CCTSI Child and Maternal Health Pilot Program (CMH-Pilot) 2018 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.

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

Any entity other than those specifically listed above is a non-affiliate organization.

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 16, 2017 5:00pm MDT
- **Cost Share Budget Review (if applicable, Sections IIIf,VI5):** August 30, 2017
- **Application DUE:** September 13, 2017 5:00pm MDT
- **Earliest Notification of Selection for Award:** February 2018
- **Earliest Possible Start of Award:** March 2018

III. General Considerations for all CMH-Pilot Applications
a) All 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) 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) Pilot awards are not federally funded, and thus pre-application review (“routing”) is not required by the UC Denver Office of Grants and Contracts before submission. However, applicants from other 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 organizations other than UC Denver from 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, SARC, IBC, CHRI, or any other regulatory groups relevant to the proposal. Applications selected for award that include Human Subjects Research MAY require NCATS review and approval of full Human Subjects IRB documentation 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.

f) Applications may include collaboration with a non-affiliate organization (Section I). If the non-affiliate organization will receive funding from the proposal, budget caps and cost share requirements for the application will necessitate Cost Share Budget Review with [Sandy Chalmers, Section II. Key Dates](#).

- **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 20K proposal:

<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>Affiliate directs</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>
</tbody>
</table>


g) 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.

h) 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 Pilot awards, but may collaborate with an eligible CCTSI affiliate 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 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.

d) 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.

e) Multiple PI roles are not supported by this program.
f) Renewal or follow-on funding to any prior funded CCTSI Pilot award is not allowed.
g) Pilot awards do not support indirect (F&A) costs.
h) Pilot awards do not support funding to international entities, although local funding (e.g., see budget items noted below) of studies where some aspects of the study, such as data or sample collection from subjects or populations, are conducted at international sites may be considered.
i) 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 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 for Mentored Pilot awards - those with a good translational research idea can consider mentoring an eligible early career 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
- CCTSI Resources
- 2018 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 Intent to Apply is an online form that must be submitted by 5pm MDT August 16, 2017. Submission access is available from the CMH-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 September 13, 2017.
Submission access is available from the CMH-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 application. 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 an Abstract, Research Plan, References, Budget and Justification, Biosketches, Letters of Support, and 2018 Checklist. No appendices.

- Formatting
  - Required Materials below must be formatted as single PDF document 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.

Required Materials
1. Abstract (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 (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.

3. References (no page limit)
4. Multiple PI Plan – not applicable to this program
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 that include collaboration with non-affiliate organizations with budget requirements: Cost Share Budget Review with Sandy Chalmers is required by the date indicated in Section II. Key Dates.

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

7. Letters of Support (no page limit)
   - Required:
     - Mentored Applications: Primary Mentor Letter, describing the mentorship plan and role of each mentor included in the proposal.
     - 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 it should be provided by the official authorized to honor the financial commitment.

8. 2018 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.

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonnie Savone</td>
<td><a href="mailto:bonnie.savone@ucdenver.edu">bonnie.savone@ucdenver.edu</a> 303-724-1602</td>
</tr>
<tr>
<td>CMH-Pilot Program Manager - Program Assistance</td>
<td></td>
</tr>
<tr>
<td>Sandy Chalmers</td>
<td><a href="mailto:sandra.chalmers@ucdenver.edu">sandra.chalmers@ucdenver.edu</a> 720-848-7797</td>
</tr>
<tr>
<td>CCTSI Pilot Programs Administrator - Technical Assistance - Pre and Post Award Management</td>
<td></td>
</tr>
</tbody>
</table>

### 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](#).