CCTSI Child and Maternal Health Pilot Program (CMH-Pilot)  
2017 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. Funding for CMH-Pilot Program awards is generously provided by the Children’s Hospital Colorado Research Institute.

This program is open to Investigators from all CCTSI affiliate organizations:
CU Boulder National Jewish Health Denver Health
CU Denver Denver VA Medical Center Kaiser Permanente of Colorado
CU Anschutz Medical Campus University of Colorado Hospital
Colorado State University Children’s Hospital Colorado
Any entity other than those listed above is a non-affiliate organization.

Pending RFA Announcements from other CCTSI Pilot Programs for 2017 Award:
Jul 2016 Colorado Pilot (CO-Pilots)
Jul 2016 Center for NeuroScience (CNS-Pilots)
Aug 2016 Community Engagement Partnership Development (CE-Pilot)
Oct 2016 Novel Clinical & Translational Methods Phase I (NM-Pilots)
Dec 2016 Colorado State University (CSU-Pilots)
Jan 2017 Community Engagement Joint Pilot (CE-Pilots)
Feb 2017 Novel Clinical & Translational Methods Phase II (NM-Pilots)

The overall goal of the CMH Component of the CCTSI is to promote a 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. The CMH-Pilot 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 if investigator is a pediatrician

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
- Intent to Apply DUE: August 17, 2016 5:00pm MDT
- Pre-application budget review, if applicable (Section IIIc) September 9, 2016
- Application DUE: September 14, 2016 5:00pm MDT
- Earliest Notification of Selection for Award: February 2017
- Earliest Start of Award: March 2017
III. General Considerations for all CMH-Pilot Applications

a) All CMH-Pilot awards are contingent upon funding made available to the CCTSI from the National Center for Advancing Translational Science (NCATS), and 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.

c) Applications may include collaboration with a non-affiliate organization (Section I). If an application includes budget requirements for the non-affiliate organization, the PI must meet budget requirements below and complete a pre-application budget review with Sandy Chalmers in the CCTSI Pilot Program Office by Sept. 9, 2016.

d) Up to 25% of a CMH-Pilot award can be budgeted for collaboration with a non-affiliate organization (Section I). The non-affiliate organization mandatory cost share requirement is 50% of the non-affiliate budget. 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 CMH-Pilot category. Example:

<table>
<thead>
<tr>
<th>Budget Line Item</th>
<th>Award Total Budget</th>
<th>Funded CCTSI</th>
<th>Funded Non-Affiliate 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>Non-affiliate</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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e) Revisions of unfunded CMH-Pilot applications from last year are encouraged. Revised proposals, however, are considered new applications rather than resubmitted applications.

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

g) CMH-Pilot awards are not federally funded, and do not require official pre-award review (routing) by CU AMC applicants from the Office of Grants and Contracts prior to submission. Applicants from affiliate organizations (Section I) may be required to complete an internal review process at that affiliate organization prior to application or issue of award. Please check with your affiliate organization sponsored projects office to ascertain if there are pre-submission/award 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. If you will use Perinatal CTRC support, you must submit a notice of intent to lucy.fashaw@ucdenver.edu and the Perinatal Research Facilitation Committee. More information is available on the Perinatal CTRC website. **NEW** Applications selected for award that include Human Subjects Research MAY require NCATS review and approval of full Human Subjects IRB documentation prior to 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.

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 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 CMH-Pilot Applications

a) Investigators from non-affiliate organizations (Section I) are ineligible to be Principal Investigators on CMH-Pilot awards, but may collaborate with an eligible CCTSI investigator serving as PI.

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

c) An individual may be included as a Principal or Co-Investigator on only one application in an award year between the CO-Pilot, CMH-Pilot, CNS-Pilot, and CE-Pilot Joint Programs. This restriction is not applicable to CSU-Pilot, NM-Pilot, and CE-Pilot Partnership Development 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) Renewal or follow-on funding to any prior funded CCTSI Pilot award is not allowed.

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

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

h) 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 - $20,000 for one year

- This award represents an opportunity for beginning 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 for Mentored Pilot awards - those with a good translational research idea can consider mentoring an eligible beginning investigator.

- Only one individual (the mentee) can be indicated as the Principal Investigator.

- Co-Mentorship is mandatory for this award, with the required Primary Mentor acting as direct supervisor for the Mentee and providing a required Letter of Support, and the required Secondary Mentor adding expertise in a related, but different discipline.

- 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 or collaborative research in a 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
- Typical Rank Eligibility Table
- CCTS Resources
- 2017 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 or Mozilla Firefox as the internet browser is recommended for best operation of online submission.
Intent to Apply:
The Mandatory Intent to Apply e-form must be submitted ONLINE by 5pm MDT August 17, 2016. Submission access is available from the CMH-Pilot website. The online form collects minimal information for development of review panels. The Intent to Apply is not binding, and information may be revised by applicants during the application process.

Application:
The Application must be submitted ONLINE by 5pm MDT September 14, 2016. 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 submission. Applications cannot be modified after submission.

Form (online)
- The online e-form prepopulates with Intent information that can be revised as needed, and requests additional detailed information.
- The online e-form will be automatically converted into a cover page for the application – please do NOT include a separate cover page.

Proposal (pdf)
- The proposal should clearly describe a one-year research project in clinical and translational research in NIH-style structure, comprised of an Abstract, Research Plan, References, Budget and Justification, Biosketches, Letters of Support, and 2017 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, or rationale for using alternative resources. (~1/2 page).
  - All applications are considered new proposals. Revisions from prior unfunded submission should be incorporated in the Research Plan within the 4 page limit.
- References (no page limit)
- 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 Organization (Section I, III 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: if required, acknowledge in justification
  - All applications that include collaboration with non-affiliate organizations with budget requirements: pre-application budget review with Sandy Chalmers in CCTSI Pilot Program Office is required by Sept. 9, 2016.

  - Biosketches (current NIH format and page limit required)
    - Required:
      ▪ All Applications: Principal Investigator and all Key Personnel
      ▪ Mentored Applications: all Mentors

  - Letters of Support (no page limit)
    - Required:
      ▪ All applications that include financial commitment, including collaboration with non-affiliate organizations with budget requirements: Letters 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: other key contributors may be provided to strengthen the application.

  - 2017 Checklist Form
    - Required checklist is available 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 peer review panel. The CMH POC 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 Executive Committee decisions will be final. Short informative critiques of application strengths and weaknesses will be provided to all applicants in February after selection notifications are made, but actual scores and reviewers’ names will not be disclosed.

Additional reviewers with specific expertise needed for individual proposals will be invited to join the CMH POC 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 the application. All reviewers must be faculty in the University of Colorado and formally affiliated CCTSI institutions. Please include the names of any potential reviewers and their contact information in the mandatory Intent to Apply online form.

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 experimental approach sound? What is 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.
• 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?
• 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 below:
  - 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 below:
  - 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, and institutions?
  - Support investigators in child and maternal-child studies, regardless of whether the investigator is a pediatrician?

VIII. Contacts

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<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
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<tbody>
<tr>
<td>Bonnie Savone</td>
<td><a href="mailto:bonnie.savone@ucdenver.edu">bonnie.savone@ucdenver.edu</a></td>
<td>303-724-1602</td>
</tr>
<tr>
<td>CMH-Pilot Program Manager</td>
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<tr>
<td>- Program Assistance</td>
<td></td>
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<tr>
<td>Sandy Chalmers</td>
<td><a href="mailto:sandra.chalmers@ucdenver.edu">sandra.chalmers@ucdenver.edu</a></td>
<td>720-848-7797</td>
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<tr>
<td>CCTSI Pilot Programs Administrator</td>
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<td>- Technical Assistance</td>
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<tr>
<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 [CMH-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 directed to CMH-Pilot Program Manager, Bonnie Savone.
3) Research questions may be directed to CMH-Pilot Program Leadership, Dr. Bill Hay, contact information on the on the [CMH-Pilot website](#).