



UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

CCTSI Pragmatic EHR-Embedded Trials (PEET)
2026 Award Cycle for PEET Request for Applications (RFA)

I. Funding Opportunity Summary

The Colorado Clinical and Translational Sciences Institute's (CCTSI) Pragmatic EHR-Embedded Trials (PEET) Program is pleased to announce a new funding opportunity for 2026. The PEET Program will fund one two-year award to conduct a pilot pragmatic, electronic health record (EHR)-embedded clinical trial. In brief, pragmatic trials are conducted in real-world settings leveraging existing clinical processes, workflows, and personnel for recruitment and intervention delivery, focus on outcomes that matter to patients and communities, have broad eligibility criteria and flexibility in delivery and adherence to interventions, and typically use "intent to treat" principles. See details here: CCTSI Pragmatic Research Resources. The PEET program funds pilot trials that are: (1) pragmatic clinical trials of interventions expected to impact patient health outcomes, with patient health outcomes assessed as either primary or secondary outcome measures; (2) conducted within UCHealth; (3) involve one or more Epic EHR integration features. EHR integration features of interest include cohort identification, recruitment, e-consent, randomization/group assignment, intervention delivery, accrual tracking, and/or outcomes assessment via the Epic EHR or affiliated databases such as Health Data Compass; and (4) are not currently funded or underway.

Research that is not directly or indirectly related to human health or does not meet the above criteria will be considered non-responsive. Applications from across the clinical and translational research spectrum (T2-T3-T4) and proposals integrating dissemination and implementation science methods are encouraged. Proposals demonstrating previous work to engage community members and clinical partners in research planning will be prioritized.

Resubmission of unfunded applications from prior years is encouraged if the applicant addresses comments from reviewers. However, all applications will be reviewed as new proposals.

Eligibility: Contact Principal investigators (PI) must be Associate or Full Professors with an established track record of obtaining research funding awards as a PI. There can be up to two multiple PIs (MPI), which includes the contact PI; MPIs must be at least at the Assistant Professor level.

II. Key Information

Award Duration: 2 Years

Award Period: August 2026 – July 2028

Contacts:

Sarah Kautz, PhD

PEET Grant Program Coordinator

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Neil Aggarwal, MD, MHSc PEET Program Co-Lead

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III. Important Dates

11/17/2025	RFA release
12/10/2025	Pre-application informational call #1 – 8:30 am (MT) via Zoom
12/16/2025	Mandatory intent to apply form submission deadline at 11:59 pm (MT)
12/19/2025	Invitation to submit full proposal
01/12/2026	Pre-application informational call #2 - 2:00 pm (MT) via Zoom
02/09/2026	Application form submission deadline at 11:59 pm (MT)
02/10/2026	Review
Late June 2026	Notice award
08/01/2026	Grant start date

Pre-application informational calls: PEET will host two optional pre-application informational calls. Questions relating to the research focus, potential new collaborations, obtaining PEET program support, and the application process will be addressed during the calls. Details about these zoom calls are located on the CCTSI Pragmatic Research Resources. Each call includes a presentation about the program, application and review criteria, definitions of pragmatic clinical trials and EHR-embedded research, a summary of currently funded PEET projects, and an open Q&A session with the PEET program leaders.

Participation in the pre-application informational calls is encouraged but not required.

IV. PEET Program Background

PEET was initiated in 2023 and is supported by the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health, Colorado Clinical and Translational Institute (CCTSI), and the University of Colorado's School of Medicine, in partnership with UCHealth. The goal of the CCTSI's PEET program is to establish infrastructure and processes to facilitate pragmatic trials through EHR integration. Guided by the NIH's principles of accessibility and inclusivity, the PEET program aims to enhance the representation of all populations in research. PEET addresses clinical and translational science challenges by reducing the burden on participants, clinicians, and researchers in research approval and conduct. This is achieved through partnerships with health system and university research regulatory, informatics, and data science units. Community engagement in designing and implementing patient-centered materials and protocols aims to build trust and ensure representativeness in trial participation. Scientific advisory on pragmatic trial design, dissemination and implementation science, and community engagement enhances research rigor. PEET supports multiple EHR integration features, including streamlined resources for decentralized clinical trials (e.g., e-consent, portal-based patient recruitment), cohort identification, randomization, intervention delivery, trial accrual monitoring, and data collection and analysis.

To develop and refine processes for local approval and conduct of pragmatic, EHR-embedded trials, the PEET program funds pilot demonstration projects. Requests for Applications (RFAs) are made available each year for two-year pilot trials. We encourage applications from all individuals including those historically underrepresented in biomedical research.

V. Available Funding

Funding for this two-year demonstration project includes a budget of \$180,000 (\$90,000/year) in direct costs available to the project teams. The PEET Program provides additional centralized infrastructure support with a fixed value of \$120,000 in direct costs over the two-year period. This support includes Epic builders and analysts, Health Data Compass analysts, community engagement, dissemination and implementation science support, grants management and PEET team support for project coordination with UCHealth, which do not need to be listed in the itemized budget. Total support is \$300,000 in direct costs. All PEET awards are contingent upon funding made available to the CCTSI from NCATS/NIH. There is one new award per year, depending on the merit of the applications each year.

VI. Definitions

<u>CCTSI Partnering Institutions:</u> University of Colorado Denver (UCD), University of Colorado Anschutz Medical Campus (CUAMC), University of Colorado Boulder (CU Boulder), Colorado State University (CSU), University of Colorado Hospital (UCH), Children's Hospital Colorado (CHCO), National Jewish Health (NJH), Denver Health and Hospital Authority (DHHA), Kaiser Foundation Research Institute, and the Rocky Mountain Regional VA Medical Center.

<u>Key Roles:</u> Individuals who accept primary responsibility for research design and/or execution, including principal investigator, multiple principal investigator (MPI), and co-investigators. Investigators receiving salary support should be listed in a key role and be included on only one application per cycle.

<u>Non-Key Roles:</u> Individuals who may offer support for the research study (with or without salary) but who do not have responsibility for the research design and/or execution may include: research staff, lab staff, graduate students, undergraduate students, tech support, fellows, consultants and directors of institutional core facilities, and individuals offering fee-based services or supplying biobank biospecimen.

VII. Eligibility

- 1. Individuals listed in **key roles** (see VI. Definitions) must hold faculty appointments with one or more CCTSI Partnering Institutions.
 - a. Volunteer faculty positions are not eligible to apply for awards.
 - b. Graduate students, undergraduate students, and research services professionals (RSPs) are encouraged to participate in non-key roles.

- c. Investigators who are not with a <u>CCTSI Partnering Institution</u> are not eligible to be in a key role but may collaborate with an eligible CCTSI partnering investigator PI in a non-key role.
- 2. Contact Principal Investigators must be Associate or Full Professors with an established record of obtaining research funding awards as a PI. There can be up to two multiple PIs (MPI), which includes the contact PI; MPIs must be at least at the Assistant Professor level. If you have eligibility questions, please contact sarah.kautz@cuanschutz.edu.
- 3. Individuals listed in key roles must be CCTSI members at the time of application. Click to <u>check</u> your membership status or to sign up for a CCTSI membership.

VIII. Exclusions/Restrictions

The following exclusions/restrictions apply to PEET awards:

- 1. Individuals who were listed in key roles on previously funded PEET awards are not eligible to apply for additional PEET awards.
- 2. Applications proposing to continue the work of previously funded CCTSI PEET projects are not allowed. All applications should have unique and distinct specific aims from any ongoing projects by the PIs.
- 3. CCTSI PEET awards may not be used to support research conducted outside of the United States.
- 4. If you are proposing a drug or device trial, applications are restricted to Phase II. Phase III or Phase IV drug or device trials will not be supported.
- 5. All funded projects related to human fetal tissue research and human stem cell and pluripotent stem cell research must undergo review by the institutional scientific ethics committee. Please contact Dr. Alison Lakin, alison.lakin@cuanschutz.edu, to discuss the institutional review process.

IX. Application Process

There are two steps to applying for CCTSI PEET grant funding. All submissions are time-stamped upon submission. Items received after the 11:59 pm MT deadline will not be accepted. Early submission is strongly encouraged.

Step 1: Intent to Apply form

Please complete the mandatory, competitive Intent to Apply form by December 16, 2025.

The Intent to Apply form requests:

- Descriptive title of proposed research
- Principal investigator name, credentials, faculty rank, CCTSI partnering institution, and department/division
- Multiple principal investigator name, credentials, faculty rank, CCTSI partnering institution, and department/division
- A PDF document including the project title, PI name, and a concise description of the proposed project that describes the research question and an overview of the study design. Word limit: 500 words

• A checklist for PEET minimum requirements and EHR integration features, as noted below (see XII. Review Criteria).

The Intent to Apply form is <u>mandatory</u> and will be used to determine which applications will move forward to full proposals. However, the information submitted is not binding and minor changes may be made at the time of application. The "Save and Return Later" button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click "Submit."

Access the Intent to Apply Form by clicking the "Intent to Apply" button on the PEET Grant Program Webpage

Applicants will be notified if they are invited to submit a full proposal by Friday December 19th, 2025.

Step 2: Application form

Individuals invited to submit full proposals will receive a unique link to the proposal's application form via email. The "Save and Return Later" button at the bottom of the online form allows applicants to access and revise information as often as needed up until they click "Submit." Once submitted, applications are considered final and cannot be modified – no exceptions.

Access the **Application Form** using the unique link that is emailed to the PI after submitting the **Intent to Apply Form**.

IMPORTANT: While there are no restrictions on the number of Intent to Apply forms submitted, individuals in key roles (see VI. Definitions) may be listed on only <u>one</u> application. (See VIII. Exclusions/Restrictions)

If you have any questions about using the CCTSI PEET system, please contact Sarah Kautz at sarah.kautz@cuanschutz.edu.

X. Proposal Requirements

The proposal should clearly describe a two-year research project that is consistent with institutional and NIH policies. All applications are considered new proposals; revisions from prior unfunded submissions should be incorporated into the research plan. Appendices are not allowed. The format must be Arial 11pt font, single-spaced, with ½ inch margins, with page numbers included.

The following proposal documents are required to be submitted online as a combined PDF in this order. Please structure your application to follow the headings and order outlined below to ensure all sections are addressed accordingly (please use the <u>checklist</u> to ensure all sections are included):

Cover Page (1 Page): Do not include images on this page.	
□ Project Title (up to 10 words)	
□ Principal Investigator(s): Name, title, affiliation, contact information, department/divisio	n, faculty
rank, etc.	

	11 Toject Overview (2-3 sentences). Ose tay terms to describe the overall goal, anticipated outcomes,
	and how the research meets the RFA objectives.
	□ Abstract (firm 250-word limit): This concise summary of the project will be used to review your
	application, and it may be used to announce the funded award.
□ Spec	cific Aims (1/2 page): Do not include images on this page. Clearly state the specific aim(s) of the
•	research project, with 1-2 concise sentences outlining the primary objectives of each aim. Additionally,
	use bullet points to indicate any applicable clinical research areas.
□ Sign	nificance and Innovation (1 ½ page limit): Provide context for the proposed study:
	□ Significance: Describe the status and existing scientific knowledge on the research topic. Preliminary
	work (e.g., to establish need/demand, build relationships) is not required but may also be included here.
	Explain the importance of the problem and barriers to progress as well as the potential impact of your
	project. Community and patient input on significance may be reflected here.
	□ Innovation: Indicate how this project will be innovative, including at least one innovation related to
	the conduct of pragmatic, EHR-embedded trials.
□ App	roach (4-page limit): Describe the overall strategy, methodology, and analyses to be used to accomplish
each S	pecific Aim of the project within the two-year timeline.
	□ Preliminary Work: Briefly describe what work has already been completed that prepares you for this
	project. Describe any community engagement and/or clinical partner engagement you have done to
	establish buy-in and identify research priorities and patient-centered outcomes.
	□ Research Question(s) and Hypotheses: Provide at least one research question and hypotheses where
	appropriate. Development/qualitative aims do not need hypotheses.
	□ Pragmatic Trial Design: Indicate the study design and clinical trial phase, noting features consistent
	with a pragmatic trial. Generate the <u>PRECIS-2 wheel</u> as described at <u>https://precis-</u>
	2.org/Help/Documentation/HowTo and include the resulting figure in the proposal. In brief, pragmatic
	trials are conducted in real-world settings leveraging existing clinical processes, workflows, and
	personnel for recruitment and intervention delivery, focus on outcomes that matter to patients and
	communities, have broad eligibility criteria and flexibility in delivery and adherence to interventions,
	and typically use "intent to treat" principles.
	□ Setting and Population: Include which UCHealth regions, locations, and clinical settings will be
	involved in this research.
	☐ Intervention(s) and Implementation Strategy(ies): Describe the intervention(s) to be tested. Provide
	citations. If relevant (e.g., involvement of clinical staff or care team members), describe implementation
	strategies such as clinical team onboarding or training.
	□ Outcomes, Measures, Data Sources, and Data Analysis: Describe and cite any outcomes,
	frameworks, survey measures, qualitative or quantitative data sources, timing of data collection, and
	respondent/unit of analysis. Patient health outcomes must be included as either primary or secondary
	outcome measures. This information can be provided in a table. Briefly describe the statistical analysis
	plan (e.g., t-test, ANOVA, regression, justification for analytic type, etc.). Include power analysis to
	justify the sample size that is being studied. Include descriptions of qualitative and mixed methods data
	collection and analyses with citations.

	where all work cannot be completed within the two-year award period (see Timeline below) will be
	considered not feasible and non-responsive to this RFA.
	☐ Timeline: Provide a timeline showing this project will be completed within two years, including any
	regulatory processes and approvals, Epic builds (assume 3-6 months minimum), recruitment,
	intervention delivery, and follow-up. IRB approval is <u>not</u> required at the time of application. All
	proposed work MUST be completed in the two-year award period; extensions will not be granted.
	Epic EHR Integration Components: Review the EHR integration features (see XII. Review
	Criteria). Select integration features that best support study objectives. Inclusion of additional features is not inherently advantageous. Provide further explanation here concerning how you anticipate these EHR
	integration components will be accomplished. Which do you already know how to do or have in place?
	What university resources are available? Which will require new builds or additional support from the
	UCHealth Epic team or other resources?
	□ Potential for Broad UCHealth Impact: Describe how this project will be transformative for
	UCHealth, including potential impact beyond the settings in which this research will be initially conducted.
	□ Patient-Centeredness and Community Engagement: Describe preliminary work to engage patients
	and other community members in planning this research. How will this project prioritize patient-
	centeredness and community needs and perspectives?
	□ Overlap Statement: It is a strict requirement that PEET projects have no overlap with existing
	funding (either now or in the future). Please describe any POTENTIAL overlap with currently funded
	and active, enrolling trials. Explain how you will ensure that the research described in this proposal will
	not have overlapping funding or currently active trials. You may leverage products and materials from
	other funding and previously conducted work if the work for this project does not "double dip." If this
	distinction is unclear, please reach out to the PEET team for clarification.
□ Refe	erences (no page limit)
which	Project Team, and Partners (1 page limit): Provide a multiple PI plan (there can be up to two MPIs, includes the contact PI) consistent with NIH policy. Roles and administrative, technical, and scientific sibilities for the project or program should be delineated for the PIs, including responsibilities. □ Indicate who will serve as project manager, including project management experience with EHR-based studies. Briefly describe other co-investigators and team members, noting subject matter and
	methods expertise relevant to the study design. Briefly describe any relevant existing partnerships,
	including patient, community, practice or health system partners.
□ Lett	ers of Support (No page limit): Letters of support from clinical leadership are required as part of the
applica such a or other	ation. Applicants must demonstrate that they have engaged clinical partners in planning their research, is through the Clinical Executive Groups (CEGs) and Clinical Outcome Group and Governance (COGGs), or decision-making structures within partnering departments. Letters of support confirm clinical ship buy-in for the proposed project and indicate that the project aligns with clinical and departmental

□ Feasibility: Discuss potential pitfalls and alternative strategies for each specific aim. Any proposal

□ Budget (1 page limit): All applicants must use the budget template (click for Excel) Provide a two-year budget of up to \$180,000 (\$90,000/year maximum; direct costs only) for your project team. The PEET Program provides additional centralized infrastructure support with a fixed value of \$120,000 in direct costs over the two-year period. This support includes Epic builders and analysts, Health Data Compass analysts, community engagement, dissemination and implementation science support, grants management and PEET team support for project coordination with UCHealth, which do not need to be listed in the itemized budget. Qualitative methods resources are not included in this infrastructure support and can be included in your budget. Biostatistics resources can be provided by your biostatistics team or by CIDA; please include a biostatistics line item in the budget. □ All costs must be reasonable and directly related to supporting the described project. □ Items in each of the budget categories should be detailed as much as possible so that it is clear what items will be purchased and in what quantities. □ Include only direct costs in your budget proposal. Indirect costs (F&A) are assessed internally by CCTSI after projects are selected for funding. Do not include F&A in the application budget. □ Salary support commensurate with the percent effort allowed for key roles (PI, MPI, co-investigator, or in a role with salary support) and lab personnel, subject to NIH-salary cap restrictions. Principal investigators must include salary support at a minimum of 0.10 total FTE across MPIs (there can be up to two MPIs, which includes the contact PI). Include support for a project manager (recommended minimum of 0.30 FTE/year). □ Unallowable expenses include but may not be limited to: indirect costs, international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, professional dues/fees/membership, costs that support future grant applications, train
□ Budget Justification (no page limit): Clearly define two-year project expenses that are consistent with NIH policy and directly related to funding activities of the proposed project, including: personnel, supplies, core fees, lab testing, human participants, etc. Whenever possible, items in each of the budget categories should be detailed as much as possible so that it is clear what items will be purchased, what quantities, and at what unit prices. Personnel costs should be itemized for each individual and include their annual salary, the FTE provided to the project and the subsequent salary support and related fringe benefits being requested. Any consultant expenses should document the rate to be paid and the expected number of hours of consultant time.
□ Biosketches (5-page limit per person listed as key personnel): A Biosketch in current NIH format is required for all individuals listed in key roles (PI, MPI, co-investigator, or in a role with salary support).
□ Institutional Prior Approval (no page limit): Applicants are strongly encouraged to work with the sponsored programs 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.

XI. Review Process

Recruited and volunteer reviewers with appropriate expertise will evaluate eligible applications with a specific emphasis on research that furthers the CCTSI mission. Applicants may request specific individuals with expertise in their specific proposed research specialty and who do not have a conflict of interest to review applications during the application process. All review panel study sections are chaired by CCTSI PEET Program Co-Leads, and funding recommendations are presented to the CCTSI Steering Committee for approval. All Executive Committee decisions will be final. Short informative critiques of application strengths and weaknesses will be provided to all applicants after awards have been officially announced.

XII. Review Criteria

The PEET review panel will use the following criteria to evaluate proposed projects to see if they meet <u>Demonstration Project minimum requirements</u>:

- 1. Meets the definition of a pragmatic-EHR embedded trial
- 2. Pragmatic clinical trial of interventions that are expected to impact patient health outcomes, with patient health outcomes assessed as either primary or secondary outcome measures
- 3. Not currently funded or underway
- 4. Conducted within UCHealth
- 5. Likely to be completed within two years of funding

The PEET review panel will evaluate the integration of EHR features to support study objectives, including:

- 1. Cohort identification
- 2. Recruitment
- 3. E-consent
- 4. Randomization/group assignment
- 5. Intervention delivery (including connection to external tools/resources)
- 6. Real-time trial data dashboards
- 7. Final data collection based on data commonly available in the EHR
- 8. Patient/participant-reported outcomes
- 9. Other (please specify)

The PEET review panel will use the NIH 9-point scoring system and rate based on the following criteria:

- 1. Significance and Innovation (builds upon the existing evidence in an innovative way; enables innovative approaches and/or infrastructure for the PEET Program)
- 2. Rigor and Feasibility (study design, methods, measures, data collection, and analysis are likely to lead to valid and generalizable conclusions; includes UCHealth EHR integration feasibility considerations, including letters of support from clinical and community members)
- 3. Expertise and Resources (investigator(s) have demonstrated background, training, and expertise, an appropriate for their career stage, to conduct the proposed work; institutional resources are appropriate to ensure the successful execution of proposed work (evaluated as appropriate, gaps identified, or gaps identified and require explanation))

The PEET review panel will use the following additional criteria to evaluate proposed projects:

1. Broad reach/potential for impact across UCHealth regions

- 2. Ease of cohort identification
- 3. Experienced/engaged principal investigator(s) and project manager (both of whom can commit substantive effort to the project)

XIII. Questions and Resources

Please refer to the <u>PEET grant program webpage</u> for information regarding RFA, frequently asked questions, informational calls, CCTSI and core resources, and past award information.