2025 Lauren S. Aaronson Frontiers Pilot Program

About Frontiers

The Frontiers Clinical and Translational Science Institute (Frontiers) is a regional initiative involving academic institutions, healthcare systems, and community organizations that address the clinical and translational research needs of Kansas and western Missouri. Frontiers supports high quality clinical and translational science innovation in research methods and training and career development of investigators committed to improving health and achieving health equity across the lifespan, with a focus on underserved and excluded populations.

The **Lauren S. Aaronson Frontiers Pilot Program** provides grant funding and other support to grow interdisciplinary, investigator-initiated clinical and translational science projects across a broad range of scientific disciplines. The Pilot Program provides funding for early- and mid-career investigators to complete one-year long, impactful, innovative, collaborative clinical and translational projects that will support applications for subsequent externally funded larger studies. The Pilot Program major goals are to: 1) boost emerging investigators' research programs to develop critical preliminary data in support of future applications, including studies leading to trials of promising treatments, interventions, devices, or novel diagnostic or analytic approaches and 2) to support research that addresses clinical challenges pertinent to historically-underserved and excluded populations and communities in Kansas and Western Missouri that can be applied to the general population.

Awarding Institute	Frontiers Clinical and Translational Science Institute
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS); Award number UL1TR002366.
Key Dates	Online System Opens and RFA Release: October 23, 2024 Letter of Intent Deadline: November 22, 2024, 11:59 pm CT Letter of Intent Status Notification: Week of December 16, 2024 Community Rapid Reactor Panels: February 4 and February 5, 2025 Full Application Deadline: February 24, 2025, 11:59 pm CT Merit Review Completion: March 31, 2025 Funding Selection Notifications: mid-April 2025 NCATS Prior Approval Submission Goal: May 15, 2025 – IRB and/or IACUC Final Approval Required: May 7, 2025 Official Notice of Award and Public Announcements: July 2025 (anticipated) Earliest Project Start Date: July 1, 2025, pending Frontiers Notice of Award for 2025-26 fiscal year. **Note: The Pilot Award Program reserves the right to extend submission deadlines to better meet Frontiers' needs; all changes will be communicated in advance.*
Award Amount	Up to $50,000 can be requested.
Maximum Award Period	July 1, 2025, through June 30, 2026. All funds must be spent by June 30, 2026 – carry over and no-cost extensions are not allowed.
Number of awards	Up to 3 awards
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

Introduction
The National Center for Advancing Translational Sciences (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.*

The Frontiers Pilot Award Program is supported by and aligned with the NCATS Clinical and Translational Science Award (CTSA) Program, focused on advancing clinical and translational science (CTS) to:

- Develop, demonstrate, and disseminate scientific and operational innovations that improve the efficiency and effectiveness of clinical translation from identification to first-in-human studies to medical practice implementation to community health dissemination.
- Promote partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally, and nationally.
- Create, provide, and disseminate innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all.
- Create and implement scientific and operational innovations that increase the quality, safety, efficiency, effectiveness, and informativeness of clinical research.

Translational Science Requirement
Pilot projects are ***required*** to focus on translational science, i.e., understanding a scientific or operational principle 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 principles but should include all relevant principles.***

Translational research focuses on advancing a step of the translational process for a specific target/disease, translational science seeks to develop, demonstrate, and disseminate generalizable innovations and strategies to improve the process of translational research.

Translational science projects seek to ***1. identify and understand barriers that delay progress or limit the quality, impact, or equity of translational research*** (e.g., clinical trial recruitment, data interoperability, implementation, etc.), and ***2. develop innovative solutions*** (e.g., methods, best practices, tools, technologies) to overcome these barriers. 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.

Applications directly related to one or more of the following priority areas will be accepted:

- Processes and programs to understand, support and advance translation, e.g., collaborative structures; diverse workforce development; integration of project management; incentives/credit for team science; incentives/credit for health improvements; education/training (scientific and cultural); biomarker qualification process.
- Data-related improvements and tools, e.g., data interoperability; Electronic Health Records for research; data transparency/release.
- Clinical research improvements and tools, e.g., clinical trial networks; clinical outcome criteria (e.g., patient-reported outcomes); clinical diagnostic criteria; contemporary clinical trial designs; single Institutional Review Board (IRB) implementation; regulatory science; shortening time of intervention adoption.
- Clinical study recruitment improvements and tools, e.g., identification, recruitment, engagement and/or retention of populations and/or subpopulations in clinical trials and studies.
- Community and stakeholder engagement.
- Methods to better measure impact on health outcomes (or lack thereof).

Examples of activities that may be supported:

- Development of new research methodology and/or new technologies/tools/resources that

will advance CTS and thus increase the efficiency and effectiveness of translation.
- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock.
- Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient.
- Dissemination of effective tools, methods, processes, and training paradigms.
- Feasibility/proof of concept studies to support future CTS projects.

LSA Pilot Award Program has identified the following areas for Programmatic Fit.
- Studies that include multidisciplinary perspectives.
- Studies that address health issues among underserved and underrepresented populations, including rural communities.
- Community-based research involving participants/patients, families, caregivers and/or communities, which test new treatments, interventions, recruitment/retention strategies, or policies that impact health outcomes.
- Implementation and dissemination studies, effectiveness, and/or dissemination of clinical research findings into practice.

Eligibility
This competition is open to principal investigators (PIs) at any partner institution who are eligible to receive investigator-initiated federal funding at their respective institutions.
- Children's Mercy Kansas City
- Kansas City University
- Kansas State University
- University of Kansas
- University of Kansas Health System
- University of Kansas Medical Center (all campuses)
- University of Missouri-Kansas City
- Saint Luke's

Academic applicants are encouraged to collaborate with community organizations to develop applications.

Early to mid-career PIs are encouraged to apply. Established PIs may apply but should justify how the pilot project is a new line of inquiry.

PIs who have received previous Frontiers funding may submit a Letter of Intent, but must describe:
- Outcomes from previous funding.
- Why this pilot funding is vital for the extension of previous work or for a new area of investigation.

PIs can apply for more than one of Frontiers funding mechanisms but will only be allowed to accept one award annually. Applicants may serve as PI on only one award but may be included as collaborators on any number of applications.

Volunteer faculty, residents, fellows, or graduate students are generally not eligible to serve as principal investigators. United States citizens, non-citizen nationals, or those who have legal admission as a permanent resident are eligible. However, any questions regarding PI eligibility should be addressed to individual institutional grants management offices before Letter of Intent submission.

Letter of Intent Requirement
Investigators must submit a Letter of Intent outlining the Importance of the Research (Significance, Innovation), Rigor and Feasibility (Approach), and impact of the project, how the project will lead to extramural funding, and how it will further their career goals. We anticipate inviting about eight full applications.

Applicants who do not advance to the full application stage will be notified via email. No scores or written comments will be provided.

Letters of Intent (LOI) must be combined into one PDF, submitted online here and should contain:

- Pilot Project Overview using the required **LOI Template**.
  - Lay Language Summary (≤ 250 words; Public relevance, target population, recruitment strategy, dissemination to key stakeholders)
  - Proposed pilot study description and future plans (3 pages maximum)
  - NIH-format Biosketch for PI
  - Prior pilot funding outcome (if relevant); Justification for established investigator (if relevant)

Letters of Intent will be evaluated on the following:

- Importance and relevance of the topics to NCATS CTSA and Frontiers as described above.
- As well as the New NIH Simplified Peer Review Criteria: (See details below)
  - Importance of the Research (Significance, Innovation)
  - Rigor and Feasibility (Approach)

Full Application Requirements

The following documents are required and must be uploaded as one PDF, in the order below, with the following naming convention: PILastNameFirstInitial – LSA Pilot

- NIH PHS 398 Forms
- NIH Biographical Sketch (for all Key Personnel)
- Research Plan
- IRB or IACUC Official Correspondence of Submission or Approval Letter or the IRB/Human Research Protection Program Correspondence that the study is Not Human Subjects Research. ***Flexible IRB Review is not allowed*. Note:** Inform the IRB this will be a federally funded project.
- Institutional Letter of Support from department or division chair, using the required template below.

PHS 398 Forms
Complete: Face Page, Project Summary, Project Relevance, Project/Performance Sites, Senior/Key Personnel, Table of Contents, and Budget with Budget Justification **online here**.

Research Plan should include the following sections and should not exceed five (5) pages **Download the Research Plan Template here.**

a. Specific Aims (1 page)
b. Research Strategy (5 pages, excluding references). See Review Criteria below for additional details.
   - Importance of the Research (Significance, Innovation)
   - Rigor and Feasibility (Approach, Rigor and Feasibility)
   - Expertise and Resources (Investigator, Environment)
c. Study Timeline. Template provided here, but any format is accepted. (1 page)
d. For Human Subject Studies: Complete the Planned Enrollment Table using this template. *Note the template requires Java Script to be enabled to calculate the totals.*
e. References (no page limit)
f. Appendix (optional; not included in page limit): Only limited Appendix are allowed. Do not include additional data or information not essential for review of the application.

Budget guidance: Applicants may request up to $50,000. All funds must be spent by June 30, 2026 – carry over and no-cost extensions are not allowed. **Contact Jen Whitaker,** jwhitaker5@kumc.edu, for institutional guidance regarding indirects.

The award may be used to fund up to $10,000 of the PI's salary. Applicants are encouraged to include and compensate a relevant community or patient representative as a team member who can make substantive contributions to project design or implementation.

Equipment may not exceed 10% of the total budget.

The following costs are not covered by these awards:

- Non-Frontiers institution staff salaries (with the exception of required consultants, if justified)
- Administrative or office costs (e.g., office supplies, telephone, etc.)
- Meals or hospitality (e.g., food, beverages or alcohol, unless justified for the study outcomes)
- Travel that is not directly related to the conduct of research
- Other items typically supported by Facilities and Administration costs

NIH Biographical Sketch: Include for all Key Personnel. Template, instructions, and samples found **here**.

IRB or IACUC Submission and/or Approval: Official documentation of IRB or IACUC application submission, approval, or IRB/Human Research Protection Program determination that the project is 'Not Human Subjects Research' is **required** before full application submission. **Flexible IRB Review is not allowed. *Note*:** Inform the IRB this will be a federally funded project.

Institutional Letter of Support: PIs must have written commitment from their department chair, or equivalent, of a minimum of 20% of the PI's 1.0 FTE to conduct the proposed research. Institutional Letter of Support Template can be accessed here.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. Applications containing information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged should identify the content by marking those paragraphs or lines with an asterisk (*). All reviewers sign a Confidentiality Agreement.

Community Engagement

Applicants who are invited to submit a full application will be required to present their proposed application to a Rapid Reactor Panel of community members. Applicants will present their projects, including plans to disseminate results to the community in lay language, to the Rapid Reactor Panel representing the ultimate consumers of biomedical research. The Rapid Reactor Panel will provide feedback on presentation, input regarding communication with the population of intent and potential challenges in study recruitment and retention. **A paragraph must be included in the final application describing modifications that resulted from the Rapid Reactor Panel feedback**.

Merit Review: Applications will be reviewed and scored using the new NIH Simplified Peer Review Framework as described below. Applicants will receive a summary statement describing strengths and weaknesses of the application in the late spring/early summer of 2025. **Applications that do not follow the requirements as detailed in this RFA and applications that are submitted late will be administratively withdrawn.**

Factor 1: Importance of the Research (Significance, Innovation), scored 1-9

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Factor 2: Rigor and Feasibility (Approach), scored 1-9

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
- the rigor of the intervention or study manipulation (if applicable to the study design).
    - Whether outcome variables are justified.
    - Whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
    - Whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain an appropriately diverse population of participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, racial, ethnic, and sex/gender categories.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Factor 3: Expertise and Resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not (in which case reviewers must provide an explanation)

Investigator(s)

- Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

- Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work**.**

Overall Impact, scored 1-9

Overall Impact is the synthesis/integration of the review criteria as well as the relevance of the budget (and budget justification) for the project to exert a sustained, powerful influence on the research field(s) involved.

Potential of pilot to result in future funding and publication. Is there evidence that successful completion of the pilot will competitively position the PI for an NIH award and an impactful publication.

Funding Selections and Notice of Award: Selections for Intent to Fund are anticipated in April 2025. Selected applications will be submitted to the NCATS for Prior Approval, when applicable. NCATS approval must be received before release of funds and any public announcements. Release of funding is also dependent on receipt of the Notice of Award for Frontiers Y4 funding year, which is anticipated in July 2025.

Post Award Requirements: Clinical trials are required to be registered prior to official approval from NCATS.

Meetings
All recipients of pilot awards are required to meet with the Communications Coordinator within four weeks following notification of Intent to Fund. A story will be prepared about awards prior to the issuance of official Notice of Awards.

Awardees will be required to meet with Frontiers Project Director, Administrative Director, who handles financial aspects and the Biomedical Communications Manager two times during the funded project to ensure the study is progressing and funds are being expended. These individuals are available to assist throughout the project period.

Dissemination: Presentations and Publications
Awardees will be required to present their awarded projects to Frontiers Advisory Groups during the funding year and at the completion of the project. Find additional information about the Advisory Groups here.

It is expected that research supported by the pilot awards will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural grant applications. Details of all published manuscripts, meeting abstracts, and grant awards that result from data obtained from pilot grants should be included in the mid-year and end of year progress reports and annual surveys. Report templates will be provided. Awardees will be sent an annual survey for up to 5 years asking about the impact of their work.

It is essential that study outcomes are disseminated to both the scientific and lay communities; therefore, Frontiers expects that awardees will also disseminate findings to participants and community groups as appropriate. Frontiers will highlight projects at the Annual Research Symposium, where awardees will be required to present.

All publications and presentations must acknowledge NIH grant support arising from any research project that used Frontiers resources. Learn how to cite Frontiers here.

Find Additional Resources and Frequently Asked Questions here.