CCTSI Colorado Pilot Program (CO-Pilot)
2019 Request For Applications

I. Description
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 Collaboration.

Principal Investigators must have full-time faculty appointments or postdoctoral/postgraduate appointments at one or more of the following CCTSI-affiliated academic 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  National Jewish Health  Colorado State University

Translational research is intentionally broadly defined, and 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.

II. Key Dates
- Mandatory Intent to Apply DUE: August 13, 2018 5:00pm MDT
- Cost Share Budget Review DUE (if applicable, IIIf): September 28, 2018
- Application DUE: October 1, 2018 5:00pm MDT
- Selection Notification: February 2019
- Start of Award (with completed regulatory approvals, Ille): March-June 2019

III. General Considerations for all CO-Pilot Applications
a) 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 Denver School of Medicine Dean’s Office.
b) Revisions of unfunded applications from last year are encouraged. Revised proposals are considered new applications rather than resubmitted applications.
c) Principal Investigators, co-Investigators and Mentors must be CCTSI Members at time of application. Check status or become members at the CCTSI Membership webpage.
d) CO-Pilot awards are supported by existing CCTSI funds, and pre-application review (“routing”) is not required for UC Denver applicants by the Office of Grants and Contracts before submission. However, applicants from affiliate organizations (Section I) may have internal pre-application review requirements. 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.
e) Regulatory approvals are not required at the time of application. Applications selected for award must obtain regulatory approvals prior to receiving award. These approvals may include COMIRB, IACUC, Biosafety, SARC, IBC, CHRI, and any other regulatory agencies relevant to the proposal.
Applications selected for award which include Human Subjects or Vertebrate Animal Research MAY require NCATS Prior Approval prior to receiving award. Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals as soon as possible upon notification of selection for award.

- Applications may include collaboration with a non-affiliate organization (Section I). If the non-affiliate organization will receive any funding from the proposal, budget caps and cost share requirements necessitate Cost Share Budget Review with Sandy Chalmers by September 28, 2018. Budget Cap: up to 25% of total award may be allocated to the non-affiliate organization.
- Cost Share Requirement: The non-affiliate organization must contribute 50% of the non-affiliate costs 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 – cost share is not additional funding to the total Pilot award.
- Calculation example based on a 30K proposal:

<table>
<thead>
<tr>
<th>Budget Items</th>
<th>Award Total Budget</th>
<th>Funded CCTSI</th>
<th>Funded Non-affiliate Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affiliate directs</td>
<td>$22,500</td>
<td>$22,500</td>
<td>$0</td>
</tr>
<tr>
<td>Non-affiliate directs</td>
<td>$7,500 (cap 25% of 30K)</td>
<td>$3,750</td>
<td>$3,750 (50% of $7,500)</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$30,000 total award</strong></td>
<td><strong>$26,250</strong></td>
<td><strong>$3,750</strong></td>
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f) 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.

g) 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. Please contact the Technology Transfer Office before presenting or publishing results.

IV. General Restrictions for all CO-Pilot Applications

- Investigators from non-affiliate organizations in (Section I) 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.
- An individual may be included in a Key Role (Principal Investigator, co-Principal Investigator, co-Investigator) on only one application in an award year between CO-Pilot, CMH-Pilot, CNS-Pilot, and CE-Pilot Joint Programs. This restriction is not applicable to NM-Pilot or CE-Pilot Partnership Development programs, or to roles such as consultant, research assistant, fellow, tech support, etc.
- Multiple PI roles are restricted in this program by category (Section V).
- 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.
- Renewal or follow-on funding to any previously funded CCTSI Pilot award is not allowed.
- Pilot awards generally do not support indirect (F&A) costs. However on CU/CSU Collaboration awards, the CSU half of award will support $30,000 direct costs plus 52% CSU indirect costs. The CU half of award will only support $30,000 direct costs.
- Pilot awards do not support funding of international entities. However, proposals with limited aspects of the research (such as data or sample collection) conducted at international sites may be considered for funding portions of the work conducted locally in Colorado.
- Any clinical trials proposed in Pilot applications are restricted to Phase I-IIA. In accordance with the congressional authorization for creation of NCATS, the CCTSI cannot directly fund Pilot Program clinical trials beyond Phase IIA. If you anticipate submitting an application including a Phase IIB or Phase III clinical trial, please contact the Pilot Program Office PRIOR to submitting Intent to Apply.
V. Award Categories

Mentored Faculty Awards - $30,000 for one year
- This award is an opportunity for early career investigators (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and junior 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 Pilot 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 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 a career development plan for the applicant.
- 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
- This award is an opportunity for junior investigators (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and junior 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.
- While this award does not have a mentoring requirement, the proposed project should emphasize 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. 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 support. 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 preaward period Feb-Apr 2019.

VI. Application Process

Information and Resources:
Please refer to the CO-Pilot website for information regarding:
- Frequently Asked Questions
- Informational Calls
- Rank Eligibility Table
- CCTS Resources
- 2019 Application Checklist
- Award Information

Submission Method:
Intent to Apply 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:
The mandatory Intent to Apply must be submitted ONLINE by 5pm MDT August 13, 2018. 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.

Application:
The Application must be submitted ONLINE by 5pm MDT October 1, 2018. 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. Final applications cannot be modified after submission – no exceptions.

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 proposal. 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 2019 Checklist. No appendices.
- 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 11pt font, single-spaced, with 1/2 inch margins.

Proposal Materials
1. Abstract (limit 250 words)
   - Provide a concise summary of project for application review and announcement of award. Include overall goal, specific aims, 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. References (no page limit)

4. Multiple PI Plan (1 page): For CSU/CU Collaboration applications only, provide a Multiple PI Plan consistent with NIH requirements:
   - 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.

5. 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), 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 Review: if required, acknowledge in Budget Justification. All applications including collaboration with non-affiliate organizations with budget requirements: Cost Share Budget Review (III#) with Sandy Chalmers required by September 28, 2018.

6. Required Biosketches (current NIH format and page limit required)
   - All individuals in Key Roles (Principal Investigators, co-Investigators, Mentors)

7. Required Letters of Support (no page limit)
   - Mentored Applications: Primary Mentor Letter, describing the mentorship/career development plan and role of each mentor included in the proposal.
   - Junior and Mentored applications with a CSU PI: signed Cover Letter from the CSU OSP
   - CSU/CU Collaboration applications: signed Cover Letter from CSU OSP for the CSU PI, Letter of Support for the CU PI from the Department Chair.
   - All applications with additional financial commitments, including departmental funding or non-affiliate collaborations with cost-share requirements: Letter should clearly indicate the scope of work and cost calculations, the amount should be aligned with the application budget, and should be provided by the official authorized to honor the financial commitment.

8. 2019 Checklist Form
   - Required checklist is available at CO-Pilot website in Information and Resources.

CO Pilot RFA 2019
VII. Review Criteria

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 made.

Factors considered in the success of the application are:

- **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? 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/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?

- **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 Design, Biostatistics, Technology Resources, Patient and Clinical Interaction Resources etc.?

VIII. Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy Chalmers</td>
<td>CCTSI Pilot Programs Administrator</td>
<td><a href="mailto:sandra.chalmers@ucdenver.edu">sandra.chalmers@ucdenver.edu</a></td>
</tr>
<tr>
<td></td>
<td>CO-Pilot Program Manager</td>
<td>720-848-7797</td>
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<tr>
<td></td>
<td>- Program and Technical Assistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Pre and Post Award Management</td>
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IX. Questions

1) The majority of Program questions are addressed directly in this RFA or on the [CO-Pilot website](#) in Frequently Asked Questions – thorough review of RFA and FAQs is strongly recommended.

2) Program questions not addressed in the RFA or FAQs may be asked during Informational Calls, dates and times posted on the [CO-Pilot website](#).

3) Research questions may be directed to CO-Pilot Program Leadership, Drs. Thomas Campbell or Natalie Ahn, contact information on the on the [CO-Pilot website](#).