

CCTSI Child and Maternity Health Pilot Grant Program (CMH-Pilot) 2024 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 NCATS requirements in addressing translational roadblocks (see below) and all revised proposals are considered new applications rather than resubmissions.

II. Key Information

Award Categories Mentored Faculty Awards

\$40,000

Junior Faculty Awards

\$40,000

Award Duration 1 Year

Award Period August 2024 – July 2025

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CCTSI Child and Maternal Health Pilot Grant Program Director

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II. Important Dates

01/16/2024	Application Form submission deadline
12/20/2023	Pre-Application Informational Call #2 – 3:00 pm via Zoom
12/04/2023	Mandatory Intent to Apply Form (LOI) submission deadline
11/13/2023	Pre-Application Informational Call #1 1:00 pm via Zoom
11/01/2023	RFA Release

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, <u>translational science roadblocks</u>, 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 <u>Child and Maternal Health Pilot Grant Program (CMH-Pilot)</u> 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 Finding 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 CMH-Pilot) has made 84 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, rare diseases, respiratory medicine and more (see Past CMH-Pilot Grant Program Awardees).

Under the new NCATS guidelines, a pilot project should address overcoming a <u>translational science roadblock</u> (see the roadblock examples on the CCTSI website) as well as a research question. In the application, the PI must state the "<u>translational science roadblock</u>" that they will be addressing in their proposal. The Pilot Grant team is available to assist you in designating a translational science roadblock specific for your specific study. 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. 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 2024 CMH-Pilot cycle.

V. Funding Priorities

The CMH-Pilot Grant Program will fund <u>one-year</u> pilot project awards meant to encourage cross-disciplinary and collaborative research in clinical and translational medicine that also addresses a roadblock in translational science. **No-cost extensions will <u>not</u> be allowed for the 2024 award cycle (all projects must be completed by 7/31/2025).**

- 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, or 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.

In keeping with the <u>CCTSI commitment to diversity</u>, <u>equity</u>, <u>inclusion and social justice in clinical and translational research</u> and the <u>NIH Policy on Diversity</u>, 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

extramural 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), Child and Maternal Health (CMH-Pilot), and Community Engagement (CE-Pilot) Pilot Grant 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 <u>translational science roadblock</u> 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 extramural 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. Co-Investigators with complementary backgrounds are encouraged.
- 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 <u>AB Nexus</u> 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

<u>CCTSI Affiliated Institutions:</u> 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.

<u>Key Roles:</u> 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 <u>one</u> 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.

<u>Non-Key Roles:</u> 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 <u>CCTSI Affiliated Institution</u> 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 <u>PI Eligibility by Academic Rank table</u>. If you have eligibility questions for atypical ranks, please contact CCTSI.
- 3. Individuals listed in Key Roles must be CCTSI Members at time of application. Click to <u>Check Membership Status</u> 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 (<u>CO-Pilot</u>), Child and Maternal Health (<u>CMH-Pilot</u>), and Community Engagement (<u>CE-Pilot</u>) Pilot Grant Programs. This restriction is not applicable to the Translational Methods (<u>TM-Pilot</u>) Pilot Grant Program, nor to Non-Key Roles.
- 2. Key Role individuals currently funded on an active CCTSI CMH-/ CO-/ CE-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. All applications should have innovative specific aims distinctive from any ongoing projects by the PIs or their mentors.
- 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 <u>clinical trials</u> 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.

XI. 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 <u>mandatory</u>, 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 <u>Child and Maternal Health Pilot Grant Program (CMH-Pilot)</u> 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 <u>one</u> Application Form between the Colorado (<u>CO-Pilot</u>), Child and Maternal Health (<u>CMH-Pilot</u>), and Community Engagement (<u>CE-Pilot</u>) 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 (please use the checklist to assure all sections are included):

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.	
senten applica	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, indicatin applicable clinical or translational research areas. Include a Specific Aim that addresses a <u>Translational Science</u> <u>Roadblock</u> that will be assessed or evaluated in this study.	
Backgr study:	ound and Significance (1 ½ page limit): Applies to all award categories. Provide context for the proposed	
	Background: Describe the status and existing scientific knowledge on the research topic. Own preliminary data are not required but may be included here.	

		of your project. Describe the <u>translational science roadblock</u> that will also be addressed by this study.
		Innovation: Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or
		interventions to be developed
		interventions to be developed
	Approa	ach (3-page limit): Applies to all award categories. Describe the overall strategy, methodology, and analyses to
		d to accomplish <u>each Specific Aim</u> 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 Cores and Shared Resources is not required but is encouraged to ensure rigor and reproducibility in the experimental design.
		Timeline (Required): Schedule for regulatory approvals, data collection, and analysis for completing the pilot
		study in the one-year award period. (IRB/IACUC approval is <u>not</u> 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.
	Refere	nces (no page limit): Applies to all award categories.
_	Manda	tow. Latters of Cumpart (no nogo limit)
		tory Letters of Support (no page limit)
		entored Faculty Award Category: A letter from the Primary Mentor, or a combined letter from the two coentors, should describe the mentorship/career development plan and role of each mentor included in the
		posal. Include the information on mentor' research and teaching background as well as monitoring the
	-	entee progress and career development.
	1110	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.
	□ Bu	dget (1 page limit): All applicants must use the Budget Template (click for Excel or PDF) on the Child and
	Ma	ternal Health Pilot Grant Program (CMH-Pilot) webpage under "Information & Resources."
		☐ All costs must be reasonable and directly related to supporting the described project
		☐ Items in each of the budget categories should be detailed as much as possible so that it is clear what items
		will be purchased and in what quantities.
		☐ 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, international entities,
		computers, telecommunications, food, furniture, administrative support, non-project specific office
		expenses, and professional dues/fees/membership, costs that support future grant applications, training

	The categories of expenses on the budget template should be edited as necessary. Funds must be fully expended by 7/31/2025; any funds remaining in the project budget after that date will be forfeited.		
policy a Fees, L should unit pri include benefit	Budget Justification (no page limit): Clearly define one-year pilot project expenses that are consistent with NIH policy and directly related to funding the activities of the proposed project, including: Personnel, Supplies, Core Fees, Lab Testing, Animals, Human Participants, etc. Wherever possible, items in each of the budget categories should be detailed as much as possible so that it is clear what items will be purchased, what quantities, and in what unit prices (click for sample budget and justification). Personnel costs should be itemized for each individual and include their annual salary, the FTE provided to the project and the subsequent salary support and related fringe benefits being requested. Any consultant expenses should document the rate to be paid and the expected number of hours of consultant time.		
curren	sketches (5-page limit per person listed as Key Personnel): Applies to all award categories. A Biosketch in rent NIH format (see NOT-OD-21-073 and current NIH template) and 5-page limit is required for all ividuals listed in Key Roles (PI, co-PI, co-Investigator, Primary Mentor, co-Mentor, or in a role with salary port).		
programa applica	tional Prior Approval (no page limit): Applicants are strongly encouraged to work with the sponsored ms office at their institution to meet all pre-application requirements specific to their organization, including tions 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. **Principal Investigators'** research qualification and collaborative potential of the team and mentors.
- 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 <u>translational science</u> roadblock that could be generalizable to other research studies?
- f. Career Development Plan for Mentored pilot applications only
- 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 <u>Child and Maternal Health Pilot Grant Program (CMH-Pilot)</u> 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 <u>Health Sciences Library</u> provides support for several tools that will make it easier for you to efficiently keep track of your research output using <u>ORCID</u>, <u>Colorado PROFILES</u>, <u>NCBI</u>, and <u>SciENcv</u>.

Additional Funding Opportunities

- <u>CCTSI Funding Opportunities</u> 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]