







Frontiers Renewal Application Element E: Clinical and Translational Science Research Program Discrete Research Project: Letter of Intent

About Frontiers Clinical & Translational Science Institute

Advancing Science, Improving Healthcare for All

The Frontiers Clinical & Translational Science Institute (Frontiers) is supported by the National Center for Advancing Translational Sciences (NCATS) <u>Clinical and Translational Science Award</u> (CTSA). The mission of Frontiers is to catalyze improvements in health and healthcare for the region and nation by training a multidisciplinary workforce, listening, learning, and partnering with all stakeholders and surmounting barriers to innovation in the communities we serve.

Purpose: Frontiers renewal application (UM1 mechanism) will be **submitted in May 2026** for the new seven-year funding cycle to begin on July 1, 2027. The <u>Notice of Funding Opportunity (NOFO)</u> is structured by Element and Modules. One component in the UM1 NOFO is **Element E: Clinical and Translational Science (CTS) Research Program,** which will support discrete research projects that address a truly significant challenge in clinical and translational science (CTS). A single discrete, well-defined, innovative project must be described in the renewal application. This single project must include specific aims, significance, and a detailed approach to addressing the specific aims and / or study proposed. The research project is suggested to be 3 -5 years in length.

Request for Applications

Frontiers is seeking Letters of Intent (LOIs) for clinical science projects that will be able to utilize a newly formed Practice Based Research Network (PBRN). LOIs should describe innovative research projects to include in Element E: CTS Research Program of our UM1 renewal application. Information about the proposed PBRN goals and the LOI requirements are described below.

Consistent with the NCATS mission to catalyze translation of discoveries, the projects must focus on CTS rather than on basic discovery research. Project(s) should not only address a translational research question in a particular disease or intervention development / dissemination context, but also **provide generalizable** CTS innovations or insights that can be applied to other translational research projects and thereby increase the overall efficiency or effectiveness of translation.

Key Dates	Online System Opens and RFA Release: April 29, 2025 Letter of Intent Deadline: May 28, 2025, 11:59 pm CT Letter of Intent Status Notification: Week of June 23, 2025 First Draft Full Application Deadline: September 1, 2025, 11:59 pm CT Earliest Project Start Date: Approximately December, 2027
Award Amount	\$250,000-\$500,000 direct costs per year
Anticipated Award Period	3-5 years
Application Selection	A single discrete research project will be submitted as the Element E: CTS project withing the UM1 renewal application. Other projects may be invited for subsequent years.
Review Criteria	Invited full applications will be reviewed using the new NIH-Simplified Peer Review
	Framework and other stated review criteria.
Contact Information	Robin Liston, MPH, Project Director, rliston2@kumc.edu

Background: As the overall goal of Frontiers, we catalyze improvements in health and healthcare for the region and nation through training the workforce, listening, learning and partnering with all stakeholders and surmounting barriers to innovation in the communities we serve. As a part of the renewal application, specifically the Element E Clinical and Translational Science (CTS) Research Program, Frontiers will create **a primary care, Practice-based Research Network (PBRN) to promote research** that encompasses primarily rural communities (and urban partnerships as needed) across Kansas and western Missouri.

The goal of the Element E: CTS Research Program is to enhance clinical science infrastructure, recruitment, and innovative study designs across Kansas and western Missouri by developing a PBRN. Rural Americans, who make up 20% of the US population, face significant health challenges and are underrepresented in biomedical research. In Kansas, 89 of 105 counties are rural and rely heavily on federally qualified health centers, critical access hospitals, rural health clinics, and local health departments for care. The western Missouri catchment area consists of 46 counties, with 29 of those are rural. Participation of rural populations in clinical research is critical to improve health. The PBRN will leverage existing research networks. The projects will implement community-informed recruitment strategies and utilize electronic health records for streamlined participant engagement. Innovative, pragmatic and decentralized trials are encouraged to minimize participant burden and maximize research impact by leveraging digital health tools, remote technologies and implementation science frameworks. The PBRN will contribute to a more accessible and relevant clinical research landscape, ultimately increasing the representation of rural populations in clinical research.

The **PBRN long-term goal** is to ensure that primarily rural communities (and urban partnerships as needed) and all stakeholders (patients, providers, practices, hospitals) actively engage in clinical research, ultimately contributing to improved health outcomes.

- **Goal 1:** Build and Optimize Infrastructure for Conducting Clinical Research in Rural Primary Care Settings.
- **Goal 2:** Enhance Participant Recruitment and Engagement in Rural Communities.
- Goal 3: Implement Innovative Study Designs to Minimize Burden and Maximize Impact.
- **Goal 4:** Developing and Implementing Studies and Use of Innovative Designs Identifying Research Areas and Community Priorities.

Translational Science Requirement: Proposed Research Projects

NCATS is charged with determining where common pitfalls exist in the translational process and developing innovative solutions that will ultimately benefit research **across a range of diseases and conditions**. This disease-agnostic approach to enhancing the efficiency and effectiveness of all translational research is known as *translational science*. Projects are *required* to focus on translational science, i.e., <u>understanding a scientific or operational principle</u> underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. *Applicants will be required to address at least one of the translational science principles but should address all relevant principles.*

<u>Translational research</u> focuses on advancing a step of the translational process for a specific target/disease.

<u>Translational science</u> focuses on:

- **1.** *Identifying and understanding barriers* that delay progress or limit the quality, impact, or equity of translational research (e.g., clinical trial recruitment, data interoperability, implementation, etc.).
- 2. Developing, demonstrating, and disseminating generalizable innovations and strategies (e.g., methods, best practices, tools, technologies) to overcome these barriers and improve the process of translational research. Addressing critical barriers will allow subsequent translational research to accelerate the time from discovery to improved human health. The innovative solutions will have broad applicability to multiple research projects, increasing capacity and efficiency.

Eligibility

This competition is open to principal investigators (PIs) at the Frontiers partner institution (listed below) who are eligible to receive investigator-initiated federal funding at their respective institutions ():

- Children's Mercy Hospital-Kansas City
- Kansas City University
- Kansas State University
- St. Luke's Hospital
- University of Kansas
- University of Kansas/Medical Center/Health System
- University of Missouri-Kansas City

Letter of Intent (LOI)

LOIs must follow the guidelines outlined below.

1. CTS Research Project Components (2-page maximum)

- Specific Aims
- Impact Statement: Explain the significance of the research and how it may impact health and medicine by advancing clinical and translational science (CTS).
- Approach
- Describe how the project will:
 - a. Identify and understand CTS barriers that delay progress or limit the quality or impact of translational research.
 - b. Develop innovative solutions.
 - c. Provide generalizable innovations or insights that increase the overall efficiency or effectiveness of translation.
- Dissemination Plan:
 - a. Describe how the study outcomes will be disseminated to communities of interest locally, regionally and nationally.
 - b. Include current or potential partners, collaborators, or communities.
- Projects should be designed to be completed in 3-5 years.

2. NIH Biosketch(s) for Key Personnel

Addressing Frontiers UM1 Aims and NCATS Translational Science Principles

Proposed research projects must address at least one Frontiers Overall Specific Aims and at least one Translational Science Principle:

1. Frontiers Overall Specific Aims

- a. Workforce Aim: Train a comprehensive workforce that leverages transdisciplinary approaches to stimulate innovative, responsive, and impactful translational science across the T1-T4 spectrum.
- b. Community Aim: Strategically engage rural and other under-researched communities, patients, providers, and researchers to assure that training and innovations in clinical and translational science benefit the health of all populations.
- c. Infrastructure Aim: Transform the research enterprise by developing, deploying, and utilizing innovative data, implementation, and translational science to create (or build) a transdisciplinary infrastructure to advance high-quality healthcare.
- d. Clinical and Translational Science (CTS) Aim: Develop and implement solutions to scientific and operational challenges facing research conducted across the continuum, accelerating translation of laboratory, bedside, and community research discoveries into innovative interventions to improve health.

2. At least one Translational Science Principle

- a. Prioritize Initiatives That Address Unmet Need
- b. Produce Generalizable Solutions for Common and Persistent Challenges

- c. Emphasize Creativity and Innovation
- d. Leverage Cross-Disciplinary Team Science
- e. Enhance the Efficiency and Speed of Translational Research
- f. Utilize Boundary-Crossing Partnerships
- g. Use Bold and Rigorous Research Approaches

Format

- Ariel 11-point font
 - o Tables and figures may use 9-point font
- Margins 0.5 inches

Submission

- Letters of Intent are due May 28, 2025, by 11:59 pm
- Submit your application through <u>REDCap</u>

Budget: Informational ONLY. Do not submit a budget with your LOI.

\$250,000-\$500,000 direct costs per year. Allowable funds include funds for personnel, research, and other expenses, as appropriate. Budget justification must clearly delineate the costs associated with the defined Element E CTS research project. Funds may not directly support any clinical trial beyond phase IIB with the exception of Phase III clinical trials for treatment of rare diseases.

Review Criteria

Applications will be reviewed using <u>NIH Simplified Peer Review Framework</u>. This new framework streamlines the peer review process and mitigates the influence of reputational bias.

NIH Review Criteria Framework:

- Factor 1: Importance of the Research (Significance, Innovation); scored 1-9.
- Factor 2: Rigor and Feasibility (Approach); scored as 1-9.
- Factor 3: Expertise and Resources (Investigator, Environment); to be evaluated as either sufficient for the proposed research or not.

Notification Information

Successful applicants will be notified of their selection to join the larger CTSA application from Frontiers via email. It is important to note that internal approval from Frontiers does not guarantee funding; the final decision on funding will depend on the successful award of the UM1 CTSA grant.

Contact

For additional information or clarification regarding this funding opportunity contact Robin Liston, Project Director, at rilston2@kumc.edu.