

CCTSI COMMUNITY ENGAGEMENT PILOT GRANT APPLICANTS' WEBINAR

November 15, 2023

12:00pm – 1:00 pm MST

IMPORTANT DATES

11/08/2023:	RFA Release Date
12/08/2023:	Mandatory Intent to Apply Form Deadline (due by 5pm MT)
01/29/2024:	Application Submission Deadline (Due by 5pm)
06/2024:	Notice of Selection
08/2024:	Financial Webinar
July 2023:	Mandatory Training (for both partners)
08/01/2024:	Notice of Award
08/01/2024:	<i>Anticipated Award Start Date</i>
05/30/2025:	<i>Anticipated Partnership Development Award End Date</i>
07/31/2025:	<i>Anticipated Joint Pilot Award End Date</i>

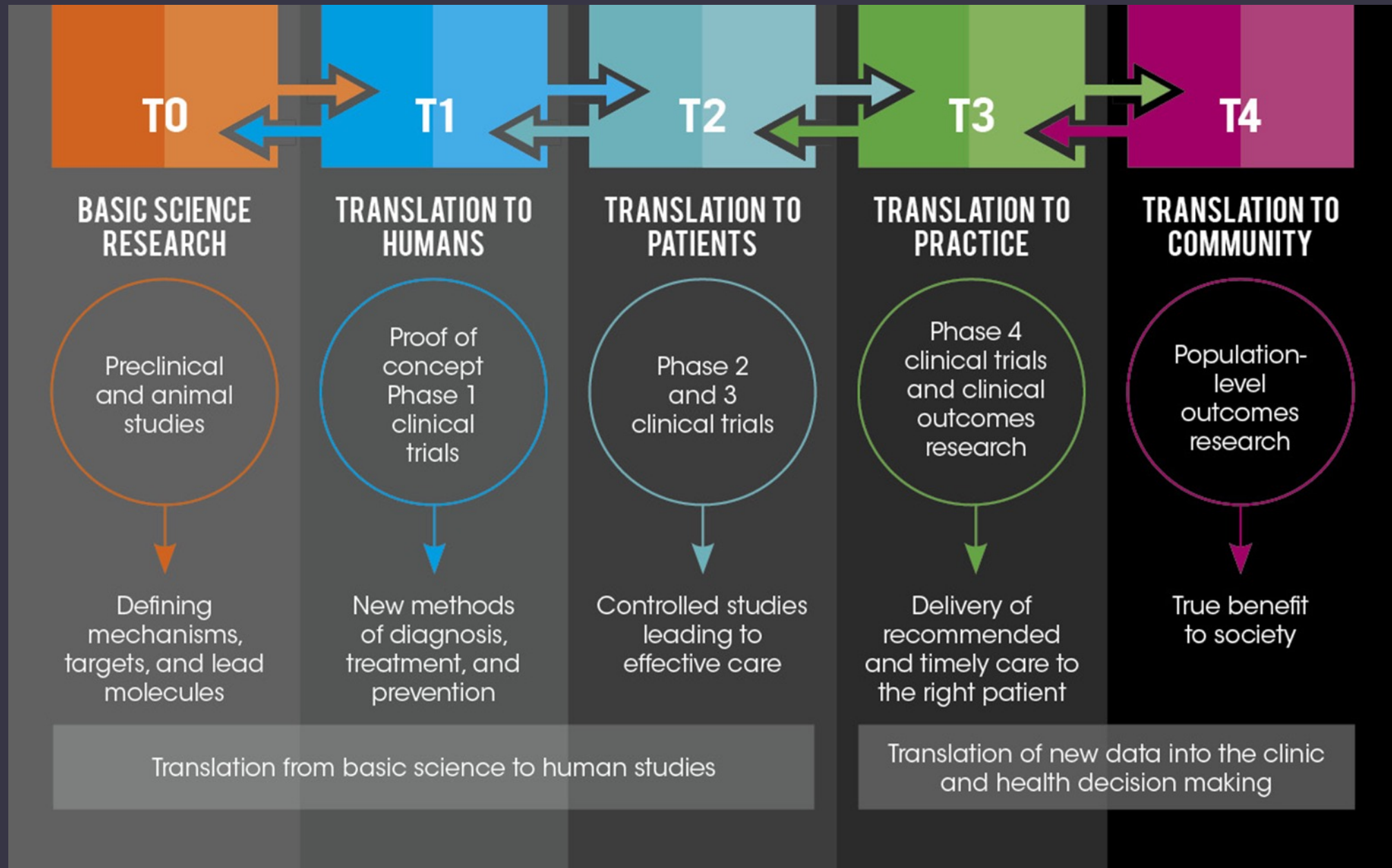
GOALS OF THE PILOT GRANT PROGRAM

- Support pilot studies that will strengthen community-academic relationships and produce preliminary data for future competitive grant applications
- Build capacity in community-academic partnerships to conduct **translational (T3/T4) research** using **community-based participatory research (CBPR)** principles to translate established efficacy into effective implementation at the community or clinic level
- Improve health equity in Colorado communities by fostering partnerships and centering community research agendas



CBPR GOES BEYOND TRADITIONAL RESEARCH FROM DESIGN TO DISSEMINATION:

- Utilizes Full participation of community in identifying issues that are relevant and important
- Community is intimately involved in designing the study
- Community representatives provide guidance for recruitment and retention
- Instruments and interventions are developed with community input and tested in similar populations
- Data is collected, shared, and interpreted with community members
- Community members assist in identifying appropriate and relevant venues to disseminate results



OVERCOMING ROADBLOCKS IN TRANSLATIONAL SCIENCES

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.”**

OVERCOMING ROADBLOCKS IN TRANSLATIONAL SCIENCES

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 “translational science roadblocks” 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

APPLICATION CATEGORIES

Partnership Development

Intended to support new or potential partnerships.

A **9-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 of a Joint Pilot Project.

Partnerships may request up to **\$8,000** (Total budget, per project, for community and academic partners combined.)

Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the community partner.

APPLICATION CATEGORIES CONTINUED

Joint Pilot Project

Intended to **support experienced and established community-academic partnerships** that seek funds for a well-defined joint research project using **community engaged and community-based participatory methods** that produces preliminary data for future competitive grant applications.

Support for clinical and translational projects addressing Translational Science Roadblocks.

Pilot Projects must be **completed within 12-months** with the goal of an extramural grant submission submitted at that time.

Applicants for Joint Pilot Projects are funded at **\$25,000**. (Total budget, per project, for community and academic partners combined.)

Applicants should consider allocations of a minimum of fifty percent (50%) of requested funds to the community partner.

PARTNERSHIP DEVELOPMENT POTENTIAL ACTIVITIES

- **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**

PARTNERSHIP DEVELOPMENT EXAMPLE

Goals and Activities (2024-2025)	August – Sept	Sept – October	October – Nov	Nov - February	February - May
Goal 1: Build relationship					
Activity 1	X				
Activity 2		X			
Goal 2: Develop Advisory Board					
Activity 1		X			
Activity 2			X	x	
Goal 3: Develop and Submit CCTSI Joint Pilot Grant					
Activity					x

JOINT PILOT POTENTIAL ACTIVITIES

- Test the feasibility, duration, cost, adverse events, of a study design
- Implement a small-scale study that can be used in obtaining funding for a larger-scale study
- Develop a proposal for larger funding through the results of the research pilot
- Disseminate and translate research findings

JOINT PILOT EXAMPLE

Goals and Activities (2024-2025)	Quarter One	Quarter Two	Quarter Three	Quarter Four
Goal 1: Community Engagement				
Activity 1	X	X		
Activity 2		X	X	
Goal 2: Implementation of Focus Groups				
Activity 1	X	X		
Activity 2		X	X	
Goal 3: Dissemination of Materials				
Activity 1			X	X
Activity 2				X

PROJECTS WE WILL **NOT** FUND...

- Projects designed to demonstrate that a health disparity exists (we want projects focused on reducing health disparities or improving health equity)
- Projects with NO community engagement
- Projects outside of the Rocky Mountain Region
- Junior Investigators who have NOT identified a mentor and included a Letter of Support in their application
- Academic Co-Principal Investigators who are currently post-docs/post-grads
- Project/program development
- Renewals or continuation funding requests from previously-funded Partnership Development or Joint Pilot Projects

ELIGIBILITY REQUIREMENTS

- All projects **must** have a community partner **and** an academic partner identified at the time the application is submitted. Both are considered co-Principal Investigators.
- **Academic Researchers:** Researchers who are housed at or working on behalf of the University of Colorado Anschutz Medical Campus or any CCTSI Affiliate Organization.
- **Community Researchers:** Researchers or other professionals who work primarily in community-based organizations, state or local government, faith-based organizations, community health clinics, private practice, etc. Community researchers also may be independent contractors who are not attached to any one organization.

ELIGIBILITY REQUIREMENTS

- Academic researchers who are listed on pilot grant applications must become members of the CCTSI in order to submit the application.
- If projects include Human Subjects Research, Institutional Review Approval must be obtained and submitted through CCTSI staff.
- All Joint Pilot Projects* will need to submit IRB approvals, through the CCTSI staff, to the National Center for Advancing Translational Sciences (NCATS).
- IRB Approval and NCATS approval must be received **prior to conducting any project activities involving human subjects.**



* Some exceptions may apply, and Partnership Development grants may need approval.

BUDGET GUIDELINES

- Requested total grant funds will be divided between Community and Academic Partners
 - Consider allocations of a minimum of fifty percent (50%) of requested funds to the community partner.
 - Funds allocated to the Community Partner flow through Trailhead Institute directly to the community partner.
 - Funds allocated to an Academic Partner come from the University and are managed by the investigator.
 - Once the allocations are made to each partner, they cannot be modified (i.e., money can't be shifted from the academic budget to the community budget and vice versa).

BUDGET GUIDELINES: UNALLOWABLE EXPENSES

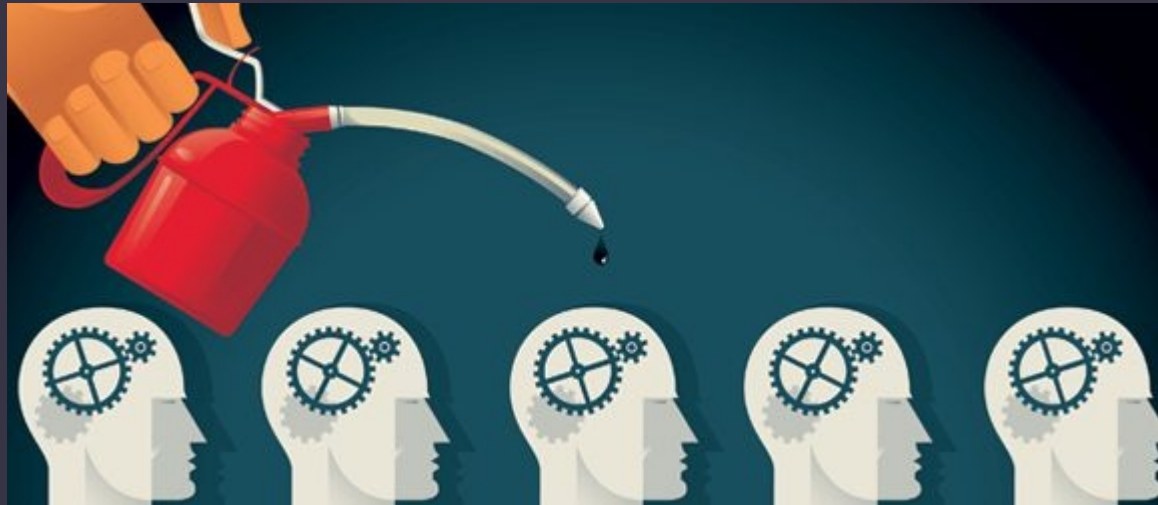
- Indirect costs are not an allowable expense for this grant program.
- Office furniture or other items not typically allowed on federal grants are not allowable expenses for this grant program unless otherwise stated in the RFA (i.e., food and other meeting expenses are allowed).
- Pilot funds cannot be used to pay for program implementation costs (i.e., costs related to program development, or for educational or dissemination programs)—funds CAN be spent on research/evaluation of such programs or for other translational research.

BUDGET GUIDELINES: ALLOWABLE EXPENSES

- **Applicants** may request funds for expenses related to developing and sustaining community-academic partnerships as outlined in the RFA, such as:
 - costs related to hosting meetings, including refreshments;
 - costs related to further developing the community-academic partnership (e.g., facilitation or training materials); and
 - costs associated with planning collaborative research projects and joint grant proposals (e.g., literature searches, printing articles, grant proposals).

BUDGET REQUIREMENTS

- 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.
- Budget for community dissemination methods



BUDGET EXAMPLE

	Academic	Community
Personnel		
Salary	\$1,995	\$1500
Other Direct Costs	\$505	
Consultants		\$2,000
Supplies		\$200
Print/Copy	\$500	
Meetings		\$500
Study Subject Incentives		\$800
Sub-Totals	\$1,995	\$5,000
Total		\$8000

PRE—AWARD REQUIREMENTS

- Awardees conducting research involving human subjects must submit their projects to an accredited Institutional Review Board (IRB) and must comply with IRB training requirements. Additionally, Institutional Review Approval must be obtained and submitted, through CCTSI staff, to the National Center for Advancing Translational Sciences (NCATS) for approval prior to the release of a letter of award and prior to the release of funding
- Awardees, both partners, must attend a mandatory Community Engagement workshop in July 2024*.

*this date may be subject to change, depending on schedules

IRB APPROVAL

- Upon award selection notification, awardees who will be engaging in Human Subjects Research (HSR) will need to prepare for IRB submission and subsequently to the National Center for the Advancement of Translational Sciences (NCATS)
 - Projects involving Human Subjects Research must have IRB approval and approval from NCATS **before doing any HSR work and prior to receiving your official Notice of Award.**
 - Assistance on NCATS approval will be provided by CCTSI staff
- Awardees conducting research involving human subjects must submit their projects to an accredited Institutional Review Board (IRB) and must comply with IRB training requirements.
- **Applicants are strongly encouraged to demonstrate their capacity to submit to IRB as soon as possible when notified of selection of award.**
- Applicants will be contacted by Kristen House to undergo a short consultation about IRB for COMIRB. This will streamline the IRB application process should the project be selected for an award: Kristen.House@cuanschutz.edu.

POST—AWARD REQUIREMENTS

- Awardees must participate in project-specific Facilitated Coaching Sessions, and additional training and technical assistance activities
- Awardees are required to attend a 30-minute finance and administration webinar
- Awardees are required to engage in 4 hours of coaching sessions
- All awardees are required to submit a mid-project progress report at the midpoint of award period and a final progress report at the end of the funded project.
 - Additional reports detailing progress to-date and all submitted publications and grant applications (pending or funded) may be required.

POST-AWARD REQUIREMENTS (CONT.)

- All awardees are required to participate in CCTSI evaluation activities related to the pilot grant program.
- All awardees will 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.
- If you intend to use any Clinical and Translational Research Centers (CTRC) resources, your research protocol also will require separate Scientific and Advisory Review Committee (SARC) submission and approval. CTRC resources include: inpatient and outpatient research facilities, clinical research nursing support, nutrition research support, exercise research laboratory, ancillary funds; and CTRC Core lab support. For more information, visit <http://www.ucdenver.edu/research/CCTSI/programs-services/ctrc/>.
- Research dissemination in scholarly peer-reviewed journals, meeting settings, and back to the community

REVIEW CRITERIA

- Applications should be well written, precise, succinct, and should answer all applicable questions in the order in which they are presented in the application.
- Preference to those that have the potential to improve community translation and improve health equity while meeting the criteria outlined in this RFA.



REVIEW CRITERIA

NIH CATEGORY	DESCRIPTION
Significance	If this project is successful, does it have the potential to change the world.
Investigators	People and background and skills. Tell us about yourself
Environment	Resources available to each Co-PI. The capacity of each Co-PI
Approach	Partnership growth, Activities, Methods/Study Design, Outcomes, Dissemination
Innovation	What's new and unique

REVIEW CRITERIA

- Scoring criteria for both categories will use:
 - NIH scoring: Scores range from 1-9, with the lower the score the better.
 - 5 categories in criteria scores
 - Overall Impact Score:
 - Overall impact, for a research project, is the project's likelihood to have a sustained, powerful influence on the research field(s) involved, but may be defined differently for different types of applications

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

SUBMISSION REQUIREMENTS

Intent to Apply form must be submitted online no later than 5:00pm on December 8, 2023. You can find the button to submit at:

<https://cctsi.cuanschultz.edu/funding/cepilot>

Applications must be submitted on-line no later than 5:00pm on January 29, 2024. The unique link to the online Application Form is included in the confirmation email that is sent after submitting the Intent to Apply Form.

FORMATTING GUIDELINES

Applications must:

- be submitted online as a single document in Adobe PDF format (applications will require some information to be completed online and some will be completed offline and uploaded in PDF format)
- be written in Arial, 11- point font
- be single-spaced with one-inch margins
- adhere to the page limits and other instructions outlined in the RFA

Applications may include up to two letters of support/commitment, up to two MOU's and a one-page bibliography as a single appendix (which means they must be merged into one, PDF document with the application).

Academic Co-Principal Investigators will be required to submit a current Biosketch.

If you are a junior investigator, include your mentoring letter/plan within the appendix

CONTACT INFORMATION

Kaylee Rivera Gordon

CCTSI CEHE Program Manager

Kaylee.Gordon@cuanschultz.edu

760-963-7818

Yuliza Hernandez

Project Manager, Trailhead Institute

yhernandez@trailhead.institute

720-398-5665