Wake Forest Clinical and Translational Science Award (CTSA)
Request for Applications for Element E Proposals

PURPOSE

The Wake Forest CTSA Element E is soliciting accepting applications for the Clinical and Translational Science Research Program Awards (Element E), funded by the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) CTSA Program.

Element E has the goal to advance clinical translational science through innovative, highly translatable research projects that address significant roadblocks in the field. The 2026 award will fund highly meritorious interdisciplinary clinical and CTSA projects that address truly significant roadblocks in translational science. Research projects should not only address a translational research question in a particular disease or intervention development/dissemination context but also provide generalizable translational science innovations or insights that can be applied to other translational research projects and thereby increase the overall efficiency or effectiveness of translation.

The organizing theme of the Wake Forest CTSA Element E is: *Enhancing patient engagement in translational science using innovative strategies and technologies.* The program focuses on three specific translational science roadblocks: using electronic health records for research, clinical trial recruitment, and optimizing translation of research into practice.

ELIGIBILITY

These awards are open to investigators in the Advocate Health enterprise with a primary faculty appointment at Wake Forest University School of Medicine. Cross department collaboration is strongly encouraged.

Additional Information:

- CTSI K12 scholars whose funding is active during the pilot project period are not eligible to apply.
- Investigators with active Ignition Funds remain eligible.

FUNDING

Element E projects are planned to be two-year projects. Successful proposals will receive **$125,000** in direct costs per year, for a maximum of $250,000. See "Budget Guidelines" below for more details. All funds must be spent within a two-year project period; no-cost extensions will not be approved.

KEY DATES

Date	Detail
05/01/26, 11:59 pm ET	Letter of Intent (LOI) Deadline
June 2026	Investigators Invited for Full Application
11/02/26, 11:59 pm ET	Full Application Deadline
12/31/26	Selection of Awardees
07/01/27	Earliest Project Start 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 provided at no cost, unless otherwise noted.

- **Element E Team:** Connect with the leaders and administrator to ensure proposal ideas fall within the scope of Translational Science.
- **Biostatistical Support:** Consult with a statistician to refine study design, measurement strategies, and statistical analysis plans prior to submission.
- **Grant Proposal Editing:** Receive expert review from a medical editor prior to submission, with detailed suggestions to strengthen clarity, rigor, and impact. Edits will be provided using track changes to facilitate review and revision.

- **Informatics Consultation:** Support for optimizing use of the electronic medical record (EMR) to extract research data (services may be free or fee-for-service, depending on scope and need).
- **Research Studio:** Engage with a multidisciplinary panel of experts to refine specific aims, hypotheses, and approaches to meeting the generalizability 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: 05/01/2026, 11:59pm

- 4 pages max (references may be additional pages). Must be uploaded in PDF format.
  - A brief abstract, including specific aims (max 500 words).
  - Project Overview
    - Part 1: Describe the translational science innovation, including the current state of science and how this project will advance it.
    - Part 2: Describe the context (particular disease or intervention development) in which you will test the innovation.
    - Part 3: How will the innovation be evaluated?
    - Part 4: How will findings be generalizable across diseases, populations, or settings?
    - Part 5: How does this project relate to the organizing Element E theme to: *Enhance patient engagement in translational science using innovative strategies and technologies.*
  - Address Roadblocks (max 1 page): Please describe which clinical and translational science roadblocks the project is addressing.
    - Clinical Trial Participant Recruitment – Element E theme
    - Electronic Health Records for Research – Element E theme
    - Optimizing Translation of Research into Practice – Element E theme
    - Registries and Natural History Studies
    - Adaptive Clinical Trial Designs
    - Incentives/Credits for Health Improvements
    - Shortening Time of Intervention Adoption
    - Patient/Community Engagement
    - Other Translational Challenges
  - A proposed timeline
- LOI applications should be completed by the deadline (**05/01/26**) 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.
2. LOIs that pass the administrative review are reviewed by the Element E and CTSA leadership for significance, innovations, and relevance to the current translational science program.
3. An invitation to apply for a full application, or notification if you are not selected, will be communicated via e-mail in June 2026.

Full Application Requirements

Deadline: 11/02/26, 11:59pm

Investigators invited to apply will receive an e-mail in June 2026 with a link to submit a full application by the deadline indicated above. **Applications received after 11/02/26 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 (300 words max)

Research Strategy

- Specific Aims (1 page max)
- Research Plan (6 pages max, all items below are required components)
    - Significance
    - Innovation
    - Approach
    - Study Team
- Study Milestones and anticipated outcomes (1 page max)

References (no page limit)

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 james.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 proposal application must submit a NIH-style biosketch using the SciENcv common form.

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.

Letters of Support

- If applicable, provide letters of support from relevant partners.

Review Criteria and Process for Full Proposals

- An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed.
- Teams that receive invitations to submit full applications are encouraged to consider the following criteria when writing their proposal:
    - Significance
        - The proposal's research question and the translational science challenges it addresses relate to primary themes of this RFA and are in scope.
        - The proposed project addresses a truly significant roadblock in translational science that if successful would have generalizable application.
        - The proposal includes a well-reasoned ethical consideration of the research and its broader implications.
    - Innovation
        - The proposed project utilizes innovative approaches to accomplish its stated aims.
        - The proposed approach is clear, reasonable and appropriate.
        - The advantage of this approach over the next best alternative is well-justified.
    - Outcomes and Evaluation
        - Proposed outcomes are new concepts, methods, technologies, or research practices that drive translational science and are reasonable, justified and worthwhile.
        - A definition of success and relevant metrics are included that are reasonable and appropriate.
    - Timeline and Budget
        - A reasonable timeline and effective key milestones are included for completing the project within two years.
        - The budget is reasonable and justified for the proposed activities and is within Clinical and Translational Science Research Program Award parameters.

BUDGET GUIDELINES

The project is two years beginning 07/01/27. 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, CTSA administrative personnel, Element E administrator, and an Element E 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).

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. 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 Element E leadership 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:

Erica Hale, Program Director
erica.hale@advocatehealth.org

Thomas Houston, MD, MPH
thomas.houston@advocatehealth.org

Caitlin Allen, PhD, MPH
caitlin.allen@wfusm.edu