2023 Lauren S. Aaronson FRONTIERS Clinical and Translational Research Pilot Program

About Frontiers

The Frontiers Clinical and Translational Science Institute at the University of Kansas 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 Clinical and Translational Research Pilot Program** provides grant funding and other support to grow interdisciplinary, investigator-initiated clinical and translational research across a broad range of scientific disciplines. The objective of this pilot program is to support new and innovative ideas that will lead to externally funded awards.

Summary

Key Dates	Online System Opens: November 10, 2022 Letter of Interest (LOI) Deadline: December 01, 2022 LOI Status Notification: December 22, 2022 Full Application Deadline: February 20, 2023 Merit Review Completion and Funding decisions: April 2023 NCATS Prior Approval Process: April-May 2023 Award Letters and Announcements: June 2023 Earliest Project Start Date: July 1, 2023 pending Frontiers Notice of Award for 2023-24 funding year. *Note: The Pilot 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 in direct costs can be requested. Indirect costs are not covered by the pilot awards.
Maximum Award Period	12 calendar months.
Number of awards	Up to 3 awards.
Review criteria	Invited full proposals will be reviewed using NIH-style review process and other stated review criteria.
Contact Information	Natalia Loskutova, MD, PhD Frontiers Pilot Program Administrator nloskutova@kumc.edu

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1. 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 (https://ncats.nih.gov/translation/spectrum).

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;
- Provide a national resource for rapidly responding to urgent public health needs; and
- Create, provide, and disseminate CTS training for clinical research professionals of all disciplines on the research team.

2. Pilot Project Research Priority Areas

Pilot projects must 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.

Proposals directly related to one or more of the following 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 (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.
- Secondary analysis of existing data (e.g., projects using the National COVID Cohort Collaborative (N3C) Data Enclave).

In addition, Frontiers Pilot Award Program has identified the following priority areas:
- Studies that include multidisciplinary perspectives.
- Studies that address health issues among underserved and underrepresented populations, including rural communities we serve.
- 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.

Final funding decisions will be made by the Funding Council, which will take note of scientific priority scores as well as fit with programmatic themes, such as:
- Applications that address health issues among underserved and underrepresented populations, including rural communities we serve.
- Applicants from populations underrepresented in the U.S. biomedical, clinical, behavioral, and social sciences research (https://diversity.nih.gov/about-us/population-underrepresented).
- Applications that address a significant public health issue in the region.

3. General Application Requirements
- Frontiers CTSI membership **is required** for submitting applications https://frontiersctsi.org/become-a-member
- A letter of interest is required.
- Engagement of community partners in design, implementation and dissemination is encouraged.
- It is expected that all research supported by the Frontiers pilot project awards will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural grant applications.

4. Eligibility
This competition is open to principal investigators who are eligible to receive federal funding and employed by any Frontiers partner institution:
- University of Kansas Medical Center (all campuses)
- University of Kansas
- University of Missouri-Kansas City
- Kansas City University
- Children's Mercy Kansas City
- St. Luke's Health System
- Kansas State University

Community organizations are encouraged to collaborate with academic partners to develop and submit an application.

Established principal investigators may apply but should strongly justify how the pilot project is a new line of inquiry.

Principal investigators who have received a previous Frontiers Pilot award may submit a LOI, but should describe:
- Detailed outcomes from previous funding and
- Why this pilot funding is vital for the extension of previous work or for a new area of investigation.

Applicants may serve as PI on only one application but may be included as collaborators on any number of applications.

Prospective PIs who are volunteer faculty, residents, fellows, or graduate students are generally not eligible but strongly encouraged to contact their grants management office and the Pilot Program administrator to determine eligibility before LOI submission.

5. Application and Selection process
Pilot grants will be reviewed through a two-stage process:
- Letter of Interest
- Full application (from selected Letters of Interest)

6. Letter of Interest Requirements and Review
Eligible investigators should submit a Letter of Interest (LOI) outlining the significance, innovation, and impact of the project, how their project will lead to extramural funding, and how it will further their career goals. Projects will be reviewed for relevance to the Frontiers themes. We anticipate inviting about 8 applicants.

Applicants who do not advance to the full application stage will be notified via email. No score or written critique/comments will be provided to the applicants at this point.

Letters of Interest must be submitted online here and should contain:
- Pilot Project Overview
- NIH-format Biosketch for PI

LOI Required Element	Description	Template
Pilot Project Overview	Page and word restrictions apply, upload as PDF PI*LastNameFirstInitial*_Project Include in this order: - Lay Language Summary (250 words; *Public relevance, target population, recruitment strategy, dissemination to consumers*) - Proposed pilot study description and future plans (3 pages maximum) - Prior pilot funding outcome (*if relevant*) - Justification for established investigator (*if relevant*)	Project Overview Template can be accessed **online here**
NIH-format Biosketch for Principal Investigator	Max 5 pages, upload as PDF PI*LastNameFirstInitial*_Bio	Biosketch format pages, instructions, and samples can be found **online here**

Letters of Interest will be evaluated based on the following:
- Importance and relevance of the topics to NCATS CTSA and Frontiers

- Potential Significance and Impact of the project
- Qualifications of investigators to complete the project
- Feasibility of proposed work

7. Full Proposal
Applicants who are invited to submit a full proposal will participate in a ***Patient and Community Partners Group (PCPG)*** Rapid Reactor Panel. Applicants will present their proposals, including plans to disseminate results to the community in lay language, to the PCPG audience representing the ultimate consumers of biomedical research. The PCPG will provide feedback on presentation and input into such topics as appeal to the community, communication with the population of interest, and potential challenges in study recruitment and retention. Frontiers Pilot Program personnel will set up the necessary consults.

Full Proposal Requirements
Invited applicants should submit their full proposals online and will receive further instructions. The full proposal will resemble an NIH R03 format. The following items are required:
- PHS 398 Forms including PHS Human Subjects and Clinical Trials Information (if applicable)
- NIH Biographical Sketches (for all key personnel)
- Research Plan
- IRB or IACUC Documentation
- Institutional Letter of Support

PHS 398 Forms
Applicants should work with their institutional grant support specialists to complete the 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**).
- Complete: PHS Human Subjects and Clinical Trials Information form, if applicable **(online here)**

Budget guidance: Applicants may request up to $50,000 in direct costs. All funds must be spent by June 30, 2024 – carry over and no-cost extensions are not expected.

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 makes substantive contributions to project design or implementation.

Equipment may not exceed 10% of the total budget (i.e., cannot exceed $5,000).

The following costs are not covered by these awards:
  a. Non-Frontiers institution staff salaries (with the exception of required consultants, if justified)
  b. Administrative or office costs (e.g., office supplies, telephone, etc.)
  c. Meals or hospitality (e.g., food, beverages, or alcohol)
  d. Travel that is not directly related to the conduct of research
  e. Other items typically supported by Facilities and Administration costs
  f. Facilities and Administration costs. These awards are direct costs only

NIH Biographical Sketch
Include for all key personnel. Template, instructions, and samples found **online here**.

Research Plan
Use Arial 11 font, 0.5-inch margins, single space format, upload as PI*LastNameFirstInitial*_Plan.pdf
Download the Research Template Plan here

Research plan should include the following:
a. Specific Aims (1 page)
b. Research Strategy (6 pages, excluding references)
    i. Significance
    ii. Innovation
    iii. Approach
c. References (only include crucial references; no page limit, not included in the 6-page limit)
d. Appendix (optional; not included in 6-page limit): Only limited Appendix materials as specified in the NOT-OD-17-098 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html) are allowed. Do not include additional data or information essential for review of the proposal.
e. Project Specific Resources (1 page)

IRB or IACUC applications and/or approval
IRB or IACUC applications, or approval, or IRB determination that the project is 'Not Human Subjects Research' are required before full application submission. The official IRB or IACUC correspondence determination should be uploaded as one pdf document. Upload as PI*LastNameFirstInitial*_IRB/IACUC.pdf.

Institutional Letter of Support
Proposal 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 their research. The letter should confirm that the organization's grants management office approves this submission. Institutional Letter of Support Template can be accessed **online here**

8. Notice of Proprietary Information
Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the full application. Applications containing information that constitutes trade secrets, that is financial or commercial, or that is confidential or privileged, should identify the pages that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph.

9. Full Proposal Merit Review
Applications will be reviewed and scored using NIH review criteria by at least three reviewers including community representatives. Applicants will receive a summary statement describing strengths and weaknesses of the proposal. The review criteria described below will be considered in the review process.

• **Significance**
Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

• **Investigator**
Is the PI well suited to the project? If early-stage investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Does the team include appropriate involvement of community members?

• **Innovation**
To what extent are innovative methods evident, such as experimental approaches to identify best practices in translational research; workforce education and training; and stakeholder outreach?

• **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?

• **Overall Impact**
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.

10. Funding Decision and Notice of Award
Funding decisions are anticipated in April 2023. Successful applications will be submitted to the NCATS for prior approval, which must be received before release of funds and any public announcements. Release of pilot project funding is dependent on receipt of the Notice of Award for Frontiers CTSI for the FY23 funding year, which is anticipated by July 01, 2023. Frontiers also reserves the right to withdraw the award for any project that has not received IRB/IACUC approval for human subjects and vertebrate animal research projects by June 1, 2023.

11. Post Award Requirement for Award Recipients
Clinical trials are required to be registered not later than 21 calendar days after the enrollment of the first participant. Please see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html for details.

All pilot awardees and their project teams are required to complete the Frontiers Training Center anti-racism and anti-bias training (or equivalent) within first 6 months of notice of award and include evidence of completion in the mid-term report. All recipients of Frontiers Pilot Awards are required to provide mid-term and final progress reports. Details of all published manuscripts, meeting abstracts, and grant applications that result from data obtained from pilot grants should be included in the reports. Report templates will be provided.

12. Resources
Grant Writing
- *NIH National Library of Medicine Resources: https://www.nlm.nih.gov/ep/Tutorial.html*
- *NIH Grant Writers Workbook: https://www.grantcentral.com/workbooks/national-institutes-of-health/*

Clinical and Translation Science
- *The National Center for Advancing Translational Sciences (NCATS): https://ncats.nih.gov/*
- *Austin, C.P. (2021), Opportunities and challenges in translational science. Clin Transl Sci, 14: 1629-1647. https://doi.org/10.1111/cts.13055: https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.13055*

Team Science
- *Northwestern University CTSI Resources: https://www.teamscience.net/*
- *National Cancer Institute Field Guide: https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide/collaboration-team-science-guide.pdf*

Community Engagement
- *Trial Innovation Network Community Engagement Resources: https://trialinnovationnetwork.org/elements/engagement-recruitment-retention/*

Anti-racism and Anti-bias Training
- *KUMC Diversity Resources and Trainings: https://www.kumc.edu/diversity/training.html*
- *UMKC Diversity Resources and Trainings: https://info.umkc.edu/diversity/initiatives/training-development/on-line/*
- *CMH Diversity Resources and Trainings: https://www.childrensmercy.org/professional-education/diversity-equity-and-inclusion/trainee-initiatives-and-education/*

Frontiers Resources
- *https://frontiersctsi.org/*