:

Ongoing technical assistance is available throughout the project period for both Academic and Community co-Principal Investigators. Trailhead Institute provides technical assistance to grantees in a variety of formats, including programmatic and fiscal support for community and academic affiliate partners.

D. Application Questions:

All Partnership Development and Joint Pilot Project applications must be completed as a **collaborative** effort between the Community and Academic co-Principal Investigators and questions specific to each partner should be answered accordingly. Please complete the application **beginning on the next page**. Answer the questions, in the order presented, adhering to the formatting guidelines listed in **Section XII**. **Application Process**.

We recommend using the form fields embedded in this document. You may delete the pages from this document that you don't need for the application and save the final, completed application as a PDF document. Combine your completed application with your appendix items, into one single PDF. Then, upload the PDF document through the online application system.

We recognize that the focus and content of these applications may change during the project period; this application represents your best ideas and plans at the time of application.

Continue to the next page to access the application documents.

PARTNERSHIP DEVELOPMENT APPLICATION

Please answer questions 1-6 in the order presented, using the formatting guidelines listed in **Section XII** of the RFA, in six pages or less. Be sure to answer each part (parts a, b, c, etc.) of each numbered question. After completing the questions below, please complete your <u>budget and budget justification</u>.

- Project Name:
- Academic Organization:
- Academic co-Principal Investigator:
- Community Organization:
- Community co-Principal Investigator:
- Academic funds requested: \$
- Community funds requested: \$
- 1. <u>Focus of Partnership Development</u>: a) What common health interest has brought you together that you want to explore or build upon? b) What community-relevant health disparity will this partnership focus on during the coming year? Note: please provide data supporting that a health disparity exists in the community. (For Colorado data, see: https://www.colorado.gov/cdphe)
- 2. <u>Desired Outcome(s)</u>: a) What do you plan to accomplish throughout this 9-month grant period and how will you measure your outcomes? b) What kind of relationship growth between you and your partner do you expect to create throughout this 9-month grant period?
- 3. <u>Description of Your Partnership</u>: a) Why do you think your chosen partner is the right one for accomplishing your goals? b) If this is a previously existing partnership, why do you think this partnership is right for this project? c) If this is a new partnership, how did you identify this partnership? d) How did each of the partners, academic and community, contribute to the development and submission of this grant proposal (give specific examples)?
- 4. <u>Applicant Background and Skills</u>: a) What background, skills, and previous experience does each partner have related to the work proposed in this application? b) What previous experience do you and/or your organization have (if any) working within a Community-Academic Partnership?
- 5. Community Engagement: a) How will your Community and Academic partner be engaged in this project? b) How/why do you think engagement is important to the proposed project and its success? c) Describe the key people and communities you plan to form connections with during this contract period. d) How will you ensure that both partners are equitably involved? Please be specific about the roles of each partner and the plan for how engagement will take place.

6.	<u>Proposed Next Steps</u> : a) What are your intermediate and long-term goals for continuing the Community-Academic partnership and research proposed in this application? The PACT Council hopes that successful partnerships move from Partnership Development into application for Joint Pilor funding, based on what a successful partnership has looked like in the past, how do you see this partnership progressing to a Joint Pilot Project?

PARTNERSHIP DEVELOPMENT BUDGET AND BUDGET JUSTIFICATION

Please provide a detailed budget and justification using the guidelines and budget template below. The budget and justification are limited to two pages (total).

Although we are flexible in how requested grant funds are used, all applicants must abide by the following budget guidelines:

- Requested total grant funds are encouraged to be divided between Community co-Principal Investigators and Academic co-Principal Investigators. Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the Community co-Principal Investigator. If awarded, Academic and Community co-Principal Investigators will each administer their own portion of the budget.
- Applicants must budget for presenting their work to the PACT Council (see Section XV, item D). The budget should include costs for poster development and printing, and necessary travel expenses for participants located outside the Denver-Metro Area. Since participation in this project requirement may occur outside of Partnership Development project period, it is recommended that expenses related to this post-award requirement are included on the academic side of the budget, which offers more flexibility in this type of spending. Expenses for other dissemination activities are also allowable.
- Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include indirect costs (F&A) in the application.
- Pilot funds <u>cannot</u> be used to pay for program-related costs (i.e., for program development, or for educational or dissemination programs)—funds CAN be spent on research/evaluation of such programs or for other translational research.
- Partnership Development applicants may request funds for a variety of expenses related to developing and sustaining a new Community-Academic partnership as outlined in this RFA. These funds can be used to meet with partners, (e.g., costs related to hosting meetings, including refreshments), further develop the community-academic partnership (e.g., facilitation or training materials), and plan collaborative research projects and joint grant proposals (e.g., literature searches, printing articles, grant proposals).

Using the table on the following page, list the total expected costs of the project, with each of the budget categories broken down to show the amounts allocated to the Academic and Community co-Principal Investigators. All budget figures should be entered to the nearest dollar. **Include a brief budget justification for these budget items**.

Budget Proposal Project Name:

Total (Academic and Community) Amount Requested: \$

Personnel	Academic Amount	Community Amount (suggested minimum of 50% of the total
Salary	\$	combined request) \$
Benefits	\$	\$
Total Personnel	\$	\$
Total i ersonner	Ψ	Ψ
OTHER DIRECT COSTS		
Consultants	\$	\$
Supplies	\$	\$
Equipment	\$	\$
Print/Copy	\$	\$
Postage	\$	\$
Functions/Events	\$	\$
Meetings	\$	\$
Study Subject Incentives	\$	\$
Other	\$	\$
Total Other Costs	\$	\$
TRAVEL		
In-State Only	\$	\$
Total Travel Costs	\$	\$
Total Academic/Community Project Costs	\$	\$
TOTAL COMBINED PROJECT COSTS	\$	

<u>Budget Justification</u>: Please include a brief justification for each budget line item. Please provide specifics about costs for each line item along with the justification.

JOINT PILOT PROJECT APPLICATION

This application is split into two Sections, Section A and Section B. **Section A is to be answered and completed by previous CCTSI Community Engagement Partnership Development grantees ONLY.** If you are a partnership who did not receive a previous CCTSI Community Engagement Partnership Development Grant, please do not respond to the two items in Section A.

For previous CCTSI Community Engagement Partnership Development Grantees, please answer questions 1-10 in the order presented, using the <u>formatting guidelines</u> listed in Section XII of the RFA, in <u>seven</u> pages or less (up to one page for Section A, six pages for Section B). Be sure to answer each part (parts a, b, c, etc.) of each numbered question. After completing the questions below, please complete your <u>budget and budget justification</u>.

For applicants who are NOT previous CCTSI Community Engagement Partnership Development Grantees, please answer questions 3-10 in the order presented, using the formatting guidelines listed in Section XII of the RFA, in six pages or less. Be sure to answer each part (parts a, b, c, etc.) of each numbered question. After completing the questions below, please complete your budget and budget justification.

- Project Name:
- Academic Organization:
- Academic co-Principal Investigator:
- Community Organization:
- Community co-Principal Investigator:
- Academic funds requested: \$
- Community funds requested: \$

PLEASE ONLY COMPLETE SECTION A IF YOU HAVE RECEIVED A CCTSI COMMUNITY ENGAGEMENT PARTNERSHIP DEVELOPMENT GRANT PRIOR TO THIS CYCLE OF FUNDING

SECTION A: ON YOUR PREVIOUS PARTNERSHIP DEVELOPMENT GRANT (up to 1 page)

- 1. <u>Partnership</u>: How has the *partnership* changed since the inception of your Partnership Development (PD) funding? Why did the changes occur? How did the partnership evolve? How have you maintained or strengthened your partnership since the start of the initial Partnership Development funding? If you have had a change in key personnel since your Partnership Development funding, why did this change occur? How will your partnership account for this personnel change within your Joint Pilot Project?
- 2. <u>Project</u>: How has the *project* changed since the inception of your Partnership Development funding? How does this differ from what you originally proposed during that year of funding? Why did any changes occur? How did the project evolve? What impact did the changes in the partnership have on the project plan or scope?

ALL JOINT PILOT PROJECT APPLICANTS MUST COMPLETE SECTION B

SECTION B: ON YOUR JOINT PILOT PROPOSAL (up to 6 pages)

- 3. <u>Focus of Pilot Project</u>: a) What is the primary focus of your community translational research project? b) What makes your research project translational? c) What health disparity will you address in the project (please provide data supporting that a health disparity exists in the community)? d) Describe the community with whom you are going to be working.
- 4. <u>Project Significance:</u> a) Describe your project's significance to the CCTSI Vision to "Accelerate and catalyze the translation of innovative science into improved health and patient care." b) Describe the translational science roadblock that your project will address and how it could be generalizable to other research studies.
- 5. <u>Desired Outcome(s)</u>: a) What do you plan to accomplish throughout this 12-month grant period and how will you measure your outcomes? b) What health disparity will this Community-Academic partnership focus on during the coming year? c) Describe how your project will benefit the community.
- 6. <u>Description of Your Partnership</u>: a) How long has this partnership existed? b) What previous collaborative work has the partnership done, including research? c) How did each of the partners, academic and community, contribute to the development and submission of this grant proposal (give specific examples)? d) Why do you think your chosen partner is the right one for accomplishing your goal?
- 7. Applicant Background and Skills: a) What background, skills, and previous experience does each partner and/or organization have related to the work proposed in this application? b) What previous experience do you and/or your organization have working within a Community-Academic Partnership? c) If the academic researcher in your partnership is a junior investigator (an investigator within the first 2 years of completion of a terminal degree or who is currently pursuing a masters or terminal degree within one of the CCTSI Affiliate Organizations), briefly describe a mentoring plan from senior investigator(s). d) Describe the mentoring or other support available to the community investigator from his/her organization's leadership. e) Describe each applicant's previous experience (if any) with the CCTSI Community Engagement Core (i.e., Pilot Grant, Immersion Participation, other projects, etc.)

- 8. Description of Academic and Community Collaboration: Joint Pilot Awardees are expected to conduct translational research projects within the framework of CBPR collaborations. a) How do you think community engagement is important to the proposed project and its success? b) How will each partner be engaged in this project? c) How will you make sure that partners are equitably involved? Please be specific about the roles of each partner and the plan for how engagement will take place.
- 9. <u>Design and Methods</u>: a) What study design will you use to address the objectives of your project? b) What specific methods will be used to implement the study design (for example, how will you recruit subjects, what methods will be used to collect data, etc.)? c) Describe how the community partner was involved in creating the study design. d) Describe how you will evaluate the translational science roadblock/s that your project will address.
- 10. <u>Proposed Next Steps</u>: a) What are your plans for continuing this work together once this one-year grant cycle ends? b) What are your intermediate and long-term goals for continuing the Community-Academic partnership and research proposed in this application? c) Please describe each partner's anticipated role in dissemination activities (i.e., how will project findings be shared with the community; will both partners participate in drafting manuscripts or making presentations detailing project findings; how will you ensure that the community partner is adequately involved in these activities, etc.).
- 11. <u>Extramural Funding</u>: a) A key deliverable for the Joint Pilot Project is an extramural grant submission using data gathered as part of the funded pilot project. Please include specific plans to secure further funding to support your work together.

JOINT PILOT PROJECT BUDGET AND BUDGET JUSTIFICATION

Please provide a detailed budget and justification using the guidelines and budget template below. The budget and justification are limited to two pages (total).

Although we are flexible in how requested grant funds are used, all applicants must abide by the following budget guidelines:

- Requested total grant funds are encouraged to be divided between Community co-Principal Investigators and Academic co-Principal Investigators. Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the Community co-Principal Investigator. If awarded, academic and community partners will each administer their own portion of the budget.
- Applicants must budget for presenting their work to the PACT Council (see Section XV, item D). The budget should include costs for poster development and printing, and necessary travel expenses for participants located outside the Denver-Metro Area. Expenses for other dissemination activities are allowable
- Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include indirect costs (F&A) in the application.
- Pilot funds <u>cannot</u> be used to pay for program-related costs (i.e., for program development, or for educational or dissemination programs)—funds CAN be spent on research/evaluation of such programs or for other translational <u>research</u>.
- Joint Pilot Project applicants may request pilot funds for many different expenses related
 to planning and implementing research projects as outlined in this RFA. (e.g., costs related
 to hosting meetings, including refreshments; personnel costs, data collection, and/or
 analysis of community-specific information or other quantitative and qualitative data;
 evaluating an existing community-based program; expenses for community facilitation or
 other consultants).

Using the table on the following page, list the total expected costs of the project, with each of the budget categories broken down to show the amounts allocated to the academic researcher and community co-Principal Investigators. All budget figures should be entered to the nearest dollar. **Include a brief budget justification for these budget items**.

Budget Proposal						
Project Name: Total (Academic and Community) Amount Requested: \$						
Personnel	Academic Amount	Community Amount (suggested minimum of 50% of the total combined request)				
Salary	\$	\$				
Benefits	\$	\$				
Total Personnel	\$ 0	\$ 0				
OTHER DIRECT COSTS						
Consultants	\$	\$				
Supplies	\$	\$				
Equipment	\$	\$				
Print/Copy	\$	\$				
Postage	\$	\$				
Functions/Events	\$	\$				
Meetings	\$	\$				
Study Subject Incentives	\$	\$				
Other	\$	\$				
Total Other Costs	\$ 0	\$ 0				
TRAVEL						
In-State Only	\$	\$				
Total Travel Costs	\$ 0	\$ 0				
Total Academic/Community Project Costs	\$ 0	\$ 0				
TOTAL COMBINED PROJECT COSTS (must not exceed \$25,000)	\$ 0					

<u>Budget Justification</u>: Please include a brief justification for each budget line item.