

#### Colorado Clinical & Translational Sciences Institute



## 2025 CCTSI Pilot Grant Program Overview



Christopher Baker, MD
CMH-Pilot Grant Program Director



**Matt Hickey, Ph.D**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

Denver Health

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/partnering-institutions

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





## 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**.





# What is new in 2025 Pilot Grant Cycle?

- We are in the new NCATS UM1 Cycle (2023-2029)
- 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 2025 award cycle (all projects must be completed by 7/31/2026)



## **2025 Pilot Grant Cycle Timeline**

	CO-Pilots	CMH-Pilots	TM-Pilots
RFA Announcement	11/4/2024	11/4/2024	11/11/2024
Informational Call #1	11/13/2024	11/13/2024	11/18/2024
Letter of Intent Due	12/9/2024	12/9/2024	12/16/2024
Informational Call #2	12/18/2024	12/18/2024	01/06/2025
Application Due Date	01/13/2025	01/13/2025	01/21/2025
2024 Award Cycle	08/01/2025 - 07/31/2026		





## 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



### **Review Criteria**

#### TM-Pilot

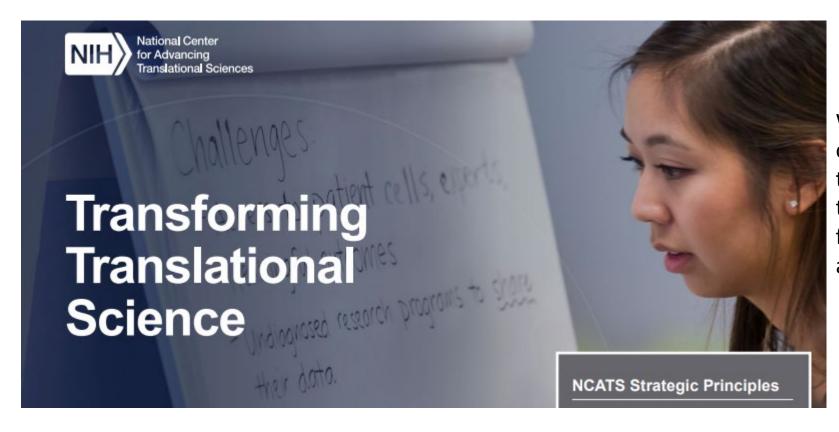


CCTSI Review Panels will use the NIH 9-point scoring system and rate based on following criteria:

- **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)







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 "<a href="translational">translational</a> 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
- 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
- Validating natural animal models of human disease in companion animal

#### Spanning the Full Spectrum of Translation

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



Translation Science Examples (PDF)





#### **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.







### Tips for Success

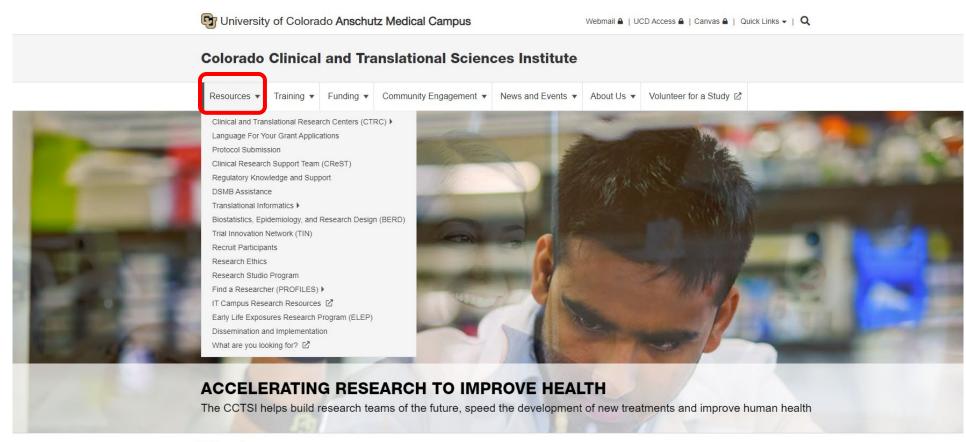
#### Please make sure that your application includes all scientific sections:

- ABSTRACT: strict 250 words
  - State clearly the scientific problem, your working hypothesis, the proposed methods, and the expected results.
- SPECIFIC AIMS:
  - 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:
  - here, you can include also your preliminary data (not required)
  - Clearly describes your translational science roadblock
- Approach:
  - 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







Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

https://cctsi.cuanschutz.edu/resources









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#### 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 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.

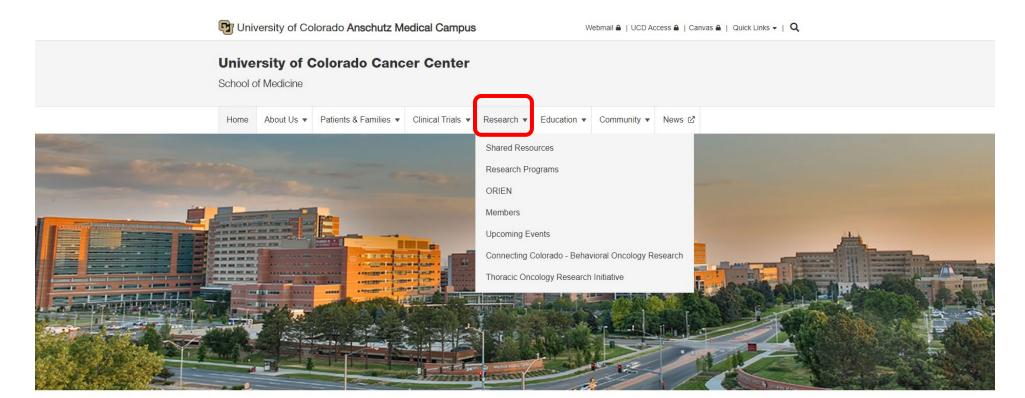
**CTRC Pricing** 

**CCTSI Research Studio Program** 

**Q** 



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







## **Application Process**

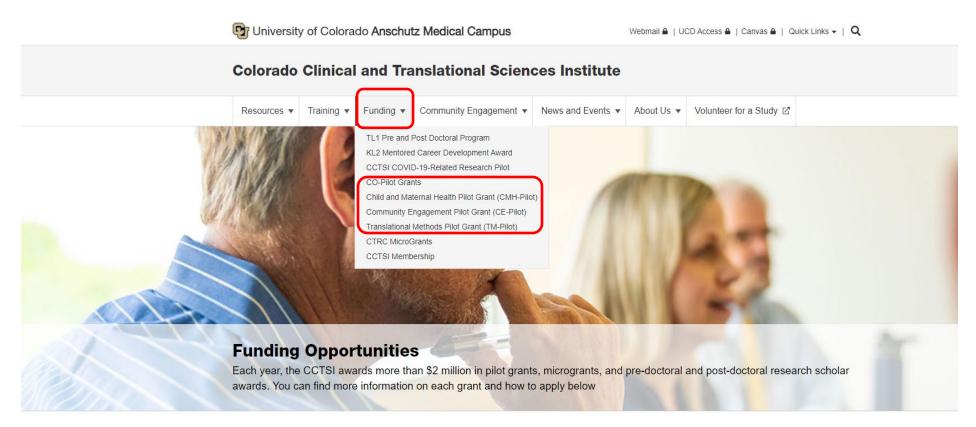
Kristen House CCTSI Pilot Program Administrator





### **How to Apply**





https://cctsi.cuanschutz.edu/funding





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



#### Information & Resources



PDF Download (122 KB)



xLsx Download (19 KB)

2025 Required Budget Template (xlsx)

XLSX Download (18 KB)

2025 Required Budget Template (pdf)

PDF Download (123 KB)

Sample Budget and Justification (pdf)

PDF Download (263 KB)

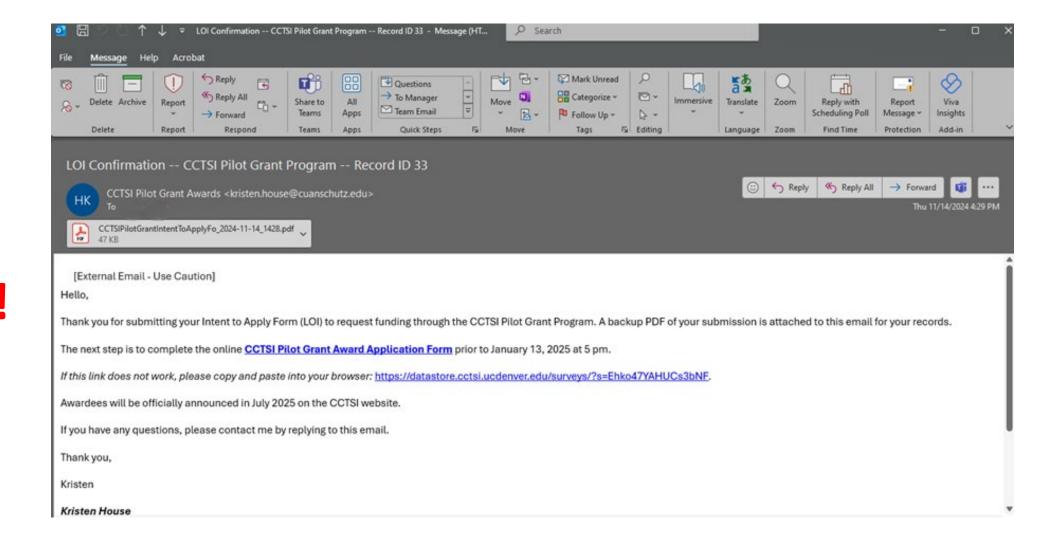
2025 PI Eligibility by Academic Rank (pdf)

PDF Download (286 KB)





# Save this email!







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

Budget and Active Award Period: August 1, 2025 to July 31, 2026 Indicate Budget for Each Location **CATEGORY** Other Total Institution CSU CU Boulder CHCO Amount CU AMC ITEM(S) (Specify Location) **Key Personnel Salary & Fringe Benefits** \$ \$ Other Personnel \$ Fee for Service (including Core Services) Supplies \$ \$ Equipment \$ Animals Participant Incentives \$ Meetings & Travel (Costs are permitted for attendance at one scientific conference) \$ Ś \$ \$ \$

Unallowable expenses include but may not be limited to: publication 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 costs (unless specifically required to carry out the investigations in the proposed project).

should customize these Categories

**Applicants** 







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





•	plication Form	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	All Applicants	Memoreu	Julioi	CO COO AWara	111111101	CSO rucuity
-	the RFA and combine into a single PDF to upload with you online Application Form. Refer to	Required					
	RFA for specific formating guidelines.	Required					
2	Project Overview (2-3 sentences)						
_	List all investigator names, titles, institutions before the Project Overview	Required					
3		Described					
	Abstract (strict 250 word limit)	Required					
4	Specific Aims, including a Translational Science Roadblock	Required					
5	<b>Background, Significance and Innovation</b> , including the description of the translational science roadblock	Required					
6	Approach, including Experimental Design, Translational Science Roadblock, Data and	Required					
	Statistical Analysis, Feasibility, Shared Resources, Timeline	Required					
7	References (no page limit)	Required					
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				
	single PDF.						
10	Career Development Plan (1 page)		Required				
11	Letters of Support (no page limit)						
	May include department chairs, consultants, foundations, commercial sources,	Optional					
	manufacturers, etc.						
12	Budget (1 page limit, vertical alignment only)	Dii					
	Please use the CCTSI Budget Template (available on the CCTSI website)	Required					
13	Budget Justification	Required					
14	Biosketches (no page limit)	Required					
15	CSU OSP Proposal Transmission Letter (no page limit)				Description		Did
	Contact Jessica Hunter (jessica.hunter@colostate.edu) for details.				Required		Required
16	Cost Share Budget (1 page limit)	See RFA, Check					
	Applications may include collaboration with non-CCTSI Affiliated organizations. Refer to RFA	with Kristen					
	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	Ob a also with					
	sponsored programs office at their institution to meet all pre-application requirements	Check with institution					
	specific to their organization, including applications for federal and non-federal (internally						
	funded) seed grant programs						

Application Checklist (Excel)





## Tips for Success

#### DEADLINE:

- Applications are due on <u>January 21, 2025</u> at 5pm MST
- No late applications will be accepted

#### FORMAT:

- Arial 11 pt font, single-spaced, with ½ inch margins, no headers/footers
- Maximum of **8 pages** 
  - Including cover page, specific aims, background and significance, approach, budget template (1 page), and budget justification (1 page)
  - Excluding references, letters of support, Biosketches, and any institutional approvals

If formatting is not followed or the proposal exceeds the page limit, the application will be administratively withdrawn





### **CCTSI Pilot Grant Contacts**

https://cctsi.cuanschutz.edu/funding

#### Kristen House

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