CCTSI Colorado Pilot Program (CO-Pilot)
2020 Award Cycle - Request for Applications

I. Funding Opportunity Summary

The CCTSI Colorado Pilot Program (CO-Pilot) supports one-year awards to encourage cross-disciplinary and collaborative research in clinical and translational medicine, with awards in three categories: Mentored, Junior, and CSU/CU Collaborations. Revisions of unfunded applications from prior years are encouraged but revised proposals are considered new applications rather than resubmitted applications.

II. Key Information

Awards available (amount):   Mentored Faculty Awards ($30,000)
                               Junior Faculty Awards ($30,000)
                               CSU/CU Collaboration Award ($60,000)

Award duration: 1 year

Award Period: May 2020 – April 2021

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III. Important Dates

07/15/2019	RFA Release
08/12/2019	Pre-application conference call *(details will be posted on the CO-Pilot website)*
09/03/2019	**Mandatory Intent-to-Apply form submission deadline 5:00 PM MDT**
09/23/2019	Pre-application conference call *(details will be posted on the CO-Pilot website)*
09/20/2019	Cost Share Budget deadline (if applicable)
10/01/2019	**Application submission deadline 5:00 PM MDT**
01/31/2020	Earliest notification of award
05/01/2020	Start of funding

Note: Participation in the pre-application conference calls is encouraged but not required. The intent-to-apply form and application due dates and 5:00 PM MDT deadlines **will be strictly enforced**.

IV. Purpose

CO-Pilot provides one year awards to encourage all types of cross-disciplinary and collaborative research in clinical and translational medicine. The program is intended to stimulate new research at CCTSI affiliate organizations that will lead to improved human health. Research that is not directly or

indirectly related to improving human health is not supported.

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 CO-Pilot program was initiated in 2009 with support from the National Center for Advancing Translational Science (NCATS), and the University of Colorado School of Medicine Dean's Office. CO-Pilot has made over 150 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.

VI. Funding Priorities

- 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 all eligible if the ultimate goal is to improve human health.
- Applications that propose new collaborations to conduct innovative research.
- 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.
- The 2019 CU-CSU Summit, "AI and Machine Learning in Biomedical Research" will be held Wednesday, August 14, 2019. Through the Summit, the CCTSI seeks to foster new collaborations across campuses in artificial intelligence and machine learning. For the 2020 award cycle, priority will be given to meritorious CO-Pilot applications that propose new research collaborations on the use of **artificial intelligence and machine learning to improve human health**. Please see website for more information the CU-CSU Summit.

VII. Award Categories

Mentored Faculty Awards - $30,000 for one year
- Mentored projects are oriented towards investigators in the beginning stage of their career.
- This award is an opportunity for early career investigators (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and assistant professors *without* previous research awards) to benefit from strong mentorship and cross-disciplinary training in clinical and translational research. Senior investigators are not eligible to apply for Mentored awards but can serve as a mentor for an eligible early career investigator.
- The Mentee is the Principal Investigator - Multiple PI roles are not supported.
- Mentorship is mandatory for this award, with a required Primary Mentor acting as direct supervisor for Mentee and providing a required Letter of Support at time of application. The Primary Mentor's Letter of support should describe: 1) information on his/her research qualifications and previous experience as a research mentor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) 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; and 4) a plan for monitoring the candidate's research, publications, and career progress.
- Optional Secondary Mentor (s) may add expertise in a related, but different discipline (Letter of Support not required but strongly advised).

Junior Faculty Awards - $30,000 for one year
- Junior Faculty applications are oriented towards investigators still at the beginning of their career but with sufficient prior research experience to independently manage a project.
- This award is an opportunity for junior investigators (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and assistant professors who may have previous research awards) to benefit from cross-disciplinary experience in clinical and translational research.
- One individual must be the 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.

CSU/CU Collaboration Award - $60,000 for one year
- This award is 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, with a PI from each institution (one listed as the Primary PI for award administration). A Multiple PI Plan must be included in the application.
- The CU half of award will be $30,000 direct costs - indirect costs are not supported. Pre-application review ("routing") is not required for UC Denver applicants by the Office of Grants and Contracts before submission. 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 52% MTDC. CSU requires pre-application review by the Office of Sponsored Programs prior to submission - scope of work, budget and budget justification must be submitted to the CSU OSP Team 2 with sufficient time for review. The signed Cover Letter from OSP review must be included in the proposal submitted to the CCTSI.
- This category requires a mandatory active award period of May 2019-April 2020. Applicants are STRONGLY encouraged to demonstrate ability to obtain all regulatory approvals during the pre-award period Feb-Apr 2019.

VIII. Available Funding

All CO-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. Typically, each year 14-16 awards are made in the combined CO-Pilot Mentored and Junior categories, and 1-3 awards in CO-Pilot CSU/CU Collaboration category.

IX. Definitions

CCTSI Affiliated Institutions - University of Colorado – Denver, 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 - 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.
Key Role - Principal Investigator, Co-Principal Investigator, Co-Investigator, Mentor, Co-Mentor, Mentee
Phase I clinical trial - Tests a new biomedical intervention in a small group of people for the first time to evaluate safety.
Phase II clinical trial - Study the biomedical or behavioral intervention in a larger group of people (several hundred) to further assess safety and gather preliminary data on efficacy in people who have a certain condition/disease. Phase IIA trials provide data for exposure-response, while Phase IIB trials provide data for dose-ranging.
Phase III clinical trial - Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.
Phase IV clinical trial - After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
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 at any of the affiliated CCTSI Institutions are eligible to apply but must have full-time faculty appointments or postdoctoral/postgraduate appointments at one or more of the following CCTSI-affiliated institutions:

CU School of Medicine	CU School of Nursing	CU Boulder
CU School of Pharmacy	CU School of Public Health	CU Denver Downtown Campus
CU School of Dentistry	Colorado State University	National Jewish Health
Denver Health and Hospitals	Rocky Mountain Regional VA Medical Center	
Kaiser Permanente		

- Principal Investigators, Co-Investigators and Mentors must be CCTSI Members at time of application. Check status or become members at the CCTSI Membership webpage.
- Investigators from non-affiliate organizations are ineligible to be Principal Investigators on CO-Pilot awards, but may collaborate with an eligible CCTSI affiliate investigator PI.
- PIs with an award in the most recent cycle are ineligible to apply for the current cycle.
- Multiple PI roles are restricted in this program, except for the CSU/CU Collaboration Award. Please see Section VII above for specific requirements in each award category.
- Residents and other post-graduate trainees, who hold a terminal degree in their field (e.g., M.D., Ph.D., Pharm.D., D.D.S, D.V.M) may apply for Mentored Faculty Awards. 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.

Underrepresented and minority applicants are particularly urged to apply. Groups that have historically been underrepresented in biomedical research include, but are not limited to, 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.

XI. Exclusions/Restrictions

- A person may be the Primary Mentor on only one Mentored Award application in an award year between the CO-Pilot and CMH-Pilot Programs but may serve as a Secondary Mentor on multiple Mentored Award applications.
- An individual may be included in a Key Role on only one application in an award year between CO-Pilot, CMH-Pilot, and CE-Pilot Joint Programs. This restriction is not applicable to TM-Pilot or CE-Pilot Partnership Development programs, or to roles such as consultant, research assistant, fellow, tech support, etc.
- Renewal or follow-on Pilot Award funding to any previously funded CCTSI Pilot award is not allowed.
- Pilot awards do not support indirect (F&A) costs except for the CSU half of the award for the CO-Pilot CU/CSU Collaboration category.
- 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.

XII. Application Process

Information and Resources:
Please refer to the CO-Pilot website for information regarding:

- Frequently Asked Questions
- Informational Calls
- Typical Rank Eligibility Table

- CCTSI Resources
- Application Checklist
- Award Information

Submission Method: Intent-to-Apply form and Application may only be submitted online, and will be time-stamped upon submission. **Items received after the deadlines will not be accepted**. A PC with Internet Explorer 10, Chrome or Mozilla Firefox as the internet browser is recommended for best operation of online submission.

Intent-to-Apply: Submission access is available from the CO-Pilot website. The online form collects minimal information for development of review panels. While submission of Intent-to-Apply is **mandatory**, the information collected **is not binding** and may be changed at the time of application. There are no restrictions on the number of Intent-to-Apply forms submitted by an individual investigator

Application: Submission access is available from the CO-Pilot website. The full application consists of an online application form that will be attached to your proposal as a cover page, and the proposal materials described below. Applicants will have the opportunity to access and revise the form and proposal as often as needed up to the time they certify and submit the final application. **Once submitted, applications are considered final and cannot be modified after submission – no exceptions.**

- Regulatory approvals (IRB, biosafety, radiation safety, animal use, etc.) are not required at the time of application submission.
- CO-Pilot awards are supported by existing CCTSI funds and pre-application review by the Office of Grants and Contracts ("routing") is not required for CU-Anschutz/UC Denver applicants.
- Applicants from other affiliate organizations may have internal pre-application review requirements at their institution. For example: Colorado State University requires full OSP review for all proposals from CSU Principal Investigators prior to application. **Applicants from affiliate organizations are strongly encouraged to work with the sponsored programs office at their institution to meet all pre-application requirements specific to their organization.**

Online Application Form: The online application form collects required information for application validation and review procedures, and will be converted into a cover page for your application. Please do NOT attach a separate cover page. **Applicants will have the opportunity to access and revise the online application form as often as needed up to the time they certify and submit the final application.**

Proposal Overview
- The proposal should clearly describe a **one-year** research project using NIH-style structure, comprised of Abstract, Research Plan, References, Multiple PI Plan (if applicable), Budget and Justification, Biosketches, Letters of Support, and the Application Checklist. **Appendices are not allowed.**
- All proposal materials below must be combined into a single PDF document uploaded with the Online Application Form. 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.

Required Materials

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

2. **Research Plan (limit 4 pages):** All applications are considered new proposals. Revisions from prior unfunded submission should be incorporated in the Research Plan within the 4 page limit.
   - Specific Aims
     - Provide a clear, concise summary of the Hypothesis to be tested and your Specific Aims, including the clinical or translational research areas applicable.
   - Research Strategy
     - 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.
     - 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.
     - 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.
   - If applicable, incorporate information on background and preliminary studies within the Significance, Innovation and Approach sections above.
   - If applicable, incorporate information on the use of CCTSI Resources, or rationale for using alternative resources, within the Significance, Innovation and Approach sections above. Use of CCTSI resources is not required but is strongly encouraged.

3. **Career Development Plan (1 page; Mentored awards only):** All applications for Mentored Faculty Awards are required to have a Career Development Plan that: 1) Describe the applicant's commitment to an academic career in translational or clinical research. 2) Describes the applicant's prior training and research experience and how it relates to the objectives and long-term career plans of the applicant. 3) Provides evidence of the applicant's potential to develop into an independent investigator and justifies the need for further research mentorship. 4) Describes the next steps in the applicants' career progression after completion of the Mentored award. 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.

4. **References (no page limit)**

5. **Multiple PI Plan (1 page):** For CSU/CU Collaboration applications only, provide a Multiple PI Plan consistent with NIH requirements, including:
   - Rationale of the multiple PI approach,
   - Description of the governance and organizational structure of the leadership team and research project including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts.
   - Roles and administrative, technical, and scientific responsibilities for the project or program should

be delineated for the PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate.

6. **Budget and Justification (2 pages):**
   - Clearly define project expenses with cost categories relevant to the project, such as Personnel, Supplies, Lab Testing, Animals, Human Subjects, Non-affiliate Organizations etc.
   - Salary support commensurate with percent effort is allowed for PI and lab personnel, subject to NIH-salary cap restrictions.
   - Unallowable expenses include but may not be limited to: Indirect costs (F&A) are restricted to the CSU half of award for CO-Pilot CU/CSU Collaboration category, international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees.
   - The justification must align with budget and any financial commitments in Letters of Support, and other support for the project should be described.
   - Cost Share Budget: Applications may include collaboration with a non-affiliate organization. **All applications that include a collaboration with a non-affiliate organization in which funds will be transferred to the non-affiliate organization require a Cost-Share Budget and a Cost Share Budget Review prior to submission.** If the non-affiliate organization will receive any funding from the proposal, the following budget caps and cost share are required:
     - Cost Share Budget Review with Debra Szuster (720-848-4327) by 09/20/2019
     - Describe the Cost Share in the Budget Justification of the application.
     - Budget Cap: up to 25% of total award 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.
     - Cost Share Requirement: The non-affiliate organization must contribute 50% of the budgeted costs for the activities to be performed at the non-affiliate organization as mandatory Cost Share. A Letter of Support is required including a detailed Scope of Work, justification of total non-affiliate budget, and statement of commitment to meet the cost share requirement. The total budget *including cost share* must not exceed the award amount of the total Pilot award (e.g., cost sharing is *not* additional funding to the total Pilot award).
     - Calculation example based on a 30K proposal:

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

7. **Biosketches (current NIH format and page limit required):** A Biosketch in NIH format is required for all individuals in Key Roles.

8. **Letters of Support (no page limit)**
   - Mentored Applications: A letter from the Primary Mentor (or Co-Mentors) is required. This letter should describing the mentorship/career development plan and role of each mentor included in the proposal. The Primary Mentor's Letter of support should describe: 1) information on his/her research qualifications and previous experience as a research mentor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) 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; and 4) a plan for monitoring the candidate's research, publications, and career progress.
   - CSU/CU Collaboration applications: A signed Cover Letter from CSU OSP for the CSU PI and a Letter of Support for the CU PI from the CU Department Chair are required.
   - Applications with additional financial commitments, including departmental funding or non-affiliate collaborations with cost-share requirements: A letter from the institutional official authorized to

honor the financial commitment is required. This letter should clearly indicate the scope of work and cost calculations, the stated amount should be aligned with the application budget.

9. **Checklist Form:** Required checklist is available at [CO-Pilot website](#) in Information and Resources.

XIII. Review Process

Reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. Recommendations will be 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 selection notifications are announced.

XIV. Review Criteria

- **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?
- **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 applicants career development adequate? Are there explicit plans for development of future funding for the project, whether from the NIH, foundations, or commercial sources?
- **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?
- **Significance**, especially to the CCTSI mission - Will the results further our understanding / diagnosis / prevention/ or treatment of human diseases?
- **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?
- **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.?

XV. Post-award Requirements

- If selected for funding, PIs must obtain research approval from appropriate 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.
- Applications selected for award which include Human Subjects Research **may require** NCATS Prior Approval of full Human Subjects Research documentation prior to receiving award.
- If funded, PIs must report monthly during the Pre-Award period to the CCTSI Pilot Program Office 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 award.
- PIs will have 12-months from Notice of Award start date 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.
- Applicants are reminded to avoid public disclosure of results without first determining if intellectual property exists, as this may result in a lost opportunity to protect and commercialize any invention. PIs

must consult with their Technology Transfer Office (TTO; e.g., CU Innovations) regarding the possibility that intellectual property (patents) may result from a funded CCTSI pilot project. In the event that a patent does arise from a funded project, it is imperative that CCTSI support is acknowledged. Please contact the Technology Transfer Office before presenting or publishing results.

- 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 pilot projects. Prompt cooperation in providing the required information is expected. PIs must complete tracking & evaluation requirements for 3 years after award.

IX. Questions

1) Please review the Frequently Asked Questions (FAQs) on the CO-Pilot website – **thorough review of the RFA and FAQs is strongly recommended.**

2) Program questions not addressed in the RFA or FAQs may be asked during the pre-application conference calls; dates and times will be posted on the CO-Pilot website.