



2024 CCTSI Pilot Grant Program Overview

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CCTSI Pilot Grant Program Director

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CSU Pilot Grant Program Director

Christopher Baker, MD

CMH-Pilot Grant Program Director

Kristen House

CCTSI Pilot Grant Program Administrator







CCTSI Funding Opportunities

CCTSI awards \$2.8 million/year in pilot grants, microgrants, and pre-doctoral and post-doctoral research scholar awards

\$520K in 2024 for CCTSI Pilot Grants

Funding Sources

- National Center for Advancing Translational Science (NCATS)
- University of Colorado School of Medicine Dean's Office
- Children's Hospital Colorado Research Institute
- Traystman' Fund

https://cctsi.cuanschutz.edu/funding



CCTSI-Pilot Grant Categories

Early Career Diversity CO-Pilots

Colorado Pilots (CO-Pilots)
Child and Maternity Health (CMH)
Community Engagement (CE)
Translational Methods (TM)

Mentored CO-Pilots

Junior CO-Pilots

CU-CSU CO-Pilots

CO-Pilots Pilots

Mentored CMH-Pilots
Junior CMH-Pilots

General TM-Pilots

CSU Investigators TM-Pilots

Biostatistics/Bioinformatics TM-Pilots

TM-Pilots CE-Pilots Joint Project CE-Pilots

Partnership Development CE-Pilots





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





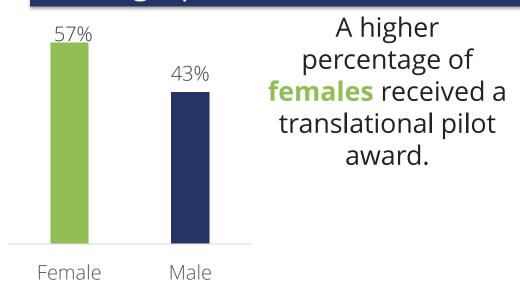
CU-Anschutz Medical Campus	Colorado State	СНСО	CU- Boulder	All other
65%	15%	11%	3%	6%

History of Applicants

Total Number of Awarded Pilots: 186



Demographics (2009 - 2022)



Of grantees who received
Translational Pilot Awards were underrepresented minorities
(URMs)





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>					





Translational Methods (TM-Pilot) Grant Program

Speed the development and application of <u>novel</u> 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



Translational Methods (TM-Pilot) Grant Program

CCTSI Pilot Grant Program: PI Eligibility by Academic Rank

These are typical rank eligibility listings for applicants from CCTSI Affiliated Institutions. If you have eligibility questions for atypical ranks, please contact the appropriate Pilot Program office.

✓= Eligible	Professor ³	Associate Professor ³	Assistant Professor ^{1,3}	Assistant Professor ^{2,3}	Instructor/ Senior Instructor ^{3,4}	Post-Doctoral Fellow/ Residents
Colorado Pilot Program (CO-P	ilot)					
Mentored				~	~	~
Junior			~	~	~	
Early-Investigator Diversity			~	~	~	
Collaboration CSU-CU	~	~	~			
Child & Maternal Health Pilot F	Program (CMH-Pi	lot)				
Mentored				~	~	~
Junior			~	~	~	
Translational Methods Pilot Pr	ogram (TM-Pilot)					
All	~	~	✓	✓	✓	
Community Engagement Pilot	Program (CE-Pil	ot)				
Joint Pilot Projects	~	~	~	~	~	
Partnership Develop. Projects	~	~	~	~	~	







¹ Later Career Assistant Professors (4-7 years of experience) typically have prior research funding

² Early Career Assistant Professors (1-3 years of experience) typically have had limited or no prior research funding

³Includes Research Scientist rank at Colorado State University

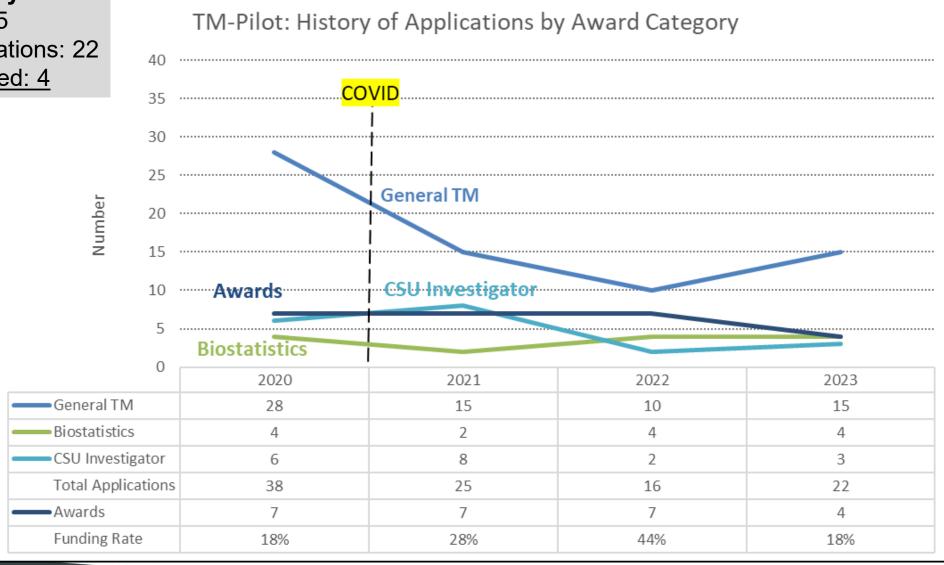
⁴Includes Research Associate

2023 Cycle:

LOI: 45

Applications: 22

Awarded: 4







Review Criteria

TM-Pilot



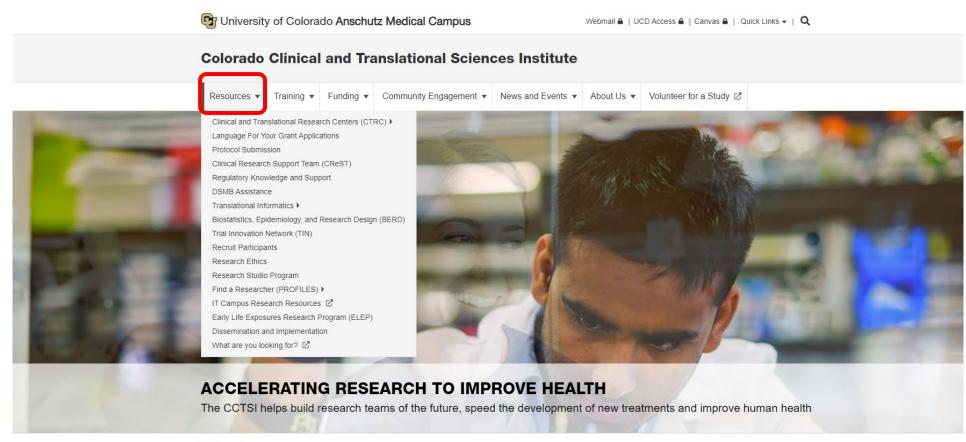
CCTSI Review Panels will use the NIH 9-point scoring system and rate based on following criteria:

- **a. Innovation** in proposed methods to be developed, approaches, and techniques.
- **b.** Approach/Scientific Merit based on rigor, transparency and <u>one-year feasibility</u> 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 <u>translational</u> <u>science roadblock</u> 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







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 trainess. We facilitate clinical and trainess. We facilitate clinical and translational research through statistical iteracy, 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.

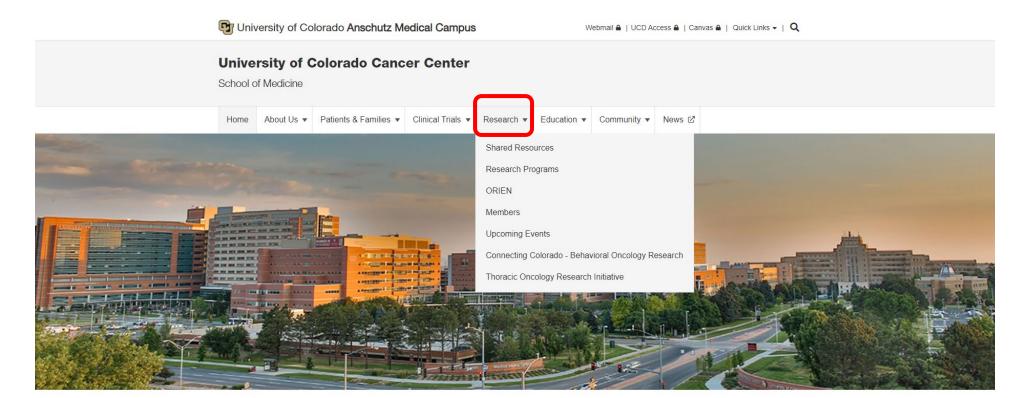
CTRC Pricing

CCTSI Research Studio Program





Colorado PROFILES



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





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

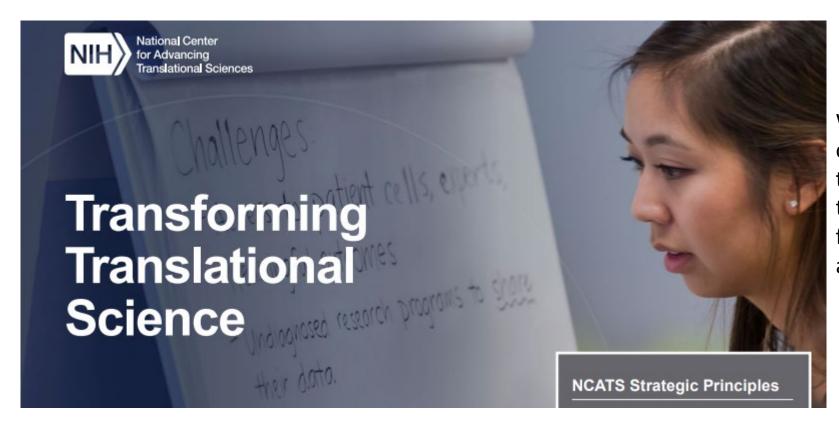


e.g., biomarker, data analysis, flow cytometry, genetic screen, proteomics

https://researchcores.cuanschutz.edu/







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 "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 carious 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, 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

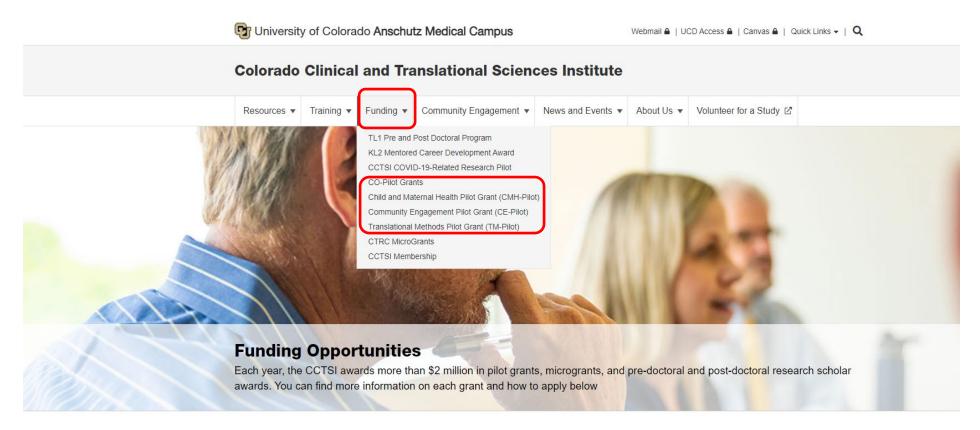
Kristen House CCTSI Pilot Program Administrator





How to Apply





https://cctsi.cuanschutz.edu/funding





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

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

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

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

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 <u>Zoom</u>

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



The TM-Pilot Request for Funding (RFA) is issued in November, applications due in January and awards are selected in May. The active funding period is September through August.



TM-Pilot Award Categories

- General Translational Methods Awards \$30,000
- Biostatistics/Bioinformatics Awards \$30,000
- . Colorado State University (CSU) Investigator Awards \$30,000

Request for Applications (RFA)

The RFA describes eligibility, award categories and application requirements.

Please check back in November 2023 for the next cycle.





2024 CCTSI TM-Pilot Grant CTS Program RFA (pdf) 292 KB

Intent to Apply Form ☑

Deadline: December 11, 2023 at 5:00 PM MT

Information & Resources





2024 CCTSI Pilot Grant Applicant Checklist (XISX)

Download (19 KB)



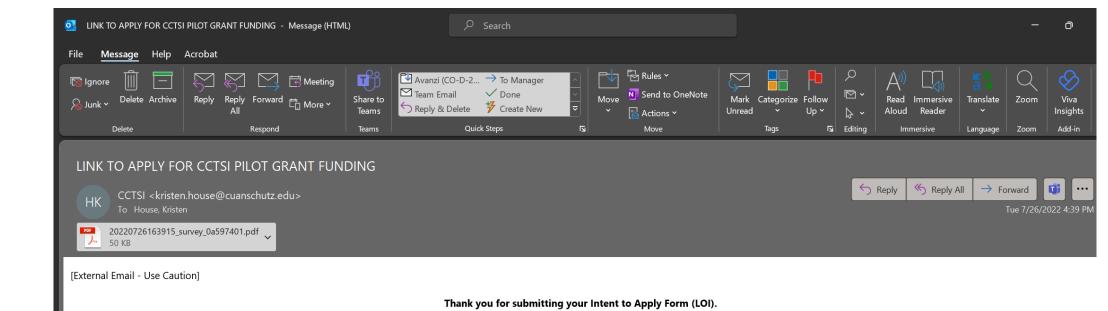
2024 CCTSI Pilot Grant Applicant Checklist (pdf)





Save this email!





SAVE THIS REUSABLE LINK TO YOUR APPLICATION FORM:

CCTSI Pilot Grant Award Application Form

Or copy and paste this link into your browser: https://datastore.cctsi.ucdenver.edu/surveys/?s=pXiVZ7HvpquMaaJx

If you require assistance, please contact kristen.house@cuanschutz.edu.

You may now close this tab/browser.





CCTSI Pilot Grant Award Budget

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

- Daaget and House							
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						\$ -	
Other Personnel						\$ -	
Fee for Service (including Core Services)						\$ -	
Supplies						\$ -	
Equipment							
						\$ -	
Animals							

Applicants
should
customize
these
Categories



	APPLICATION CH	HECKLIST					
	This checklist is for informational purposes only. All applicants must comply with the requirement	nts of the official R	equest for Fundin	g Appliactions (RFA) posted on the C	CTSI website.	
Int	ent 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)





20								
21 /	Αр	plication Form						
2			All Applicants	Mentored	Junior	CU-CSU Award	TM-Pilot	CSU Faculty
	1	Confirm all contact information from LOI is accurate. Combine all documentation required in	Did					
3		the RFA and combine into a single PDF to upload with you online Application Form.	Required					
	2	Project Overview (2-3 sentences)	Danisha d					
4		List all investigator names, titles, institutions before the Project Overview	Required					
5	3	Abstract (strict 250 word limit)	Required					
6	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	Did					
7		translational science roadblock	Required					
	6	Approach (3 page limits), including Experimental Design, Translational Science Roadblock,	Doguirod					
8		Data and Statistical Analysis, Feasibility, Shared Resources, Timeline	Required					
9	7	References (no page limit)	Required					
0	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				
1		single PDF.						
_		Career Development Plan (1 page)		Required				
1	11	Letters of Support (no page limit)						
		May include department chairs, consultants, foundations, commercial sources,	Optional					
3		manufacturers, etc.						
1		Budget (1 page limit, vertical alignment only)	Required					
4		Please use the CCTSI Budget Template (available on the CCTSI website)	Nequired					
_		Budget Justification (1 page limit)	Required					
_	_	Biosketches (no page limit)	Required					
1		CSU OSP Proposal Transmission Letter (no page limit)				Required		Required
7	_	Contact Jessica Hunter (jessica.hunter@colostate.edu) for details.				neganea		nequired
1		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					
1		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						
9		funded) seed grant programs.						

Application Checklist (Excel) or (PDF)





2024 TM Application Cycle Dates 2024 Key Dates

November 8, 2023

Request for Funding Announcement (RFA)

November 21, 2023

December 11, 2023

January 3, 2024

January 22, 2024

April – 2024

June – 2024

August 1, 2024

TM Informational Call #1 (Zoom)

TM-Pilot Intent-to-Apply Form due - 5 pm

TM Informational Call #2 (Zoom)

TM-Pilot Application Form due - 5 pm

CCTSI Review Panels

Notice of Selection

Active Funding Period Begins

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