![Colorado Clinical and Translational Sciences Institute (CCTSI) logo — University of Colorado Denver | Anschutz Medical Campus]

CCTSI Translational Methods Pilot Program (TM-Pilot)
2021 Award Cycle - Request for Applications (RFA)

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the fourteenth consecutive year. The CCTSI Translational Methods Pilot Program (TM-Pilot), formerly the Novel Methods Program, supports one-year awards to develop novel methods and innovative technologies for clinical and translational research to faculty members of CCTSI Affiliated Institutions. This includes the development of new assays, methods, or technologies which are not currently available to the CU Anschutz Medical Campus and CCTSI Affiliated Institutions. 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.

II. Key Information

Award Categories	General Translational Methods Awards
	Biostatistics/Bioinformatics Awards
	Colorado State University Awards
Award Amount	$20,000
Award Duration	1 Year
Award Period	May 2021 – April 2022

Contacts

Debra Szuster, MS
CCTSI Pilot Project Program Coordinator
720-848-4327
debra.szuster@cuanschutz.edu

Natalie Serkova, PhD
CCTSI TM-Pilot Program Director
Director, Colorado Animal Imaging Shared Resource
303-724-1086
natalie.serkova@cuanschutz.edu

III. Important Dates

08/28/2020	RFA Release
09/14/2020	Pre-application conference call (2-3 pm) – Details also posted on TM-Pilot webpage
	Zoom (click to join) or dial (346) 248-7799, meeting ID 914 1818 4099
10/14/2020	**Mandatory Intent to Apply Form (LOI) submission deadline 5:00 PM MDT**
10/28/2020	Pre-application conference call (10-11 am) – Details also posted on TM-Pilot webpage
	Zoom (click to join) or dial (346) 248-7799, meeting ID 973 6406 5002
11/04/2020	**Application Form submission deadline 5:00 PM MDT**
01/31/2021	Earliest notification of award
05/01/2021	Start of funding

Note: Participation in the pre-application conference calls is encouraged but not required. The Intent to Apply Form (LOI) and Application Form submission due dates and 5:00 PM MDT deadlines **will be strictly enforced**.

IV. Purpose

The Translational Methods (TM-Pilot) Program provides one-year awards to develop **novel** (non-existing) methods, technological platforms or analytical assays for clinical and translational research. 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. This includes the development of innovative assays, devices, animal models, software, protocols or technologies which will readily enhance clinical and translational research of CCTSI members. If your research focuses on pilot work with an **established** method, please consider alternative options for CCTSI pilot project funding (CCTSI Funding Opportunities webpage).

The TM-Pilot Program also enables to match 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 Program Director, Dr. Natalie Serkova (natalie.serkova@cuanschutz.edu) well in advance to help identify a potential technology-driven co-PI.

V. Background

Each year, the CCTSI awards more than $3 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. 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 TM-Pilot Program (formerly Novel Methods, established 2009) has made over 60 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. Past awardees have included faculty at the Anschutz Medical Campus, Colorado State University, University of Colorado Boulder and University of Colorado Denver. View our current and past awardees on the CCTSI TM-Pilot Past Awards webpage.

VI. Funding Priorities

The TM-Pilot Program will fund one-year pilot project awards meant to encourage cross-disciplinary and collaborative research in clinical and translational medicine.
- Proposed projects must represent the development of a **novel** (non-existing) assay, device, software, animal models, 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 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.
- Cross-disciplinary and collaborative projects are encouraged.
- For the CSU Award category, proposals on developing new animal models highly relevant to human disease are encouraged.
- The 2020 CU-CSU Summit, "COVID-19 and the Colorado Research Environment," was held online Wednesday, August 19, 2020. Through the Summit, the CCTSI seeks to foster new collaborations across campuses in COVID-19 research. For the 2021 award cycle, priority will be given to meritorious TM-Pilot applications that propose new research collaborations on the topic of COVID-19.

- Proposals that have high potential to lead to subsequent extramural awards from the National Institutes of Health, other government agencies, and private foundations are given high priority.
- Proposals that contribute to enhancing diversity in the translational research pipeline, address health inequities, and/or the social determinants of health will be given priority.

In keeping with the CCTSI commitment to improving the diversity of the research work force, and our mission to improve the health of vulnerable communities, we encourage applications from individuals that have historically been underrepresented in biomedical research. These include African Americans, Hispanic Americans, Native Americans (including Alaska Natives), natives of the U.S. Pacific Islands, individuals with disabilities and individuals from socially, culturally, economically or educationally disadvantaged backgrounds.

VII. Award Categories

General Translational Methods Pilot Awards - $20,000 for one year
Biostatistics/Bioinformatics Awards - $20,000 for one year
Colorado State University Awards - $20,000 for one year

VIII. Available Funding

All TM-Pilot awards are contingent upon funding made available to the CCTSI from the National Center for Advancing Translational Science (NCATS), 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.

IX. Definitions

CCTSI Affiliated Institutions (link): University of Colorado Denver (Downtown Campus and Anschutz Medical Campus), University of Colorado Boulder, Colorado State University, University of Colorado Health, Children's Hospital Colorado, National Jewish Health, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.
Clinical Trial (link): 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.

> **Phases 1-4 (link):** The stage of a clinical trial studying a drug or biological product, based on definitions 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. Any clinical trials proposed in Pilot applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported by CCTSI pilot award funds.

Human Subject Research (HSR): Research involving direct and/or indirect interaction with human participants, biospecimen, samples, existing data sets, etc. For federal regulatory purposes, this may also include studies involving identifiable and/or deidentified data, and analysis of specimen that may have been collected for another study.
Key Roles: Principal Investigator, Co-Principal Investigator, Co-Investigator.
Non-Key Roles: Consultants, Advisory Committee, Professional Research Assistants, Postdoctoral Students, Graduate Students, Fellows, Undergraduate Students, Tech Support, Fellows, etc.
Translational Research: Translational research includes any basic, pre-clinical or clinical research with promise to improve human health. Basic research at the cellular and molecular level, pre-clinical research in animal models, clinical research in humans, and outcomes or health services research are eligible if the ultimate goal is to improve human health.

X. Eligibility

- Principal Investigators must meet criteria listed on the "PI Eligibility by Rank" table (PDF). If you have eligibility question for atypical ranks, please contact CCTSI.
- Individuals listed in Key Roles must hold instructor level (or above) faculty appointments with CCTSI Affiliated Institutions. This includes PI, co-PI, and co-Investigator(s).
- Investigators from non-affiliated organizations are ineligible to be Principal Investigators on CCTSI Pilot Awards but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.
- Graduate, undergraduate, postdoctoral students, fellows and PRAs are encouraged to participate in Non-Key Roles.
- CCTSI Membership (mandatory): 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.

XI. Exclusions/Restrictions

The following exclusions/restrictions apply to all CCTSI Pilot Grant Awards:
- An individual may be included in a Key Role on only one application in an award year between Colorado (CO-Pilot), Child and Maternal Health (CMH-Pilot), and Community Engagement (CE-Pilot) Programs. Investigators applying for Translational Methods (TM-Pilot) funding are also eligible to concurrently apply for funding from CO-Pilot, CMH-Pilot, and CE-Pilot. There is no limit to an individual being included in Non-Key Roles across CO-Pilot, CMH-Pilot, and/or TM-Pilot applications.
- Pilot 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 of the portion of the work conducted locally at CCTSI Affiliated Institutions.
- Any clinical trials proposed in Pilot applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported.
- All NIH regulations related to human fetal tissue research and human stem cell and pluripotent stem cell research flow down to CCTSI Pilot Grant Awards. If funded, projects involving these types of research must undergo review by the institutional scientific ethics committee. Please contact Alison Lakin (alison.lakin@cuanschutz.edu) to discuss the institutional review process.

The following additional exclusions/restrictions apply to all TM-Pilot Awards:
- Projects which are focused on validation of an **existing** technology will not be accepted.
- Award funds can only be used to support research at CCTSI Affiliated Institutions.
- Renewal or follow-on CCTSI Pilot Award funding to any previously funded CCTSI Pilot Award project is not allowed.
- Investigators in a Key Role with an actively funded CCTSI Pilot Award (either from the most recent grant cycle or funded under a No Cost Extension) are ineligible to apply for the current cycle in a Key Role.
- If you are involved in a Key Role on an application in this cycle, you may not participate in the Review Panel for the same award category.

XII. Proposal Requirements

The proposal should clearly describe a one-year research project using NIH-style structure, comprised of Abstract, Research Plan, Specific Aims, Background and Significance, Approach, Education Mission, References, Budget and Justification, Biosketches, and Letters of Support. Appendices are not allowed. You may use standard PHS 398 forms, although this is not required unless otherwise noted. Format must be Arial 11 pt font, single-spaced, with ½ inch margins, no footers.

When you submit your Application Form online (see "XIII. Application Process"), you will be required to attach a combined PDF of all required proposal material listed in the order below:

1) Abstract (250 word limit): This concise summary of the project will be used to review your application, and it may be used to announce funded awards. Include header with project title and name/title/affiliation of investigators, overall goal, anticipated outcomes, and how the research meets RFA objectives.

2) Research Plan (total 4 page limit): All applications must provide a research plan consistent with NIH requirements. All applications are considered new proposals; revisions from prior unfunded submission should be incorporated in the research plan. Incorporate information on background and preliminary studies, where appropriate, and information on use of CCTSI resources (or rationale for using alternative resources). 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.

> **2.1) Specific Aims** (½ page limit): Provide a clear, concise summary of the hypothesis to be tested and your Specific Aims, including the clinical or translational research areas applicable.
>
> **2.2) Background and Significance** (1 page limit): Explain the importance of the problem or barrier to progress in the field that the proposal addresses. Provide clear evidence that the methodology or technology to be developed is innovative and does not exist at any CCTSI Affiliated Institution. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. Preliminary data, which shows PI expertise in developing the proposed methodology, are encouraged.
>
> **2.3) Approach** (1-2 pages suggested): Describe the overall strategy, methodology, and analysis to be used to accomplish the specific aims of the project within the one-year timeline. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Describe proposed tests, procedures, subject population and ages in enough detail to allow an adequate evaluation of your approach.
>
> **2.4) Education Mission** (¼ to ½ page suggested): Describe how this proposal relates to the educational mission of the PI's institution. Include involvement of K12 awardees, residents, post-Docs or students involved in the project. Describe how the resulting novel technology/method could be disseminated.

3) References (no page limit)

4) Optional Letters of Support (no page limit): Optional LOS from department chairs, consultants, foundations, commercial sources, manufacturers, other financial commitments, etc.

5) Budget (1 page limit, use the **Budget Template** on the TM-Pilot webpage under "Information & Resources"): Provide a one-year budget and budget justification consistent with NIH requirements. Click the link above to download the budget template.

- Award funds can only be used to support research at CCTSI Affiliated Institutions, so there are no cost-share budget reviews required.
- Define project expenses with cost categories relevant to the project, such as Personnel, Supplies, Lab Testing, Animals, Human Subjects, etc.
- Salary support commensurate with percent effort is allowed for PI and lab personnel, subject to NIH-salary cap restrictions.
- Salary support for individuals in Non-Key roles, who are also employed by CCTSI Affiliated Institutions, may be included in the budget (may include tuition, stipend, fringe for graduate students). Salary support for individuals in Non-Key Roles who are not CCTSI affiliates is not permitted.
- Include only direct costs (up to $20K) in your budget proposal. Indirect costs are assessed internally by CCTSI and do not need to be included in your budget proposal.
- Unallowable expenses include but may not be limited to: International entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees. Support of research at non-CCTSI Affiliate Institutions or outside the United States is not allowed.

6) Budget Justification (1 page limit): The justification must align with budget and any financial commitments in Letters of Support, and other support for the project should be described.

- Proposals that utilize 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 are highly encouraged. If you are using other facilities for your research, include your rationale in your Budget Justification.
- Describe any other sources of funding that are involved in this project, how this project differs from those proposals, and any other sources of funding that may have been sought in the Budget Justification.

7) Biosketches (no page limit): A Biosketch in current NIH format and page limit is required for each individual listed in in a Key Role. This includes PI, co-PI, and co-Investigator(s).

8) 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.

- **University of Colorado (AMC/Downtown Campus) Applicants:** TM-Pilot awards are supported by existing CCTSI funds and pre-application review by the Office of Grants and Contracts ("routing") is not required.
- **Colorado State University (CSU) Applicants:** All proposals involving CSU investigator(s) in Key Roles must submit a signed OSP Proposal Transmission Letter with their Application Form. All CSU investigators must complete the institutional proposal review process prior to submission, which includes review by the CVMBS college office (cvmbs_proposals@mail.colostate.edu) and Office of Sponsored Programs Research Administrator, Julie Harvey. A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the Pilot Award application. Please contact Aimee Oke (aimee.oke@colostate.edu) for details.
- **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.

XIII. Application Process

Information and Resources are available on the Translational Methods Pilot Program (TM-Pilot) webpage:

- Award Categories
- Request for Applications (RFA)
- Informational Calls: left sidebar
- PI Eligibility by Rank table
- Application Guidelines & Checklist

- Frequently Asked Questions
- CCTSI Resources
- Review Criteria
- Award Cycle
- Past Award Information

Informational Calls: Specific questions not addressed in the RFA or FAQs may be asked during the pre-application conference calls. Details and Zoom links are located on the left sidebar of the TM-Pilot webpage.

Submission Method: Access the online submission system by clicking "Submit Intent to Apply Form (LOI)" on the TM-Pilot webpage. The mandatory Intent to Apply Form (LOI) and Application Form are submitted online and are time-stamped upon submission. The "Save and Return Later" button at the bottom of the online forms allows applicants to access and revise information as often as needed up until they click "Submit." This program does not utilize an invitation process; however, only applicants who submit a mandatory Intent-to-Apply Form are eligible to submit an Application Form. ***Items received after the 5 pm MST deadlines will not be accepted.***

Application Guidelines & Checklist: Refer to the Application Guidelines & Checklist posted on the TM-Pilot webpage for information and documentation that is collected in the online Intent to Apply Form (LOI) and Application Form.

Intent to Apply Form (LOI): This online form collects minimal information about the proposal for development of review panels. A formal letter is not required. While submission of the Intent to Apply Form (LOI) is **mandatory**, the information collected is **not binding** and may be minimally changed at the time of application. Upon submission, the PI 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 (LOIs) submitted by an individual investigator; however, the investigator and other individuals listed in Key Roles may apply for funding for only one project from the TM-Pilot Program per application cycle.*

Application Form: The unique link to the online Application Form is included in the confirmation email that is sent after submitting the Intent to Apply Form (LOI). Upon submission, the PI should receive an immediate email confirmation, including a PDF of the full application submission. The same Application Form may be revised and re-submitted up until the 5 pm MST deadline. A new confirmation email will be sent after each re-submission; only the most recently submitted Application Form will be evaluated by the Review Panel.

If you have any questions about using the CCTSI online submission system, please contact Debra Szuster (debra.szuster@cuanschutz.edu) for assistance.

XIV. Review Process

Recruited and volunteer reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. 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 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.

XV. Review Criteria

All TM-Pilot applications are reviewed based on the following criteria:

1. **Innovation:** Is the proposal innovative and novel in developing new technologies/assays/models? Are the proposed technologies presently not available to CCTSI members? Will the novel technologies enhance science and potential NIH proposals in the future?
2. **Approach/Scientific Merit:** Will the proposed study design achieve the aims of developing a new method or technology? What is the likelihood of success given the experiments/proposal as outlined? How feasible is the proposed one-year time frame to successfully develop the proposed technology? Are alternative approaches presented? Are there explicit plans for development of future funding for the project, whether from the NIH, foundations, or commercial sources?
3. **Significance (especially to the CCTSI mission):** Can the new method or technology be generalized and translated to other scientific settings/ applications? Are the technologies translational in their nature? Will the results further our understanding, diagnosis, prevention, and/or treatment of human disease?
4. **Investigators:** Do the investigators have the necessary expertise and capacity to complete the proposed research? is all necessary technological expertise present? Will the award provide opportunity for individuals from traditionally underrepresented backgrounds to conduct translational research?
5. **Environment:** Does the research environment improve the likelihood that the proposed research can be completed and have an impact? Does the proposal consider use of CCTSI resources, including Study Design, Biostatistics, CTRCs, Core laboratories, Bionutrition core, etc?

6. **Responsiveness to the CCTSI Educational Mission:** Does the proposal explain how the technology will be disseminated among the CCTSI members (giving workshops, collaborating with Shared Resources)? Are students and fellows are involved in the project?
7. **Health Equity:** Will the award contribute to improving diversity in translational research at CCTSI Affiliated Institutions? Will the proposed research address health inequities and/or the impact of the social determinants of health?

XVI. Pre-Award Requirements

CCTSI Pilot Grant awards are distributed only after institutional regulatory, federal pre-approval, and CCTSI Pilot Program requirements have been met. Principal Investigators must report monthly during the Pre-Award phase (Feb-April) to the CCTSI Pilot Program Office regarding progress towards completion of all requirements noted in the Notice of Selection for award funding. Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals upon receiving a Notice of Selection for funding to avoid delays in releasing award funds (May).

Institutional Regulatory Approvals: If funded, it is the Principal Investigator's responsibility to obtain 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 CTRC resources, PIs 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.

Federal NIH/NCATS Prior-Approvals: If selected for funding, some projects involving Human Subject Research (HSR) and/or Vertebrate Animal Research (VAR) may require additional NIH/NCATS review prior to initiating research activities. The CCTSI administrative staff will coordinate this process. The CCTSI administrative contact for NIH/NCATS Prior-Approval review is Misty Bear (misty.bear@cuanschutz.edu).

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. PIs are required 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 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 ([How to Site our CTSA Grant](#)).

Spending Account Setup: CCTSI will coordinate the primary spending account setup for each award at the PI/co-PI's institution, including speedtypes. Spending account number(s) are included in the Notice of Award.

XVI. Post-Award Requirements

Project/Budget Award Period: All TM-Pilot awards are active from May 1 through April 30 the following year. Funds become available after a) all institutional approvals are on file with CCTSI, and b) CCTSI and your local institution have set up your spending account(s). No Cost Extensions are granted on a limited basis for extraordinary circumstances, including delays due to the COVID-19 pandemic, and may not be allowed on all awards.

Progress and Closeout Reports: PIs must complete tracking & evaluation requirements for 3 years after award, including publications, patents, tangibles, and follow-on funding arising from CCTSI funded projects. Prompt cooperation in providing the required information is expected.
- The CCTSI is required to submit a detailed annual progress report to the NIH that includes the progress of all federally funded pilot projects in January each year.
- Investigators are expected to complete a brief closeout report at the end of their award.

- The CCTSI Evaluation Core will contact PIs annually for three years following the close of the award for updates.

Citing CCTSI Funding: Please refer to the How to Cite our CCTSI Grant for all publications, patents, or other tangible outcomes from this project during and after project completion.

XVII. Questions

Please refer to the TM-Pilot webpage for information regarding: Frequently Asked Questions, Informational Calls, CCTSI Resources, Application Guidelines and Checklist, and for Award Information.

For questions not addressed in the RFA or FAQs, please attend a pre-application Informational Call. Dates and times are posted on the TM-Pilot webpage in the left sidebar. All applicants are encouraged to participate.

Additional funding opportunities are periodically posted on the CCTSI Funding Opportunities webpage.