CCTSI Colorado “CO-Pilot” Program
2015-2016 Request For Applications

I. Description

The CCTSI Colorado Pilot Program (CO-Pilot) supports a series of one-year awards to encourage cross-disciplinary and collaborative research in clinical and translational medicine, with awards in Mentored, Junior, Independent, CSU/CU Collaboration, and Team Science categories.

Other CCTSI Pilot Funding Opportunities under separate announcement include:
- Child & Maternal Health (CMH-Pilots),
- Community Engagement (CE-Pilots),
- Novel Clinical & Translational Methods (NM-Pilots),
- Center for NeuroScience (CNS-Pilots), and
- Colorado State University (CSU-Pilots).

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 all included.

II. Key Dates

- Mandatory Letter of Intent Submission Period: 07/01/15 – 08/17/15
- Mandatory Letter of Intent Deadline REVISED 08/24/15 5pm MDT
- Application Submission Period: 08/19/15 – 09/14/15
- Application Deadline 09/14/15 5pm MDT
- Earliest Notification of Selection: January 2016

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) All clinical and translational research is eligible for funding under the CO-Pilot Program, and proposed research must represent a cross-disciplinary effort.

c) Principal Investigators from any CCTSI affiliate organizations are eligible to apply: University of Colorado Denver (Anschutz and Downtown), University of Colorado at Boulder, Colorado State University, National Jewish Health, Denver Veterans Administration Medical Center, University of Colorado Hospital, Children’s Hospital Colorado, Denver Health, and Kaiser Permanente of Colorado.

d) Applications may include collaboration with external organizations (non-affiliates). If such an application includes budget requirements for the external organization, the PI must complete a pre-application budget review with Sandy Chalmers in the CCTSI Pilot Program Office by Sept. 4, 2015.

e) Up to 25% of a CO-Pilot award can be budgeted for an external organization. The external organization must meet a mandatory cost share requirement of 50% of external organization budget. A Letter of Support from the external organization is required with application, and must include a detailed Scope of Work, justification of total external 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 CO-Pilot category.

Example:

<table>
<thead>
<tr>
<th>Budget Line Item</th>
<th>Award Total Budget</th>
<th>Funded CCTSI</th>
<th>Funded External Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel/Other</td>
<td>$75,000</td>
<td>$75,000</td>
<td>$ 0</td>
</tr>
<tr>
<td>External</td>
<td>$25,000 (cap 25% 100K)</td>
<td>$12,500</td>
<td>$12,500 (50% 25K)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$100,000 total award</td>
<td>$87,500</td>
<td>$ 12,500</td>
</tr>
</tbody>
</table>

f) Revisions of unfunded CO-Pilot applications from last year are encouraged.

g) Principal Investigators, Co-Investigators and Mentors must be CCTSI Members at time of application. Check status or become members at the [CCTSI Membership](#) webpage.

h) CO-Pilot awards are not federally funded, and do not require official pre-award review (routing) by UC Denver applicants via the Office of Grants and Contracts prior to submission. Applicants from affiliate organizations may be required to complete an internal review process at that affiliate organization prior to submission or award. Please check with the affiliate organization’s sponsored projects office to ascertain if there are pre-submission/award review requirements for programs such as Academic Enrichment Funds (AEF) or internally funded award programs.

i) Regulatory approvals are not required at the time of application. Applications selected for award must obtain regulatory approvals prior to implementation of the award. These approvals may include COMIRB, IACUC, SARC, IBC, CHRI, or any other regulatory groups relevant to the proposal. Applicants are strongly encouraged to demonstrate capacity to obtain regulatory approvals as soon as possible upon notification of selection for award.

j) 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.

k) Applicants are reminded to avoid public disclosure of results, in either text or verbal form, 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

a) Investigators from external organizations (non-affiliates) are ineligible to be Principal Investigators on CO-Pilot awards, but are encouraged to collaborate with an eligible investigator from a CCTSI affiliate who could serve as PI on an application.

b) PIs with an award in the most recent cycle are ineligible to apply for the current cycle.

c) A person can be Principal or Co-Investigator on only ONE application among the CO-Pilot, CMH-Pilot, CNS-Pilot, and CE-Pilot Programs.

d) A person may only be the Primary Mentor on ONE Mentored Award application - but may serve as a Secondary Mentor on multiple Mentored Award applications.

e) Renewals or follow-on funding to prior funded CCTSI Pilot Grants are not allowed.

f) CO-Pilot awards do not support indirect (F&A) costs.

g) CO-PI and Multiple PI roles are restricted in this program. Please see Section V below for specific requirements in each award category.

h) All Pilot Grants 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 a Pilot Program application for a Phase IIB or Phase III clinical trial, please contact us PRIOR to submitting a Letter of Intent.
V. Award Categories

Mentored Faculty Awards - $30,000 for one year

- This award is an opportunity for beginning investigators (typically post-doctoral fellows, 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.
- Only one individual (the mentee) can be indicated as the Principal Investigator - Co-PI or Multiple PI roles are not supported under this category.
- 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.
- Optional Secondary Mentor(s) may add expertise in a related, but different discipline (Letter of Support not required but strongly advised).
- While senior investigators are not eligible, those with a good translational research idea can consider mentoring a beginning investigator who is eligible for a Mentored Pilot Award.

Junior Faculty Awards - $30,000 for one year

- This award is an opportunity for junior investigators (typically post-doctoral fellows, instructors in tenure or research tracks, and junior assistant professors who may have previous research awards) to benefit from strong cross-disciplinary experience in clinical and translational research.
- Only one individual can be indicated as the Principal Investigator - Co-PI or Multiple PI roles are not supported under this category.
- While this award does not have a mentoring requirement, the proposed project should emphasize collaborations and interactions for clinical and translational research.

Independent Career Development / Mini-Sabbatical Awards - $60,000 for one year

- This award is an opportunity for experienced investigators (typically senior assistant with prior research funding, associate or full professors) seeking to incorporate a new clinical direction in their interdisciplinary research.
- Only one individual can be indicated as the Principal Investigator - Co-PI or Multiple PI roles are not supported under this category.
- Applications relating to career development are expected to demonstrate collaborative interactions in concise areas of translational and clinical investigation which represent a new career direction.
- Included within this category are mini-sabbatical awards, granted to individuals to facilitate acquiring new experiences and knowledge in clinical and translational research.
- Mini-sabbatical awards require a Letter of Salary Support from the home department for the award period (a Pilot award may not serve as salary support for a sabbatical).

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

- This award is an opportunity for specific collaboration in clinical and translational research between CSU and University of Colorado (CU), and must include an investigator from each institution.
- An individual from each institution will be listed as Co-PI, with one person designated as the primary contact for award administration. A Multiple PI Plan must be included in the application.
- This award will provide funding to experienced investigators (typically assistant, associate or full professor) to support novel collaborative translational research between Colorado State University and the University of Colorado in clinical and basic research areas.
- This award mechanism is not designed to support pre-existing collaborative projects.
- Budget must be equally distributed between the institutions ($30,000 at CU provided by the CCTSI, and $30,000 at CSU provided by the home department). A pre-application CSU budget review with CSU college pre-award staff is required by Sept. 11, 2015. The CSU budget approval page from that review must be attached to the CSU Letter of Support. For more information, contact Aimee Oke.
- Applications must include a Letter of Support from each institution outlining programmatic support. The CU Letter of Support must be from the Department Chair. The CSU Letter of Support must include the required $30,000 department commitment and be from the CSU College or Department official authorized to honor that commitment.
Team Science Award - $100,000 for one year

- This award is an opportunity for interdisciplinary research by experienced investigators (typically senior assistant with prior research funding, associate or full professors) seeking to bridge either basic and translational or translational and clinical or community studies with cross-disciplinary project leadership.
- This award supports Multiple PI roles, with one person designated as the primary contact for award administration. A Multiple PI Plan must be included in the application.
- In effect, the goal of team science awards is to facilitate integration between discovery translation, clinical research, and community translation.

VI. Application Process

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

- Frequently Asked Questions
- Informational Calls
- Typical Rank Eligibility Table
- Example: Letter of Intent Form
- Example: Application Form
- CCTS! Resources
- Application Checklist Form
- Review Criteria
- Award Information

Submission Method:
Letters of Intent and Applications 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 or Mozilla Firefox as the internet browser is recommended for best operation of online submission.

Letter of Intent Form (online):
The Mandatory Letter of Intent Form must be submitted ONLINE by 5pm MDT August 17, 2015.
Submission access is available from the CO-Pilot website. The LOI collects minimal information, is not binding, and may be updated by applicants during the application process.

Application:
The Application must be submitted ONLINE by 5pm MDT September 14, 2015.
Submission access is available from the CO-Pilot website. The full application consists of an online form and the proposal. Applicants will have the opportunity to access and revise the form and proposal as often as needed up to the submission deadline. Applications cannot be modified after the submission deadline.

Form (online)
- The online form prepopulates with LOI information that can be modified as needed, and requests additional detailed information.
- The online form will be automatically converted into a cover page for the proposal.

Proposal (pdf)
- The proposal should clearly describe a one-year research project in clinical and translational research in a shortened NIH-style structure, comprised of Abstract, Research Plan, References, Multiple PI Plan (if applicable), Budget and Justification, Biosketches, Letters of Support, and Checklist. No appendices.
- Formatting
  - Must be formatted as single document in PDF to be attached to the online application form.
  - 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.
- Abstract (250 words)
  - Provide a concise summary of project for application review and public announcement of award.
• Research Plan (4 pages)
  - 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. Explain how the proposal will improve knowledge, capability or practice. Describe how concepts, methods, technologies, treatments, services or interventions will be changed if objectives are achieved.
    ▪ Innovation: Explain how the proposal challenges and seeks to shift current research or practices. Describe novel theoretical concepts, approaches or methodologies, instrumentation or intervention to be developed or used, and any advantages of existing such elements.
    ▪ Approach: Describe the overall strategy, one-year timeline, methodology and analyses to be used to accomplish the specific aims. Discuss potential problems, alternative strategies and benchmarks to achieve aims. Describe proposed tests, procedures, subject population and ages in sufficient detail to allow adequate evaluation of your approach. Include details of the relative involvement of mentors and the applicant in Mentored Pilot Award applications. Include details of different collaborators’ roles in Team and Collaboration applications. Roles of Multiple PIs will be addressed in separate section.
  - Background and Preliminary Work, if applicable
  - Use of CCTSI Resources, or rationale for using alternative resources
• References (no page limit)
• Multiple PI Plan (1 page)
  - For all CSU/CU Collaboration applications, and any Team Science applications with multiple PIs
    - Provide a Multiple PI Plan consistent with NIH requirements, including:
      ▪ Rationale for choosing a 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.
• Budget and Justification (1 page budget and 1 page justification)
  - Clearly define project expenses with cost categories relevant to the project, such as Personnel, Supplies, Lab Testing, Animals, Human Subjects, External Collaborator (subject to cost-share and pre-application budget review).
  - 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), 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.
  - Pre-application budget review may be required:
    ▪ All applications that include non-affiliate collaborators with budget requirements: pre-application budget review with Sandy Chalmers in CCTSI Pilot Program Office is required by Sept. 4, 2015.
    ▪ CSU/CU Collaboration applications: pre-application CSU 30K budget review with CSU college pre-award staff is required by Sept. 11, 2015. The CSU budget approval page from that review must be attached to the CSU Letter of Support. For more information, contact Aimee Oke.
• Biosketches (NIH format required, 4 pages per person)
  - All applications: Required for all Principal Investigators and all Co-Investigators
  - Mentored applications: Required for Primary Mentor, optional for any Secondary Mentor(s)
Letters of Support (no page limit)
- Required from:
  - Mentored applications: Primary Mentor Letter, describing the mentorship plan and role of each mentor included in the proposal.
  - Independent Mini-sabbatical applications: Department Chair Letter demonstrating institutional salary support for the sabbatical time is required. The CO-Pilot grant may not serve as salary support for a sabbatical.
  - CSU/CU Collaboration applications: Letters of Support required for both investigators (PI and lead Co-Investigator). The CU Letter of Support must be from the Department Chair. The CSU Letter of Support must include the required $30,000 department commitment from the CSU College or Department official authorized to honor that commitment.
  - All applications that include financial commitment, including non-affiliate collaborators with budget requirements: Letter should clearly indicate the scope of work and cost calculations, the amount should be aligned with the application budget, and it should be provided by the official authorized to honor the commitment.
- Optional from: other key contributors to strengthen the application.

Checklist Form
- Required form is provided at CO-Pilot website in Information and Resources.

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 Committee decisions will be final. Short informative critiques of application strengths and weaknesses will be provided to all applicants in January after section 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?
- 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? (Not applicable to Independent mini-sabbatical applications)
- Significance, especially to the CCTSI mission - Will the results further our understanding / diagnosis / prevention/ or treatment of human diseases? Making use of CCTSI resources is encouraged and will be taken into account in review.
- 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
Sandy Chalmers
CCTSI Pilot Programs Administrator
CO-Pilot Program Manager
- Program Assistance
- Technical Assistance
- Pre and Post Award Management

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720-848-7797