

CCTSI Translational Methods Pilot Grant Program (TM-Pilot) 2026 Award Cycle for Clinical Translational Science (CTS) Pilots - Request for Applications (RFA)

I. Funding Opportunity Summary

The Colorado Clinical and Translational Sciences Institute (CCTSI) is pleased to announce funding opportunities for the 18th 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 Partnering Institutions. This program is intended to speed up the development and application of new technologies or methodologies that will improve clinical and translational science 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 (but not required) to ensure future application and dissemination of newly developed state-of-the-art technologies. Pilot projects must include a specific aim addressing a translational science roadblock, with an ultimate goal of providing insights that could be generalizable to other healthrelated areas. Applications that do not include a specific aim that specifically addresses a Translational Science Roadblock will not be reviewed and will be returned to the applicant. Research that does not involve 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 National Center for Advancing Translational Sciences (NCATS) requirements in addressing translational roadblocks and all revised proposals are considered new applications rather than resubmissions.

II. Key Information

| Award Categories | General Translational Methods Awards Biostatistics/ Bioinformatics Awards Colorado State University TM-Awards | \$30,000 \$30,000 \$30,000 |
|------------------|---|--|
| Award Duration | 1 Year | |
| Award Period | August 1, 2026 – July 31, 2027 | |
| 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

| 11/10/2025 | RFA Release |
|------------|--|
| 11/12/2025 | Pre-LOI Informational Webinar #1 – 10 am – 11 am via Zoom* |
| 11/17/2025 | Pre-LOI Informational Webinar #2 – 12:30 pm – 1:30 pm via Zoom* |
| 12/15/2025 | Mandatory Intent to Apply Form (LOI) submission deadline 5:00 pm Mountain Time |
| 01/07/2026 | Pre-Application Informational Webinar – 10 am – 11 am via Zoom |
| 01/20/2026 | Application Form submission deadline 5:00 PM Mountain Time |

^{*}NEW Mandatory Pre-LOI Webinars: Each applicant will be required to attend one of the Pre-LOI webinars for better

understanding of Translational Science and addressing translational science roadblocks. The link for LOI submission will be provided for those who attended the pre-LOI webinar. Participation in one of the two pre-LOI informational calls is mandatory. If you are unable to attend either session, please contact Kristen House at kristen.house@cuanschutz.edu to discuss alternative arrangements.

All questions related to the research focus, <u>translational science roadblocks</u>, potential new collaborations, obtaining Shared Resource/ Core support, and application process may be addressed during the calls. Details and Zoom links are located on the left sidebar of the <u>CCTSI Translational Methods Pilot Grant Program (TM-Pilot)</u> 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.

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 85 awards to investigators in various 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 NCATS guidelines, pilot projects must address a <u>translational science roadblock</u> as well as a research question. In the Letter of Intent (LOI) and application, the PI must state as a specific aim the "<u>translational science roadblock</u>" that they will be addressing in their proposal. The CCTSI Pilot Grant team is available to assist you in designating a translational science roadblock for your specific study. Successful applicants should clearly identify in the Specific Aims section a **translational science** question/roadblock specific aim to be addressed in addition to their particular 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.

V. Funding Priorities

The TM-Pilot Grant Program will fund <u>one-year</u> 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 2026 award cycle (all projects must be completed by 07/31/2027).**

- 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 encouraged to use institutional state-of-the-art technology available from CCTSI Resources and CCTRCs) 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, or private foundations, will be given high priority.
- Applications not aligned with federal funding priories at the time of award, or not eligible to be accepted by your home institution if funded, cannot be funded by this mechanism. CU Anschutz applicants, please refer to this <u>campus guidance</u> and <u>rubric</u>, and work closely with the research administration in your school or college while developing your funding applications. For all other institutions, please work with the CCTSI Pilot contact at your institution or the Pilot Program Director.

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 specific aim addressing translational science roadblock that the novel technology will address. Proposals without a translational science specific aim will not be reviewed.

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 specific aim addressing translational science roadblock that the novel biostatistical or bioinformatics technology will address. Proposals without a translational science specific aim will not be reviewed.

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 specific aim addressing translational science roadblock that the novel technology will address. Proposals without a translational science specific aim will not be reviewed.

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 Partner Institutions: University of Colorado Denver, University of Colorado Anschutz, 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. Individuals receiving salary support through this program may be designated in a Key Role on only one application per funding cycle. Individuals serving as unfunded mentors may be listed as the Primary Mentor or co-Mentor on multiple applications within the

same cycle. However, they **may not** be listed in any other Key Role (e.g., Principal Investigator, co-Principal Investigator, or co-Investigator) on additional applications during that cycle.

<u>Non-Key Roles:</u> 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: Research Services Professionals and Research Associates (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 Partner 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 <u>CCTSI Partner Institution</u> 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 <u>PI Eligibility by Academic Rank table</u>. If you have eligibility questions for atypical ranks, contact Kristen House at <u>kristen.house@cuanschutz.edu</u>.
- 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 Translational Methods (<u>TM-Pilot</u>) Pilot Grant Program in an award.
- 2. Applications proposing to continue the work of a previously funded CCTSI Pilot Grant Project are not allowed. All applications should have innovative specific aims distinctive from any ongoing projects by the PIs.
- 3. 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 Partner Institutions.
- 4. Any <u>clinical trials</u> 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.
- 5. 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.
- 6. <u>Animal only research</u> should be rigorously justified in the application according to new NIH guidelines on reducing animal use and prioritizing human-based and new approach methodologies (NAM).

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) - mandatory

This online form collects minimal information about the proposal and the translational science roadblock to be addressed. This takes 10-20 minutes to complete. 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 will receive a link to the **Intent to Apply Form (LOI)** after attending one of the two required pre-LOI informational calls. If you are unable to attend either session, please contact Kristen House at kristen.house@cuanschutz.edu to discuss alternative arrangements.

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. If your LOI does not address an appropriate translational science roadblock and the project is not relevant to human health, you will not be invited to submit a full 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." 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 <u>Kristen.house@cuanschutz.edu</u>.

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 and a maximum of <u>8 pages</u>. This limit includes the cover page (1 page), specific aims, importance of the research, approach, expertise and resources, budget template (1 page), and budget justification (1 page) and excluding references, letters of support, Biosketches, multiple PI plan, and any institutional approvals. If formatting is not followed or the proposal exceeds the page limit, the application will be administratively withdrawn.

The following proposal documents are required to be submitted online as a combined PDF in this order (please use the checklist to assure all selections are included):

- Cover Page: Applies to all award categories. Do not include images on this page.
 - Project Title
 - o **Investigators:** name, title, affiliation, contact information, etc.
 - Project Overview (2-3 sentences): use laypersons' 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. Applications with Abstracts over the 250-word limit will not be accepted for review.
- Specific Aims: 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. One Specific Aim must focus on addressing a translational science roadblock that will
 be assessed or evaluated in this study; a failure to address this requirement will result in administrative withdrawal of

the proposal and it will not be reviewed.

- Importance of the Research: Applies to all award categories. Provide context for the proposed study:
 - o **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 <u>translational science roadblock</u> that will also be addressed by this study.
 - <u>Translational science roadblock:</u> The CTS that will be specifically addressed by this study should be clearly designated and described.
 - o **Innovation:** Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed.
- Approach: Applies to all award categories. Describe the overall strategy, methodology, and analyses to be used to
 accomplish <u>each Specific Aim</u> of the project within the one-year timeline. The project must be feasible within the oneyear timeline. No-cost extensions are not allowed.
 - Experimental Design: Describe the study population/ animal models and analytical methods for data collection that will be used to address each Specific Aim.
 - o **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. Include data analysis for the Translational Science Roadblock specific aim.
 - Rigor and 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.
 - Timeline (Required): Schedule for regulatory approvals, data collection, and analysis for completing the pilot study in the one-year award period. (IRB/IACUC approval is <u>not</u> 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.
- **Expertise and Resources:** Without duplicating information in the biosketches, describe the role(s) of key investigators. Use of Cores and Shared Resources is not required but is encouraged to ensure rigor and reproducibility in the experimental design.
- 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 Pl'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."
 - All costs must be reasonable and directly related to supporting the described project.
 - Items in each of the budget categories should be detailed as much as possible so that it is clear what items will be purchased and in what quantities.
 - Include only direct costs in your budget proposal. Indirect costs (F&A) are assessed internally by the CCTSI after projects are selected for funding. For projects ultimately funded by the NIH CTSA grant, the federally negotiated F&A rate will be used to add the appropriate F&A to the funded budget. For projects ultimately funded by CCTSI Institutional funds, F&A costs are not permitted. Do not include F&A in the Pilot grant 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, students and fellows, subject to NIH-salary cap restrictions.
 - Only one local/ national meeting/conference is allowed per project.
 - Unallowable expenses include but may not be limited to: indirect costs, international entities, publication costs, equipment ≥\$5,000, computers, telecommunications, food, furniture, administrative support, nonproject specific office expenses, and professional dues/fees/membership, expenses that support future grant applications, training costs (unless specifically required to carry out the investigations in the proposed project).
 - The categories of expenses on the budget template should be edited, as necessary.
 - Funds must be fully expended by 7/31/2027; 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 and directly related to funding the activities of the proposed project, including: Personnel, Supplies, Core Fees, Lab Testing, Animals, Human Participants, etc. Wherever possible, items in each of the budget categories should be detailed as much as possible so that it is clear what items will be purchased, what quantities, and in what unit prices (click for sample budget and justification). Personnel costs should be itemized for each individual and include their annual salary, the FTE provided to the project and the subsequent salary support and related fringe benefits being requested. Any consultant expenses should document the rate to be paid and the expected number of hours of consultant time.
- Biosketches (5-page limit per person listed as Key Personnel): 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.
 - o CU Anschutz and CU Denver applicants: CCTSI Pilot Grant Awards are supported by internal funds and preapplication 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 <u>NIH 9-point scoring system</u> and rate based on the <u>new 3-Factor Review System</u>. Reviewers will consider Factors 1, 2 and 3 in the determination of scientific merit, and in providing an overall impact score. In addition, Factors 1 and 2 will each receive a separate factor score.

Factor #1. Importance of the Research (Should it be done?): Scored 1-9

- Is the approach innovative in its potential to advance translational science?
- Will the findings have meaningful impact on health or scientific progress?
- Does the proposed research address a significant TS Roadblock?

Factor #2. Rigor and Feasibility (Can it be done well?): Scored 1-9

- Are the methods and study design appropriate and well-justified?
- Is the timeline realistic for completion within the pilot funding period?
- Are potential challenges and mitigation strategies clearly described?

Factor #3. Expertise and Resources (Are there any gaps?): Binary Rating "Appropriate OR Additional Expertise Needed"

- Does the investigative team have the necessary expertise to carry out the proposed work?
- Are institutional resources, cores and environment adequate to support the project?

Additional Considerations:

Applicants should also address the following:

- Dissemination Potential: How will results be shared with other investigators or institutions?
- Product Generation: Anticipated outputs (e.g., publications, presentations, patents).
- Future Funding Plans: Intent to pursue additional funding based on pilot results.

XV. Questions and Resources

Please refer to the <u>Colorado Pilot Grant Program (TM-Pilot)</u> 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 <u>Health Sciences Library</u> 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.
- Consider working with CU Innovation to protect your intellectual property and disseminate your scientific discoveries

Additional Funding Opportunities

- <u>CCTSI Funding Opportunities</u> 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]