Colorado Clinical and Translational Sciences Institute (CCTSI)
UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

CCTSI Translational Methods Pilot Grant Program (TM-Pilot)
2023 Award Cycle for Clinical Translational Science (CTS) Pilots - Request for Applications (RFA)

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the sixteenth consecutive year. The CCTSI Translational Methods Pilot Grant Program (TM-Pilot) supports one-year awards to develop **novel** (non-existing) methods and innovative technologies, technological platforms, or analytical assays for clinical and translational research to faculty members of CCTSI Affiliated Institutions. This program is intended to speed the development and application of new technologies or methodologies that will improve clinical and translational research but are presently lacking or not available to CCTSI members. The development of innovative assays, devices, animal models, software, protocols, or technologies which will readily enhance in **translational science**, and also provide insights that could be generalizable to other health-related areas, will be given high priority. Applications with two Co-Principal Investigators, one for technology development and another for a scientific application, are especially encouraged to ensure future application and dissemination of newly developed state-of-the-art technologies. Research that does not involve a novel/innovative technology will not be supported. If your research focuses on pilot work with an **established** method, please consider alternative options for CCTSI pilot project funding (see CCTSI Funding Opportunities webpage). 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.

II. Key Information

Award Categories	General Translational Methods Awards	$30,000 (increased award amount this year!)
	Biostatistics/ Bioinformatics Awards	$30,000 (increased award amount this year!)
	Colorado State University TM-Awards	$30,000 (increased award amount this year!)
Award Duration	1 Year	
Award Period	May 2023 – April 2024	
Contacts	Kristen House CCTSI Pilot Grant Program Administrator kristen.house@cuanschutz.edu	Natalie Serkova, PhD CCTSI Pilot Grant Program Director natalie.serkova@cuanschutz.edu

III. Important Dates

08/01/2022	RFA Release
08/24/2022	Pre-Application Informational Call #1 -- 2:00 pm via Zoom
09/26/2022	**Mandatory Intent to Apply Form (LOI) submission deadline -- 5:00 pm Mountain Time**
10/19/2022	Pre-Application Informational Call #2 – 2:00 pm via Zoom
11/07/2022	**Application Form submission deadline -- 5:00 PM Mountain Time**
02/15/2023	Earliest Notification Award Date
05/01/2023	Start of Award Funding

Pre-Application Informational Calls: Specific questions not addressed in the RFA or website FAQs may be asked during the pre-application conference calls. All questions related to the research focus, potential new collaborations, obtaining Core support, and application process may be addressed during the calls. Details and Zoom links are located on the left sidebar of the CCTSI Translational Methods Pilot Grant Program (TM-Pilot) webpage. Each call includes a presentation about the program, application and review criteria, and resources plus an open Q&A session with the program director. Participation in the pre-application conference calls is encouraged but not required.

IV. Background

Each year, the CCTSI awards more than $3 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards (see CCTSI Funding Opportunities). 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 Traystman Fund. The CCTSI Translational Methods Pilot Grant Program (TM-Pilot) has made over 75 awards to investigators in diverse areas of translational medicine including cancer, cardiovascular disease, drug addiction, endocrinology, gastrointestinal disease, hepatology, infectious disease, mental health, neurologic disease, ophthalmology, orthopedics and respiratory medicine (see Past TM-Pilot Grant Program Awardees).

Under the new NCATS guidelines, a pilot project should address overcoming a barrier or roadblock in **translational science** as well as a research question. NCATS defines translational science as the field of investigation which seeks to understand the scientific and operational principles underlying each step of the translational process. Whereas "translational research" focuses on crossing a particular step of the translational process for a particular target or disease, translational science is focused on the general case that applies to any/multiple targets or diseases. A key tenet of translational science is to understand common causes of inefficiency and failure to complete translational research projects in a timely fashion, which may present a common barrier across various research targets, diseases, and therapeutic areas. Projects that address a relevant question in translational science, and also provide insights that could be generalizable to other health-related areas, will be given high priority in this 2023 TM-Pilot cycle.

Successful applicants should clearly identify in the Specific Aims section a **translational science** question/roadblock to be addressed in addition to particular targeted research questions. The applicants should emphasize (in "Significance") how the results from this study 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:

- Discovering new therapeutic targets and molecular pathways which play crucial roles across carious therapeutic areas
- 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
- Developing or testing novel methods, processes or study designs to address health disparities
- 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)
- Developing and testing new tools for engagement of underserved populations
- Developing or testing processes to improve enrollment of diverse populations in a hypothesis-driven research pilot study

It should be noted that in most small clinical research projects there are specific barriers, so-called "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

In the application, the PI must state clearly what is your "translational science roadblock" that you will be addressing in your proposal. The Pilot Grant team is available to assist you in designating a translational science roadblock in your study.

V. Funding Priorities

The TM-Pilot Grant Program will fund one-year pilot project awards meant to encourage cross-disciplinary and collaborative research in clinical and translational medicine that also address a roadblock in translational science. **No-cost extensions will not be allowed for the 2023 award cycle (all projects must be completed by 4/30/2024).**

- Proposed projects must represent the development of a novel (non-existing) assay, device, software, animal model, statistical method, protocol or technology. A practical application and/or implementation component can also be included in the proposal, but it is not required.
- Collaborative and cross-disciplinary projects between two teams – a technology-developing team and a technology application team – are encouraged, but not mandatory.
- Applicants are highly encouraged to use institutional state-of-the-art technology available from CCTSI Resources and CU Cancer Center Shared Resources and CCTSI Research Core Facilities (CTRCs) and Biostatistical Epidemiology and Research Design (BERD) for TM-Pilot projects, but they are not required to do so if not applicable to the project OR if they can justify use of alternate resources.
- For the CSU Award category, proposals on developing new animal models highly relevant to human disease are encouraged.
- Proposals that have high potential to lead to subsequent extramural awards from the National Institutes of Health, other government agencies, and private foundations will be given high priority.
- In keeping with the CCTSI commitment to diversity, equity, inclusion and social justice in clinical and translational research and the NIH Policy on Diversity, we encourage applications from individuals that have historically been underrepresented in biomedical research.
- The CTS-Pilot Program **is not designed to** fund "translational research projects" (which are only focused on crossing a particular step of the translational process for a particular target or disease) that do not also address to some extent a generalizable translational roadblock in **translational science.**

The TM-Pilot Grant Program can assist with matching a PI with a strong research question (but no established method) with a Co-PI with a strong technological background. Please contact the TM-Pilot Grant Program Director, Dr. Natalie Serkova, natalie.serkova@cuanschutz.edu, well in advance to help identify a potential technology-driven Co-PI.

VI. Award Categories

General Translational Methods Awards - $30,000 for one year

General Translational Methods Awards are focused on developing novel innovative methods, processes, software and technologies (devices, assays, digital platforms) to advance translational science. The proposed methods/ technologies should fill the gap and not be currently available at the CCTSI. Further dissemination and broad application of the proposed methods is expected. All proposed projects must also specifically describe a translational science roadblock that the novel technology will address.

Biostatistics/ Bioinformatics Awards - $30,000 for one year

Biostatistics/ Bioinformatics Awards are oriented towards developing innovative statistical approaches, artificial intelligence algorithms and bioinformatics software to address the complexity of analyzing and managing biomedical data sets. Further dissemination and broad application of the proposed methods is expected. The proposed project must

also describe a translational science roadblock that the novel biostatistical or bioinformatics technology will address.

Colorado State University (CSU) TM-Awards - $30,000 for one year
CSU Investigator TM-Awards will be an opportunity to develop new animal models and other innovative methods to advance the science of comparative medicine (such as spontaneous diseases in animals as models for human disease and human drug and device development). The PIs must be a faculty of the CSU College of Veterinary Medicine. Further dissemination and broad application of the proposed methods and their translation into human medicine is encouraged. The proposed project must also describe a translational science roadblock that the novel technology will address.

CSU requires pre-application review by the **CSU Office of Sponsored Programs (OSP)** prior to submission. Submit scope of work, budget and budget justification to CSU OSP with sufficient time for review. The signed Cover Letter from OSP review must be included in the proposal submitted to the CCTSI. Please contact Jessica Hunter, jessica.hunter@colostate.edu, for details.

VII. Available Funding

All TM-Pilot Grant Awards are contingent upon funding made available to the CCTSI from the National Center for Advancing Translational Science (NCATS/NIH) and the University of Colorado School of Medicine Dean's Office. 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.

VIII. Definitions

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.
Key Roles: Individuals who accept primary responsibility for the research design and/or execution, including Principal Investigator, co-Principal Investigator, co-Investigators, Primary Mentor and a co-Mentor. Investigators/Mentors receiving salary support should be listed in a Key Role and be included on only one Application Form per cycle. Unfunded mentors may be listed as the Key Role Primary Mentor (or a Key Role co-Mentor) on multiple applications, but not in any other type of Key Role (PI, co-PI, or co-Investigator) on any other application.
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. Individuals listed in Key Roles *(see VIII. Definitions)* must hold full-time faculty appointments or postdoctoral/postgraduate appointments with one or more CCTSI Affiliated Institutions.
    a. Volunteer Faculty positions are not eligible to apply for awards.
    b. Graduate students, undergraduate students, and PRAs are encouraged to participate in Non-Key Roles
    c. 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.
2. 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.
3. Individuals listed in Key Roles must be CCTSI Members at time of application. Click to Check Membership Status or to Sign Up for CCTSI Membership.

X. Exclusions/Restrictions

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

1. An individual may apply 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.
2. Key Role individuals on a no-cost extension (NCE) Pilot award are not allowed to apply for the new cycle.
3. Applications proposing to continue the work of a previously funded CCTSI Pilot Grant Project are not allowed.
4. CCTSI Pilot Grant Awards may not be used to support research conducted outside of the United States. However, proposals that use data or samples collected at international sites through other means may be considered for funding if the portion of the work conducted locally occurs at CCTSI Affiliated Institutions.
5. Any clinical trials proposed in CCTSI Pilot Grant Award applications are restricted to Phase I through Phase IIB. Phase III or Phase IV clinical trials will not be supported.
6. All funded projects related to human fetal tissue research and human stem cell and pluripotent stem cell research must undergo review by the institutional scientific ethics committee. Please contact Dr. Alison Lakin, alison.lakin@cuanschutz.edu, to discuss the institutional review process.

XII. 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. While submission of the Intent to Apply Form (LOI) is mandatory, 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."

> Access the **Intent to Apply Form (LOI) by** clicking the "Intent to Apply (LOI)" button on the Colorado Pilot Grant Program (TM-Pilot) webpage.

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." Once submitted, applications are considered final and cannot be modified – no exceptions.

> Access the **Application Form** using the unique link that is emailed to the PI after submitting the LOI.

IMPORTANT: While there are no restrictions on the number of Intent to Apply Forms (LOIs) submitted, individuals in Key Roles *(see VIII. Definitions*) may be listed on only one TM-Application Form. *(see X. Exclusions/Restrictions).*

If you have any questions about using the CCTSI online submission system, please contact Kristen House at Kristen.house@cuanschutz.edu.

XII. Proposal Requirements

The proposal should clearly describe a one-year research project that is consistent with institutional and NIH policy. All applications are considered new proposals; revisions from prior unfunded submissions should be incorporated in the

research plan. Appendices are not allowed. Format must be Arial 11 pt font, single-spaced, with ½ inch margins, no headers/footers.

The following proposal documents are required to be submitted online as a combined PDF in this order:

- **Cover Page** (1 page): Applies to all award categories. Do not include images on this page.
    - **Project Title**
    - **Investigators:** name, title, affiliation, contact information, etc.
    - **Project Overview (2-3 sentences):** use laymen's terms to describe the overall goal, anticipated outcomes, and how the research meets RFA objectives.
    - **Abstract (firm 250 word limit):** Applies to all award categories. This concise summary of the project will be used to review your application, and it may be used to announce funded awards.

- **Specific Aims** (½ page): Applies to all award categories. Do not include images on this page. Provide 2-3 concise sentences with a bullet point list, including the hypotheses and specific aims being tested in the research, indicating applicable clinical or translational research areas. Include a Specific Aim that addresses a Translational Science Roadblock that will be assessed or evaluated in this study.

- **Background and Significance** (1 ½ page limit): Applies to all award categories. Provide context for the proposed study:
    - **Background:** Describe the status and existing scientific knowledge on the research topic. Own preliminary data are not required, but may be included here.
    - **Significance:** Explain the importance of the problem and barriers to progress as well as the potential impact of your project. Describe the translational science roadblock that will also be addressed by this study.
    - **Innovation:** Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed

- **Approach** (3 page limit): Applies to all award categories. Describe the overall strategy, methodology, and analyses to be used to accomplish each Specific Aim of the project within the one-year timeline.
    - **Experimental Design:** Describe the study population/ animal models and analytical methods for data collection that will be used to address each Specific Aim.
    - **Translational Science Roadblock:** Describe how this study will assess or evaluate the Translational Science roadblock that is being addressed.
    - **Data Analysis and Statistical Analysis:** List the outcome measures and data analysis plan (e.g., t-test, ANOVA, regression, justification for analytic type, etc.). Include a power analysis to justify the sample size that is being studied.
    - **Feasibility:** Discuss potential pitfalls and alternative strategies for each Specific Aim. Any proposal where all work cannot be completed within the one-year award period,(see Timeline below) will be considered not feasible and non -responsive to this RFA.
    - **Shared Resources:** Use of CCTSI resources is not required but is encouraged to ensure rigor and reproducibility in the experimental design
    - **Timeline:** Schedule for regulatory approvals, data collection, and analysis for completing the pilot study in the one-year award period. (IRB/IACUC approval is not required at the time of application.) All proposed work MUST be completed in the one-year award period; no-cost extensions will **not** be granted.

- **References** (no page limit): Applies to all award categories.

- **Multiple PI Plan** (1 page limit): Multi-PIs are allowed for TM-Pilots if the main PI is a technology-based scientist, and the co-PI is an application scientist. Provide a Multiple PI Plan consistent with NIH policy. Roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs, including responsibilities for human and/or live vertebrate animal subject studies as appropriate and communication plan among two PIs.

- **Mandatory Letters of Support** (no page limit)
  - **CSU Investigator TM-Award Category**
    - **CSU Investigator:** The CSU investigator must complete the institutional proposal review process prior to applying, which includes review by the CSU PI's department research administrator and the Office of Sponsored Programs (OSP) Research Administrator. A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the CCTSI Pilot Grant Application. Please contact Jessica Hunter, jessica.hunter@colostate.edu, for details.

  - **Budget** (1 page limit): All applicants must use the Budget Template (click for Excel or PDF) on the CCTSI Translational Methods Pilot Grant Program (TM-Pilot) webpage under "Information & Resources."
    - Include only direct costs in your budget proposal. Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include F&A in the application budget.
    - Salary support commensurate with percent effort is allowed for Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) and lab personnel, subject to NIH-salary cap restrictions.
    - Unallowable expenses include but may not be limited to: Indirect costs, F&A (except for the CSU half of award for CO-Pilot CU/CSU Collaboration category), international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees.
    - The categories of expenses on the budget template should be edited as necessary.
    - Funds must be fully expended by 4/30/2024; any funds remaining in the project budget after that date will be forfeited.

  - **Budget Justification** (1 page limit): Clearly define one-year pilot project expenses that are consistent with NIH policy, including: Personnel, Supplies, Lab Testing, Animals, Human Participants, Non-affiliate Organizations, etc. Align budget and justification with any financial commitments noted in Letters of Support and describe any other support for the project.

  - **Biosketches** (no page limit): Applies to all award categories. A Biosketch in current NIH format (see NOT-OD-21-073 and current NIH template) and 5-page limit is required for all individuals listed in Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support).

  - **Institutional Prior Approval** (no page limit): Applicants are strongly encouraged to work with the sponsored programs office at their institution to meet all pre-application requirements specific to their organization, including applications for federal and non-federal (internally funded) seed grant programs.
    - **CU Anschutz and CU Denver applicants:** CCTSI Pilot Grant Awards are supported by internal funds and pre-application review by the Office of Grants and Contracts ("routing") is not required.
    - **CU Boulder applicants**: You are required to complete an internal review process prior to receiving an award, but no prior approval for applying is required. Please contact Nikki Leonardo, Leonardo@Colorado.edu, for details.
    - **CSU OSP Proposal Transmission Letter**: Applies to all proposals involving a CSU investigator. Applicant must complete the institutional proposal review process prior to applying, which includes review by the CSU PI's department research administrator and the Office of Sponsored Programs (OSP) Research Administrator. A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the CCTSI Pilot Grant Application. Please contact Jessica Hunter, jessica.hunter@colostate.edu for details.

XIII. Review Process

Recruited and volunteer reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission and addresses translational roadblocks. Applicants may request specific individuals

with expertise in their specific proposed research specialty and who do not have a conflict of interest to review applications during the application process. All Review Panel Study Sections are chaired by CCTSI Pilot Grant Program Director(s) or Chair(s), and funding recommendations are presented to the CCTSI Executive Committee for approval. All Executive Committee decisions will be final. Short informative critiques of application strengths and weaknesses will be provided to all applicants after awards have been officially announced.

XIV. Review Criteria

CCTSI Review Panels will use the NIH 9-point scoring system and rate based on following criteria:

a. **Innovation** in proposed methods to be developed, approaches, and techniques.
b. **Approach/Scientific Merit** based on rigor, transparency and one-year feasibility of the proposed study design.
c. **Cross-disciplinary or Collaborative Focus** to bridge basic and translational researchers in discovery translation.
d. **Significance** to the CCTSI Vision to "Accelerate and catalyze the translation of innovative science into improved health and patient care."
e. **Translational Science Roadblock:** does the Pilot proposal address a translational science roadblock that could be generalizable to other research studies?
f. **Investigators'** research qualification and collaborative potential
g. **Environment** and institutional support to the PI and the proposal
h. **Health Equity and Diversity (Non-Scoring Criteria)**

XVII. Questions and Resources

Please refer to the Colorado Pilot Grant Program (TM-Pilot) webpage for information regarding RFA, Frequently Asked Questions, Informational Calls, CCTSI and Core Resources, and Past Award Information.

Research Core Services

- CCTSI Research Core Facilities (CTRC, etc.)
- CU Anschutz Core Facilities
- University of Colorado Cancer Center (Shared Resources)
- CSU Research Core Facilities
- CU Boulder Shared Instrumentation Network

How do I keep track of my research output?

- The Health Sciences Library provides support for several tools that will make it easier for you to efficiently keep track of your research output using ORCID, Colorado PROFILES, NCBI, and SciENcv.

Additional Funding Opportunities

- CCTSI Funding Opportunities include CTRC Microgrants, CCTSI Pilot Grant Programs, and Education, Training & Career Development
- AB Nexus expands research collaborations between the CU Anschutz Medical Campus and CU Boulder campuses

[End]