CCTSI Child and Maternal Health “CMH-Pilot” Program  
2015-2016 Request For Applications

I. Description

The CCTSI Child and Maternal Health Pilot Program (CMH-Pilot) supports a series of one-year awards to encourage cross-disciplinary and collaborative research in clinical and translational medicine focused on the goals of the CCTSI Child and Maternal Health Component, with awards in Mentored and Junior categories. Funding for CMH-Pilot Program awards is generously provided by the Children’s Hospital Colorado Research Institute.

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

The overall goal of the CMH Component of the CCTSI is to establish a new clinical translational research program focused on research in children of all ages as well as pregnant women and mothers of newborn and young infants that will ultimately improve child and maternal health and prevent diseases that begin in early life. To help achieve this goal the Child and Maternal Health Program will fund one year pilot project awards meant to encourage cross-disciplinary and collaborative research that contributes to this goal. These awards are designed to:
- Promote research in children of all ages
- Promote investigation of mother-child pair and prevention-oriented, life-course outcomes research
- Promote innovative research teams, particularly including trainees, capable of interacting across disciplines, schools, institutions
- Support investigators in child and maternal-child studies, regardless of whether the investigator is a pediatrician

Translational research is intentionally broadly defined, and includes any basic, pre-clinical or clinical research with promise to improve child 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 CMH-Pilot Applications

a) All CMH-Pilot program is contingent upon funding made available to the CCTSI from the National Center for Advancing Translational Science (NCATS), and CMH-Pilot awards are contingent upon funding from the Children’s Hospital Colorado Research Institute.

b) All clinical and translational research focused on the goals of the CCTSI Child and Maternal Health Component is eligible for funding under the CMH-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 CMH-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 CMH-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>$15,000</td>
<td>$15,000</td>
<td>$0</td>
</tr>
<tr>
<td>External</td>
<td>$5,000 (cap 25% of 20K)</td>
<td>$2,500</td>
<td>$2,500 (50% of 5K)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$20,000 total award</td>
<td>$17,500</td>
<td>$2,500</td>
</tr>
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f) Revisions of unfunded CMH-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) CMH-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 your 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. If you will use Perinatal CTRC support, you must submit a letter of intent to lucy.fashaw@ucdenver.edu in the Perinatal CTRC Triage Committee. For more information, please see the Perinatal CTRC website.

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 your invention. Please contact the Technology Transfer Office before presenting or publishing results.
IV. General Restrictions for all CMH-Pilot Applications

a) Investigators from external organizations (non-affiliates) are ineligible to be Principal Investigators on CMH-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) CMH-Pilot awards do not support indirect (F&A) costs.

g) Co-PI or Multiple PI roles are not supported by the CMH Pilot program. Only one individual can be indicated as the Principal Investigator on an application.

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 - $20,000 for one year

- The Mentee is the Principal Investigator on these awards.
- This award represents 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.
- Co-Mentorship is mandatory for this award, with the required Primary Mentor acting as direct supervisor for Mentee and providing a required Letter of Support, and the required Secondary Mentor adding expertise in a related, but different discipline.
- Senior investigators are not eligible for Mentored Pilot awards - those with a good translational research idea can consider mentoring a beginning investigator who is eligible.
- Mentored applications are eligible for a cursory pre-review upon request, to help beginning investigators with proper assembly of application. Contact CMH Pilot Program Manager Bonnie Savone at least 2 weeks prior to submission deadline to request this review.

Junior Faculty Awards - $20,000 for one year

- This award is an opportunity for junior investigators (typically instructors in tenure or research tracks, and assistant professors) with research experience seeking funds for independent of collaborative research in leadership role.
- While this award does not have a mentoring requirement, the proposed project should emphasize collaborations and interactions for clinical and translational research.

VI. Application Process

Information and Resources:
Please refer to the CMH-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 CMH-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 CMH-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. Include overall goal, specific aims, anticipated outcomes, and how the research meets the goals of the Child and Maternal Health Program.
- Research Plan (4 pages)
  - Goals/objectives/specific aims (~1/2 page) – provide a clear, concise summary of hypothesis to be tested, the specific aims, anticipated outcomes, and how the research meets the goals of the Child and Maternal Health Program.
  - Background and Preliminary Work for the proposal (~1 page)
  - Experimental Design and Methods (~2 pages) – Clearly describe the overall plan for methods development. Describe proposed tests, procedures, subject population and ages in sufficient detail to allow adequate evaluation of your approach. Include a projected time-line. Include details of the relative involvement of mentors and the applicant in Mentored Award applications or details of different collaborators’ expected roles in applications involving collaboration.
  - Use of CCTSI resources (~1/2 page).
- References (no page limit)
- 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 Principal Investigator
  - All applications: Required for Key Personnel
  - Mentored applications: Required for all Mentors

- Letters of Support
  - Required from:
    - 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.
    - Mentored applications: Primary Mentor Letter, describing the mentorship plan and role of each mentor included in the proposal.
  - Optional from: from other key contributors may be provided to strengthen the application.

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

**VII. Review Criteria**

The CMH Planning and Oversight Committee (CMH POC) will serve as the CMH Pilot Grant peer review panel. The Committee and ad hoc reviewers as needed and/or recommended will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission and focuses specifically on Child and Maternal Health issues and the goals of the CMH Program. Special consideration will be given to applications from underrepresented minorities, children, and women. Recommendations will be presented to the CCTSI Executive Committee for approval. All Committee decisions will be final.

Additional reviewers with specific expertise needed for individual proposals will be invited to join the committee as needed. The Program requests that applicants identify local reviewers who are expert in their specific proposed research specialty and who would not have a conflict of interest reviewing the applications. This will provide the CMH POC with more knowledgeable reviews of the proposed science in your application. All reviewers must be faculty in the University of Colorado and related CCTSI institutions. Please include the names of any potential reviewers and their contact information in the mandatory Letter of Intent online form.

Short informative critiques of application strengths and weaknesses will be provided to all applicants in January after selection notifications are made, but actual scores and reviewers’ names will not be disclosed.

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 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** - 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? Making use of CCTSI resources is encouraged and will be taken into account in review.
• Investigator – 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?
• Relevance to Child and Maternal Health Issues - Does the application relate to Child and Maternal Health problems and the goals of the CMH Program as specified by the application review criteria:
  - Is there attention given to the determinants or causes of health and disease?
  - Is the pilot focused on critical or sensitive developmental periods?
  - Are latent effects, pathway effects, and/or cumulative effects examined or considered?
  - Are implications of study findings for health promotion or disease prevention considered?
• Promotion of Child and Maternal Health Issues - Does the application promote Child and Maternal Health problems and the goals of the CMH Program?
  - Promote research in children of all ages?
  - Promote investigation of the mother-child pair and prevention-oriented, life-course outcomes research?
  - Promote innovative research teams, particularly including trainees, capable of interacting across disciplines, schools, institutions?
  - Support investigators in child and maternal-child studies, regardless of whether the investigator is a pediatrician?

### VIII. Contacts

<table>
<thead>
<tr>
<th>Bonnie Savone</th>
<th><a href="mailto:bonnie.savone@ucdenver.edu">bonnie.savone@ucdenver.edu</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>CMH-Pilot Program Manager</td>
<td>303-724-1602</td>
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<td>- Program Assistance</td>
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<table>
<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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