



**CCTSI Child and Maternity Health Pilot Grant Program (CMH-Pilot)
2023 Award Cycle for Clinical Translational Science (CTS) Pilots - Request for Applications (RFA)**

I. Funding Opportunity Summary

The Colorado Clinical and Translational Institute (CCTSI) is pleased to announce funding opportunities for the sixteenth consecutive year. The [CCTSI Child and Maternity Health Pilot Grant Program \(CMH-Pilot\)](#) supports one-year Clinical Translational Science (CTS) 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 mentored and junior faculty of [CCTSI Affiliated Institutions](#). CTS CMH Projects are intended to provide initial support to mentored and junior investigators to establish proof of concept. The program is intended to fund early-stage, preparatory, or feasibility studies to overcome roadblocks in the translational process that apply to the applicability of new disease pathways, technologies, protocols, or participant recruitments strategies (to name a few) as stepping-stones toward a full, hypothesis-testing investigation. Projects that address an important question in [translational science](#), and also provide insights that could be generalizable to other health-related areas, will be given high priority. Research that is not directly or indirectly related to improving human health is not supported. Revisions of unfunded applications from prior years are encouraged as long as they address new NCARS requirements in addressing translational roadblocks (see below) and all revised proposals are considered new applications rather than resubmissions.

II. Key Information

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|------------------|---|--|
| Award Categories | Mentored Faculty Awards Junior Faculty Awards | \$40,000 (increased award amount this year!) \$40,000 (increased award amount this year!) |
| Award Duration | 1 Year | |
| Award Period | May 2023 – April 2024 | |
| Contacts | Kristen House CCTSI Pilot Grant Program Administrator kristen.house@cuanschutz.edu Philip Zeitler, MD CCTSI Child and Maternal Health Pilot Grant Program Co-Director philip.zeitler@childrenscolorado.org Christopher Baker, MD CCTSI Child and Maternal Health Pilot Grant Program Co-Director christopher.baker@childrenscolorado.org | |

II. Important Dates

| | |
|-------------------|--|
| 07/25/2022 | RFA Release |
| 08/09/2022 | Pre-Application Informational Call #1 -- 2:00 pm via Zoom |
| 09/09/2022 | Mandatory Intent to Apply Form (LOI) submission deadline -- 5:00 pm Mountain Time |
| 09/19/2022 | Pre-Application Informational Call #2 – 10:00 am via Zoom |

10/03/2022

Application Form submission deadline -- 5:00 PM Mountain Time

02/15/2023

Earliest Notification Award Date

05/01/2023

Start of Award Funding

Pre-Application Informational Calls: Specific questions not addressed in the RFA or website FAQs may be asked during the pre-application conference calls. All questions related to the research focus, potential new collaborations, obtaining Core support, and application process may be addressed during the calls. Details and Zoom links are located on the left sidebar of the [Child and Maternal Health Pilot Grant Program \(CMH-Pilot\)](#) webpage. Each call includes a presentation about the program, application and review criteria, and resources plus an open Q&A session with the program director. Participation in the pre-application conference calls is encouraged but not required.

IV. Background

Each year, the CCTSI awards more than \$3 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards (see [CCTSI Funding Opportunities](#)). 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 [Child and Maternal Health Pilot Grant Program \(CMH-Pilot\)](#) has made 81 awards to investigators in diverse areas of translational CMH medicine including cancer, cardiovascular disease, drug addiction, endocrinology, gastrointestinal disease, hepatology, infectious disease, mental health, neurologic disease, ophthalmology, orthopedics, respiratory medicine and more (see [Past CMH-Pilot Grant Program Awardees](#)).

Under the new NCATS guidelines, a pilot project should address overcoming a barrier or roadblock in [translational science](#) as well as a research question. NCATS defines [translational science](#) as the field of investigation which seeks to understand the scientific and operational principles underlying each step of the [translational process](#). Whereas “translational research” focuses on crossing a particular step of the translational process for a particular target or disease, [translational science](#) is focused on the general case that applies to any/multiple targets or diseases. A key tenet of [translational science](#) is to understand common causes of inefficiency and failure to complete translational research projects in a timely fashion, which may present a common barrier across various research targets, diseases, and therapeutic areas. Projects that address a relevant question in translational science, and also provide insights that could be generalizable to other health-related areas, will be given high priority in this 2023 CMH-Pilot cycle.

Successful applicants should clearly identify in the Specific Aims section a **translational science** question/roadblock to be addressed in addition to particular targeted research questions. The applicants should emphasize (in “Significance”) how the results from this study could potentially be generalized to improve other areas of translational science (e.g., processes used to make research more efficient) and address translational science roadblocks, such as:

- Discovering new therapeutic targets and molecular pathways which play crucial roles across various therapeutic areas
- Developing or testing models that better predict a person's response to treatment
- Using novel methods to translate findings from the laboratory, clinic, or community into treatments and interventions
- Developing data acquisition methods or post-processing that will facilitate use of complex technologies and datasets in clinical research
- Novel use of informatics or big data to answer important clinical questions
- Developing or testing novel methods in early stage (Phase 1-2) clinical trials to make the trial more efficient
- Developing or testing novel methods, processes or study designs to address health disparities
- Enhancing the design and conduct of clinical trials so the results more accurately reflect the patient population generally affected by a disease (to enhance clinical relevance)
- Developing and testing new tools for engagement of underserved populations
- Developing or testing processes to improve enrollment of diverse populations in a hypothesis-driven research pilot study

It should be noted that in most small clinical research projects there are specific barriers, so-called “translational science roadblocks”, that need to be overcome:

- improved study design by improving rigor and transparency in major generalizable areas of translational discovery
- technical execution of complex mechanistic studies in humans or animal models
- challenges to data acquisition, integrity and analysis
- translational barrier from animal models to human trials; or between adult and pediatric patient populations
- timely participant recruitment and retention
- enhance recruitments and engagement of underserved populations

In the application, the PI must state clearly what is your “translational science roadblock” that you will be addressing in your proposal. The Pilot Grant team is available to assist you in designating a translational science roadblock in your study.

V. Funding Priorities

The CMH-Pilot Grant Program will fund one-year pilot project awards meant to encourage cross-disciplinary and collaborative research in clinical and translational medicine that also address a roadblock in translational science. **No-cost extensions will not be allowed for the 2023 award cycle (all projects must be completed by 4/30/2024).**

- Promote research in children of all ages.
- Promote investigation of mother-child pair and prevention-oriented, life-course outcome 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, or not, the investigator is a pediatrician.
- Proposals that have high potential to lead to subsequent extramural awards from the National Institutes of Health, other government agencies, and private foundations will be 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 high priority.
- The CTS-Pilot Program **is not designed to** fund “translational research projects” (which are only focused on crossing a particular step of the translational process for a particular target or disease) that do not also address to some extent a generalizable translational roadblock in **translational science**.

In keeping with the [CCTSI commitment to diversity, equity, inclusion and social justice in clinical and translational research](#) and the [NIH Policy on Diversity](#), we encourage applications from individuals that have historically been underrepresented in biomedical research.

VI. Award Categories

Mentored Faculty Awards - \$40,000 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 early assistant professors *without* previous research awards) who would benefit from strong mentorship and cross-disciplinary training in clinical and translational research.

Mentorship is mandatory for this award, with a required Primary Mentor(s) acting as direct supervisor for Mentee and providing a required **Letter of Support** at time of application (*see XII. Proposal Requirements*) and participating in the **Mentorship Progress Report**.

- The Mentee is the sole 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 and protected time 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.

- 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 if the proposed budget includes salary support for the mentor. Mentors without salary support from the Pilot grant may be listed as the Key Role Primary Mentor (or a Co-Mentor) on multiple applications, but not in any other type of Key Role (PI, Co-PI, or Co-Investigator) on any other application.
- The proposed project must also specifically describe a translational science roadblock that the study will address.
- Past recipients of Mentored Awards are encouraged to apply for Junior Faculty awards or CU-CSU Collaboration awards.

Junior Faculty Awards - \$40,000 for one year

Junior Faculty Awards are oriented towards investigators still at the early stage of their career (typically instructors in tenure or research tracks, or assistant professors) who may have previous research awards and have sufficient prior research experience to independently manage a project.

- One individual must be the sole 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.
- The proposed project must also describe a translational science roadblock that the study will address.
- Past recipients of CCTSI Junior Faculty Awards are encouraged to apply for K-award or R01 funding through the NIH or other agencies. Junior researchers with more advanced projects that are based on collaborations between CU AMC and CU Boulder are encouraged to apply for [AB Nexus](#) funding.

VII. Available Funding

All CMH-Pilot Grant Awards are contingent upon funding made available to the CCTSI from the National Center for Advancing Translational Science (NCATS/NIH) 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. The funding rate for CCTSI Pilot Grant Awards has averaged 19-27% over the past three years, similar to or better than NIH funding rates.

VIII. Definitions

CCTSI Affiliated Institutions: University of Colorado Denver, University of Colorado Anschutz Medical Campus, University of Colorado Boulder, Colorado State University, University of Colorado Hospital, Children's Hospital Colorado, National Jewish Health, Denver Health and Hospital Authority, Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.

Key Roles: Individuals who accept primary responsibility for the research design and/or execution, including Principal Investigator, co-Principal Investigator, co-Investigators, Primary Mentor and a co-Mentor. Investigators/Mentors receiving salary support should be listed in a Key Role and be included on only one Application Form per cycle. Unfunded mentors may be listed as the Key Role Primary Mentor (or a Key Role co-Mentor) on multiple applications, but not in any other type of Key Role (PI, co-PI, or co-Investigator) on any other application.

Non-Key Roles: Individuals who may offer support for the research study (with or without salary) but who do not have responsibility for the research design and/or execution may include: Professional Research Assistants (with or without salary), lab staff, graduate students, undergraduate students, tech support, fellows, consultants and directors of institutional core facilities, individuals offering fee-based services or supplying biobank biospecimen.

IX. Eligibility

1. Individuals listed in Key Roles (*see VIII. Definitions*) must hold full-time faculty appointments or postdoctoral/postgraduate appointments with one or more [CCTSI Affiliated Institutions](#).
 - a. Volunteer Faculty positions are not eligible to apply for awards.
 - b. Graduate students, undergraduate students, and PRAs are encouraged to participate in Non-Key Roles
 - c. Investigators who are not with a [CCTSI Affiliated Institution](#) are not eligible to be in a Key Role but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.
2. Principal Investigators must be eligible according to the [PI Eligibility by Academic Rank table](#). If you have eligibility question for atypical ranks, please contact CCTSI.
3. 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](#).

X. Exclusions/Restrictions

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

1. An individual may apply in a Key Role on only one application in an award year between the Colorado ([CO-Pilot](#)), Child and Maternal Health ([CMH-Pilot](#)), and Community Engagement ([CE-Pilot](#)) Pilot Grant Programs. This restriction is not applicable to the Translational Methods ([TM-Pilot](#)) Pilot Grant Program, nor to Non-Key Roles.
2. Key Role individuals on a no-cost extension (NCE) Pilot award are not allowed to apply for the new cycle.
3. Applications proposing to continue the work of a previously funded CCTSI Pilot Grant Project are not allowed.
4. CCTSI Pilot Grant 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 if the portion of the work conducted locally occurs at [CCTSI Affiliated Institutions](#).
5. Any [clinical trials](#) proposed in CCTSI Pilot Grant Award applications are restricted to Phase I through Phase IIB. Phase III or Phase IV clinical trials will not be supported.
6. All funded projects related to [human fetal tissue research](#) and [human stem cell and pluripotent stem cell research](#) must undergo review by the institutional scientific ethics committee. Please contact Dr. Alison Lakin, alison.lakin@cuanschutz.edu, to discuss the institutional review process.

XII. Application Process

There are two steps to applying for CCTSI Pilot Grant Funding. All submissions are time stamped upon submission. Items received after the 5 pm deadline will not be accepted. **Early submission is strongly encouraged.**

Step 1) Intent to Apply Form (LOI)

This online form collects minimal information about the proposal for development of review panels and takes 10-20 minutes to complete. While submission of the Intent to Apply Form (LOI) is mandatory, the information collected is not binding and minor changes may be made at the time of application. The “Save and Return Later” button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click “Submit.”

Access the **Intent to Apply Form (LOI)** by clicking the “Intent to Apply (LOI)” button on the [Child and Maternal Health Pilot Grant Program \(CMH-Pilot\)](#) webpage.

Step 2) Application Form

Individuals who submit the mandatory Intent to Apply Form (LOI) will immediately receive a unique link to the proposal’s Application Form via email. The “Save and Return Later” button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click “Submit.” Once submitted, applications are considered final and cannot be modified – no exceptions.

Access the **Application Form** using the unique link that is
emailed to the PI after submitting the LOI.

IMPORTANT: While there are no restrictions on the number of Intent to Apply Forms (LOIs) submitted, individuals in Key Roles (*see VIII. Definitions*) may be listed on only one Application Form between the Colorado ([CO-Pilot](#)), Child and Maternal Health ([CMH-Pilot](#)), and Community Engagement ([CE-Pilot](#)) Pilot Grant Programs (*see X. Exclusions/Restrictions*).

If you have any questions about using the CCTSI online submission system, please contact Kristen House at kristen.house@cuanschutz.edu.

XII. Proposal Requirements

The proposal should clearly describe a one-year research project that is consistent with institutional and NIH policy. All applications are considered new proposals; revisions from prior unfunded submissions should be incorporated in the research plan. Appendices are not allowed. Format must be Arial 11 pt font, single-spaced, with ½ inch margins, no headers/footers.

The following proposal documents are required to be submitted online as a combined PDF in this order:

- Cover Page** (1 page): Applies to all award categories. Do not include images on this page.
 - Project Title**
 - Investigators:** name, title, affiliation, contact information, etc.
 - Project Overview (2-3 sentences):** use laymen’s terms to describe the overall goal, anticipated outcomes, and how the research meets RFA objectives.
 - Abstract (firm 250 word limit):** Applies to all award categories. This concise summary of the project will be used to review your application, and it may be used to announce funded awards.

- Specific Aims** (½ page): Applies to all award categories. Do not include images on this page. Provide 2-3 concise sentences with a bullet point list, including the hypotheses and specific aims being tested in the research, indicating applicable clinical or translational research areas. Include a Specific Aim that addresses a Translational Science Roadblock that will be assessed or evaluated in this study.

- Background and Significance** (1 ½ page limit): Applies to all award categories. Provide context for the proposed study:
 - Background:** Describe the status and existing scientific knowledge on the research topic. Own preliminary data are not required, but may be included here.
 - Significance:** Explain the importance of the problem and barriers to progress as well as the potential impact of your project. Describe the translational science roadblock that will also be addressed by this study.
 - Innovation:** Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed

- Approach** (3 page limit): Applies to all award categories. Describe the overall strategy, methodology, and analyses to be used to accomplish each Specific Aim of the project within the one-year timeline.
 - Experimental Design:** Describe the study population/ animal models and analytical methods for data collection that will be used to address each Specific Aim.
 - Translational Science Roadblock:** Describe how this study will assess or evaluate the Translational Science roadblock that is being addressed.
 - Data Analysis and Statistical Analysis:** List the outcome measures and data analysis plan (e.g., t-test, ANOVA, regression, justification for analytic type, etc.). Include a power analysis to justify the sample size

that is being studied.

- Feasibility:** Discuss potential pitfalls and alternative strategies for each Specific Aim. Any proposal where all work cannot be completed within the one year award period,(see Timeline below) will be considered not feasible and non -responsive to this RFA.
- Shared Resources:** Use of CCTSI resources is not required but is encouraged to ensure rigor and reproducibility in the experimental design
- Timeline:** Schedule for regulatory approvals, data collection, and analysis for completing the pilot study in the one-year award period. (IRB/IACUC approval is not required at the time of application.) All proposed work MUST be completed in the one year award period; no-cost extensions will **not** be granted.

- References** (no page limit): Applies to all award categories.

- Multiple PI Plan** (1 page limit): Applies to CU-CSU Collaboration applicants only. Provide a Multiple PI Plan consistent with [NIH policy](#). Roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs, including responsibilities for human and/or live vertebrate animal subject studies as appropriate and communication plan among two PIs.

- Mandatory Letters of Support** (no page limit)
 - Mentored Faculty Award Category:** A letter from the Primary Mentor, or a combined letter from the two co-Mentors, should describe the mentorship/career development plan and role of each mentor included in the proposal. Include the information on mentor’ research and teaching background as well as monitoring the mentee progress and career development.
 - Career Development Plan** (1 page): Applies to Mentored Faculty Awards only. 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. Include applicant’s prior training and new research development in the proposed Pilot proposal, as well as potential barriers to a career in research and the path to overcome. Describe next steps in the applicants’ career progression after completion of the Mentored award.

 - Budget** (1 page limit): All applicants must use the Budget Template (click for [Excel](#) or [PDF](#)) on the [Child and Maternal Health Pilot Grant Program \(CMH-Pilot\)](#) webpage under “Information & Resources.”
 - Include only direct costs in your budget proposal. Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include F&A in the application budget.
 - Salary support commensurate with percent effort is allowed for Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary support) and lab personnel, subject to NIH-salary cap restrictions.
 - Unallowable expenses include but may not be limited to: Indirect costs, F&A (except for the CSU half of award for CO-Pilot CU/CSU Collaboration category), international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees.
 - The categories of expenses on the budget template should be edited as necessary.
 - Funds must be fully expended by 4/30/2024; any funds remaining in the project budget after that date will be forfeited.

 - Budget Justification** (1 page limit): Clearly define one-year pilot project expenses that are consistent with NIH policy, including: Personnel, Supplies, Lab Testing, Animals, Human Participants, Non-affiliate Organizations, etc. Align budget and justification with any financial commitments noted in Letters of Support and describe any other support for the project, including cost share agreement.

 - Biosketches** (no page limit): Applies to all award categories. A Biosketch in current NIH format (see [NOT-OD-21-073](#) and current [NIH template](#)) and 5-page limit is required for all individuals listed in Key Roles (PI, co-PI, co-

Investigator, Primary Mentor, co-Mentor, or in a role with salary support).

- **Institutional Prior Approval** (no page limit): Applicants 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.
 - **CU Anschutz and CU Denver applicants:** CCTSI Pilot Grant Awards are supported by internal 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.
 - **CSU OSP Proposal Transmission Letter:** Applies to all proposals involving a CSU investigator. Applicant must complete the institutional proposal review process prior to applying, which includes review by the CSU PI’s department research administrator and the Office of Sponsored Programs (OSP) Research Administrator. A signed proposal transmission letter from the CSU Office of Sponsored Programs (OSP) is required to be submitted with the CCTSI Pilot Grant Application. Please contact Jessica Hunter, jessica.hunter@colostate.edu for details.
 - **Cost Sharing Agreement with non-CCTSI Affiliates:** You are required to complete a cost-share agreement process prior to submitting the application. Please contact Kristen House, kristen.House@cuanschutz.edu for details.

XIII. Review Process

Recruited and volunteer reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission and addresses translational roadblocks. 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 Grant 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.

XIV. Review Criteria

CCTSI Review Panels will use the NIH 9-point scoring system and rate based on following criteria:

- a. **Innovation** in research hypotheses, approaches, and techniques.
- b. **Approach/Scientific Merit** based on rigor, transparency and one-year feasibility of the proposed study design.
- c. **Cross-disciplinary or Collaborative Focus** to bridge basic and translational researchers in discovery translation.
- d. **Significance** to the CCTSI Vision to “Accelerate and catalyze the translation of innovative science into improved health and patient care.”
- e. **Translational Science Roadblock:** does the Pilot proposal address a translational science roadblock that could be generalizable to other research studies?
- f. **Investigators’** research qualification and collaborative potential
- g. **Environment** and institutional support to the PI and the proposal
- h. **Health Equity and Diversity (Non-Scoring Criteria)**

XVII. Questions and Resources

Please refer to the [Child and Maternal Health Pilot Grant Program \(CMH-Pilot\)](#) webpage for information regarding RFA, Frequently Asked Questions, Informational Calls, CCTSI and Core Resources, and Past Award Information.

Research Core Services

- [CCTSI Research Core Facilities \(CTRC, etc.\)](#)

- [CU Anschutz Core Facilities](#)
- [University of Colorado Cancer Center \(Shared Resources\)](#)
- [CSU Research Core Facilities](#)
- [CU Boulder Shared Instrumentation Network](#)

How do I keep track of my research output?

- The [Health Sciences Library](#) provides support for several tools that will make it easier for you to efficiently keep track of your research output using [ORCID](#), [Colorado PROFILES](#), [NCBI](#), and [SciENcv](#).

Additional Funding Opportunities

- [CCTSI Funding Opportunities](#) include CTRC Microgrants, CCTSI Pilot Grant Programs, and Education, Training & Career Development
- [AB Nexus](#) expands research collaborations between the CU Anschutz Medical Campus and CU Boulder campuses

[End]