CCTSI Child and Maternal Health Pilot Program (CMH-Pilot)  
2021 Award Cycle - Request for Applications

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the fourteenth consecutive year. The CCTSI Child and Maternal Health Pilot Program supports one-year awards to encourage cross-disciplinary and collaborative research in clinical and translational medicine, focusing on children of all ages as well as pregnant women and mothers of newborn and young infants, to faculty members of CCTSI Affiliated Institutions. Revisions of unfunded applications from prior years are encouraged but revised proposals are considered new applications rather than resubmitted applications.

II. Key Information

<table>
<thead>
<tr>
<th>Award Amount</th>
<th>Mentored Faculty Awards</th>
<th>$30,000</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Junior Faculty Awards</td>
<td>$30,000</td>
</tr>
</tbody>
</table>

Award Duration 1 Year

Award Period May 2021 – April 2022

Contacts

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Christopher Baker, MD  
CCTSI Child and Maternal Health Pilot Program Co-Director  
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III. Important Dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/20/2020</td>
<td>RFA Release</td>
</tr>
<tr>
<td>08/10/2020</td>
<td>Pre-application conference call (2-3 pm) – Details posted on CMH-Pilot webpage</td>
</tr>
<tr>
<td></td>
<td>Zoom (click to join) or dial (346) 248-7799, meeting ID 920 8845 7789</td>
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<tr>
<td>09/08/2020</td>
<td>Mandatory Letter-of-Intent submission deadline 5:00 PM MDT</td>
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<tr>
<td>09/23/2020</td>
<td>Pre-application conference call (10-11 am) – Details posted on CMH-Pilot webpage</td>
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<tr>
<td></td>
<td>Zoom (click to join) or dial (346) 248-7799, meeting ID 977 6176 4834</td>
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<tr>
<td>09/25/2020</td>
<td>Cost Share Budget deadline (if applicable)</td>
</tr>
<tr>
<td>10/01/2020</td>
<td>Application Form submission deadline 5:00 PM MDT</td>
</tr>
<tr>
<td>01/31/2021</td>
<td>Earliest notification of award</td>
</tr>
<tr>
<td>05/01/2021</td>
<td>Start of funding</td>
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Note: Participation in the pre-application conference calls is encouraged but not required. The Intent to Apply Form and Application Form submission due dates and 5:00 PM MDT deadlines will be strictly enforced.
IV. Purpose

CMH-Pilot provides one-year awards to encourage all types of cross-disciplinary and collaborative research in clinical and translational medicine. The program is intended to stimulate new research at CCTSI affiliate organizations that will lead to improved human health. Research that is not directly or indirectly related to improving child and/or maternal health is not supported.

The overall goal of the CMH Pilot Award 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.

V. Background

Each year, the CCTSI awards more than $3 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. The CCTSI Pilot Grant Program was initiated in 2009 and is supported by the National Center for Advancing Translational Science (NCATS), the University of Colorado School of Medicine Dean’s Office, and the Traystman Fund. The CMH-Pilot Program has made over 75 awards to investigators in diverse areas of child and maternal health including allergies, cancer, cardiovascular disease, endocrinology, gastrointestinal disease, hepatology, human genetics infectious disease, mental health, metabolism, neurologic disease, nutrition, ophthalmology, respiratory medicine and teenage pregnancy. View our current and past awardees on the CCTSI CMH-Pilot Past Awards webpage.

VI. Funding Priorities

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 whether, or not, the investigator is a pediatrician
- The 2020 CU-CSU Summit, “COVID-19 and the Colorado Research Environment,” will be held online Wednesday, August 19, 2020. Through the Summit, the CCTSI seeks to foster new collaborations across campuses in COVID-19 research. For the 2021 award cycle, priority will be given to meritorious CMH-Pilot applications that propose new research collaborations on the topic of COVID-19.
- Proposals that have high potential to lead to subsequent extramural awards from the National Institutes of Health, other government agencies, and private foundations are given high priority.
- Proposals that contribute to enhancing diversity in the translational research pipeline, address health inequities, and/or the social determinants of health will be given priority.

In keeping with the CCTSI commitment to improving the diversity of the research work force, and our mission to improve the health of vulnerable communities, we encourage applications from individuals that have historically been underrepresented in biomedical research. These include 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.

VII. Award Categories

Mentored Faculty Awards - $30,000 for one year
Mentored Faculty Awards are an opportunity for investigators in the beginning stage of their career (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and assistant professors without previous research awards) to benefit from strong mentorship and cross-disciplinary training in clinical and translational research.
• The Mentee is the Principal Investigator - Multiple PI roles are not supported.
• Senior investigators are not eligible to apply for Mentored awards but can serve as a mentor for an eligible early career investigator.
• All applicants must demonstrate they will have sufficient effort on the project for the duration of the project (most of the year, not just nights and weekends), and have the necessary prior research experience and commitment to a research-focused academic career in the future.
• Past recipients of Mentored Awards are encouraged to apply for Junior Faculty awards.

Mentorship is mandatory for this award, with a required Primary Mentor (or two co-Mentors) acting as direct supervisor for Mentee and providing a required Letter of Support at time of application.
• The Primary Mentor’s (or two co-Mentors) Letter of Support should describe: 1) information on his/her research qualifications and previous experience as a research mentor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the mentee to move to the next stage of his/her career path during the project period of the award; and 4) a plan for monitoring the candidate’s research, publications, and career progress.
• Optional Secondary Mentor(s) may add expertise in a related, but different discipline (Letter of Support not required but strongly advised).
• A person may be the Primary Mentor (or a Co-Mentor) on only one Mentored Award application in an award year between the Colorado (CO-Pilot) and Child and Maternal Health (CMH-Pilot) Programs.
• A person may serve as a Secondary Mentor on multiple Mentored Award applications across the Colorado (CO-Pilot) and Child and Maternal Health (CMH-Pilot) Programs.

Junior Faculty Awards - $30,000 for one year
Junior Faculty Awards are oriented towards investigators still at the early stage of their career (typically post-doctoral fellows/trainees, instructors in tenure or research tracks, and assistant professors) who may have previous research awards and have sufficient prior research experience to independently manage a project.
• One individual must be the Principal Investigator - Multiple PI roles are not supported.
• This award does not have a mentoring requirement.
• The proposed project should emphasize cross-disciplinary collaborations and interactions for clinical and translational research.

VIII. Available Funding
All CMH-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 School of Medicine Dean’s Office. The number of awards in each category varies each year depending on the merit of applications in each category.

IX. Definitions

CCTSI Affiliated Institutions: University of Colorado Denver (Downtown Campus and Anschutz Medical Campus), University of Colorado Boulder, Colorado State University, University of Colorado Health, Children’s Hospital Colorado, National Jewish Health, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.
Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
Phases 1-4: The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study’s objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions. (Any clinical trials proposed in Pilot applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported.)
Human Subject Research (HSR): Research involving direct and/or indirect interaction with human participants, biospecimen, samples, existing data sets, etc. This includes identifiable and deidentified data, and analysis of specimen that may have been collected for another study.

**Key Roles:** Principal Investigator, Co-Principal Investigator, Co-Investigator, Primary Mentor, co-Mentor, Mentee.

**Non-Key Roles:** Secondary Mentors, Consultants, Advisory Committee, Professional Research Assistants, Graduate Students, Undergraduate Students, Tech Support, Fellows, etc.

**Translational Research:** Translational research 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 eligible if the ultimate goal is to improve human health.

X. Eligibility

Individuals listed in Key Roles must hold full-time faculty appointments or postdoctoral/postgraduate appointments with a CCTSI Affiliated Institution:

- CU School of Medicine
- CU Denver (Downtown Campus)
- Kaiser Permanente
- CU School of Pharmacy
- CU Boulder
- Denver Health and Hospitals
- CU School of Dentistry
- Colorado State University
- National Jewish Health
- CU School of Nursing
- Rocky Mountain Regional VA
- CU School of Public Health
- Medical Center

Principal Investigators must meet criteria listed on the [Rank Eligibility Table (PDF)](#). If you have eligibility question for atypical ranks, please contact CCTSI.

- **Mentored Faculty Award:** Post-Doctoral Fellows, Instructor/Senior Instructor, Assistant Professor with limited or no prior research funding, Residents and other post-graduate trainees who hold a terminal degree in their field (e.g., MD, PhD, PharmD, DDS, DVM)
- **Junior Faculty Award:** Post-Doctoral Fellows, Instructor/Senior Instructor, Assistant Professor with or without prior research funding, Residents and other post-graduate trainees who hold a terminal degree in their field (e.g., MD, PhD, PharmD, DDS, DVM)

Investigators from non-affiliate organizations are ineligible to be Principal Investigators on CCTSI Pilot Awards but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.

**CCTSI Membership (mandatory):** Individuals listed in Key Roles must be CCTSI Members at time of application. Click to [Check Membership Status](#) or to [Sign Up for CCTSI Membership](#).

XI. Exclusions/Restrictions

The following exclusions/ restrictions apply to all CCTSI Pilot Grant Awards:

- An individual may be included in a Key Role on only one application in an award year between Colorado (CO-Pilot), Child and Maternal Health (CMH-Pilot), and Community Engagement Joint Project (CE-JP) Programs. This restriction is not applicable to Translational Methods (TM-Pilot) or to Community Engagement Partnership Development (CE-PD) Programs, or to Non-Key Roles.
- Pilot awards may not be used to support research conducted outside of the United States. However, proposals that use data or samples collected at international sites through other means may be considered for funding of the portion of the work conducted locally at CCTSI Affiliated Institutions.
- CMH-Pilot Awards do not support indirect (F&A) costs.
- Any clinical trials proposed in Pilot applications are restricted to Phase I or Phase IIA. Phase IIB, Phase III or Phase IV clinical trials will not be supported.
- All NIH regulations related to human fetal tissue research and human stem cell or pluripotent stem cell research flow down to CCTSI Pilot Grant Awards. If funded, projects involving these types of research must undergo review by the institutional scientific ethics committee. Please contact Alison Lakin ([alison.lakin@cuanschutz.edu](mailto:alison.lakin@cuanschutz.edu)) to discuss the institutional review process.
- If you are involved in a Key Role on an application in this cycle, you may not participate in the Review
Panel for the same award category.

The following additional exclusions/restrictions apply to all CMH-Pilot Awards:

- Investigators in a Key Role with an actively funded CCTSI Pilot Award (or NCE) are ineligible to apply for the current cycle in a Key Role. This includes PI, co-PI, co-Investigator, Mentor and/or Mentee.
- Renewal or follow-on CCTSI Pilot Award funding to any previously funded CCTSI Pilot Award project is not allowed.

XII. Proposal Requirements

The proposal should clearly describe a one-year research project using NIH-style structure, comprised of Abstract, Research Plan, References, Multiple PI Plan (if applicable), Career Development Plan (if applicable), Budget and Justification, Biosketches, and Letters of Support. Appendices are not allowed. You may use standard PHS 398 forms, although this is not required unless otherwise noted. Format must be Arial 11 pt font, single-spaced, with ½ inch margins, no footers.

The following proposal documents should be combined as a single PDF:

1) Abstract (250 word limit, single PDF): Applies to all applications. This concise summary of the project will be used to review your application, and it may be used to announce funded awards. Include header with project title and name/title/affiliation of investigators, overall goal, anticipated outcomes, and how the research meets RFA objectives.

2) Research Plan (4 page limit, single PDF): Applies to all applications. All applications must provide a research plan consistent with NIH requirements. All applications are considered new proposals; revisions from prior unfunded submission should be incorporated in the research plan. Include Specific Aims, Research Strategy (Significance, Innovation, Approach), Background and Preliminary Studies (if applicable), and CCTSI Resources (if applicable).

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: Incorporate information on background and preliminary studies, if applicable. Also incorporate information on the use of CCTSI Resources, or rationale for using alternative resources, if applicable. Use of CCTSI resources is not required but is strongly encouraged.

- 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.
3) References (no page limit, single PDF): Applies to all applications.

4) Career Development Plan (1 page; single PDF): Applies to Mentored Faculty Awards only. Applicants are required to have a Career Development Plan that:
   • Describe experiences that have been important to the applicant’s development or that have presented potential barriers to a career in research. Explain how these factors may have influenced your career development goals and preparation for a career in translational or clinical research and how you have overcome challenges or barriers.
   • Describe the applicant's commitment to an academic career in translational or clinical research.
   • Describes the applicant’s prior training and research experience and how it relates to the objectives and long-term career plans of the applicant.
   • Provides evidence of the applicant's potential to develop into an independent investigator and justifies the need for further research mentorship.
   • Describes the next steps in the applicants’ career progression after completion of the Mentored award.

The applicant and the mentor should jointly prepare the career development plan. A career development timeline and a mentoring team (or advisory committee) to monitor the candidate's progress through the career development program are recommended.

5) Letter of Support (LOS): Primary Mentor or two co-Mentors (no page limit, single PDF for all): Applies to Mentored Faculty applicants only. A letter from the Primary Mentor (or two co-Mentors) is required for all Mentored Faculty Award applications. (If there are two co-Mentors, a combined letter or two separate letters will be accepted as a single PDF). This letter should describe the mentorship/career development plan and role of each mentor included in the proposal. Include:
   • Information on his/her research qualifications and previous experience as a research mentor.
   • A plan that describes the nature of the supervision and mentoring that will occur during the proposed award period.
   • A plan for career progression for the mentee to move to the next stage of his/her career path during the project period of the award.
   • A plan for monitoring the candidate's research, publications, and career progress.

6) Optional Letters of Support (no page limit, single combined PDF): Applies to all applications. Optional LOS from department chairs, consultants, foundations, commercial sources, manufacturers, etc.

7) Budget (1 page limit, use the Budget Template on the CMH-Pilot webpage under “Information & Resources”): Applies to all applications. Provide a one-year budget (including other project support) and budget justification consistent with NIH requirements. Click the link above to download the budget template.
   • 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.

8) Budget Justification (1 page limit, single PDF): Applies to all applications. The justification must align with budget and any financial commitments in Letters of Support, and other support for the project should be described. If applicable, describe the Cost Share in the Budget Justification of the application.

9) Cost Share Budget (1 page limit, single PDF): Applications may include collaboration with non-CCTSI Affiliated organizations. All applications that include a collaboration with a non-affiliate organization in which award funds will be transferred to the non-affiliate organization require a Cost-Share Budget, a Cost Share Budget Review, and a signed Letter of Commitment from the non-CCTSI Affiliated organization.

Cost Share Budget Requirements (See Table 1 for example)
   • Budget Cap: up to 25% of total project budget may be allocated to the activities at the non-affiliate organization. The non-affiliate budget will be funded 50% by CCTSI and 50% by non-affiliate cost-sharing.
The total budget including cost share must not exceed the CCTSI Pilot Program Award amount (e.g., cost sharing is not additional funding to the total Pilot award).

Table 1: Example of cost share budget calculation based on a 30K Pilot Program Award amount

<table>
<thead>
<tr>
<th>Budget Items</th>
<th>Award Total Budget</th>
<th>Funded CCTSI</th>
<th>Funded Non-affiliate Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affiliate DC</td>
<td>$22,500</td>
<td>$22,500</td>
<td>$0</td>
</tr>
<tr>
<td>Non-affiliate DC</td>
<td>$7,500 (cap at 25% of 30K)</td>
<td>$3,750</td>
<td>$3,750 (50% of $7,500)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$30,000 total award DC</td>
<td>$26,250</td>
<td>$3,750</td>
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Cost Share Budget Review: Contact Debra Szuster (debra.szuster@cuanschuz.edu) to review the proposed cost-share budget no less than one week prior to the Application Form deadline.

10) Cost Share Letter of Commitment (no page limit, single PDF): Applies to applications that include a collaboration with a non-CCTSI Affiliated organization in which award funds will be transferred to that organization. Provide a signed letter from authorized official(s) from external organizations, departments, or other institutions. This letter should clearly indicate the Scope of Work, timeline, justification of total non-affiliate budget, and statement of commitment to meet the cost share requirement. The stated amount should be aligned with the application budget and budget justification.

11) Biosketches (no page limit, individual PDFs for each investigator): Applies to all award categories. A Biosketch in current NIH format and page limit is required for each individual listed in a Key Role.

12) CSU OSP Proposal Transmission Letter (no page limit, single PDF): Applies to all CSU applicants listed in any Key Role. CSU investigators must complete the institutional proposal review process prior to submission, which includes review by the CVMBS college office (cvmbs_proposals@mail.colostate.edu) and Office of Sponsored Programs Research Administrator, Julie Harvey. A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the Pilot Award application. Please contact Aimee Oke (aimee.oke@colostate.edu) for details.

13) Other Institutional Prior Approval (no page limit, single PDF): Applicants based at CCTSI Affiliated Institutions are strongly encouraged to work with the sponsored programs office at their institution to meet all pre-application requirements specific to their organization, including applications for federal and non-federal (internally funded) seed grant programs.

   • UC Denver and UC Boulder applicants: CMH-Pilot awards are supported by existing CCTSI funds and pre-application review by the Office of Grants and Contracts (“routing”) is not required.
   • CU Boulder applicants: You are required to complete an internal review process prior to receiving an award, but no prior approval for applying is required. Please contact Nikki Leonardo (Leonardo@Colorado.edu) for details.

XIII. Application Process

Information and Resources are available on the [Colorado Pilot Program (CMH-Pilot) webpage](#):

• Award Categories
• Request for Applications (RFA)
• Informational Calls: left sidebar
• Rank Eligibility Table
• Application Guidelines & Checklist
• Frequently Asked Questions
• CCTSI Resources
• Review Criteria
• Award Cycle
• Past Award Information

Informational Calls: Specific questions not addressed in the RFA or FAQs may be asked during the pre-application conference calls. Details and Zoom links are located on the left sidebar of the CMH-Pilot webpage.

Submission Method: Access the online submission system by clicking “Submit Intent to Apply Form (LOI)” on the [CMH-Pilot webpage](#). The mandatory Intent to Apply Form (LOI) and Application Form are submitted online and are time-stamped upon submission. The “Save and Return Later” button at the bottom of the online forms...
allows applicants to access and revise information as often as needed up until they click “Submit.” Items received after the deadlines will not be accepted.

Application Guidelines & Checklist: Refer to the Application Guidelines & Checklist posted on the CMH-Pilot webpage for information and documentation that is collected in the online Intent to Apply Form (LOI) and Application Form.

Intent to Apply Form (LOI): This online form collects minimal information about the proposal for development of review panels. A formal letter is not required. While submission of the Intent to Apply Form (LOI) is mandatory, the information collected is not binding and may be minimally changed at the time of application. Upon submission, the PI should receive an immediate confirmation email, which includes a unique link to the online Application Form. There are no restrictions on the number of Intent to Apply Forms (LOIs) submitted by an individual investigator; however, the investigator and other individuals listed in Key Roles may apply for only one project across the current CO-Pilot, CMH-Pilot, and CE-Pilot award cycle (see XI. Exclusions/Restrictions).

Application Form: The unique link to the online Application Form is included in the confirmation email that is sent after submitting the Intent to Apply Form (LOI). Upon submission, the PI should receive an immediate email confirmation, including a PDF of the full application submission. Once submitted, applications are considered final and cannot be modified – no exceptions.

If you have any questions about using the CCTSI online submission system, please contact Debra Szuster (debra.szuster@cuanschutz.edu) for assistance.

XIV. Review Process

Recruited and volunteer reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. Applicants may request specific individuals with expertise in their specific proposed research specialty and who do not have a conflict of interest to review applications during the application process. All Review Panel Study Sections are chaired by CCTSI Pilot Program Director(s) or Chair(s), and funding recommendations are 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 after awards have been officially announced.

XV. Review Criteria

All CMH-Pilot applications are reviewed based on the following criteria:

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 hypotheses and experimental approach sound? What is the likelihood of success given the experiments / proposal as outlined? For Mentored awards, are the plans for the applicant’s career development adequate? 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 and/or treatment of human diseases?

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? For Mentored awards, is
there sufficient justification for continued mentorship, does the mentor have adequate prior experience and is a strong mentorship plan proposed? Will the award provide opportunity for individuals from traditionally underrepresented backgrounds to conduct translational research?

**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 Study Design, Biostatistics, CTRCs, Core laboratories, Bionutrition core, etc.?

**Health Equity** – Will the award contribute to improving diversity in translational research at CCTSI affiliated institutions? Will the proposed research address health inequities and/or the impact of the social determinants of health?

**XVI. Pre-Award Requirements**

CCTSI Pilot Grant awards are distributed only after CCTSI, institutional, and federal pre-approval requirements have been met.

**Institutional Approvals:** Projects that are approved for funding must obtain research approval from appropriate institutional review bodies, such as COMIRB, IACUC, Biosafety, IBC, Children’s Hospital Research Institute, CSU IRB or any other regulatory group relevant to their project.

- If funded, PIs must report monthly during the Pre-Award period to the CCTSI Pilot Program Office regarding progress toward completion of all CCTSI Pilot Program, institutional, and federal regulatory requirements outlined in the Notice of Selection for award funding.
- Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals upon Notice of Selection for funding (Jan-Feb) to avoid delays in releasing award funds (May).
- If a funded project will use CTRC resources, PIs must obtain Scientific Advisory and Review Committee (SARC) approval. CTRC resources include: inpatient/outpatient research facilities, clinical research nursing support, nutrition research support, exercise research laboratory, and CTRC Core Lab support.

**NIH/NCATS Approvals:** If selected for funding, some projects involving Human Subject Research (HSR) or Vertebrate Animal Research (VAR) may require additional NIH/NCATS review prior to initiating research activities. Contact Misty Bear (misty.bear@cuanschutz.edu) for information.

**Intellectual Property and Products:** Applicants are reminded to avoid public disclosure (text or verbal) of results without first determining if intellectual property exists, as this may result in a lost opportunity to protect and commercialize any invention. PIs are required to contact Paul Tabor at CU Innovations Office (303-724-0221) to discuss the possibility of intellectual property (including patents), publications, and presentations prior to receiving CCTSI Pilot Award funds. In the event that publications, patents, or other tangible outcomes do arise from a CCTSI funded project, it is imperative that CCTSI support is acknowledged (How to Cite our CTSA Grant).

**Spending Account Setup:** CCTSI will coordinate the primary spending account setup for each award at the PI/co-PI’s institution, including speedtypes. Spending account number(s) are included in the Notice of Award.

**XVII. Post-Award Requirements**

**Project/Budget Award Period:** All CMH-Pilot awards are active from May 1 through April 30 the following year. Funds become available after a) all institutional approvals are on file with CCTSI, and b) CCTSI and your local institution have set up your spending account(s). No Cost Extensions are granted on a very limited basis for extraordinary circumstances and may not be allowed on all programs.

**Progress and Closeout Reports:** PIs must complete tracking & evaluation requirements for 3 years after award, including publications, patents, tangibles, and follow-on funding arising from CCTSI funded projects. Prompt cooperation in providing the required information is expected.
• The CCTSI is required to submit a detailed annual progress report to the NIH that includes the progress of all federally funded pilot projects in January each year.
• Investigators are expected to complete a brief closeout report at the end of their award.
• The CCTSI Evaluation Core will contact PIs annually for three years following the close of the award for updates.

Citing CCTSI Funding: Please refer to the How to Cite our CCTSI Grant for all publications, patents, or other tangible outcomes from this project during and after project completion.

XVIII. Questions

Please refer to the CMH-Pilot webpage for information regarding: Frequently Asked Questions, Informational Calls, CCTSI Resources, Application Guidelines and Checklist, and for Award Information.

For questions not addressed in the RFA or FAQs, please attend a pre-application Informational Call. Dates and times are posted on the CMH-Pilot webpage in the left sidebar. All applicants are encouraged to participate.

Additional funding opportunities are periodically posted on the CCTSI Website.