

2025 CCTSI

PEET Grant Program

Overview

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cctsi.cuanschutz.edu



Colorado Clinical and Translational
Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS



CCTSI Element E: PEET

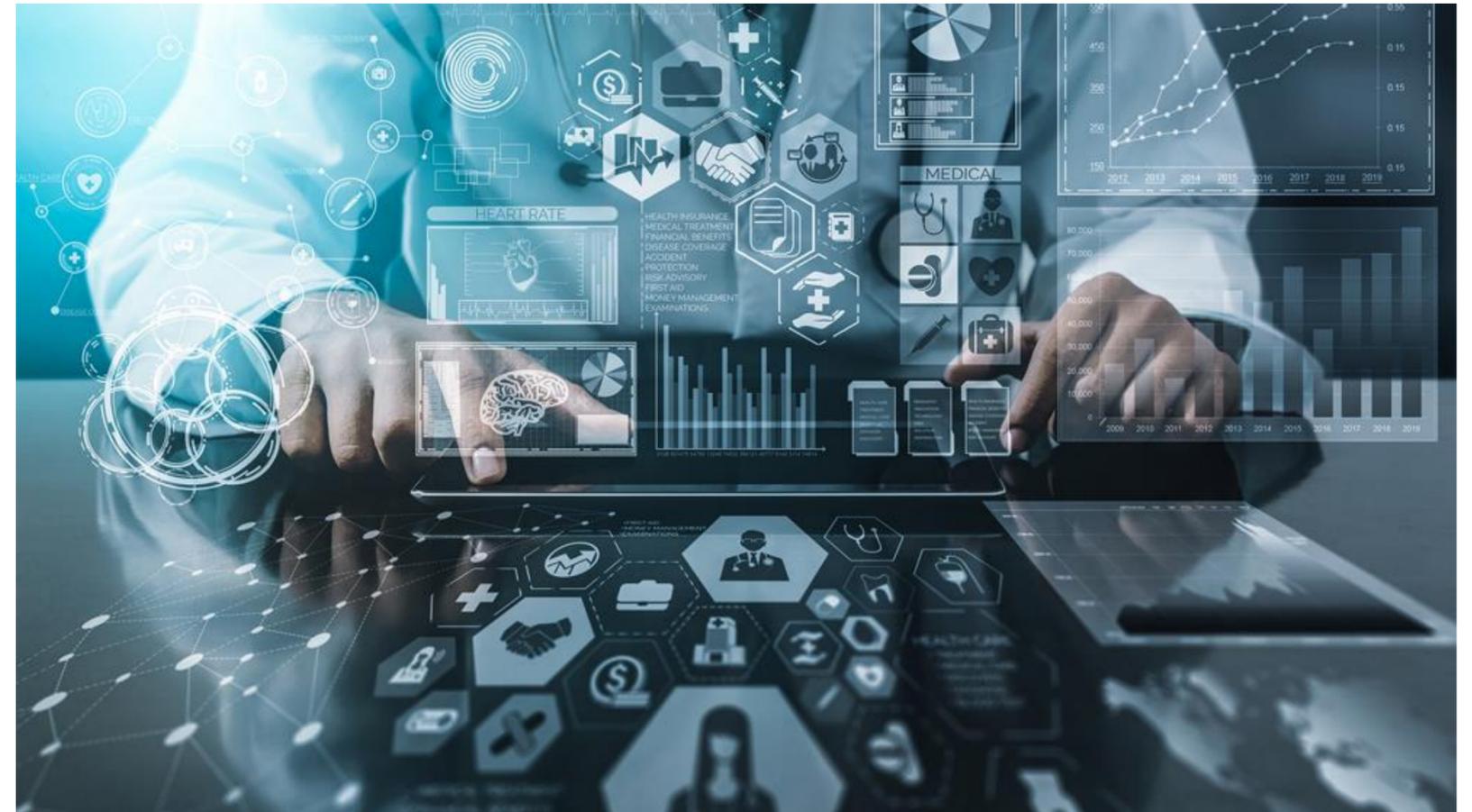
Pragmatic EHR-Embedded Trials (PEET)

2023-2030



Colorado Clinical and Translational
Sciences Institute (CCTSI)

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



Pragmatic Trials

Pragmatic Clinical Trials

Large-scale trials conducted in routine clinical care settings, involving:

- Interventions delivered by existed health care personnel through usual processes and systems of care
- Evaluations of outcomes using data collected as part of routine care

Weinfurt KP, Hernandez AF, Coronado GD, et al. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. BMC medical research methodology. 2017 Dec;17:1-0.

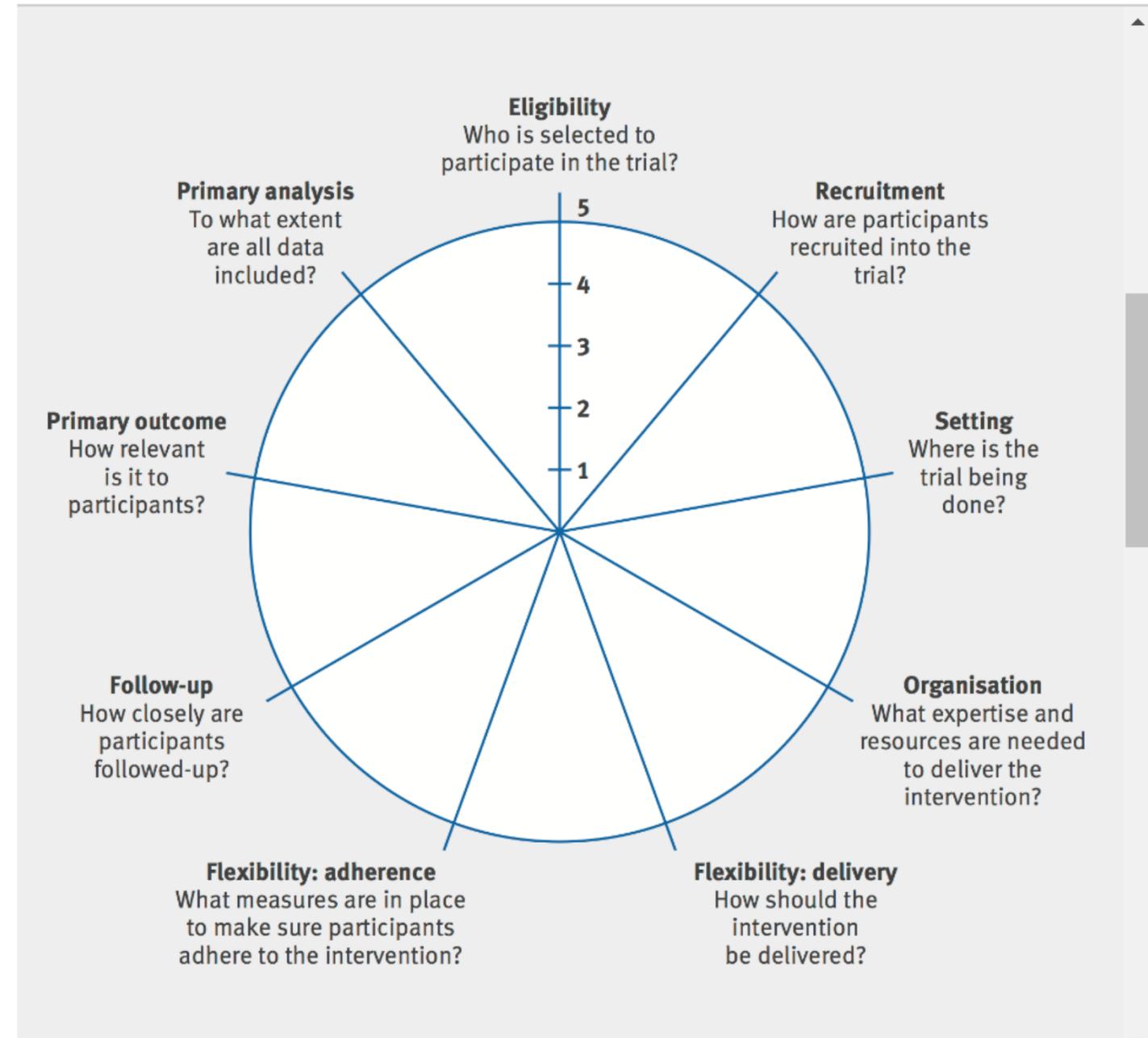


Figure: The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

Adapted from [BMJ 2015;350:h2147](https://doi.org/10.1136/bmj-2015-027032)

<https://precis-2.org/>



EHR-Embedded Trials

EHR-Embedded Trials

Use of EHR systems to conduct pragmatic clinical trials to facilitate:

- Identifying patient participants/cohorts and/or clinical phenotypes
- E-consent and participant communication
- Randomization, assignment, and delivery of interventions
- Assessment of outcomes/safety (including patient-reported outcomes and free text/narrative)
- Real-time tracking of accrual, trial data, diversity, and representativeness



PEET Goals

PEET Program Goals

1

Build

...the PEET Research Program infrastructure and governance needed for prioritization and support of proposed pragmatic EHR-embedded clinical trials in the UHealth system.

2

Engage

...partners in co-design of user guidance materials and protocols for implementation and use PEET infrastructure, including patient and clinician engagement processes.

3

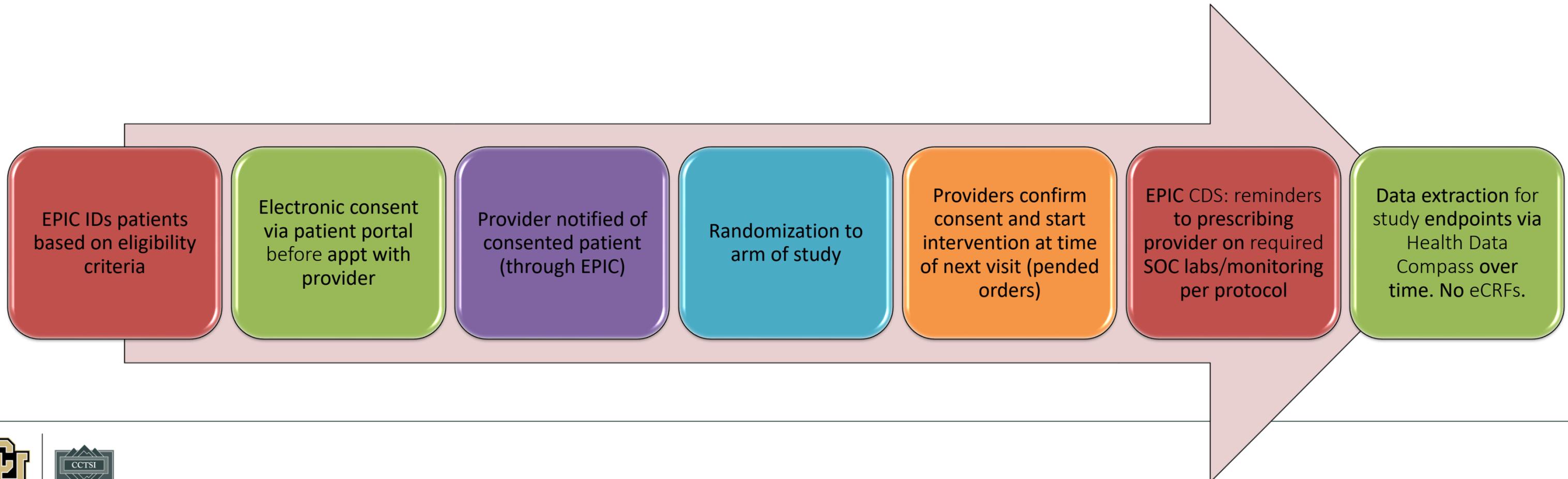
Conduct

...pragmatic EHR-embedded clinical trials and use lessons learned to inform procedures for other EHR-embedded trials, with funding for up to 2 ongoing demonstration projects per year.



PEET Demonstration Projects

PEET Demonstration Project #1 (2023-2025): A Randomized, Pragmatic, Adaptive Trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients (PragMet) (Principal Investigator: Thomas Flaig, MD)



PEET Demonstration Projects

PEET Demonstration Project #2 (2024-2026):

Optimizing Care in Critically ill at UCHealth by Liberalizing the Target O2 in mechanically-ventilated ICU patients (OCCULT O2) (Principal Investigators: Neil Aggarwal, MD and Peter Sottile, MD)



Two phase study:

Phase 1: Implement an EHR (Epic) orderset with a higher oxygen saturation target range (SpO2 90-96%) in a randomized order and evaluate outcomes including occult hypoxemia (OH).

Phase 2: Assess effectiveness of an EHR-based clinical decision support tool for OH detection and mitigation.





CCTSI PEET Grant Award Eligibility

- CCTSI Members
- Experienced Principal Investigator (Associate Professors or above at least one R01-equivalent research award) or experienced Principal Investigators paired with later stage Assistant Professors (who have 3+ years of experience and have prior research funding)
- **Underrepresented, female, and minority researchers** are particularly urged to apply

Partnering Institutions

- CU Anschutz Medical Campus
- CU Boulder
- CU Denver
- Colorado State University
- University of Colorado Hospital
- Children's Hospital Colorado
- VA Eastern CO Health Care System
- Kaiser Permanente Colorado

<https://cctsi.cuanschutz.edu/aboutus/partnering-institutions>

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



Exclusions/Restrictions

- Key Role individuals currently funded on an active CCTSI-PEET award are not allowed to apply for new cycle on CCTSI-PEET awards.
- 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.
- CCTSI PEET Awards may not be used to support research conducted outside of the United States.
- Any clinical trials proposed in the CCTSI PEET Grant applications are restricted to Phase I through Phase II or the equivalent. Phase III or Phase IV drug or device trials will not be supported.

2025 PEET Grant Cycle Timeline

	PEET GRANT
RFA Announcement	11/18/2024
Informational Call #1	12/02/2024 at 3:00pm MST
Letter of Intent Due	12/17/2024 by 5:00pm MST
Informational Call #2	01/10/2025 at 10:00am MST
Application Due Date	01/31/2025 by 5:00pm MST
Review	04/07/2025
Notice of Award	Mid to Late May 2025
2025 Award Cycle	08/01/2025-07/31/2027





PEET Grant Program

Budget:

\$300k (\$150k per year) in total budget (study team and PEET team resources)

\$180k (\$90k per year) allocable to the study team

Duration: 2 years

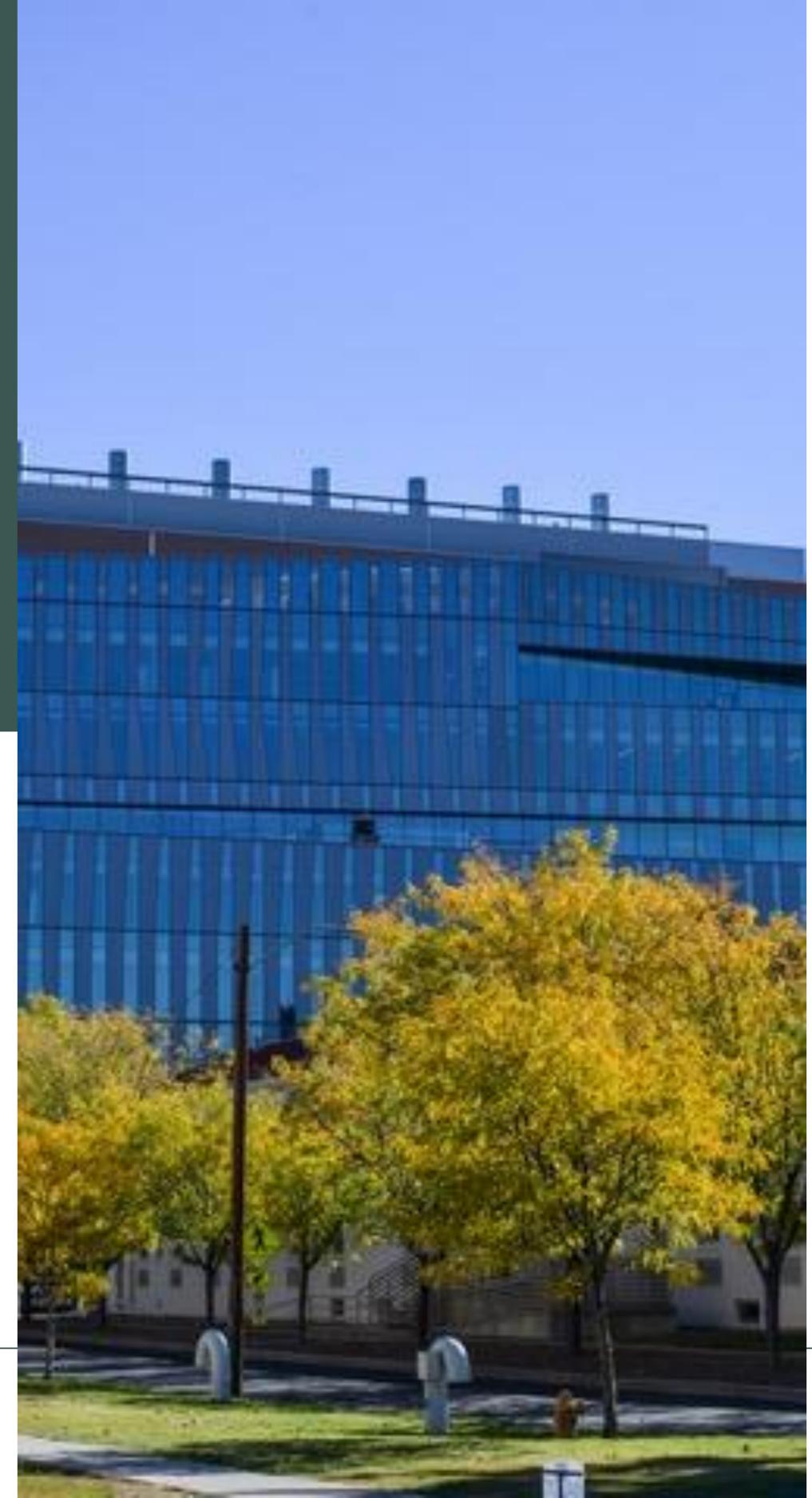
Major Goals: To demonstrate conduct of PEET-style projects in partnership with UHealth and develop governance and user guidance materials for others conducting these types of trials

All PEET awards are contingent upon funding made available to the CCTSI from National Center for Advancing Translational Science (NCATS)/National Institutes of Health (NIH).

PEET Review Criteria

CCTSI PEET Review Panels will use the following criteria to evaluate proposed projects to see if they meet Demonstration Project Minimum Requirements:

1. Meets 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



PEET Review Criteria: Novel EHR Integration Features

CCTSI PEET Review Panel will evaluate potential for demonstration of novel 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)

PEET Review Criteria

Innovation

Builds upon the existing evidence in an innovative way; enables innovative approaches an/or infrastructure for the PEET program.

Rigor

Study design, methods, measures, data collection, and analysis are likely to lead to valid and generalizable conclusions.

Impact

Important topic, addresses a significant problem, addresses health equity, will directly inform clinical practice, leverages an effective intervention or approach.





Review Criteria for PEET Grant



CCTSI PEET Review Panels will use the following criteria to evaluate proposed projects to see if they meet PEET specific requirements:

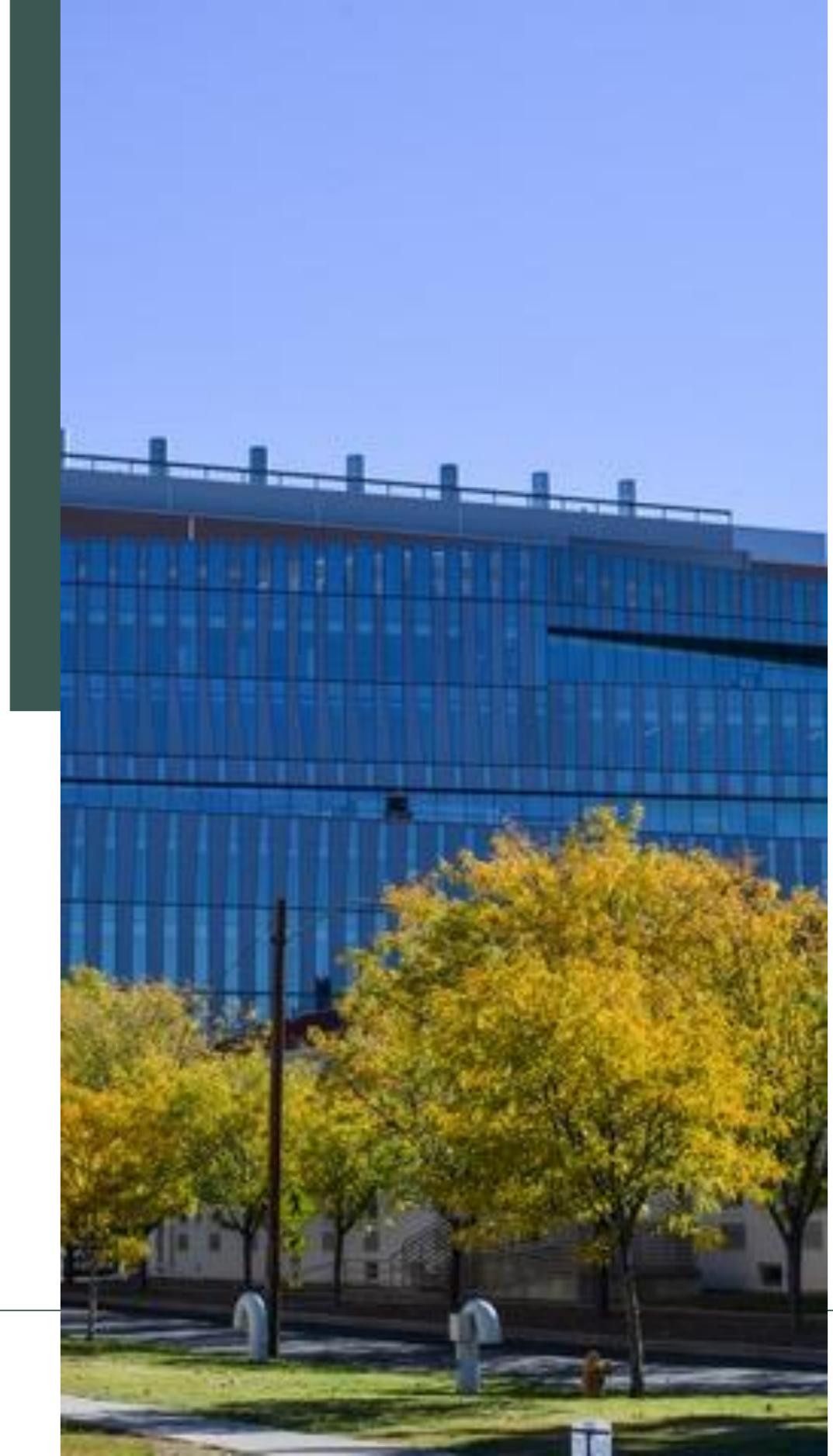
1. Broad reach/potential for impact across UCHHealth regions
2. Ease of cohort identification
3. Experiences/engaged principal investigator and program manager (who can commit substantive effort to the project)



Application Process

Sarah Kautz, Ph.D.

PEET Grant Program Coordinator



How to Apply

Pragmatic Research Resources



Biostatistics, Epidemiology, and Research Design (BERD)

Trial Innovation Network (TIN)

Research Ethics

Research Studio Program

Find a Researcher (PROFILES) [↗](#)

Early Life Exposures Research Program (ELEP)

Dissemination and Implementation

Pragmatic Research Resources

How can we help you? [↗](#)

2025 Key Dates

RFA Posted

November 18, 2024

Intent to Apply Due

December 17, 2024 by 5:00 PM MT

Informational Call #1

December 2, 2024 at 3:00 PM MT

Informational Call #2

January 10, 2025 at 10:00 AM MT

Applications Due

January 31, 2025 by 5:00 PM MT

Notice of Selection

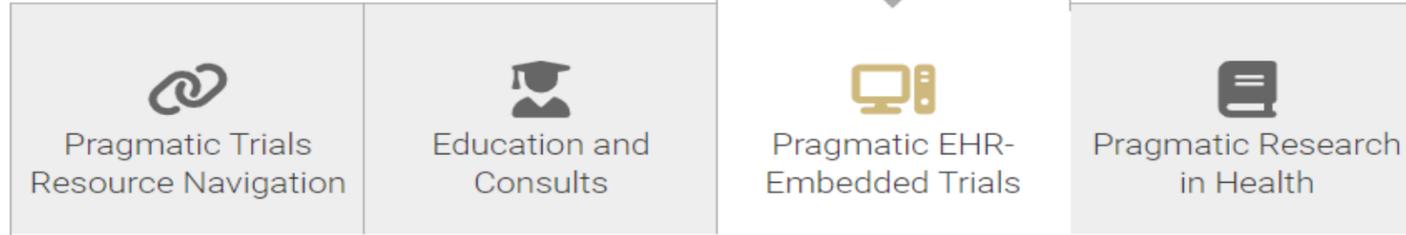
Mid to late May 2025

Award Start Date

August 1, 2025

Contact Us

Use the tabs below to learn more about resources available to CCTSI investigators to support pragmatic research.



PEET Program Overview

The goal of the CCTSI's Pragmatic Electronic Health Record (EHR)-Embedded Trials (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. 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 2-year pilot trials. Current priorities relate to studies conducted in adult populations within UHealth. See below for relevant deadlines for the 2024-2025 review cycle.

Request for Applications (RFA)

The RFA describes eligibility and application requirements

[CCTSI PEET 2025 Request for Application \(PDF\)](#) (226KB)

Information & Resources

[CCTSI PEET 2025 Required Budget Template \(.xlsx\)](#) (15.2KB)

[CCTSI PEET 2025 Grant Applicant Checklist \(.xlsx\)](#) (12.2KB)

If you have any questions about eligibility or the application please [contact Sarah Kautz](#), PEET Program Coordinator.

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Previously Funded PEET Demonstration Projects



Application Checklist

Application Checklist
([Excel](#))



Application Checklist		
The checklist is for informational purposes only. All applicants must comply with the requirements of the official Request for Funding Applications (RFA) posted on the CCTSI website.		
Intent to Apply Form		
		PEET Program
1	Certify this project meets RFA Eligibility and Exclusion criteria	Required
2	Project Title	Required
3	Contact Information (Name, Credentials, Faculty Rank, CCTSI partner institution, and Department/Division): Principal Investigator	Required
4	Contact Information (Name, Credentials, Faculty Rank, CCTSI partner institution, and Department/Division): Multiple Principal Investigator	
5	A PDF document including the project title, PI name, and concise description of the proposed project that describes the research question and an overview of the study design. Word limit: 300 words.	Required
6	Certify this project meets PEET minimum requirements	Required
7	Certify this project includes EHR integration features	Required
Application Form		
1	Confirm all contact information from Intent to Apply Form is accurate. Combine all documentation required in the RFA and combine into a single PDF to upload with your online Application Form.	Required
2	Project Overview (2-3 sentences) List all investigator names, titles, faculty rank, department/division institutions before the Project Overview	Required
3	Abstract (Firm 250 word limit)	Required
4	Specific Aims (1/2 page)	Required
5	Significance and Intervention (1 and 1/2 pages)	Required
6	Approach (4 page limit), including Preliminary Work; Research Question(s) and Hypotheses; Pragmatic Trial Design; Setting and Population; Intervention(s) and Implementations; Outcomes, Measures, Data Sources, Data Analysis and Analysis; Feasibility; Timeline; Epic EHR Integration Components; Potential Impact and Equity Consideration; Overlap Statement	Required
7	References (no page limit)	Required
8	PI, Project Team and Partners (1 page limit)	Required
9	Letters of Support (no page limit)	
10	Budget (1 page limit, vertical alignment only) Please use the CCTSI PEET Budget Template (available on the CCTSI PEET Website)	Required
11	Budget Justification (no page limit)	Required
12	Biosketches (5-page limit per person listed as Key Personnel)	Required
13	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.	Check with institution
DO NOT INCLUDE		

Budget

Applicants should customize these categories



CCTSI PEET Grant Award Budget

Budget and Active Award Period: August 1, 2025 to July 31, 2027

CATEGORY & ITEM(S)	Indicate Budget for Each Location					Total Amount
	CU AMC	CSU	CU Boulder	CHCO	Other Institution (Specify Location)	
Key Personnel Salary & Fringe Benefits						\$ -
Other Personnel						\$ -
Fee for Service (including Core Services)						\$ -
Supplies						\$ -
Equipment						\$ -
Participant Incentives						\$ -
Meetings & Travel (Costs are permitted for attendance at one scientific conference)						\$ -

Budget Template ([Excel](#))



Intent to Apply

Pragmatic Research Resources

Gold Box with the direct Intent to Apply Redcap link will appear on PEET website on Tuesday December 3rd, 2024



- 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
- **Mandatory Intent to Apply form by December 17, 2024, by 5pm**



Questions?



Email



Sarah.Kautz@cuanschutz.edu

