



### **Colorado Clinical & Translational Sciences Institute**

# 2024 CCTSI Pilot Grant Program Overview

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CCTSI Pilot Grant Program Director

**Christopher Baker, MD** CMH-Pilot Grant Program Director

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CSU Pilot Grant Program Director

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# **CCTSI Pilot Grant Award Eligibility**



Faculty at CCTSI Partner Institutions

**Graduate, undergraduate, postdoctoral students, fellows and PRAs** are encouraged to participate in Non-Key Roles.

**Underrepresented, female, and minority researchers** are particularly urged to apply, as the CCTSI intends to contribute to the creation of a research workforce that is representative of the U.S. population.

# vuchealth

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**CU Anschutz Medical Campus** CU Boulder CU Denver Colorado State University University of Colorado Hospital Children's Hospital Colorado National Jewish Hospital VA Eastern CO Health Care System Kaiser Permanente Colorado

https://cctsi.cuanschutz.edu/aboutus/affiliated-institutions

https://cctsi.cuanschutz.edu/funding/membership



# What is new in 2024 Pilot Grant Cycle?

- We are in the new NCATS UM1 Cycle (2023-2029)
- We have increased \$\$ amount per Pilot Award!
- Under the new NCATS guidelines, a pilot project should address overcoming a barrier or roadblock in <u>translational</u> <u>science</u> as well as a research question
- No-cost extensions will <u>not</u> be allowed for the 2024 award cycle (all projects must be completed by 7/31/2025)



# Exclusions/ Restrictions

- 1. An individual may apply in a Key Role on only one application between the CO-/ CMH-/ CE-Pilots. This restriction is not applicable to the TM-Pilots, 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 Affiliate Institutions.
- 5. 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 <u>do not also address</u> to some extent a generalizable translational roadblock in **translational science.**



# **2024 Pilot Grant Cycle Timeline**

	CO-Pilots	CMH-Pilots	TM-Pilots			
RFA Announcement	11/1/2023	11/1/2023	11/8/2023			
Informational Call #1	11/13/2023	11/13/2023	11/21/2023			
Letter of Intent Due	12/4/2023	12/4/2023	12/11/2023			
Informational Call #2	12/20/2023	12/20/2023	01/03/2024			
Application Due Date	01/16/2024	01/16/2024	01/22/2023			
2024 Award Cycle	<u>08/01/2024 – 07/31/2025</u>					



# Colorado (CO-Pilot) Grant Program

### To encourage cross-disciplinary and collaborative research in clinical and translational medicine focused on improving human health

Basic research at the cellular and molecular level, pre-clinical research in animal models, clinical research in humans, outcomes, and health services research

### **Program Directors**

Natalie Serkova, PhD Sue VandeWoude, DVM

### **Award Categories**

- Early-Stage Investigator Diversity Award
- Mentored Faculty
- Junior Faculty
- CSU/ CU Collaboration



# Colorado (CO-Pilot) Grant Program

- Amount:\$40K (Mentored/ Junior/ Early Career Diversity)\$60K (CSU/CU Collaboration)
- **Duration:** 1 year

### Major goals

- Support junior faculty/ early-stage investigators in their efforts to become an independent PI
- Facilitate developing preliminary data on hypothesis–driven projects to help securing future federal funds
- Foster new collaborations among established CSU/ CU investigators



# Child and Maternal Health (CMH-Pilot) Grant Program

Cross-disciplinary and collaborative research focused on children of all ages as well as pregnant women and mothers of newborn and young infants that will ultimately improve child and maternal health

Basic research at the cellular and molecular level, pre-clinical research in animal models, clinical research in humans, outcomes, and health services research

**Program Directors** Christopher Baker, MD

### Award Categories

- Mentored Faculty
- Junior Faculty



# Child and Maternal Health (CMH-Pilot) Grant Program

Amount:\$40KDuration:1 year

### Major goals

- Support junior faculty/ early-stage investigators in their efforts to become an independent PI
- Facilitate developing preliminary data on hypothesis—driven projects to help securing future federal funds



# **Review Criteria**



### CO-Pilot and CMH-Pilot

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 <u>one-year feasibility</u> 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)



# **Tips for Success**

University of Colorado Anschutz Medical Campus

Webmail 🔒 | UCD Access 🔒 | Canvas 🔒 | Quick Links 🗸 | 🝳

#### **Colorado Clinical and Translational Sciences Institute**

Resources v

Training 🔻 Funding 👻 Community Engagement 👻 News and Events 💌 About Us 💌 Volunteer for a Study 🖄



Clinical and Translational Research Centers (CTRC) > Language For Your Grant Applications Protocol Submission Clinical Research Support Team (CReST) Regulatory Knowledge and Support DSMB Assistance Translational Informatics > Biostatistics, Epidemiology, and Research Design (BERD) Trial Innovation Network (TIN) Recruit Participants Research Ethics Research Studio Program Find a Researcher (PROFILES) > IT Campus Research Resources 🗹 Early Life Exposures Research Program (ELEP) Dissemination and Implementation What are you looking for?



#### **ACCELERATING RESEARCH TO IMPROVE HEALTH**

The CCTSI helps build research teams of the future, speed the development of new treatments and improve human health



CCTSI

Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

https://cctsi.cuanschutz.edu/resources



# **Tips for Success**

### **Please make sure that your application includes all scientific sections:**

- ABSTRACT: strict 250 words
  - State clearly the scientific problem, your working hypothesis, the proposed methods, and the expected results.
- SPECIFIC AIMS: ½ page
  - usually 2 specific aims,
  - with an additional third one being your Translational Science Roadblock
  - please do NOT copy and paste specific aims from a larger applications (such as yours, or your mentors, R01) – this is a PILOT grant
- Background, Significance and Innovation: 1 and ½ pages
  - here, you can include also your preliminary data (not required)
  - Clearly describes your translational science roadblock
- Approach: 3 pages
  - Experimental Design (don't forget anticipated challenges and alternative approaches)
  - Explain (2-3 sentences) how the rigor of your experimental design and data will address the translational science roadblock(s)
  - Don't forget (i) data analysis and statistics; (ii) shared resources; (iii) feasibility and timeline



HOME FAQ CONTACT

### **Research Core Labs**



One of the defining features of a top-tier research university is the availability of core facilities that provide a spectrum of contemporary analytic tools that can be shared across the campus. Ideally these cores provide both technical and consultative services at modest cost and, as a result, elevate the quality of the overall research enterprise. It is appropriate that the core landscape evolves as new technologies emerge and others become obsolete.

Below is a list to the current operational research cores supported by the School of Medicine and the research leadership on the Anschutz Medical Campus.

#### Search our Core Labs

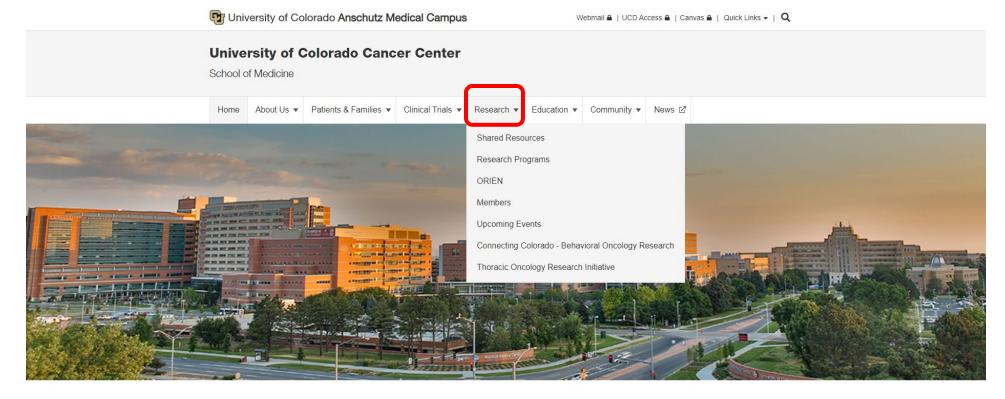
Keyword or Phrase

Q

e.g., biomarker, data analysis, flow cytometry, genetic screen, proteomics

https://researchcores.cuanschutz.edu/



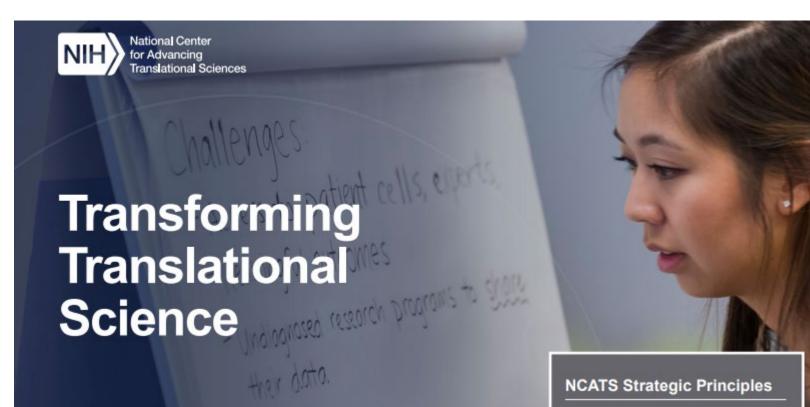


The CU Cancer Center supports a variety of state-of-the-art technological shared resources – *their incorporation into* <u>**CO/CMH/TM-Pilot**</u> proposals is encouraged!

Animal Imaging – Biostatistics and Bioinformatics – Cell Technologies – Drug Discovery and Development – Flow Cytometry – Functional Genomics – Genomics – Human Immune Monitoring – Mass Spectrometry – Population Health – Structural Biology – Pathology

https://medschool.cuanschutz.edu/colorado-cancer-center#CUMain





Whereas "translational research" focuses on crossing a particular step of the translational process for a particular target or disease, <u>translational science</u> is focused on the general case that applies to any/multiple targets or diseases.

A key tenet of <u>translational science</u> 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.



### **Examples of Translational Science Roadblocks**

In the application, the PI must state clearly what is your "<u>translational</u> <u>science roadblock</u>" that you will be addressing in your proposal:

- 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
- enhanced recruitments and engagement of underserved populations

#### Spanning the Full Spectrum of Translation

NCATS' programs, initiatives and other resources span the entire spectrum of translational science.





- 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
- Validating natural animal models of human disease in companion animals

#### Spanning the Full Spectrum of Translation

NCATS' programs, initiatives and other resources span the entire spectrum of translational science.



<u>How to Address</u> <u>Translational Science Roadblocks?</u>



### **Some Examples of Translational Science Pilot Focus**

**Establishing Molecular Mechanisms of Polymorphism of Cytochrome P450:** This study will be performed in vitro using Tg and KO epithelial and hepatic cells using novel immunosuppressive drug (CU AMC Drug Discovery Core). CYP450 polymorphism is a very generalized problem, and its understanding will help to establish pharmacokinetic properties of over 75% of existing therapeutic agents (CSU Drug Discovery Core). The pilot addresses the barrier of rigor and transparency in major generalizable areas of translational discovery.

Advanced Bulimia Treatment in Adolescent Girls: Efforts will be made to enroll young female participants from diverse geo-economic and racial background to address eating and behavioral disorders. fMRI at a 3 Tesla MRI (CU AMC Brain Imaging Core) will provide pharmacodynamics readouts. Addresses enhanced recruitments and engagement of underserved populations

#### Spanning the Full Spectrum of Translation

NCATS' programs, initiatives and other resources span the entire spectrum of translational science.





### **Some Examples of Translational Science Pilot Focus**

*Validating Natural Animal Translational Disease Models:* Many diseases of dogs, cats, horses and other animals are more similar to diseases in people than induced diseases in traditional rodent models. For example, osteosarcoma in dogs is genetically similar to the same tumor in people and responds to similar therapies. Idiopathic epilepsy in dogs has many symptoms that mimic childhood epilepsies. Accordingly, validating the molecular, diagnostic, and therapeutic features of these diseases in veterinary clinical trials (so called "T0.5") is a mechanism for improving translational science, <u>addressing translational barrier from animal models to human trials.</u>

**Retrospective Analysis on Multi-Institutional CU-CSU Omics Data:** These pilots could leverage the pilot to address the issue of performing team science across institutions and data harmonization and transfer between institutions, etc. Address challenges in data acquisition, integrity and analysis

#### Spanning the Full Spectrum of Translation

NCATS' programs, initiatives and other resources span the entire spectrum of translational science.







# **Application Process**

## Kristen House CCTSI Pilot Program Administrator



# How to Apply



University of Colorado Anschutz Medical Campus Webmail 🏔 | UCD Access 🕰 | Canvas 🚔 | Quick Links 🗸 | 🔍 **Colorado Clinical and Translational Sciences Institute** Funding ▼ Community Engagement ▼ News and Events ▼ About Us ▼ Volunteer for a Study 🖄 Resources 
Training TL1 Pre and Post Doctoral Program KL2 Mentored Career Development Award CCTSI COVID-19-Related Research Pilot CO-Pilot Grants Child and Maternal Health Pilot Grant (CMH-Pilot) Community Engagement Pilot Grant (CE-Pilot) Translational Methods Pilot Grant (TM-Pilot) CTRC MicroGrants CCTSI Membership **Funding Opportunities** Each year, the CCTSI awards more than \$2 million in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards. You can find more information on each grant and how to apply below

https://cctsi.cuanschutz.edu/funding



### Request for Applications (RFA)

The RFA describes eligibility, award categories and application requirements. The window for Please check back in November 2024 for the next cycle.



### Information & Resources

- 2024 CCTSI Pilot Grant Applicant Checklist (xlsx) XLSX Download (19 KB)
- 2024 CCTSI Pilot Grant Applicant Checklist (pdf)
   POF Download (120 KB)
- 2024-CCTSI-CO-CMH-InformationalCall (pdf)
   Download (2705 KB)
- 2024 Sample Budget and Justification (pdf)
   POF Download (215 KB)
- 2024 Required Budget Template (pdf)
   Download (98 KB)

2024 Required Budget Template (xlsx)
 Download (13 KB)

https://cctsi.cuanschutz.edu/funding/copilot https://cctsi.cuanschutz.edu/funding/cmh https://cctsi.cuanschutz.edu/funding/tm https://cctsi.cuanschutz.edu/funding/cepilot



APPLICATION CH	AECKLIST					
This checklist is for informational purposes only. All applicants must comply with the requirement	nts of the official R	equest for Fundinc	J Appliactions (	(RFA) posted on the C	CTSI website.	
Intent to Apply Form (LOI)		(				
	All Applicants	Mentored	Junior	CU-CSU Award	TM-Pilot	CSU Faculty
1 Select CCTSI Pilot Grant Program	Required					
2 Select Pilot Award Category	Required					
3 Certify this project meets RFA Eligiblity & Exlcusion critera	Required					
4 Does this study involve collaboration with non-CCTSI Affiliated Institution(s)?	Required					
5 Are any investigators involved with this project associated with Colorado State University?	Required					
6 Project Title	Required					
7 Translational Science Roadblock	Required					
8 Contact Information: Principal Investigator	Required					
9 Contact Information: Co-Principal Investigator				Required	Optional	
10 Contact Information: Co-Investigator(s)	If Applicable					
11 Contact Information: Primary Mentor (or two Co-Mentors)		Required				
12 Contact Information: Requested Reviewer(s)	Optional					
13 Research Topics (Used to pair applications with reviewers)	Optional					

Application Checklist (Excel) or (PDF)



1	Ap	plication Form						
2			All Applicants	Mentored	Junior	CU-CSU Award	TM-Pilot	CSU Faculty
	1	Confirm all contact informaiton from LOI is accurate. Combine all documentation required in	Description					
23		the RFA and combine into a single PDF to upload with you online Application Form.	Required					
	2	Project Overview (2-3 sentences)	Required					
24		List all investigator names, titles, institutions before the Project Overview	Required					
25	3	Abstract (strict 250 word limit)	Required					
26	4	Specific Aims (1/2 page), including a Translational Science Roadblock	Required					
	5	Background, Significance and Innovation (1 and 1/2 pages), including the description of the	Required					
27		translational science roadblock	Required					
	6	Approach (3 page limits), including Experimental Design, Translational Science Roadblock,	Required					
28		Data and Statistical Analysis, Feasibility, Shared Resources, Timeline	Nequireu					
_		References (no page limit)	Required					
30	8	Multiple PI Plan (1 page limit)				Required	Optional	
	9	Mentor Letter of Support (no page limit)						
		If there are two co-Mentors, a combined letter or two separate letters will be accepted as a		Required				
31		single PDF.						
-		Career Development Plan (1 page)		Required				
	11	Letters of Support (no page limit)						
		May include department chairs, consultants, foundations, commercial sources,	Optional					
3		manufacturers, etc.						
		Budget (1 page limit, vertical alignment only)	Required					
4		Please use the CCTSI Budget Template (available on the CCTSI website)						
-		Budget Justification (1 page limit)	Required					
		Biosketches (no page limit)	Required					
	15	CSU OSP Proposal Transmission Letter (no page limit)				Required		Required
37		Contact Jessica Hunter (jessica.hunter@colostate.edu) for details.						
		Cost Share Budget (1 page limit)	See RFA, Check					
		Applications may include collaboration with non-CCTSI Affiliated organizations. Refer to RFA	with Kristen					
8		for specific instructions.	House					
	17	Other: Institutional Prior Approval (no page limit)						
		Applicants based at CCTSI Affiliated Institutions are strongly encouraged to work with the	Check with					
		sponsored programs office at their institution to meet all pre-application requirements	institution					
		specific to their organization, including applications for federal and non-federal (internally						
39		funded) seed grant programs.						

Application Checklist (Excel) or (PDF)



#### **CCTSI Pilot Grant Award Budget**

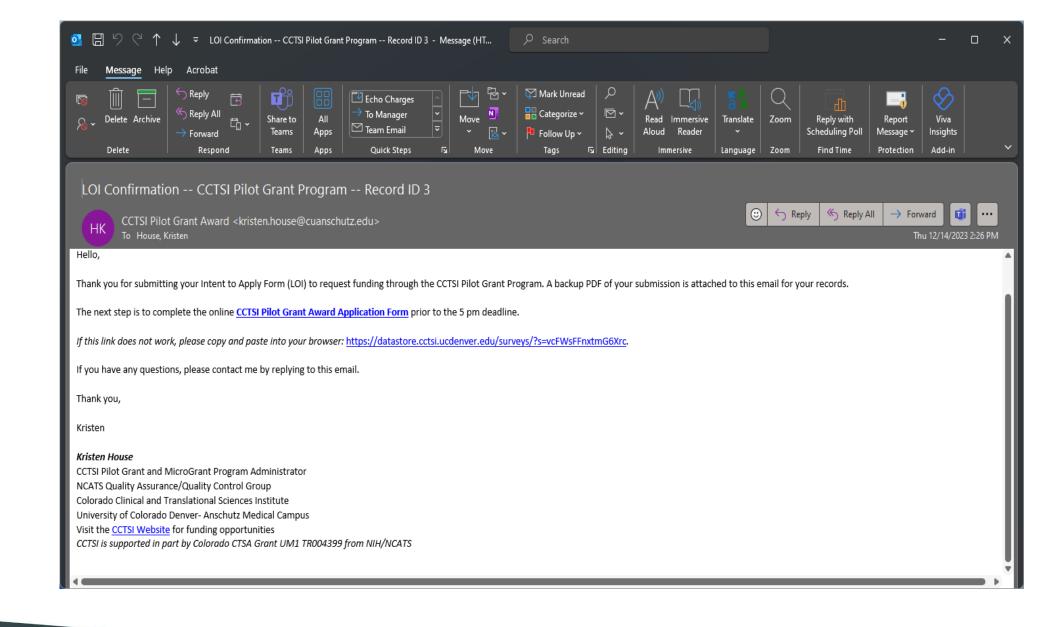
Budget and Active Award Period: August 1, 2024 to July 31, 2025								
	Indicate Budget for Each Location							
CATEGORY & ITEM(S)	CU AMC	csu	CU Boulder	снсо	Other Institution (Specify Location)	Total Amount		
Key Personnel Salary & Fringe Benefits								
						<u> </u>		
Other Personnel						\$-		
Fee for Service (including Core Services)						\$-		
Supplies	1	I	1		1	\$-		
Equipment						\$ -		
						Ŷ		
Animals						\$-		

Applicants should customize these Categories



Budget Template (Excel) and (PDF)

Use the link in this email to access the REDCap application form





You can click "Save and Return Later" if you need more time to complete this form.

You can email yourself a unique link to this partially completed form.

Only click "Submit" when you are done and have no additional edits. Once you hit "Submit", the application is final. Make sure you hit "Submit" before the deadline!

#### **General Proposal Information**

#### 1) Final Proposal Title

This title may be modified slightly on the Application Form; however, CCTSI strongly recommends the fuding application title match study title on all IRB/IACUC documentation.

Title on Intent to Apply Form (LOI): Test

Test Expand 2) Abstract Text only (no special characters or bullet points). Firm 250 word limit. 250 words remaining Expand 3) Upload a single PDF of all documentation required in the RFA. You may check the CCTSI website (link) for this Program's Application Checklist (recommended). Omission of any document(s) may adversely affect the Review Panel's overall score for this project, or lead to application disgualification. House (CO-J--3) ▲ Upload file **Regulatory Approvals** 1) Please indicate PI name and Institution for anticipated regulatory approvals. Example: Dr. X will obtain IACUC from CSU.

Example: Dr. X Will obtain IACUC from CSU. Example: COIMIRB Protocol 20-123 (PI Dr. Y)



# 2024 CO/CMH Application Cycle

# Dates

November 1, 2023

Request for Funding Announcement (RFA)

November 13, 2023 December 4, 2023 December 20, 2023 January 16, 2024 CO/CMH Informational Call #1 (Zoom) CO/CMH-Pilot Intent-to-Apply Form due - 5 pm CO/CMH Informational Call #2 (Zoom) CO/CMH-Pilot Application Form due - 5 pm

April – 2024 June – 2024 August 1, 2024 CCTSI Review Panels Notice of Selection Active Funding Period Begins

#### 2024 Key Dates

RFA Posted November 1, 2023

Intent to Apply Due December 4, 2023 at 5:00 pm MT

Informational Call #1 November 13, 2023 from 1:00 - 2:00 pm MT via Zoom

Informational Call #2 December 20, 2023 from 3:00 to 4:00 pm MT via Zoom

Application Deadline January 16, 2024, 5:00 pm MT

Scientific Merit Review April 2024

Start of Award August 1, 2024

Award Expiration Date July 31, 2025

Email Pilot Grant Program



# **CCTSI Pilot Grant Contacts**

https://cctsi.cuanschutz.edu/funding

### **Kristen House**

**CCTSI Pilot Program Administrator** 

kristen.house@cuanschutz.edu

Jessica Hunter

CSU Pilot Program Administrator jessica.hunter@colostate.edu

### Nikki Leonardo

CU Boulder Pilot Program Administrator

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**Dr. Natalie Serkova** CO/TM-Pilot Program Director

natlie.serkova@cuanschutz.edu

Dr. Christopher Baker

**CMH-Pilot Director** 

christopher.baker@childrenscolorado.org

Dr. Sue VandeWoude

CSU Pilot Program Director

sue.vandewoude@colostate.edu

