



Colorado Clinical & Translational Sciences Institute

2024 CCTSI Pilot Grant Program Overview

Natalie Julie Serkova, Ph.D.

CCTSI Pilot Grant Program Director
CO-Pilot Grant Program Director
TM-Pilot Grant Program Director

Christopher Baker, MD

CMH-Pilot Grant Program Director

Sue VandeWoude, DVM

CSU Pilot Grant Program Director

Kristen House

CCTSI Pilot Grant Program Administrator



CCTSI Pilot Grant Award Eligibility



- CCTSI Members
- 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.

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 [translational science](#) as well as a research question
- No-cost extensions will not 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 do not also address 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>		



Translational Methods (TM-Pilot) Grant Program

Speed the development and application of novel technologies, methods, or analytical assays for clinical and translational research that are presently lacking or not available to CCTSI members

Facilitate developing functioning and validated methodologies which are not yet available in Colorado, foster new collaborations, and disseminate new technologies across the CCTSI

Program Director

Natalie Serkova, PhD

Award Categories

- Translational Methods
- Biostatistics & Bioinformatics
- Colorado State University (PI)



Translational Methods (TM-Pilot) Grant Program

Amount: \$30K

Duration: 1 year

Major goals

- Provide support for developing new technologies, assays, algorithms, animal models
- Support new collaborations between a “technology driven PI” and an “application PI”
- Facilitate dissemination of the newly developed technologies among CCTSI research community



Review Criteria

TM-Pilot



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

- a. **Innovation** in proposed methods to be developed, 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 team
- 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. **Dissemination** of the to-be-developed methods/ technology among CCTSI members
- g. **Environment** and institutional support to the PI and the proposal
- h. ***Health Equity and Diversity (Non-Scoring Criteria)***



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



Tips for Success



University of Colorado Anschutz Medical Campus

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Funding ▾

Community Engagement ▾

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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



Colorado Clinical and Translational
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

<https://cctsi.cuanschutz.edu/resources>





Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS



Regulatory Knowledge and Support

The Regulatory Knowledge and Support Core (RKSC) of the CCTSI provides a support structure to deal with the complexities of research regulatory compliance.



Research Ethics

This free consultative service is sponsored by the CCTSI and is available to all biomedical and behavioral researchers at CU Anschutz, as well as its institutional partners and clinical affiliates, who seek advice about ethically complex aspects of their research.



Trial Innovation Network

The Trial Innovation Network is a new collaborative initiative within the CTSA Program and is composed of three key organizational partners – the CTSA Program Hubs, the Trial Innovation Centers (TICs) and the Recruitment Innovation Center (RIC).



Clinical Research Support Team

Provides a pool of experienced study coordinators and regulatory staff to assist with clinical research study start-up, implementation and closeout.



Biostatistics, Epidemiology and Research Design (BERD)

Providing statistical collaboration and resources to CCTSI investigators and trainees. We facilitate clinical and translational research through statistical consultation, improved statistical literacy, through seminars and short courses, and advanced tools.



Recruit Participants

Access the many resources necessary for successful recruitment of participants for clinical research studies. Learn how to develop and implement a well-planned strategy.



Funding

Each year, the CCTSI awards more than \$2 million in pilot grants, microgrants and pre-doctoral and post-doctoral research scholar awards.



Language for Grant Applications

CCTSI resources and other support details for your grant applications.



Protocol Submission

The Research Submission Portal process will ensure that your human subject research is ready for IRB submission.



Find a Researcher

The Colorado PROFILES search engine and social networking platform for biomedical researchers provides tools to help investigators and students find experts, potential collaborators or mentors.

[CTRC Pricing](#)

[CCTSI Research Studio Program](#)

[Colorado PROFILES](#)

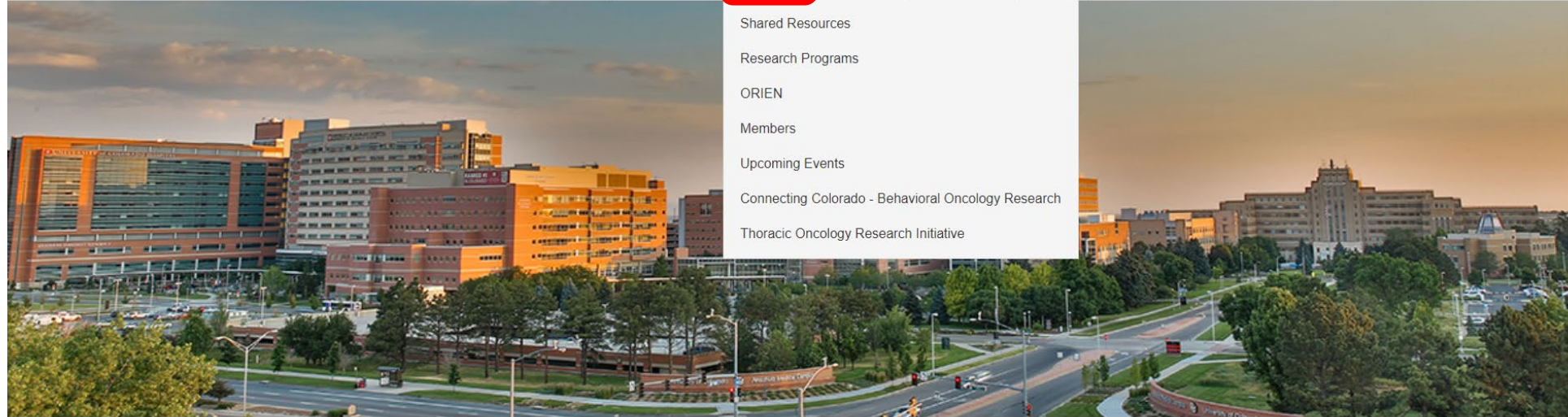


University of Colorado Cancer Center

School of Medicine

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- Shared Resources
- Research Programs
- ORIEN
- Members
- Upcoming Events
- Connecting Colorado - Behavioral Oncology Research
- Thoracic Oncology Research Initiative



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



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



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

<https://researchcores.cuanschutz.edu/>



National Center
for Advancing
Translational Sciences

Transforming Translational Science

NCATS Strategic Principles

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.



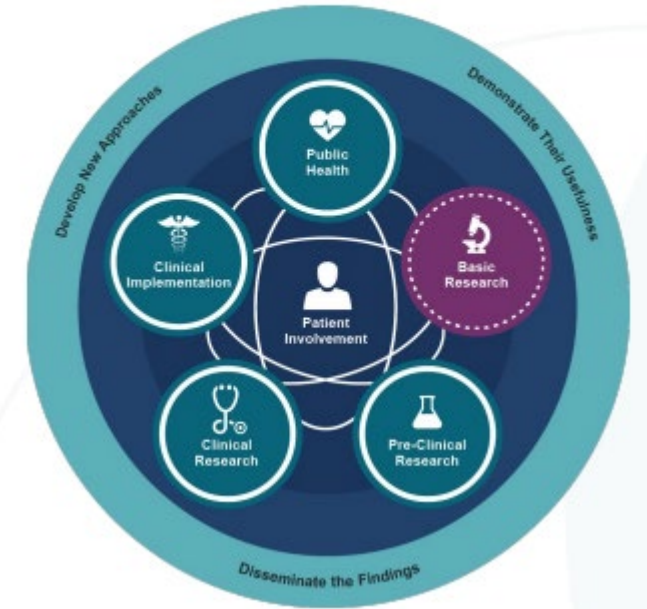
Examples of Translational Science Roadblocks

In the application, the PI must state clearly what is your “translational science roadblock” 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

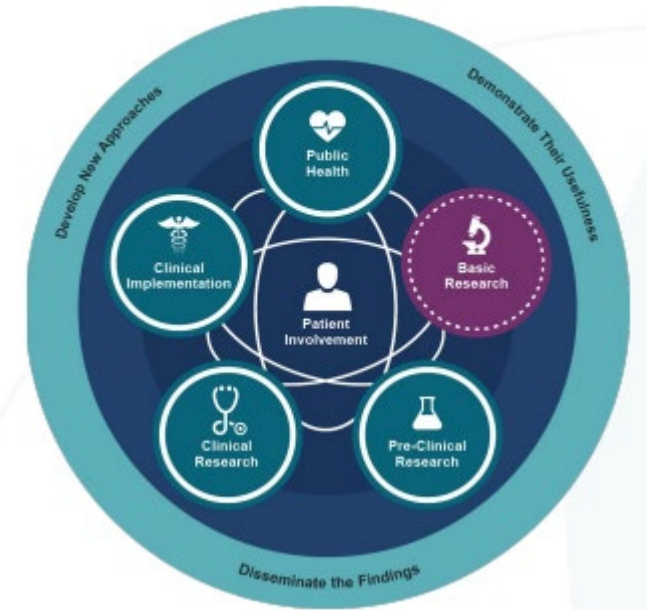
NCATS' programs, initiatives and other resources span the entire spectrum of translational science.



- 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.



How to Address Translational Science Roadblocks?



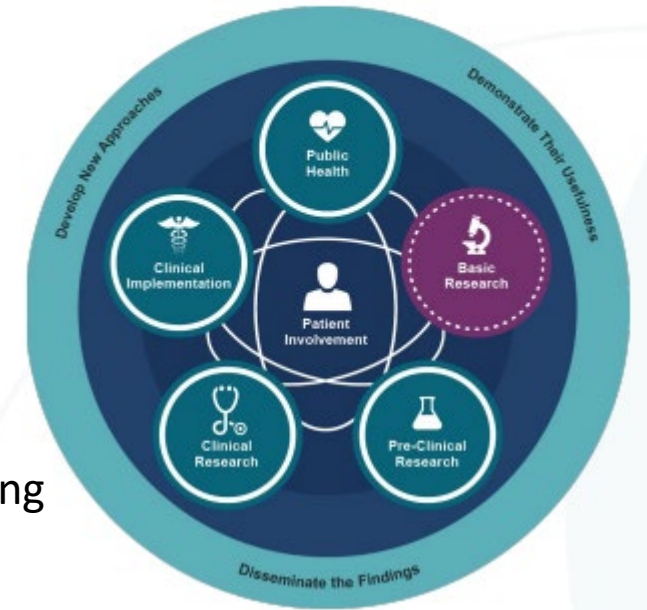
Some Examples of Translational Science Pilot Focus

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.



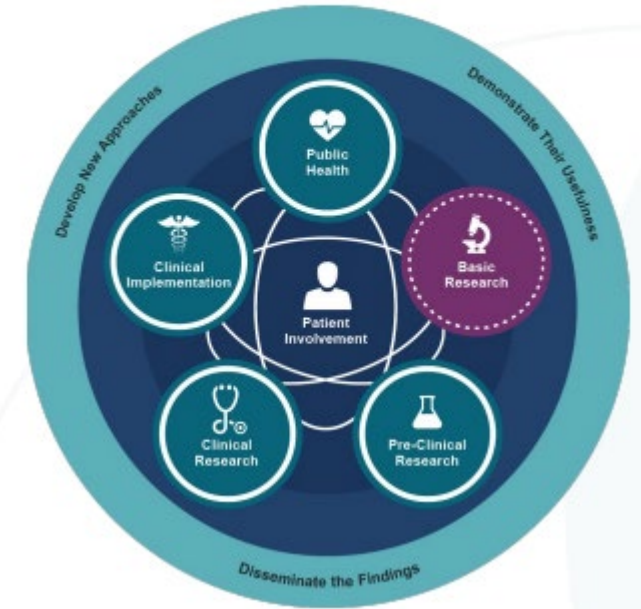
Some Examples of Translational Science Pilot Focus

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, addressing translational barrier from animal models to human trials.

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



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- 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 sending a letter of intent has ended. Please check back in November 202



2024 CCTSI TM-Pilot Grant CTS Program RFA (pdf)

292 KB

<https://cctsi.cuanschultz.edu/funding/copilot>

<https://cctsi.cuanschultz.edu/funding/cmh>

<https://cctsi.cuanschultz.edu/funding/tm>

<https://cctsi.cuanschultz.edu/funding/cepilot>

Information & Resources



2024-CCTSI-CO-CMH-InformationalCall#2 (pdf)

Download (2165 KB)



2024 CCTSI Pilot Grant Applicant Checklist (xlsx)

Download (19 KB)



2024 CCTSI Pilot Grant Applicant Checklist (pdf)

Download (120 KB)



2024-CCTSI-CO-CMH-InformationalCall (pdf)

Download (2705 KB)



2024 Sample Budget and Justification (pdf)

Download (215 KB)



2024 Required Budget Template (pdf)

Download (98 KB)



2024 Required Budget Template (xlsx)

Download (13 KB)



APPLICATION CHECKLIST

This checklist is for informational purposes only. All applicants must comply with the requirements of the official Request for Funding Applications (RFA) posted on the CCTSI 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 Eligibility & Exclusion criteria	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](#))



20							
21	Application Form						
22			All Applicants	Mentored	Junior	CU-CSU Award	TM-Pilot
23	1	Confirm all contact information from LOI is accurate. Combine all documentation required in the RFA and combine into a single PDF to upload with your online Application Form.	Required				
24	2	Project Overview (2-3 sentences) 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				
27	5	Background, Significance and Innovation (1 and 1/2 pages), including the description of the translational science roadblock	Required				
28	6	Approach (3 page limits), including Experimental Design, Translational Science Roadblock, Data and Statistical Analysis, Feasibility, Shared Resources, Timeline	Required				
29	7	References (no page limit)	Required				
30	8	Multiple PI Plan (1 page limit)				Required	Optional
31	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 single PDF.		Required			
32	10	Career Development Plan (1 page)		Required			
33	11	Letters of Support (no page limit) May include department chairs, consultants, foundations, commercial sources, manufacturers, etc.	Optional				
34	12	Budget (1 page limit, vertical alignment only) Please use the CCTSI Budget Template (available on the CCTSI website)	Required				
35	13	Budget Justification (1 page limit)	Required				
36	14	Biosketches (no page limit)	Required				
37	15	CSU OSP Proposal Transmission Letter (no page limit) Contact Jessica Hunter (jessica.hunter@colostate.edu) for details.				Required	Required
38	16	Cost Share Budget (1 page limit) Applications may include collaboration with non-CCTSI Affiliated organizations. Refer to RFA for specific instructions.	See RFA, Check with Kristen House				
39	17	Other: Institutional Prior Approval (no page limit) 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.	Check with institution				

Application Checklist ([Excel](#)) or ([PDF](#))



CCTSI Pilot Grant Award Budget

Budget and Active Award Period: August 1, 2024 to July 31, 2025

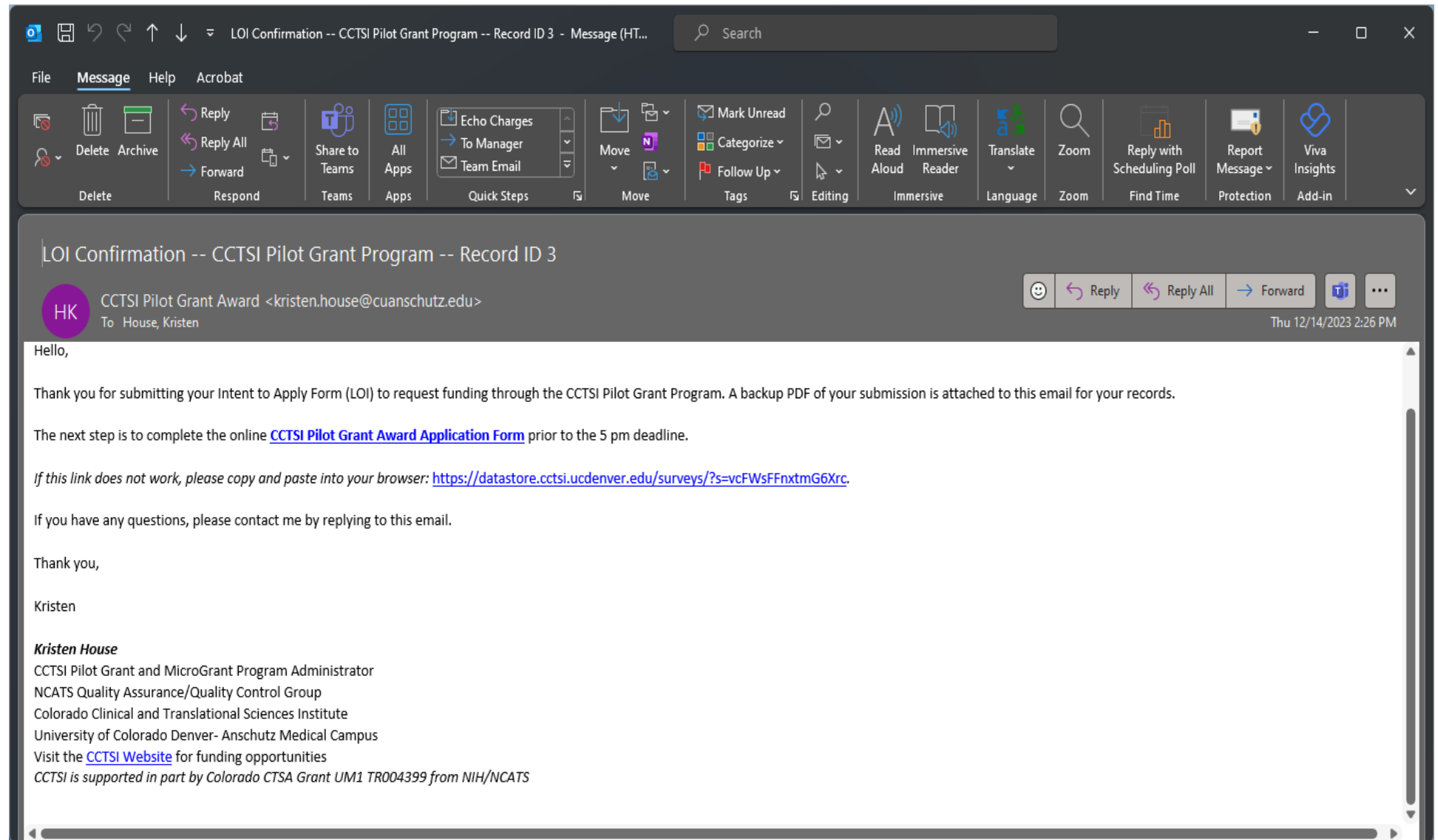
CATEGORY & ITEM(S)	Indicate Budget for Each Location					Total Amount
	CU AMC	CSU	CU Boulder	CHCO	Other Institution (Specify Location)	
Key Personnel Salary & Fringe Benefits						\$ -
Other Personnel						\$ -
Fee for Service (including Core Services)						\$ -
Supplies						\$ -
Equipment						\$ -
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 funding 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 disqualification.

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: COIMIRB Protocol 20-123 (PI Dr. Y)



2024 TM Application Cycle Dates

November 8, 2023	Request for Funding Announcement (RFA)
November 21, 2023	TM Informational Call #1 (Zoom)
December 11, 2023	TM-Pilot Intent-to-Apply Form due - 5 pm
January 3, 2024	TM Informational Call #2 (Zoom)
January 22, 2024	TM-Pilot Application Form due - 5 pm
April – 2024	CCTSI Review Panels
June – 2024	Notice of Selection
August 1, 2024	Active Funding Period Begins

2024 Key Dates

RFA Posted

November 8, 2023

Intent to Apply Form Due

December 11, 2023 at 5:00 pm MT

Informational Call #1

November 21, 2023 from 1:00 - 2:00 pm via [Zoom](#)

[CCTSI Pilot Grant Program Overview](#)

Informational Call #2

January 3, 2024 from 1:00 - 2:00 pm via [Zoom](#)

Application Due

January 22, 2024, 5:00 pm MT

Scientific Merit Review

April 2024

Start of Award

August 1, 2024

Award Expiration Date

July 31, 2025



CCTSI Pilot Grant Contacts

<https://cctsi.cuanschultz.edu/funding>

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Dr. Christopher Baker

CMH-Pilot Director

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Dr. Sue VandeWoude

CSU Pilot Program Director

sue.vandewoude@colostate.edu

