CCTSI Center for NeuroScience “CNS-Pilot” Program
2015-2016 Request For Applications

I. Description
The CCTSI Center for NeuroScience Pilot Program (CNS-Pilot) supports a series of one-year awards to encourage cross-disciplinary and collaborative research in basic and translational neuroscience, with awards in Basic Research Independent, Basic Research Team Science, Translational Research Independent, and Translational Research Team Science categories.

Other CCTSI Pilot Funding Opportunities under separate announcement include:
- Colorado (CO-Pilots),
- Child & Maternal Health (CMH-Pilots),
- Community Engagement (CE-Pilots),
- Novel Clinical & Translational Methods (NM-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
- REVISED Mandatory Letter of Intent Deadline: 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 CNS-Pilot Applications
a) All CNS-Pilot awards are contingent upon funding made available to CNS from UC Denver School of Medicine, and to CCTSI from National Center for Advancing Translational Science (NCATS).
b) 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.

c) 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.
d) Up to 25% of a CNS-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 CNS-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>
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e) Revisions of unfunded CNS-Pilot applications from last year that meet the CNS Pilot Program requirements are encouraged.

f) Principal Investigators, Co-Investigators and Mentors must be CCTSI Members at time of application. Check status or become members at CCTSI Membership webpage. These individuals must also be Center for Neuroscience members upon award, and may register at CNS Membership webpage.

g) CNS-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.

h) 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.

i) 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.

j) 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 CNS-Pilot Applications

a) Investigators from external organizations (non-affiliates) are ineligible to be Principal Investigators on CNS-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) Renewals or follow-on funding to prior funded CCTSI Pilot Grants are not allowed.

e) CNS-Pilot awards do not support indirect (F&A) costs.

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

g) 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

The CCTSI is partnering with the Center for NeuroScience (CNS) to provide opportunities for innovation and collaborative research in neuroscience.

Basic Research Independent Awards - $30,000 for one year
- Funding is comprised of $20,000 from CNS, and $10,000 match from the PI’s department.
- This award is an opportunity for investigators (typically assistant, associate or full professors) to complete data collection for a novel grant application in basic neuroscience research.
- Only one individual can be indicated as the Principal Investigator - Co-PI or Multiple PI roles are not supported under this category.
- These applications must be accompanied by a Letter of Support from department chair(s) committing financial support for the application.

Basic Research Team Science Awards - $75,000 for one year
- Funding is comprised of $50,000 from CNS, and $25,000 match from the PI’s department.
- This award is an opportunity for experienced investigators (typically senior assistant with prior research funding, associate or full professor) to support novel cross-disciplinary collaborative basic neuroscience research between investigators in clinical and basic research departments.
- 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.
- This award mechanism is not designed to support pre-existing collaborative projects.
- These applications must be accompanied by a Letter of Support from department chair(s) committing financial support for the application.

Translational Independent Awards - $30,000 for one year
- Funding is comprised of $20,000 from CNS, and $10,000 match from the PI’s department.
- This award is an opportunity for investigators (typically assistant, associate or full professors) to complete data collection for a novel grant application in translational neuroscience research.
- Only one individual can be indicated as the Principal Investigator - Co-PI or Multiple PI roles are not supported under this category.
- These applications must be accompanied by a Letter of Support from department chair(s) committing financial support for the application.

Translational Team Science Awards - $100,000 for one year
- Funding is comprised of $54,000 from CNS, $20,000 from CCTSI, and $26,000 match from the PI’s department.
- This award is an opportunity for experienced investigators (typically senior assistant with prior research funding, associate or full professor) to support novel collaborative translational neuroscience research between investigators in clinical and basic research departments.
- 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.
- This award mechanism is not designed to support pre-existing collaborative projects.
- This award is an opportunity for experienced investigators to benefit from strong cross-disciplinary collaboration in translational neuroscience research.
- These applications must be accompanied by a Letter of Support from department chair(s) committing financial support for the application.
VI. Application Process

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

- Frequently Asked Questions
- Rank Eligibility Table
- Example: Letter of Intent Form
- Example: Application Form
- CCTSI 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 CNS-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 CNS-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 an 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 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.
  - 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.

• **Biosketches** (NIH format required, 4 pages per person)
  - All applications: Required for all Principal Investigators and all Co-Investigators

• **Letters of Support**
  - Required from:
    • All applications: Department Chair letter demonstrating the CNS eligibility and financial support for required matching funds.
    • 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: from other key contributors may be provided to strengthen the application.

• **Checklist Form**
  - Required form is provided at CNS-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 neuroscience research. Recommendations will be presented to the CCTSI and/or Center for NeuroScience Executive Committees as appropriate for approval. All Committee decisions will be final. Short informative critiques of application strengths and weaknesses will be provided to all applicants on January 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?
- **Approach/Scientific Merit** - Are the hypotheses and the 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** – For Team Science applications, does the research involve a cross-disciplinary or collaborative focus? For Translational applications, are attempts made to bridge basic and translational researchers in discovery translation?
- **Significance** - 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

<table>
<thead>
<tr>
<th>Sandra Logue</th>
<th><a href="mailto:sandra.logue@ucdenver.edu">sandra.logue@ucdenver.edu</a></th>
</tr>
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<tbody>
<tr>
<td>CNS-Pilot Program Manager</td>
<td>303-724-6193</td>
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<td>- Program Assistance</td>
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<thead>
<tr>
<th>Sandy Chalmers</th>
<th><a href="mailto:sandra.chalmers@ucdenver.edu">sandra.chalmers@ucdenver.edu</a></th>
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<tbody>
<tr>
<td>CCTSI Pilot Programs Administrator</td>
<td>720-848-7797</td>
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<tr>
<td>- Technical Assistance</td>
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<tr>
<td>- Pre and Post Award Management</td>
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