Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

CCTSI Pragmatic EHR-Embedded Trials (PEET)
2025 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 2025. The PEET Program will fund one 2-year award to conduct a pilot pragmatic, electronic health record (EHR)-embedded clinical trial (see definitions here: Pragmatic Research Resources | CCTSI). The program is intended to fund projects that have the following features: (1) phase 2 pragmatic clinical trial of any patient-level treatment or intervention; (2) enrolls UCHealth patients; (3) the trial is to be implemented supported by the UCHealth Epic EHR. Trials are encouraged to reflect multiple trial EHR integration features (cohort identification, recruitment, e-consent, randomization/group assignment, intervention delivery, accrual tracking, and/or outcomes assessment); (4) 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 and that address health disparities will be prioritized. Note, that 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: Principal Investigators must be Associate Professors or above with at least one R01-equivalent research award. Multiple Principal Investigators (MPIs) may be included; MPIs can be later-stage Assistant Professors (3+ years at rank) or above.

II. Key Information

Award Duration: 2 Years
Award Period: August 2025 – July 2027

Contacts:

Sarah Kautz, PhD
PEET Grant Program Coordinator
sarah.kautz@cuanschutz.edu

Bethany Kwan, PhD, MSPH
PEET Program Co-Lead, D&I Research Core Lead
bethany.kwan@cuanschutz.edu

Adit Ginde, MD, MPH
PEET Program Co-Lead
Adit.ginde@cuanschutz.edu

III. Important Dates

11/18/2024	RFA Release
12/02/2024	Pre-Application Informational Call #1 – 3:00 pm (MST) via Zoom
12/17/2024	**Mandatory Intent to Apply Form Submission Deadline at 5:00 pm (MST)**
01/10/2025	Pre-Application Informational Call #2 - 10:00 am (MST) via Zoom
01/31/2025	**Application Form Submission Deadline at 5:00 pm (MST)**
04/07/2025	Review
Late May 2025	Notice Award
08/01/2025	Grant Start Date

Pre-Application Informational Calls: Specific questions not addressed in the RFA may be asked during the pre-application conference calls. All questions, including those related to the research focus, potential new collaborations, obtaining PEET program support, and the application process will be addressed during the calls. Details and Zoom links are located on the CCTSI Pragmatic Research Resources webpage. 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 procedures to facilitate pragmatic trials through EHR integration. Guided by health equity principles of accessibility, diversity, 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 while addressing issues of health equity. 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. In keeping with the CCTSI commitment to diversity, equity, inclusion and social justice in

clinical and translational research and the NIH Policy on Diversity, we encourage applications from individuals who historically been underrepresented in biomedical research.

V. Available Funding

PEET demonstration projects are 2-year awards up to $300,000 in direct costs, including $120,000 ($60,000/year) for PEET central infrastructure support and $180,000 ($90,000/year) in funds directly available to the project team. 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

CCTSI Partnered Institutions: 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.

Key Roles: Individuals who accept primary responsibility for research design and/or execution, including Principal Investigator, Multiple Principal Investigator, and co-Investigators. Investigators receiving salary support should be listed in a Key Role and be included on only one Application Form per cycle.

Non-Key Roles: 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 Services Professionals (with or without salary), 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 Definitions) must hold full-time faculty appointments with one or more CCTSI affiliated 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 CCTSI Partnered Institution are not eligible to be in a Key Role but may collaborate with an eligible CCTSI affiliate investigator PI in a Non-Key Role.
2. Principal Investigators must be Associate Professors or above with at least one R01-equivalent research award. Multiple Principal Investigators (MPIs) may be included; MPIs can be later-stage Assistant Professors (3+ years at rank) or above. 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 check your membership status or to sign up for a CCTSI membership.

VIII. Exclusions/Restrictions

The following exclusions/restrictions apply to PEET Awards:

1. Key Role individuals 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 innovative specific aims distinctive 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. Any clinical trial proposed in the CCTSI PEET Grant applications is restricted to Phase II or the equivalent. 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 5:00 pm MST deadline will not be accepted. Early submission is strongly encouraged.

Step 1: Intent to Apply Form
Please complete the mandatory Intent to Apply form by December 17, 2024.

The Intent to Apply form requests:

- Descriptive Title of Proposed Research
- Principal Investigator Name, Credentials, Faculty Rank, CCTSI Partner Institution, and Department/Division
- Multiple Principal Investigator Name, Credentials, Faculty Rank, CCTSI Partner 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: 300 words
- A checklist for PEET minimum requirements and EHR integration features, as noted below (See Section XII Review Criteria).

This online form collects minimal information about the proposal for review planning and takes 10-20 minutes to complete. While submission of the Intent to Apply Form is mandatory, the information collected 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

Step 2: Application Form

Individuals who submit the mandatory Intent to Apply Form will immediately 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 Definitions) may be listed on only one Application Form. (See 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, and no headers/footers.

The following proposal documents are required to be submitted online as a combined PDF in this order (please use the checklist 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/division, faculty rank, etc.
- □ **Project Overview (2-3 sentences):** Use lay 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.

□ **Specific Aims (1/2 page):** Do not include images on this page. Provide 2-3 concise sentences with a bullet point list, including specific aims being tested in the research, as well as indicating any applicable clinical research areas.

□ **Significance 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 data are not required but may 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.

□ **Approach (4-page limit):** Describe the overall strategy, methodology, and analyses to be used to accomplish each Specific 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 PRECIS-2 wheel as described at https://precis-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 mention of 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. This information can be provided in a table. Briefly describe the data 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 analyses with citations.

□ **Feasibility:** Discuss potential pitfalls and alternative strategies for each Specific Aim. Any proposal 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 2 years, including any regulatory processes and approvals, Epic builds (assume 3-6 months minimum), recruitment, intervention delivery, and follow-up. IRB approval is not required at the time of application. All proposed work MUST be completed in the two-year award period; no-cost extensions will **not** be granted.

□ **Epic EHR Integration Components:** Complete the EHR integration checklist. 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 Impact and Equity Considerations:** Describe how this project will be transformative for UCHealth, including potential impact beyond the settings in which this research will be initially conducted. Describe at least two ways in which this project would address health equity in Colorado.

□ **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 POTENTIALLY overlapping funding or currently active, enrolling trials. Explain how you will ensure that the research described in this concept paper 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.

□ **References (no page limit)**

□ **PI, Project Team, and Partners (1 page limit):** Provide a Multiple PI Plan (up to two) consistent with NIH policy. Roles and administrative, technical, and scientific responsibilities 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-investigator 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.

□ **Letters of Support (No page limit)**

□ Letters of support from clinical departments are also encouraged.

□ **Budget (1 page limit):** All applicants must use the Budget Template (click for Excel)
Provide a 2-year budget of up to $180,000 ($90,000/year maximum; direct costs only). Projects will also receive an additional $60,000/year of support from the CCTSI PEET centralized infrastructure including 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. Please provide a budget for the remaining $180,000 ($90,000/year maximum). Biostatistics resources can be provided by your biostatistics team or by CIDA; please include a biostatistics line item in the budget). Qualitative methods resources are not included and can be included 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, Multiple PI, co-Investigator, or in a role with salary support) and lab personnel, subject to NIH-salary cap restrictions.

Principal Investigators can include salary support at no more than 0.10 FTE total; if more than 1 PI, this effort is combined/shared (e.g., 0.05 FTE each). Include support for a project manager (recommended .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, training costs (unless specifically required to carry out the investigations in the proposed project).

□ The categories of expenses on the budget template should be edited as necessary.

□ Funds must be expended by 7/31/2027; any funds remaining in the project budget after that date will be forfeited.

□ **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 (see NOT-OD-21-073) and current NIH template) and 5-page limit 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

CCTSI PEET Review Panel will use the following criteria to evaluate proposed projects to see if they meet Demonstration Project minimum requirements:

1. Meets the definition of a pragmatic-EHR embedded trial
2. Patient-level treatment/intervention

3. Phase 2 clinical trial or equivalent
4. Not currently funded or underway
5. UCHealth population
6. Likely to be completed within 2 years of funding

CCTSI PEET Review Panel will use the following criteria to evaluate proposed projects to evaluate consideration of EHR Integration features:

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

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

1. Innovation/Intervention/Implementation (builds upon the existing evidence in an innovative way; enables innovative approaches and/or infrastructure for the PEET Program)
2. Rigor (study design, methods, measures, data collection, and analysis are likely to lead to valid and generalizable conclusions)
3. Impact (important topic, addresses a significant problem, addresses health equity, will directly inform clinical practice, leverages an effective intervention or approach)

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 and project manager (who can commit substantive effort to the project)

XIII. Questions and Resources

Please refer to the PEET Grant Program webpage for information regarding RFA, Frequently Asked Questions, Informational Calls, CCTSI and Core Resources, and Past Award Information.