

Wake Forest Clinical and Translational Science Institute (CTSI) Request for Applications for Translational Research Pilot Awards

PURPOSE

The purpose of this RFA is to support high impact pilot projects that help catalyze translation of discoveries to treatments or the delivery of care. The ultimate aim of this program is to make research investments that maximize healthcare value and improve population health. The immediate aim is to allow investigators to develop, test, or disseminate novel approaches to a translational research question and obtain preliminary data in support of larger follow-up investigations. Examples of pilot studies include feasibility studies, secondary analysis of existing data, development of new research methodology and/or new tools, dissemination of effective tools, methods, processes, or early development of new therapy/technology and can include investigation of patient or health care provider behaviors. A preferred, but not required, characteristic is that such research not only addresses a translational research question, but also provide insights that could be generalized to other projects. Generalizable solutions are ones that can be applied to other patient populations or disease mechanisms (e.g. how the technique can be used in other disease states; how the process can be used in a different patient population).

Successful proposals will clearly state:

- How the proposed project advances research in a particular field to address health care needs within the population
- A rationale and potential for generalizability (if applicable)
- How the proposed project is translational (e.g., identify translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them)
- A feasible project plan for the one-year award period
- Address next steps for this project: Will it lead to larger, subsequent grant applications (be specific: indicate RFA you will submit to and when)? Can it be applied to improve health or how we deliver care? How will results be disseminated? Is the project scalable? Consider the full range of possibilities for how the Medical Center and/or our community will benefit.

No pilot data is necessary to apply for this RFA, however supporting data from the recent literature is appropriate, if available. A list of previously funded CTSI Translational Research Pilots can be found [here](#).

PILOT AWARD CATEGORIES & FOCUS AREAS

This RFA is open to research project proposals in one of the following categories:

- **Basic Research (T0):**
Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. Every stage of the translational research spectrum builds upon and informs basic research.
- **Preclinical Research (T1):**
Preclinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.
- **Clinical Research (T2):**
Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.
- **Clinical Implementation (T3):**
The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.
- **Public Health (T4):**
In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Translational Research projects are encouraged, but not required, to focus on the following areas: the **Academic Learning Health System, Community-Engaged Research, Health Informatics, Implementation Science**. More information about these focus areas can be found on the [CTSI Pilot Program website](#).

The WF CTSI seeks to ensure we reach all populations to engage them in clinical and translational research. Over time, we seek to fund community-oriented research that improves health for all at parity with biomedical research. Pilots that identify a clear impact on improving community health broadly will be considered as maximally responsive to the solicitation, assuming that other criteria are met. While projects are not required to have this type of focus, applicants are encouraged to document the potential impact of their project on improving health in a broad array of communities and individuals.

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 are 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).
- PIs may only apply to one CTSI Pilot RFA per cycle (PIs 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

Successful pilots will receive **up to \$40,000** in direct costs. All projects must meet the above specifications outlined under “Purpose.” 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 be spent within a one-year project period; no-cost extensions will not be approved.

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
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 highly encouraged 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 fee-for-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.
 - A brief abstract, including specific aims.
 - A clear statement of how the project will overcome translational barriers that impede advancement of research translation, and a statement of what makes the project generalizable to other populations or disease mechanisms. 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).
2. 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.
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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 pages 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 not required for full application submission)
- Clinical Trial Classification Questions
 - If your project requires an IND/IDE submission or exemption, please use the [CTSI Service Request](#) 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)
- Targeted Enrollment Table (using [NIH Targeted Enrollment Table](#))

- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable (1 page max)
 - 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 [budget template form](#) 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 not 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.
- 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.
- 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 work proposed. 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:
 - 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. 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.
3. 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.

4. Any awardee who leaves his or her position should contact the CTSI to discuss future 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 Translational Science and Translational Research?
 - a. Translational Science (TS) 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	X	X	X	X									
Activity/Aim/Milestone 2	X	X											
Activity/Aim/Milestone 3		X	X	X									
Activity/Aim/Milestone 4					X	X	X	X	X	X			
Activity/Aim/Milestone 5					X								
Activity/Aim/Milestone 6						X	X						
Activity/Aim/Milestone 7								X		X			
Activity/Aim/Milestone 8											X	X	

Example 3:

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

Aim 1 Anticipated Outcomes: Detail

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

Aim 2 Anticipated Outcomes: Detail

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

Aim 3 Anticipated Outcomes: Detail