Wake Forest Clinical and Translational Science Institute Request for Applications for the Science of Translation Pilot Award

PURPOSE

This RFA aims to support innovative 1-year pilot projects that advance the <u>science of translation</u>. Projects must investigate a scientific or operational principle underlying a step in the translational process, with the goal of improving translational efficiency and accelerating the development of health-improving interventions. <u>Projects focused solely on advancing a specific target or disease through a particular translational stage (e.g., T1 to T2) are not eligible.</u>

Science of Translation pilot projects must address a specific <u>translational roadblock</u> (as defined by Austin et al.). The WF CTSI has identified eight priority roadblocks that align with its strategic initiatives including:

- Clinical Trial Participant Recruitment
- Data Interoperability and Transparency
- Education and Training
- Electronic Health Records (EHR) for Research
- Innovative Clinical Trial Design
- Patient and Community Engagement
- Shortening Time of Intervention Adoption
- Understanding of Translation and Translational Science

No pilot data is necessary to apply for this RFA; however, supporting data from recent literature, is appropriate. A list of previously funded CTSI Science of Translation Pilots can be found here.

Examples of activities that may be supported

- Development of new research methodology and/or new technologies/tools/resources that accelerate the realization of interventions to improve human health.
- Early-stage development of new therapies/technologies 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.

Exemplar Science of Translation Pilot Topics

Developing Accelerated Contrast-Free MRI Protocol in Patient-Derived Mouse Models of Pediatric Brain Tumors:MRI is a gold-standard translational neuroimaging technique where shorted image times without the need of intravenous contrast are desired. Orthotopic mouse models will be used to establish faithful animal models of pediatric malignancies. A novel multiparametric MRI protocol with advanced MR sequences will be developed using a 9.4 Tesla MRI scanner. This project addresses the barriers in technical execution of complex mechanistic studies in humans or animal models AND translational barriers from animal models to human trials.

Engaging Rural Older Adults and Communities in the Refinement and Implementation of WalkOn!: This project aims to adapt and expand WalkOn!, a group-based walking program for older adults, to rural communities. Using surveys and community input, the team will identify unique needs and implementation strategies to support healthy aging and reduce isolation in underserved areas. This project addresses Patient and Community Engagement as well as Understanding Translation and Translational Science.

ELIGIBILITY

These awards are open to investigators with faculty rank across the Southeast region of Advocate Health. This includes Atrium Health, Atrium Health Navicent, and Atrium Health Wake Forest Baptist, including Wake Forest University School of Medicine (WFUSM). Wake Forest University (Reynolda Campus) faculty and all CTSI affiliated institutions with a WFUSM co-investigator are also invited to apply.

The CTSI will allow a Co-PI structure if both PIs have expertise relevant to the project with distinct contributions to its design and implementation. Non-Faculty Researchers (allied health disciplines) may serve as a Co-PI with a WFUSM faculty researcher.

For projects that are focused on Community-Engaged Research and intend to have a community representative serve as a Co-PI, the community-representative must work for a non-profit community organization or local government agency that serves the community within the Southeast Region of Advocate Health.

Additional Information

- Projects previously submitted as CTSI or other intramural Pilot Proposals <u>are</u> eligible for resubmission but must incorporate reviewer feedback. A one-page document summarizing how the feedback was incorporated into the application can be uploaded in the "Additional Document" field in the eApplication.
- Each applicant may submit only one proposal to this RFA per cycle, either as Principal Investigator (PI) or Co-Principal Investigator (Co-PI).
- Pls may only apply to one CTSI Pilot RFA per cycle (Pls may apply to both Science of Translation and Translational Research in the same cycle).
- CTSI K12 scholars whose funding is active during the pilot project period are not eligible to apply.
- Projects that have been previously funded (or projects with very similar ideas) will not be considered.
- PIs are limited to two funded CTSI pilots unless special permission is granted in advance of the Letter of Intent submission deadline. Please email Brittney Patterson at brittney.patterson@advocatehealth.org to request permission.
- Investigators with active Ignition Funds remain eligible.

FUNDING

Up to four projects will be funded. Successful pilots will receive **up to \$40,000** in direct costs. All projects must meet the above specifications outlined under "Purpose."

Projects that include one or more of the following criteria will receive up to an additional \$10,000 resulting in an increased total award **up to \$50,000** in direct costs.

- 1) Investigators from multiple regions and/or markets within the health system;
- 2) Community partners as collaborators and/or project leaders;
- 3) Demonstrates substantive contribution from the community partner (e.g., funds support community partner activities and roles).

Project final budgets will be based on a complete review of the budget and budget justification. See "Budget Guidelines" below for more details. All funds must spent within a one-year project period; <u>due to the restrictions</u> on CTSA funding, no-cost extensions cannot be approved.

Supplements

The Center for Artificial Intelligence Research (CAIR) is offering a \$10,000 bonus for one pilot award if the proposed project involves artificial intelligence faculty, techniques, and methods. This bonus will be awarded to one pilot proposal evaluated as meritorious by CTSI Administrators and the IRSC. After an additional review by the CAIR leadership, the resulting pilot award will be supported in the amount of up to \$50,000. The awardees (all key study personnel) are required to be members of CAIR to receive the artificial intelligence bonus. Please indicate in your application if you would like to be considered for this bonus award.

KEY DATES

Date	Detail
10/08/25, 11:59 pm	Letter of Intent (LOI) Deadline
11/10/25	Investigators Invited for Full Application
12/17/25, 11:59 pm	Full Application Deadline
03/04/26	Selection of Awardees
05/30/26	If applicable, completed materials sent to NCATS for approval
07/01/26	Project Start Date
06/30/27	Project End Date

CTSI RESOURCES AVAILABLE TO SUPPORT INVESTIGATORS

The CTSI offers several resources to help submit a strong application; while they are not required as part of the submission, investigators are <u>highly encouraged</u> to seek additional assistance. All services can be requested through the CTSI Service Request form and are free for everyone, unless otherwise noted.

- **Biostatistical Support:** meet with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission.
- Community & Stakeholder Engagement Consultation: meet with the Community and Stakeholder Engagement team to discuss recruiting special populations and working with community partners.
- CTSI Pilot Consultation: meet with a CTSI faculty member (clinician, basic scientist, or behavioral scientist) to talk through project ideas or to find research/clinical partners.
- **Grant Proposal Editing:** have an expert medical editor review your proposal prior to submission. They will offer suggestions on how to refine your writing and thinking. Your proposal will be edited in "track changes" so that you can easily accept or reject edits.
- **Informatics Consultation:** optimization of the EMR to extract data for research purposes (free or feefor-service, depending on need).
- **Research Studio:** meet with a multi-disciplinary panel of experts to work through specific aims, hypotheses, or ways to address the generalizable requirement.

APPLICATION PROCEDURE

LOIs and Full Applications that do not comply with these guidelines will not be considered for review.

Letter of Intent (LOI) Requirements

Deadline: 10/08/2025, 11:59pm

- 1 page max (references may be additional pages). Must be uploaded in PDF format.
 - o A brief abstract, including specific aims.
 - A clear statement of how the project aligns with the RFA purpose with the goal of improving translational efficiency and accelerating the development of health-improving interventions. A brief overview of study methods and the feasibility of completing the project in the 1-year time period should also be included.
 - A list of study team members for the proposed project. All team members should have agreed to participate in the proposed study.
- LOI applications should be completed by the deadline (10/08/25) at the link below.

Click here to access the ePilot Electronic Submission Form

Review Criteria and Process for LOIs

- 1. An administrative review will be completed to verify all required components were submitted and formatting guidelines were followed (e.g. does not exceed page limit).
- LOIs that pass the administrative review are reviewed by the WF Intramural Research Support Committee (IRSC), a Dean-appointed committee of selected expert faculty. Reviewers at this stage will be looking for whether proposed projects can help advance translational science and to ensure the project is responsive to the RFA.
- 3. An invitation to apply for a full application, or notification if you are not selected, will be communicated via e-mail by 11/10/25.

Full Application Requirements

Deadline: 12/17/25, 11:59pm

Investigators invited to apply will receive an e-mail by 11/10/25 with a link to submit a full application by the deadline indicated above. **Applications received after 12/17/25 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top, and bottom)
- Single-spaced lines
- All uploaded documents must be in PDF format

Submission/Applicant Information

- Project Title
- Submitting Principal Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (250 words max)

Research Strategy (4 pages max, all items below are required components)

- Specific Aims (1/2 page minimum; 1 page max)
- Research Plan (3 page minimum; 3.5 pages max)
 - Significance
 - Innovation
 - Approach
 - Study Team
- Study Milestones and anticipated outcomes (see Appendix I for examples)

References (no page limit)

Statement on Health for All Populations (300 words max - optional)

Please provide a statement describing how your proposed project will promote health for all
populations. Describe how your research design, methods, and goals address significant health
challenges. Explain how your approach considers the varied needs of affected populations. Include any
strategies you will use to promote broad engagement and ensure that the outcomes of your research
are available and beneficial to those impacted.

Information Regarding Human Subjects

Address the following if the project involves human subjects.

- IRB Approval Status (note: IRB approval is <u>not required</u> for full application submission)
- Clinical Trial Classification Questions
 - If your project requires an IND/IDE submission or exemption, please use the <u>CTSI Service</u> <u>Request</u> form to schedule a consultation for support and to discuss timelines. The timelines can impact your project timeline and should be considered in the project plans.
- Protection of Human Subjects (2 pages max)
 - Needs to clearly describe risk, protections, benefits, and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions.
- Inclusion of Individuals Across the Lifespan (1 page max)
- Inclusion Plans for Women and Minorities, if applicable (1 page max)
- Recruitment and Retention Plan (2 pages max)
- Target Enrollment Table (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable (1 page max)
 - o If you are unsure how much safety monitoring your study will need, please contact the IRB/HRPP Director, Brian Moore at justin.b.moore@advocatehealth.org.

Information Regarding Live Vertebrates

Address the following if the project involves live vertebrates.

- IACUC Approval Status (note: IACUC approval is not required for full application submission)
- IACUC approval will be required (as 'just in time' information) for implementation of projects with live vertebrate animals

Budget and Justification (budget template plus 1 page justification)

- Complete the <u>budget template form</u> and a brief justification for the funds requested. Please explain how other resources may be leveraged to support the project. If the proposed research will be done on more than one campus/institution, please include details in the justification.
- If salaried effort is not included in the budget for key study personnel, please explain.

NIH-style biographical sketch for all Key Personnel

All key personnel listed on the grant application (e.g., PI, Co-PI, Co-Investigators) must submit a NIH-style biosketch using the current format (OMB No. 0925-0001 and 0925-0002). Templates and instructions are available on the NIH Biosketch Format page.

Translational Science Benefit Model (TSBM)

- This funding mechanism utilizes the TSBM as a foundational framework to help plan, show, and explain how your proposed work can make a real impact. Applicants are required to select a maximum of 5 TSBM indicators that pertain to the proposed project.
- While this portion of the application is required, this information will <u>not</u> be included in funding decisions.

Review Criteria and Process for Full Proposals

- An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed. Applications that do not comply with guidelines will be automatically disqualified and will not be considered for review.
- 2. Proposals that pass the Administrative Review are peer-reviewed by the WF Intramural Research Support Committee (IRSC) using NIH review criteria and scoring. Budgets will be reviewed by both CTSI Administrators and IRSC for appropriateness.
- 3. Final award approval will be at the recommendation of CTSI Leadership.

Reviewers will score applications from 1 to 9 based on:

- 1. Importance of the Research (Significance and Innovation)
- 2. Rigor and Feasibility (Approach)
- 3. Expertise and Resources (Investigator and Environment), to be evaluated as either sufficient for the proposed research or not
- 4. Clear project milestones and reporting plan
- 5. The likelihood that the investment will lead to external funding, publication, or a licensable innovation.

BUDGET GUIDELINES

The project is one year beginning 07/01/26 and ending 06/30/27. Funded projects receive certain CTSI Services free of charge. If the proposed project plans to use these services, they should be included in the budget at \$0 and in the budget justification. For a list of CTSI services and associated fees, see the CTSI Hourly Services Pricing Grid.

Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Travel, if necessary to perform the research
- Small equipment, research supplies, and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may not be budgeted for:

- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Capital equipment

- Manuscript preparation and submission
- General materials that are utilized across multiple projects or for broader-use
- Indirect costs

Awarded funds must be used to conduct the proposed work. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. The CTSI reserves the right to revoke funding if it is determined that funds were not spent in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects are set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

PROGRAM EXPECTATIONS

Prior to funding, awardees will be assigned to a Research Navigator to: 1) assist with study initiation; 2) convene an initial meeting with the project PI, CTSI administrative personnel, and a senior CTSI leader to discuss the project and how CTSI resources can be leveraged for the pilot grant; and 3) monitor progress throughout the life of the study. If any significant issues arise, the study team will be required to work with the CTSI to determine solutions so that the study can be successfully completed (or in rare cases, terminated).

Pilot projects that involve new teams from different markets or outside community partners will be required to engage the CTSA Team Effectiveness Consultation Service to facilitate collaboration and successful team management.

Specific Deliverables

- Participation in the study initiation meeting
- Participation in a 6-month check-in meeting and report
- Upon completion of the project:
 - o Close-out report, with plans for implementing and disseminating innovations
- Presentation of findings at requested events (i.e. CTSI Day, CTSI Seminar Series, Service Line Meeting, CTSI's annual External Advisory Committee meeting)
- Manuscript submitted within one year of the end of the pilot award
- Disclosure of 1) how results will be implemented and/or disseminated; 2) applications for extramural funding beyond the pilot grant; 3) what subsequent notification of funds occurred; and 4) related publications or significant collaborations resulted from the project, for a minimum of 5 years after completion of the award.

Other Guidelines

- 1. Prior to receiving funds, research involving human subjects must have appropriate approval from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CTSI prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
- 2. Research involving human subjects must also have approval from the National Center for Advancing Translational Sciences (NCATS). NCATS has defined human subjects research (HSR) categories and determined the approval procedures per category. NCATS submission will be facilitated by the CTSI. Note: The study cannot be submitted to NCATS until after IRB approval has been given.
 - a. Category 1: Greater Than Minimal Risk studies and all NIH-defined Clinical Trials
 - i. Category 1 studies/trials require approval from NCATS to begin.
 - b. Category 2: Minimal Risk and Exempt Studies
 - i. HSR study is exempt and/or considered minimal risk by the IRB
 - ii. Category 2 studies must be submitted to NCATS, but do not require formal approval.
- 3. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the CTSI prior to funds being released.

- 4. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UM1TR004929. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Publications must also be registered in PubMed Central.
- 5. Any awardee who leaves his or her position should contact the CTSI to discuss plans for the project.

GRANT ADMINISTRATION

The Principal Investigator is responsible for the administration of grant funds.

CONTACTS

Questions about your research project or the ePilot electronic submission system should be directed to Katelyn Still at katelyn.still@advocatehealth.org.

CTSI PILOT FREQUENTLY ASKED QUESTIONS (FAQS)

- 1. What is the difference between Science of Translation and Translational Research?
 - a. The science of translation (SoT) is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

 Translational Research (TR) is the endeavor to traverse a particular step of the translational process for a particular target or disease. More information can be found on the CTSI Pilot Program website.
- 2. I submitted a pilot application last year that was not funded. Can I resubmit to this RFA?
 - a. Yes, you can resubmit an application from a previous year. It is expected that reviewer feedback from the previous submission should be included in the resubmission. A one-page document summarizing how the feedback was incorporated into the application can be uploaded in the "Additional Document" field in the eApplication.
- 3. Are investigators/institutions from outside the Southeast Region of Advocate Health allowed?
 - a. Investigators from institutions outside the Southeast Region of Advocate Health are allowed only if they are listed as key study personnel. They cannot be listed as PI or Co-PI.
- 4. Are international partners allowed?
 - a. No, international partners are not permitted for pilot funding.
- 5. Do I need to submit this application with OSP?
 - a. As this is internal funding, applications do not need to go through the Office of Sponsored Programs. Please apply directly to the link above in this RFA.
- 6. How do I note that I would like to be considered for the CAIR supplement?
 - a. Include the supplemental funding in your budget and note in the budget justification what the supplemental funding will be used for.
- 7. If I include references in my LOI, does this count towards the 2-page limit?
 - a. No, references for your LOI are not included in the 2-page limit.
- 8. Will I receive written feedback from the review of my LOI?
 - a. Yes, after the LOIs are reviewed, all applicants will receive reviewer comments and feedback.
- 9. Will I receive written feedback from the review of my full application?
 - a. Yes, after the full application review, all applicants will receive reviewer comments and feedback.
- 10. Are sub-awards allowed?
 - a. Sub-awards to other institutions are permissible, provided that most of the pilot project's activities and dollars spent occur within WF or one of its affiliates. Please note CTSI Pilots are 1-year grants and sub-award set-up can take a significant amount of time that is outside the control of the investigative teams.

APPENDIX I: STUDY MILESTONE EXAMPLES

Below are examples of study milestones, outcomes, and timelines. However, these formats are not required.

Example 1:

- Milestone 1 (0-1.5 months): Milestone 1 Details Outcome: Outcome 1 Details
- Milestone 2 (1.5-4 months): Milestone 2 Details Outcome: Outcome 2 Details
- Milestone 3 (4-6 months): Milestone 3 Details Outcome: Outcome 3 Details
- Milestone 4 (6-12 months): Milestone 4 Details Outcome: Outcome 4 Details
- Milestone 5 (8-12 months): Milestone 5 Details Outcome: Outcome 5 Details

Example 2:

Timeline and Milestones												
Month	1	2	3	4	5	6	7	8	9	10	11	12
Activity/Aim/Milestone 1	Х	Х	Х	Х								
Activity/Aim/Milestone 2	Х	Х										
Activity/Aim/Milestone 3		Х	Х	Х								
Activity/Aim/Milestone 4					Χ	Х	Χ	Х	Х	Χ		
Activity/Aim/Milestone 5					Χ							
Activity/Aim/Milestone 6						Χ	Χ					
Activity/Aim/Milestone 7								Χ		Χ		
Activity/Aim/Milestone 8											Χ	Χ

Example 3:

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
1	Milestone 1	Χ	Χ		
	Milestone 2		Χ		

Aim 1 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
2	Milestone 1		X	Χ	
	Milestone 2		X		
	Milestone 3			Χ	

Aim 2 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
3	Milestone 1			Χ	
	Milestone 2			Χ	Χ

Aim 3 Anticipated Outcomes: Detail