Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

CCTSI Translational Methods Pilot Program (TM-Pilot)
2020 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 ninth year of the Translational Methods Pilot Program (TM-Pilot). The TM-Pilot Program (formerly known as Novel Method Development) supports the development of novel methods and innovative technologies for clinical and translational research. This includes the development of new assays, methods or technologies which are not currently available to the CU Anschutz campus and CCTSI affiliated institutions. Applications with two co-PIs, one for technology development and another for a scientific application, are especially encouraged to ensure future application and dissemination of newly developed technologies.

II. Key Information

Awards available:	General TM-Pilot Awards Biostatistics/ Bioinformatics TM-Pilot Award CSU TM-Pilot Award
Award Amount:	$20,000
Award Duration:	1 year
Award Period:	May 2020 – April 2021
Contacts:	Debra Szuster, MS CCTSI Pilot Grant Program Coordinator 720-848-4327 debra.szuster@cuanschutz.edu Natalie Serkova, PhD Director, Animal Imaging Shared Resource and CCTSI TM-Pilot Program 303-724-1086 natalie.serkova@cuanschutz.edu

III. Important Dates

10/19/2019	RFA Release
11/13/2019	Pre-application conference call (details posted on the TM-Pilot website in early October)
12/02/2019	**Mandatory Intent-to-Apply submission deadline 5:00 PM MDT**
12/11/2019	Pre-application conference call (details posted on the TM-Pilot website in early October)
01/08/2020	**Application Submission Deadline 5:00 PM MDT**
03/16/2020	Notification of Selection for awards
05/01/2020	Earliest start of active funding period (ends 4/30/2021)

IV. Purpose

- The Translational Methods Pilot Program (TM-Pilot) 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, software, protocols or technologies which will readily enhance clinical and translational research of CCTSI members.
- An alternative goal of the TM-Pilot Program is to help 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 Grant Program Chair, Dr. Natalie Serkova at natalie.serkova@cuanschutz.edu, well in advance to help identify a potential technology-driven co-PI.
- This RFA is separate from other CCTSI Colorado Pilot opportunities (CO-Pilot and CU/CSU-Collaboration Pilot), Community Engagement Pilot Program (CE-Pilot), and the Child and Maternal Health Pilot Program (CMH-Pilot). If your research focuses on pilot work with an established method, please consider these alternative options for pilot project funding.

V. Background

Each year, the CCTSI awards more than $3 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards through funding from the National Center on Advancing Translational Science (NCATS), which is an institute of the National Institutes of Health (NIH), and the University of Colorado School of Medicine Dean's Office. The CCTSI Translational Methods Pilot Program (previously known as Novel Method Development) was initiated in 2009. Past TM-Pilot Awards can be viewed on the CCTSI website.

VI. Funding Priorities

- Proposed projects must represent the development of a novel (non-existing) assay, device, software, 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 AMC Research Core Facilities 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.

VII. Award Categories

TM-Pilot awards will be awarded in these categories:
- Translational Methods (TM) Pilot Awards
- Biostatistics/Bioinformatics TM-Pilot Award
- Colorado State University TM-Pilot Award

VIII. Available Funding

Each award is for up to $20,000 (direct costs) for one year. Indirect costs are assessed internally by CCTSI and do not need to be included in your budget proposal, with the exception of proposals submitted by Colorado State University. CSU proposals should include Indirect costs at their federally negotiated rate. This will be in addition to the $20,000 direct cost budget. All TM-Pilot funds are distributed to CCTSI Affiliated Institutions only, so there are no cost-share budget reviews required.

IX. Definitions

CCTSI Affiliated Institutions: University of Colorado Anschutz Medical Campus, University of Colorado Boulder, Children's Hospital Colorado, Colorado State University, Denver Health, Kaiser Permanente of Colorado, National Jewish Health, University of Colorado Denver, University of Colorado Hospital, VA Eastern Colorado Health Care System (see the CCTSI website for information about CCTSI Affiliated Institutions).

Clinical Trials: The NIH defines clinical trials as clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.
Key Roles: Principal Investigator, co-Principal Investigator, co-Investigator (all must be CCTSI Affiliates)
Non-Key Roles: Consultants, Advisory Committee, etc. (Professional Research Assistants, Graduate Students, Undergraduate Students, Fellows, Postdoctoral students are encouraged)
Translational research: Translational research is intentionally broadly construed and includes any basic (animal or laboratory), pre-clinical, clinical, behavioral, community-based, and population based translational research with promise to improve human health.
Underrepresented, minority, and female researchers: Groups that have historically been underrepresented in biomedical research include, but are not limited to: women, 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 that have inhibited their ability to pursue research careers.

X. Eligibility

- The Principal Investigator, the co-Principal Investigator, and all co-Investigator(s) all must hold Instructor level (or above) appointments with a CCTSI Affiliated Institution. (See the CCTSI website for a list of CCTSI Affiliated Institutions)
- All individuals in Key Roles must be CCTSI Members at the time of application. Verify membership status and/or sign up for free membership via the CCTSI Membership webpage.
- Investigators from non-CCTSI Affiliate Institutions may participate in Non-Key Roles only. They must collaborate with a faculty (Instructor level and above) from a CCTSI Affiliated Institution who would be eligible to serve as PI on an application.
- Underrepresented, female, and minority researchers are particularly urged to apply, as the CCTSI intends to contribute to the creation of a research workforce that is representative of the U.S. population.
- Graduate, undergraduate, postdoctoral students, fellows and PRAs are encouraged to participate in Non-Key Roles.

XI. Exclusions/Restrictions

- Projects, which are focused on validation of an existing technology, will not be accepted.
- Investigators applying for TM-Pilot funding are also eligible to concurrently apply for funding from any other CCTSI Pilot Grant Program, including CO-Pilot, CMH-Pilot, and CE-Pilot.
- Recipients of past CCTSI Pilot Awards are not permitted to apply for renewal or follow-on funding for the same project that was previously funded.
- Awardees from the most recent grant cycle (currently funded) are not permitted to apply for this grant cycle.
- Recipients who are currently funded under a No-Cost Extension (NCE) are not permitted to apply for this grant cycle.
- 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.
- Award funds can only be used to support research at CCTSI Affiliate Institutions. Support of research at non-CCTSI Affiliate Institutions or outside the United States is not allowed.
- Any clinical trials proposed in CCTSI Pilot applications are restricted to Phase I or Phase IIA. Clinical trials in Phase IIB, Phase III or Phase IV will not be supported.

XII. Pre-Application Policies

Affiliate home organizations may require applicants to complete an internal review process prior to submission. Applicants should check with their institutional grants or sponsored projects office to ascertain if their institution has pre-submission requirements for programs related to non-federal internally funded seed grant programs.

Any awarded projects that have not met these requirements prior to submission will not be activated until all such affiliate institutional requirements are met.

- **For CU Anschutz and CU Denver Investigators:** Applications do <u>not</u> require official pre-award review (routing) through the CU Denver Office of Grants and Contracts (OGC) prior to submission.
- **For CSU Investigators:** 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 at aimee.oke@colostate.edu for details.
- **For 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.

XIII. Required Application Documentation

Applicants 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.

Prepare a <u>single</u> PDF of the following proposal materials (#1-7.4) to be uploaded to the online Application Form:

1. Abstract (limit 250 words)
- ☐ Provide a concise summary of the project for application review and announcement of awards.
- ☐ Include overall goal, anticipated outcomes, and how the research meets RFA objectives.

2. Research Plan (4 page limit)
- ☐ All applications are considered new proposals. Revisions from prior unfunded submission should be incorporated in this section within the 4-page limit.
- ☐ 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 AMC Research Core Facilities 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 (limit ½ page)
- ☐ 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 (limit 1 page)
- ☐ 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 (suggested 1-2 pages)
- ☐ 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.

3. Education Mission (suggested ¼ to ½ page)
- ☐ 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.

4. References
- There is no page limit for references.

5. Budget and Justification (2 page limit)
- Award funds can only be used to support research at CCTSI Affiliate Institutions. Support of research at non-CCTSI Affiliate Institutions or outside the United States is not allowed.
- All applications must provide a one-year budget (including other project support) and budget justification consistent with NIH requirements.
- Each award is for up to $20,000 (direct costs) for one year. Indirect costs are assessed internally by CCTSI and do not need to be included in your budget proposal, with the exception of proposals submitted by Colorado State University. CSU proposals should include Indirect costs at their federally negotiated rate. This will be in addition to the $20,000 direct cost budget.
- All TM-Pilot funds are distributed to CCTSI Affiliated Institutions only, so there are no cost-share budget reviews required.
- Clearly define the project expenses with cost categories relevant to the project, such as Personnel, Supplies, Lab Testing, Animals, Human Subjects, etc.
- While salary support commensurate with percent effort is allowed for PI and personnel from CCTSI Affiliated Institutions, this is 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. Salary support for individuals in Non-Key Roles who are not CCTSI affiliates is not permitted.
- Proposals that utilize institutional state-of-the-art technology available from [CCTSI Resources](#) and [CU Cancer Center Shared Resources](#) and [AMC Research Core Facilities](#) 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.
- Unallowable expenses include but may not be limited to: non-CCTSI Affiliate Institutions budgets, international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees.

6. Biosketches (current NIH format and page limit)
- A Biosketch in current NIH format and page limit is required for all individuals in Key Roles (Principal Investigator, co-Principal Investigator, co-Investigator).

7. Letters of Support (no page limit)
- There is no limit to the number of Letters of Support you include in your application.

7.1 Institutional Prior Approval LOS: For CSU Investigators
- 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 at aimee.oke@colostate.edu for details.

7.2 Institutional Prior Approval LOS: For Investigators Outside CU Denver and AMC
- CCTSI Affiliate home organizations may require applicants to complete an internal review process prior to submission. Applicants should check with their institutional grants or sponsored projects office to ascertain if their institution has pre-submission requirements for programs related to non-federal internally funded seed grant programs. If so, documentation of compliance must be submitted with the application.

7.3 Other Financial Commitments LOS (if applicable)

☐ Letter(s) of support from the authorized official(s) from external organizations, departments, or non-CCISI Affiliated Institution collaborators with cost-share requirements who have agreed to honor their financial commitment must be submitted with the application.

7.4 Other Letters of Support (optional)
☐ Letters of Support may be included from department chairs, consultants, foundations, commercial sources, manufacturers, etc.

In addition, prepare a <u>single</u> PDF of all Biosketches to be uploaded to the online Application Form.

XIII. Application Process

<p style="color:red; text-align:center">New this year, all applicants must use the CCTSI website to apply for TM-Pilot funding.
Applicants may no longer submit their Intent-to-Submit or Application via email.</p>

Submission Method: Intent-to-Apply and Application may only be submitted online via the TM-Pilot webpage. If an applicant intends to apply for funding for multiple projects, then each project must be submitted separately online. All submissions will be time-stamped. Submissions received after the 5pm MDT deadline will not be accepted. This program does not utilize an invitation process; however, only applicants who submit a mandatory Intent-to-Apply are eligible to submit an Application.

Part 1) Intent-to-Apply Form
The mandatory online Intent-to-Apply Form collects minimal information via an online survey. The Intent-to-Apply is not binding, and information may be revised by applicants during the application process. Submission of your Intent-to-Apply Form will automatically generate an email confirmation with a PDF of your submission.

Part 2) Application Form
The online Application Form collects detailed information about the project via an online survey. The Application Form can be accessed via the "Survey Queue" after submitting the mandatory Intent-to-Apply Form. The online system will allow you to save, exit, return, review, and revise your submission as often as you wish using the "Save and Return Later" function up until the 5pm MDT submission deadline. Submission of the Application will generate a confirmation email.

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

XIV. Review Process
Peer Reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. 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 are final. Short informative critiques of application strengths and weaknesses are provided to all applicants after Notice of Selection for Awards are announced.

XV. Review Criteria
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?
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?

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?

Investigators: Do the investigators have the necessary expertise and capacity to complete the proposed research? is all necessary technological expertise present?

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?

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?

XVI. Post-award Requirements

Regulatory Requirements: All approvals/exemptions from appropriate review bodies or regulatory groups must be provided by the PI prior to the release of funds. This includes, but is not limited to: COMIRB, IACUC, Biosafety, IBC, Children's Hospital Research Institute (CHRI), CSU IRB, and/or other regulatory groups relevant to the proposal and applicant's institution.

- **For HSR/VAR projects:** If a funded proposal involves human subject research (HSR) and/or vertebrate animal research (VAR), The PI must provide an institutionally approved IRB protocol prior to the start of funding. Some funded HSR/VAR projects will require additional documentation for the NCATS Prior-Approval process; the CCTSI Pilot Grant Program Coordinator, Debra Szuster (debra.szuster@cuanschutz.edu) will work with awardees on a case-by-case basis to submit required documentation.
- **For CTRC projects:** PIs are required to obtain Scientific Advisory and Review Committee (SARC) approval for all projects using CTRC resources (inpatient/outpatient research facilities, clinical research nursing support, nutrition research support, exercise research laboratory, and CTRC Core Lab support).

Technology Transfer Office (TTO): Public disclosure, either in text or verbal form, may result in a lost opportunity to protect and commercialize your invention. All Principal Investigators of all funded CCTSI Pilot Grant Awards must connect with the CU Innovations Office (303-724-0221) for a consultation prior to receiving funds.

Monthly Reporting: If funded, PIs must report monthly during the pre-award period to the CCTSI Pilot Program Coordinator, Debra Szuster (debra.szuster@cuanschutz.edu) regarding progress toward completion of all Pilot Program and regulatory requirements. Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals as soon as possible upon notification of selection for the award.

Active Awards: PIs will have until May 1 of the calendar year after receiving their Notice of Award to complete their projects. No-cost extensions are granted on a very limited basis for extraordinary circumstances and may not be allowed on all programs.

Annual Reporting: The CCTSI is required to submit a detailed annual progress report to the NIH that includes the progress of all funded pilot projects. In January of each year, PIs will be asked for brief information on publications and follow-on funding resulting from CCTSI-funded pilot projects. Prompt cooperation in providing the required information is expected. PIs must complete tracking and evaluation requirements for 3 years after award.

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 website 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 website in the left sidebar. All applicants are encouraged to participate.

CCTSI Application Checklist
TM-Pilot Program

When you submit your Pilot Program application online, you will be required to attach a single PDF of all the required proposal material listed in the order below. You will also need to upload a second PDF of the Biosketches alone.

#	Description of Required Materials	☑
1	**Abstract** This concise summary of the project will be used to review your application, and it may be used to announce funded awards. Upload a single PDF of your abstract (250 word limit)	☐
2	**Research Plan** All applications must provide a research plan consistent with NIH requirements. Include Specific Aims, Research Strategy (Significance, Innovation, Approach), Background and Preliminary Studies (if applicable), and CCTSI Resources (if applicable). Upload a single PDF (4 page limit).	☐
3	**Education Mission** Upload a single PDF of your education plan (suggested 1/4 to 1/2 page)	☐
4	**References** Upload a single PDF of your references (no page limit)	☐
5	**Budget and Justification** All applications must provide a one-year budget (including other project support) and budget justification consistent with NIH requirements. Upload a single PDF of your references (2 page limit)	☐
6	**Biosketches** A Biosketch in current NIH format and page limit is required for all individuals in Key Roles (Principal Investigator, co-Principal Investigator, co-Investigator). Upload a single PDF of all Biosketches.	☐
7	**Letters of Support (LOS) – no page limit** **Institutional Prior Approval LOS: For CSU Investigators** A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the Pilot Award application.	☐
	Institutional Prior Approval LOS: For Investigators Outside CU Denver and AMC CCTSI Affiliate home organizations may require applicants to complete an internal review process prior to submission.	☐
	Other Financial Commitments LOS (if applicable) Please upload a single PDF of all Letter(s) of Support from the authorized official(s) from external organizations, departments, or non-CCISI Affiliated Institution collaborators with cost-share requirements who have agreed to honor their financial commitment.	☐
	Other Letters of Support (optional)	☐