



**CCTSI Colorado Pilot Grant Program (CO-Pilot)
2022 Award Cycle - Request for Applications**

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the fifteenth consecutive year. The [CCTSI Colorado Pilot Grant Program \(CO-Pilot\)](#) supports one-year awards to encourage cross-disciplinary and collaborative research in clinical and translational medicine to junior and senior faculty members of [CCTSI Affiliated Institutions](#). The program is intended to stimulate new research, especially for mentored and junior faculty, that will lead to improved human health, including basic research at the cellular and molecular level (T0/1), pre-clinical research in animal models (T2), clinical research in humans (T3), and outcomes or health services research (T4). Research that is not directly or indirectly related to improving human health is not supported. Revisions of unfunded applications from prior years are encouraged but revised proposals are considered new applications rather than resubmissions.

II. Key Information

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| Award Categories | Mentored Faculty Awards | \$30,000 |
| | Junior Faculty Awards | \$30,000 |
| | Early-Stage Investigator Diversity Award | \$30,000 |
| | CU-CSU Collaboration Award | \$60,000 |
| Award Duration | 1 Year | |
| Award Period | May 2022 – April 2023 | |
| Contacts | Debra Szuster, MS, CAPM CCTSI Pilot Project Program Coordinator (720) 848-4327 debra.szuster@cuanschutz.edu | Natalie Serkova, PhD CCTSI Pilot Grant Program Director (303)724-1086 natalie.serkova@cuanschutz.edu |

III. Important Dates

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|-------------------|--|
| 07/21/2021 | RFA Release |
| 08/09/2021 | Pre-Application Informational Call #1 -- 2:00 pm via Zoom |
| 09/06/2021 | Mandatory Intent to Apply Form (LOI) submission deadline -- 5:00 pm Mountain Time |
| 09/23/2021 | Pre-Application Informational Call #2 – 10:00 am via Zoom |
| 09/25/2021 | Cost Share Budget deadline (if applicable) |
| 10/04/2021 | Application Form submission deadline -- 5:00 PM Mountain Time |
| 03/01/2022 | Notification of Award |
| 05/01/2022 | 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. Details and Zoom links are located on the left sidebar of the [Colorado Pilot Grant Program \(CO-Pilot\)](#) 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 [Colorado Pilot Grant Program \(CO-Pilot\)](#) has made over 175 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 CO-Pilot Grant Program Awardees](#)).

V. Funding Priorities

The CO-Pilot Grant Program will fund one-year pilot project awards meant to encourage cross-disciplinary and collaborative research in clinical and translational medicine.

- 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.
- Proposals that contribute to enhancing diversity in the translational research pipeline, address health inequities, and/or the social determinants of health will be given high priority.
- The [2021 CU-CSU Summit](#), "Evolving Impacts of COVID-19: Research Advances in Colorado and Beyond," will be held online August 18, 2021. For the current CCTSI Pilot Grant Award application cycle, priority will be given to meritorious applications that propose new research collaborations on this topic.
- Please see the Community Engagement Pilot Grant Program ([CE-Pilot](#)) webpage for funding priorities for community-based translational research.

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.

VI. Award Categories

Mentored Faculty Awards - \$30,000 for one year

Mentored Faculty Awards are an opportunity for investigators in the beginning stage of their career (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and assistant professors *without* previous research awards) who would benefit from strong mentorship and cross-disciplinary training in clinical and translational research.

Mentorship is mandatory for this award, with a required Primary Mentor (or two co-Mentors) acting as direct supervisor for Mentee and providing a required **Letter of Support** at time of application (*see XII. Proposal Requirements*) and participating in the **Mentorship Progress Report** (*see XVI. Post-Award Requirements*).

- The Mentee is the sole Principal Investigator. Multiple PI roles are not supported.
- Senior investigators are not eligible to apply for Mentored awards but can serve as a mentor for an eligible early career investigator.
- All applicants must demonstrate they will have sufficient effort on the project for the duration of the project (most of the year, not just nights and weekends), and have the necessary prior research experience and commitment to a research-focused academic career in the future.
- A person may be the Primary Mentor (or a Co-Mentor) on only one Mentored Award application in an award year between the Colorado ([CO-Pilot](#)) and Child and Maternal Health ([CMH-Pilot](#)) Programs.
- Past recipients of Mentored Awards are encouraged to apply for Junior Faculty awards or CU-CSU Collaboration awards.

Junior Faculty Awards - \$30,000 for one year

Junior Faculty Awards are oriented towards investigators still at the early stage of their career (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, or assistant professors) who may have previous research awards and have sufficient prior research experience to independently manage a project.

- One individual must be the sole Principal Investigator. Multiple PI roles are not supported.
- This award does not have a mentoring requirement.
- The proposed project should emphasize cross-disciplinary collaborations and interactions for clinical and translational research.
- Past recipients of Junior Faculty Awards are encouraged to apply for R01 funding through the NIH. Junior researchers with more advanced projects that are based on collaborations between CU AMC and CU Boulder are encouraged to apply for [AB Nexus](#) funding.

Early-Stage Investigator Diversity Award - \$30,000 for one year

Early-Stage Investigator Diversity Awards are oriented towards investigators from groups traditionally underrepresented in scientific research. These awards are intended for young investigators who are still at the early stage of their career (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, or assistant professors) who may or may not have had previous research awards. Applicants who are not funded in the Early-Stage Investigator award category are automatically considered for funding in the Junior Faculty award category.

- One individual must be the sole Principal Investigator. Multiple PI roles are not supported.
- This award does not have a mentoring requirement.
- The proposed project should emphasize cross-disciplinary collaborations and interactions for clinical and translational research.
- The proposal should include a brief statement describing how the pilot project will contribute to improving diversity in translational research at CCTSI Affiliated Institutions, address health inequities and/or the impact of the social determinants of health, enhance diversity in the translational research pipeline, etc.

CU-CSU Collaboration Award - \$60,000 for one year

CU-CSU Collaboration Awards are an opportunity for experienced investigators (typically assistant, associate or full professor) to support new cross-disciplinary collaborative translational research between Colorado State University and the University of Colorado campuses. This award mechanism is not designed to support pre-existing collaborative projects. This award will be evenly distributed between CSU and CU AMC, with a co-PI from each institution.

- A Multiple PI Plan for two Co-Investigators must be included in the application.
- The CU half of award will be \$30,000 direct costs - indirect costs are not supported. This portion of the award is supported by internal funds and pre-application review by the Office of Grants and Contracts ("routing") is not required. A **Letter of Support from the CU Department Chair** is required.
- The CSU half of award will be \$30,000 direct costs plus F&A at the negotiated rate (when federally funded). 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 CO-Pilot Grant 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. The funding rate for CCTSI Pilot Grant Awards has averaged 19-27% over the past three years, similar to NIH funding rates.

VIII. Definitions

[CCTSI Affiliated Institutions](#): 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, Denver Health and Hospital Authority, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.

Clinical Trial: 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: 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. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions. (Any clinical trials proposed in CCTSI Pilot Grant Applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported.)

Human Subject Research (HSR): Research involving direct and/or indirect interaction with human participants, biospecimen, samples, existing data sets, etc. (including exempt studies). In some cases, this may include identifiable and deidentified data, and may include analysis of specimen that may have been collected for another study.

Key Roles: Individuals who accept primary responsibility for the research design and/or execution, including Principal Investigator, co-Principal Investigator, co-Investigators, Primary Mentor or two Co-Mentors, or anyone receiving salary support.

NCATS (National Center for Advancing Translational Science): This is the federal equivalent of IACUC/IRB. Some CCTSI funded pilot projects will require NCATS Prior-Approval during the pre-award phase in addition to IRB/IACUC approval.

Non-Key Roles: Individuals who may offer support for the research study but who do not have responsibility for the research design and/or execution, including consultants and directors of institutional core facilities (see *XVII. Questions and Resources*), individuals offering fee-based services or supplying biobank biospecimen, lab staff, secondary/other mentors not listed in a Key Role, advisory committee, professional research assistants, graduate students, undergraduate students, tech support, fellows, etc. Note: Individuals receiving salary support should be listed in a Key Role.

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.

IX. Eligibility

1. Individuals listed in Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) must hold full-time faculty appointments or postdoctoral/postgraduate appointments with one or more [CCTSI Affiliated Institutions](#).
2. Investigators from non-affiliate organizations are not eligible to be in a Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) on CCTSI Pilot Grant Awards but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.
3. 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.
4. Individuals listed in Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) 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 (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) 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. Individuals who are currently funded through an active CCTSI Pilot Grant Award, including a No Cost Extension, may not apply as a PI, co-PI, co-Investigator, or in a role with salary support. Mentors who are not receiving

- salary support may be included as Primary Mentor (or Co-Mentor) on multiple applications.
3. Renewal or follow-on CCTSI Pilot Grant Award funding to any previously funded CCTSI Pilot Grant Award project is 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 of the portion of the work conducted locally at [CCTSI Affiliated Institutions](#).
 5. CCTSI Pilot Grant Awards do not support indirect (F&A) costs except for the CSU half of the award for the CO-Pilot CU-CSU Collaboration category (when federally funded).
 6. Any [clinical trials](#) proposed in CCTSI Pilot Grant Award applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported.
 7. 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 Dr. Alison Lakin, alison.lakin@cuanschultz.edu, to discuss the institutional review process.
 8. If you are applying for funding in this application cycle, you may not participate in the Review Panel for the same award category, but you may be asked to review application(s) in non-competing award categories.

XII. Application Process

Submission Method: Access the online submission system by clicking “Apply Now” on the [Colorado Pilot Grant Program \(CO-Pilot\)](#) webpage. 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.” The mandatory Intent to Apply Form (LOI) and Application Form are submitted online and are time-stamped upon submission. **Items received after the 5 pm deadlines will not be accepted.**

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 minor changes may be made at the time of application.

Application Form: Individuals who submit the mandatory Intent to Apply Form (LOI) will receive a unique link to the proposal’s Application Form via email. Once submitted, applications are considered final and cannot be modified – no exceptions. Early submission is encouraged.

IMPORTANT: While there are no restrictions on the number of Intent to Apply Forms (LOIs) submitted, individuals in Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) may be listed on only one Application Form between the Colorado (CO-Pilot), Child and Maternal Health (CMH-Pilot), and Community Engagement (CE-Pilot) Pilot Grant Programs (see X. Exclusions/Restrictions).

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

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 submission 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:

1. **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. Include project title and

name/title/affiliation of investigators, overall goal, anticipated outcomes, and how the research meets RFA objectives. (Title and names of investigators are not included in the 250 word limit.)

2. **Hypotheses and Specific Aims** (1 paragraph): Include the hypotheses and specific aims being tested in the research, including applicable clinical or translational research areas. Note: If your study design involves QA/QI/PE, you should not use terms like “hypothesis” or “research;” Instead, use the terms “aims” or “goals” and “evaluation.”
3. **Research Plan** (4 page limit): Applies to all award categories.
 - a. **Background and Significance:** Explain the importance of the problem or barrier to progress in field that the proposal addresses. Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
 - b. **Research Strategy:** State how research activities funded by CCTSI will achieve pilot study objectives. Clearly indicate what procedures/processes you plan to conduct, and how you will obtain the data/biospecimen you propose to analyze in your pilot study. If you are using data/biospecimen from a different study, provide context for the relationship between the two studies. Describe the inclusion and exclusion criteria for your subject selection, if applicable. Incorporate information on the use of shared institutional resources (see XVII. Questions and Resources) or rationale for using alternative resources. Use of CCTSI resources is not required but is strongly encouraged. List the primary and secondary (if applicable) outcome measures you will use in this study, and describe your data analysis plan (e.g., t-test, ANOVA, regression, justification for analytic type, etc.). Demonstrate the feasibility of obtaining regulatory approvals and completing the pilot study in the one-year award period. (IRB/IACUC approval is not required at the time of application.)
 - c. **Innovation:** Explain how the application challenges and seeks to shift current research or clinical practice paradigms. 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. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
 - d. **Approach:** Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project within the one-year timeline. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Describe proposed tests, procedures, subject population, and ages in sufficient detail to allow adequate evaluation of your approach.
4. **References** (no page limit): Applies to all award categories.
5. **Multiple PI Plan** (1 page limit): Applies to CU-CSU Collaboration applicants only. 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. Include:
 - a. Rationale and justification for choosing the multiple PI approach.
 - b. Governance and organizational structure of the team.
 - c. Procedures for resolving conflicts.
 - d. Process for making decisions on scientific direction and allocating funds and resources.
 - e. Communication plan
6. **Mandatory Letters of Support** (no page limit)
 - a. **CU-CSU Collaboration Award Category**
 - i. **CU Investigator:** The CU investigator must submit a Letter of Support from their department head during the application process.

- ii. **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.
 - b. **Mentored Faculty Award Category:** A letter from the Primary Mentor, or a combined letter from the two co-Mentors, should describe the mentorship/career development plan and role of each mentor included in the proposal. Include:
 - i. Information on his/her research qualifications and previous experience as a research mentor.
 - ii. A plan that describes the nature of the supervision and mentoring that will occur during the proposed award period.
 - iii. A plan for career progression for the mentee to move to the next stage of his/her career path during the project period of the award.
 - iv. A plan for monitoring the candidate's research, publications, and career progress.
7. **Career Development Plan** (1 page): Applies to Mentored Faculty Awards only. The applicant and the mentor should jointly prepare the career development plan. A career development timeline and a mentoring team (or advisory committee) to monitor the candidate's progress through the career development program are recommended. Include:
- a. Experiences that have been important to the applicant's development or that have presented potential barriers to a career in research. Explain how these factors may have influenced your career development goals and preparation for a career in translational or clinical research and how you have overcome challenges or barriers.
 - b. Applicant's commitment to an academic career in translational or clinical research.
 - c. Applicant's prior training and research experience and how it relates to the objectives and long-term career plans of the applicant.
 - d. Evidence of the applicant's potential to develop into an independent investigator and justifies the need for further research mentorship.
 - e. Next steps in the applicants' career progression after completion of the Mentored award.
8. **Optional Letters of Support** (no page limit): Applies to all award categories. Optional LOS from secondary mentors with expertise in a related but different discipline, department chairs, consultants, foundations, commercial sources, manufacturers, etc. are not required but strongly advised, if applicable.
9. **Budget** (1 page limit): All applicants must use the Budget Template (click for [Excel](#) or [PDF](#)) on the [Colorado Pilot Grant Program \(CO-Pilot\)](#) webpage under "Information & Resources."
- a. 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.
 - b. 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.
10. **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 Subjects, 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, including cost share agreement.
11. **Cost-Share Agreement** (no page limit): Not applicable to Translational Methods (TM-Pilot) proposals. All other proposals that involve meaningful research collaboration with non-CCTSI Affiliated organizations, in which award funds will be transferred to that organization, must demonstrate financial commitment from the non CCTSI-Affiliated organization to the shared development of design, execution, and/or data collection for the study.
- a. **Cost-Share Letter of Commitment:** a signed letter from authorized official(s) from external organizations, departments, or other institutions. This letter should clearly indicate the Scope of Work, timeline, justification of total non-affiliate budget, and statement of commitment to meet the cost share

requirement. The stated amount should be aligned with the application budget and budget justification.

b. Cost-Share Budget

- i. Budget Cap: up to 25% of total project budget may be allocated to the activities at the non-affiliate organization. The non-affiliate budget will be funded 50% by CCTSI and 50% by non-affiliate cost-sharing.
- ii. The total budget including cost share must not exceed the CCTSI Pilot Grant Award amount (e.g., cost sharing is not additional funding to the total Pilot Grant Award). Use this sample cost-share budget calculation based on a 30K Pilot Grant Award amount to prepare your cost-share budget:

| Budget Items | Award Total Budget | Funded CCTSI | Funded Non-affiliate Cost Share |
|------------------|--------------------------------|-----------------|---------------------------------|
| Affiliate DC | \$22,500 | \$22,500 | \$ 0 |
| Non-affiliate DC | \$7,500 (cap at 25% of 30K) | \$3,750 | \$ 3,750 (50% of \$7,500) |
| TOTAL | \$30,000 total award DC | \$26,250 | \$ 3,750 |

c.

Cost-Share Budget Review: Contact Debra Szuster, debra.szuster@cuaneschuz.edu, to review the proposed cost-share budget no less than one week prior to the CCTSI Pilot Grant Application deadline.

- 12. **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 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).
- 13. **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.
 - a. **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.
 - b. **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.
 - c. **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. 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 use the NIH 9-point scoring system to review the following criteria:

- a. **Innovation:** Is the proposal innovative and novel in its hypotheses, approaches, and techniques? Does the application represent a changing research direction or a transition to a new area of research that broadens an investigator’s research program in clinical and translational areas?
- b. **Approach/Scientific Merit:** Are hypotheses and experimental approach sound? What is the likelihood of success given the experiments / proposal as outlined? For Mentored awards, are the plans for the applicant’s career development adequate? Are there explicit plans for development of future funding for the project, whether from

the NIH, foundations, or commercial sources? Include a specific comment on the feasibility of this study to obtain IRB and/or IACUC approvals for Human Subject Research and/or Vertebrate Animal Research, or other institutional approvals. Also include comments on administrative or budgetary concerns.

- c. **Cross-disciplinary or Collaborative Focus:** Does the research involve a new collaboration, especially one that increases its translational nature? Are attempts made to bridge basic and translational researchers in discovery translation?
- d. **Significance:** Would the proposed research be likely to further the CCTSI Mission to “Improve the health of the population of Colorado by speeding the translation of biomedical discoveries into prevention and intervention strategies in the community, and by reducing health disparities.”
- e. **Investigators:** Do the investigators have the necessary expertise and capacity to complete the proposed research? Have the investigators made use of new collaborations? Are attempts made to integrate basic and translational researchers in discovery translation? Are efforts made to collaborate with community researchers or community members, if relevant? Is the Multiple PI Plan appropriate, if applicable? For Mentored awards, is there sufficient justification for continued mentorship, does the mentor have adequate prior experience and is a strong mentorship plan proposed? Will the award provide opportunity for individuals from traditionally underrepresented backgrounds to conduct translational research?
- f. **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Does the application adequately address the capability and ability to conduct the study at the proposed site? Include a specific comment on the use of CCTSI Resources, or justification of alternate resources.
- g. **Health Equity and Diversity (Non-Scoring Criteria):** Reviewers are asked to comment how this proposal contributes to improving diversity in translational research at CCTSI Affiliated Institutions, address health inequities and/or the impact of the social determinants of health, enhance diversity in the translational research pipeline, etc.

XV. Pre-Award Requirements

Institutional Approvals: Awardees must obtain research 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 Services](#), 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.

NIH/NCATS Prior-Approvals: Some pilot projects involving Human Subject Research (HSR) or Vertebrate Animal Research (VAR) may require additional review by the National Center for Advancing Translational Sciences (NCATS) prior to initiating research activities. Contact Debra Szuster, debra.szuster@cuanschutz.edu, for details.

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 Grant 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 (see [How to Site the CTSA Grant](#)).

Spending Account Setup: CCTSI will coordinate the primary spending account/speedtype setup for each award at the PI/Co-PI’s institution. Spending account number/speedtype are included in the Notice of Award.

XVI. Post-Award Requirements

Project/Budget Award Period: All CO-Pilot Grant 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 the PI/Co-PI’s local institution

have set up spending account(s). No Cost Extensions are granted on a limited basis only for extraordinary circumstances.

Progress Reports (all awards): Please respect the need for the CCTSI to obtain, track, and report information on funded pilot projects. Prompt cooperation in providing the necessary information for reporting is expected. This includes a Pilot Project Progress Report (January-February), Closeout Report (May-June), and annual progress reporting for 5 years after the award ends. Information is collected through periodic surveys by the CCTSI Pilot Project Program Coordinator, debra.szuster@cuanschutz.edu, and the CCTSI Evaluation Core, Goldie Komaie, goldie.komaie@cuanschutz.edu, and Liz Sweitzer, liz.sweitzer@cuanschutz.edu. PIs are expected to report the following:

- **Publications:** PubMed Central reference number (PMCID) or other identifier
- **Presentations:** event, venue, abstract title, audience, etc.
- **Products/Inventions:** patent number(s), PMCID, USPTO or other relevant identifiers; also provide information about non-CCTSI (other) projects or publications utilizing technology/outcomes that have resulted from this award
- **Follow-on funding:** resulting from research supported by this award
- **Collaborations:** with members of your CCTSI funded Pilot Project team

Mentored Faculty Award Progress Report: Mentors are required to track their participation in actively mentoring the investigator team throughout the study and report mentoring activities. This annual report will be reviewed by CCTSI Pilot Grant Program Directors in January-February.

- Nature of the supervision and mentoring that occurred during the active award period.
- Career progression for the mentee to move to the next stage of his/her career path during the active award period.
- Monitoring the candidate's research, publications, and career progress during the active award period.

Citing CCTSI Funding: Any publications, patents, or projects that benefit from any CCTSI resources (including use of REDCap) must credit the CTSA Grant. See [How to Site the CTSA Grant](#) for additional details.

HOW TO CITE THE CCTSI GRANT

"This [publication, patent, REDCap survey, product, etc.] is supported by
NIH/NCATS Colorado CTSA Grant Number **UL1 TR002535."**

And Register your Publications in **PMCID.**

XVII. Questions and Resources

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

Research Core Services

- [CU AMC Research Core Facilities \(CTRC\)](#)
- [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]