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

Purpose

The purpose of this RFA is to support new and innovative research projects relevant to the science of translation. **These pilot projects must be focused on advancing translational science and not just be translational in nature**. They must be focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of laying the scientific foundation for improvements in translational efficiency that will accelerate the realization of interventions that improve human health. While critically important, projects focused on crossing a particular step of the translational process (i.e. T1 to T2) for a particular target or disease, are not allowed.

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 therapy/technology with generalizable application to an identified translational roadblock (as defined in this publication by C. Austin).
- 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) (https://ncats.nih.gov/n3c) Data Enclave).

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 Science Pilots can be found here.

Focus Areas

Projects that focus on the **Academic Learning Health System** (Appendix I), **Community-Engaged Research** (Appendix II), **Health Disparities** (Appendix III), **Health Informatics** (Appendix IV), and **Implementation Science** (Appendix V) are encouraged, but not required.

The WF CTSI is continuing to address disparities by deconstructing structural inequities in clinical and translational research. Over time, we seek to fund health equity and community-oriented research at parity with biomedical research. Pilots that identify a clear impact on improving health equity will be considered as maximally responsive to the solicitation, assuming that other criteria are met. While projects are not required to focus on health equity, applicants are encouraged to document the potential impact of their project on equity.

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. Wake Forest University (Reynolda Campus) faculty and all CTSI affiliated institutions with a Wake Forest 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 traditional 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.
- Only one proposal may be submitted per faculty member serving as PI or co-PI.
- CTSI KL2/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.
- Investigators 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 britjack@wakehealth.edu 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 are to be spent within a one-year project period; **due to the restrictions on CTSA funding, no-cost extensions cannot be approved**. Funds for these projects are provided by NCATS.

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 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 want to be considered for this bonus award.

The Perioperative Outcomes and Informatics Collaborative (POIC) is offering a $5,000 bonus for one pilot award if the proposed project investigates perioperative outcomes and/or informatics. After an additional review by the POIC leadership, the resulting pilot award will be in the amount of up to $45,000. Preference will be given to projects that include a multi-disciplinary team of clinicians and non-clinician scientists across the Southeast Region of Advocate Health. Please indicate in your application if you want to be considered for this bonus award.

Key Dates

Date	Detail
10/11/24, 11:59 pm	Letter of Intent (LOI) Deadline
11/12/24	Investigators Invited for Full Application
12/13/24, 11:59 pm	Full Application Deadline
03/05/24	Selection of Awardees
05/19/25	If applicable, completed materials sent to NCATS for approval (Appendix VI)
07/01/25	Project Start Date
06/30/26	Project End Date

CTSI Resources Available to Support Investigators

Several resources are available in the CTSI to help submit a strong application; while they are not required as part of the submission, investigators are highly encouraged to seek out additional assistance. All services can be requested through the CTSI Service Request form.

- **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 (free to everyone).
- **Biostatistical Support:** meet with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission (free to everyone).
- **Research Studio:** meet with a multi-disciplinary panel of experts to work through specific aims, hypotheses, or ways to address the generalizable requirement (free to everyone).
- **CTSI Faculty Consultation:** meet with a CTSI faculty member (clinician, basic scientist, or behavioral scientist) to talk through project ideas or to find research/clinical partners (free to everyone).
- **Informatics:** optimization of the EMR to extract data for research purposes (free or fee-for-service, depending on need).
- **Community & Stakeholder Engagement Consultation:** meet with the Community and Stakeholder Engagement team to discuss recruiting special populations and working with community partners (free to everyone).

Application Procedure

1. Letter of Intent Deadline: 10/11/24, 11:59 pm

Letters of Intent (LOI) (2 pages max) require the following:

- 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. Study methods and feasibility of projects should also be included.
- A list of study team members for the proposed project. All team members should have agreed.

The LOI should be submitted through the ePilot electronic submission system by the deadline noted above.

Review Criteria and Process for Letters of Intent

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed (e.g. does not exceed page limit).
2. Letters of Intent 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 11/12/24.

2. Full Application Deadline: 12/13/24, 11:59 pm

Investigators invited to apply will receive an e-mail by 11/12/24 with a link to submit a full by **12/13/24.** **Applications received after 12/13/24 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

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

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 should 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 (**6 pages max**, **all items below are required components**)

- Specific Aims (1 page max)
- Research Plan
  - Significance
  - Innovation
  - Approach
  - Study Team
- Study milestones and anticipated outcomes (e.g. publication, presentation, grant submission, patent) with timeline (see Appendix VII for examples)

References (**no page limit**)

Statement on Health Equity Impact (300 words max)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- IRB Approval Status (please 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 full project timeline and should be considered in the project plans.
- Protection of Human Subjects (1 page 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
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Recruitment and Retention Plan
- Targeted Enrollment Table (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
  - If you are unsure how much safety monitoring your study will need, please contact the IRB/HRPP Director, Brian Moore at jbmoore@wakehealth.edu.

Information Regarding Live Vertebrates

Address the following if the project **involves live vertebrates**.

- IACUC Approval Status (please 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.
- 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.
- 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.

NIH-style biographical sketch for all Key Personnel

Review Criteria and Process for Full Proposals

1. 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. Significance of the problem to be addressed
2. Innovation of the proposed solutions
3. Strength and breadth (interdisciplinary nature) of the investigative team
4. Methodological rigor, feasibility, and generalizability
5. Clear project milestones and reporting plan
6. Potential of scalability and potential to affect quality and efficiency of care
7. Inclusivity of the study team participants
8. Impact of the work on health equity
9. The likelihood that the investment will lead to external funding, publication, or a licensable innovation; early-career faculty involvement, race/gender inclusiveness of the research team; and inclusion of women, minorities, older adults, and children as potential study participants.

Budget Guidelines

The project is one year beginning 07/01/25 and ending 06/30/26.

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
- Upon completion of the project:
    - Close-out report, with plans for implementing and disseminating innovations
- Presentation of findings at requested events (i.e. 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 4 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. CTSI staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
5. 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 UL1TR001420. 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.
6. 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 Brittney Patterson at britjack@wakehealth.edu. ***New*** FAQs page for more tips and information.

Appendix I: Academic Learning Health System

Quality, safety, and outcomes could be markedly improved if demonstrated best practices were universally adopted. However, the traditional healthcare system does not promote a culture of institutional learning to improve practices, apply research principles, evaluate change, or share best practices between systems to rapidly and widely disseminate innovations.[1] Advocate Health is growing as an academic Learning Health System. Expanding from the standard definition of a Learning Healthcare System,[2] (see definition below), we define an Academic Learning Health System (aLHS) as a particular Learning Health System built around a robust academic community with a central academic mission,[3] with six differentiating features (see full definition below). Aligned with the national CTSA program emphasis on implementation, a further recent commentary has highlighted the potential role of dissemination and implementation science in addressing challenges in operationalizing LHS.[4]

As academic Learning Health Systems seek to integrate research and clinical operations, so does this pilot award. The academic Learning Health System Pilot Award is designed to incentivize and support a broad range of research (exploratory studies, QI projects, evaluations of interventions, evaluations of barriers to implementing interventions) that either answer questions about how to create an academic Learning Health System, or where and how research is an intentional element in the growth to an academic Learning Health System. Thus, the purpose of this RFA is to stimulate *innovative research ideas that can transform the way we deliver care.*

Definitions:

A **Learning Healthcare System** is defined, by the Institute of Medicine, as a system in which, "science, informatics, incentives and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the delivery experience."[2] Five key components of LHS include Organizational Learning (innovation and quality improvement), Translating Research into Practice, Engagement with Key Stakeholders (e.g.: leaders, clinical teams, clinicians, patients, community and state organizations), and Building New Knowledge.[5]

An **Academic Learning Health System** (aLHS) as a particular Learning Healthcare System built around a robust academic community with a central academic mission. An aLHS 1. capitalizes on embedded academic expertise in health system sciences; 2. engages the full spectrum of translational investigation from mechanistic basic sciences to population health; 3. builds pipelines of experts in Learning Health Systems Sciences and clinicians with fluency in practicing in learning health systems; 4. applies core LHS principles to the development of curricula and clinical rotations for medical students, house staff, and other learners; 5. disseminates knowledge more broadly to advance the evidence for clinical practice and health systems science methods; 6. addresses social determinants of health and creates community partnerships to mitigate disparities and improve health equity. [3]

Translational science, as defined by the NIH, "represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. **Translation** is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes. **Translational Science** is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process." [6]

Projects that address the academic Learning Health System topic and are both generalizable and translational are encouraged. These include, but are not limited to projects that:

- **Move QI / system change projects into publishable and generalizable research.** Examples: Test whether process changes that worked at WF also work at other hospitals; implement a tested quality improvement method at WF; increase the reliability of quality improvement initiatives by incorporating prospective non-randomized controlled trial designs or quasi-experiments (enhanced observational study designs), using staggered implementation, risk adjustment, or case matching approaches.
- **Import practices from other healthcare systems.** The challenges we face as a healthcare system are certainly not unique. We should learn from others who have managed the same challenges. Example: Import features of other healthcare systems -national or international- and adapt them for use in our system.

- **Test ways to engage clinicians in research**. Bringing together clinicians (who can identify healthcare delivery problems) and researchers (who can develop and test research questions) can lead to an evidence-based pipeline that moves clinicians' ideas into research and then back into clinical practice. Examples: Embed a researcher into a service line to find healthcare delivery problems we need to address with research. Invite clinicians to bring the top two clinical issues they have observed to a meeting with researchers ("Which process issues you have observed? What do you notice every time you deliver care to a certain group of people? Which questions would you test if only you could pull the data from the EMR?"). Test strategies to bring clinicians into clinical trials or other ongoing studies. The success of the clinician-researcher interactions might be measured via process measures such as the number of ideas generated, or whether a clinical issue is turned into a research question that is explored further (e.g., results in a ticket to Encompass for a data pull).
- **Engage patients and other healthcare stakeholders to influence research and improve care.** Example: Engaging non-traditional research partners and incorporating perspectives beyond those of the research team – from topic selection to outcome selection and study design to conduct and dissemination of the results – can improve the utility of research for patients and providers. For example, one approach could involve capturing ideas from patients (or parents of patients) treated within our healthcare system, asking them about their concerns, and then rank ordering them (using the Delphi method). Items could be ranked as most pressing or most testable (e.g., medication list is not current on the patient printout; test results are shared with the patient through myAtriumHealth before the clinician interprets them).
- **Test ways to change culture / form identity so that all faculty and staff understand that they are part of a Learning Healthcare System.** Example: Strategies could focus on education about research or evidence-based practice, institutional campaigns, or group discussions. For example, one approach might be to ask staff at department meetings to list how they are contributing to a LHS and to conduct a pre/post-test of clinicians and staff identifying as researchers after the intervention. Test strategies to develop and maintain a continuous learning culture, or strategies to align healthcare delivery incentives to support the Learning Healthcare System goals.

Examples of projects that focus on aLHS will meet some or all of the below criteria:

- Project addresses a problem facing the Advocate Health system.
- The project involves the development of practices, treatments, tools or approaches that will improve care.
- If the project involves an intervention, the intervention is informed by published research (i.e., based on pre-existing evidence).
- Inclusion of both a skilled researcher and clinician with expertise relevant to the project contributes to designing and implementing the approach used for learning and for testing the intervention.
- Results from the research are delivered in a timely/expedited fashion.
- The analysis of clinical data is a central aspect of the project.
- Results from the learning process are disseminated throughout the organization in a manner that leads to better patient care and improved organizational practices and policies.
- The project has **demonstrated support** from a clinical unit, service, and/or leadership, and the clinical unit, service, and/or leadership has participated in the conceptualization of the pilot.
- The project products could be more **widely adopted** by Advocate Health if the strategy being implemented was found to be effective.
- The project will test strategies designed to translate research into practice (specifically to implement into practice guidelines, processes, delivery models, new tools and other innovations that are supported by the prior literature and/or national organizations).
- The project will result in pilot data that can be leveraged to apply for a **larger grant** from an external funding entity (NIH, NSF, PCORI, non-governmental, etc).
- The project holds the potential for intellectual property development through Wake Forest Innovations.
- The project involves inter-professional collaboration.

Appendix II: Community-Engaged Research

The primary focus of the Patient Engagement Research and/or Community-Engaged Research award supplement is to promote the development or application of patient or community engaged research, community-based participatory research (CBPR), or citizen science projects.

Justification for the Patient Engagement Research and/or Community-Engaged Research project should include the following:

- Explanation of how patient engagement research, community-engaged research (CEnR), community-based participatory research (CBPR), and/or citizen science best practices will be applied
- Describe how community and patient partners will inform and guide the study across the research process from idea generation, study design and methods, recruitment and retention, data collection, interpretation and dissemination of results.
- Include a description of how this role is reflected in the research study budget (e.g. stipend, honorarium, consultant fees, percentage of salary, flat payment amount)
- Describe the relevance of the community and patient engagement as it relates to the study focus and design.

Projects that are Patient Engagement Research and/or Community-Engaged Research (for the purposes of this award) must include the following:

- Roles, and/or tasks and activities that are included in the project, specifically for patient, family of patient, or community partners in the research other than research participant (e.g. Co-PI, consultant, member of steering committee, advisory group, working group, community engagement studio)
- Process for bidirectional communication between the members of the research team and select members of the patient population, family member of patient, and/or select community members outside of the research team.
- Bidirectional communication and co-learning.

Examples of Projects that are NOT Patient Engagement Research and/or Community-Engaged Research (for the purposes of this award):

- Projects whose aim is to improve patient health or improved community health, but do not have an active role for patient, family or community representatives in the research other than research participant.
- Projects that are community-oriented but lack scientific rigor and the use of best practices will not be funded.

Definitions and related references can be found below:

Community Engagement

According to the CDC, community engagement is the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being. In practice, community engagement is a blend of science and art. For further detail, see: https://www.atsdr.cdc.gov/communityengagement/

Community-Engaged Research (CEnR)

Community-engaged research includes local people in the research process, especially people who could benefit from or be affected by the research.
Community representatives bring their lived experiences, insights and strengths to these studies to:

- Craft research questions and inform study details
- Collect research data using community-informed strategies to connect with participants and get meaningful data
- Advise on policies and decisions related to safe and effective research conduct
- Co-create interventions or programs that fit well within the community
- Co-design appropriate materials and messages tailored for specific cultures and languages
- Analyze and report data in a way that is relevant and meaningful to the community while acknowledging strengths and opportunities

For further detail, see: https://nihceal.org/about-community-engaged-research-and-ceal#:~:text=Community%2Dengaged%20approaches%20effectively%20address,improves%20the%20health%20of%20communities.

Patient Engagement in Research

Patient engagement in research involves patients and/or family of patients working with researchers to improve the quality of research and services. The goal is to improve healthcare outcomes by actively involving patients at various levels of the research process. Patient engagement in research is intended to foster a more accountable research agenda, enhance the usefulness and relevance of findings, and increase the uptake of evidence in clinical care. For further details, see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7206899/pdf/cer-09-387.pdf or https://cihr-irsc.gc.ca/e/documents/spor_framework-en.pdfhttps://cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf

Community-Based Participatory Research (CBPR)

Community-based participatory research is: An applied collaborative approach that enables community residents to more actively participate in the full spectrum of research (from conception – design – conduct – analysis – interpretation – conclusions – communication of results) with a goal of influencing change in community health, systems, programs or policies. Community members and researchers partner to combine knowledge and action for social change to improve community health and often reduce health disparities. Academic/research and community partners join to develop models and approaches to building communication, trust and capacity, with the final goal of increasing community participation in the research process. It is an orientation to research, which equitably involves all partners in the research process and recognizes the unique strengths that each brings. For further detail, see: https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf

Citizen Science

Citizen science is scientific work undertaken by members of the general public, often in collaboration with or under the direction of professional scientists and scientific institutions. Citizen science efforts are driven by community concerns. Citizen scientists, in the modern sense, are defined as a scientist whose work is characterized by a sense of responsibility to serve the best interests of the wider community. For further detail, see: https://scistarter.org/citizen-science and https://www.citizenscience.gov/#

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Appendix III: Health Disparities

Health Disparity: A health difference that more adversely affects National Institute of Health (NIH) designated populations with health disparities in comparison to a reference population, based on one or more health outcomes. Social disadvantage is due to being underserved in health care and being subject to discrimination.

NIH-designated populations with health disparities:

- Racial and ethnic minority groups
- People with lower socioeconomic status (SES)
- Underserved rural communities
- Sexual and gender minority groups
- People with disabilities

Racial and Ethnic Minority Populations (as defined by US Office of Management & Budget):

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino American
- Middle Eastern or North African
- Native Hawaiian or Pacific Islander

Examples of Health Outcomes reflective of Health Disparity:

- Higher incidence and/or prevalence of disease, including earlier onset or more aggressive progression of disease
- Premature or excessive mortality from specific health conditions
- Greater global burden of disease, such as Disability Adjusted Life Years (DALY), as measured by population health metrics
- Poorer health behaviors and clinical outcomes related to the topics mentioned above
- Worse outcomes on validated self-reported measures that reflect daily functioning or symptoms from specific conditions

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Appendix IV: Health Informatics

The primary focus of a **Health Informatics** project is to address gaps in knowledge or other barriers to translational research problems by leveraging one or more Informatics tools and methods.

A project focused on health informatics is intended to evaluate strategies in one of the following areas:

1. Creation, evaluation, and implementation of Clinical Decision Support Systems;
2. Improving and evaluating electronic information capture and data flow of both clinical and patient derived data;
3. Development of improved analytical methods for clinically derived data;
4. Creation of informatics tools to improve population health management;
5. Creation, evaluation, or implementation of health informatics tools and algorithms.

The project must be translational in nature and should help to close the gaps in establishing a true academic Learning Healthcare System.

Successful proposals will create, evaluate, or implement Health Informatics tools and algorithms while providing a rationale for local relevance and potential for generalizability, explaining how the proposed project advances research in Health Informatics, and identifying translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them with the informatics.

Appendix V: Implementation Science

The primary focus of an **Implementation Science** award is to support the development of methods to promote the dissemination, adoption, integration, and/or effectiveness of promising practices, strategies, and/or technologies in clinical and/or community settings. Implementation scientists are committed to closing the gap between “what we know” as scientists and “what we do” as practitioners. A pilot focusing on implementation science is intended to elicit proposals that evaluate different strategies for closing the research-to-practice chasm through the development and testing of tailored implementation frameworks, identification of organizational and community levers to facilitate translation, determination of the feasibility of new implementation models, identification of strategies for scale-up, and/or development of strategies to disseminate knowledge or practices to a broad audience.

Successful proposals should test a practice, strategy, or technology that can be used to foster the translation of “what we know” to “what we do”.

Appendix VI: NCATS Approval

Projects that meet the definition of human subjects research will require prior approval from the National Center for Advancing Translational Sciences (NCATS), the funding source of the CTSA grant. This means that no funds will be released to the award recipient until NCATS has provided approval.

The following items are needed for the NCATS submission by 05/19/25 (if an investigator is not ready to submit to NCATS by 05/19/25, their project timeline <u>will not</u> be altered to accommodate):

- Project Information (i.e. submitting investigator, project title)
- IRB Approval
    - We do not require an initiated IRB application/approval by the Full Application Deadline; however, in order to submit for NCATS approval, certification of IRB approval is required. Therefore, we encourage draft protocols/consent documents be created as far in advance as possible. Notifications of funding will be sent by 03/05/25.
- Project Abstract
- IRB Approved Protocol
- IRB Approved Consent/Assent/waiver
- Protection of Human Subjects
- Inclusion of Individuals Across the Lifespan
- Inclusion of women, minorities, and children
- Recruitment and Retention Plan
- Targeted Enrollment Table
- Biosketches (PI and Key Personnel)
- Documentation of CITI certification
- Data and Safety Monitoring Plan
- IND/IDE Documentation, if applicable
- Budget and Budget Justification

Please note: additional documentation will be required if project is classified as a Clinical Trial.

Appendix VII: 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

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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.
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 and/or the POIC supplement?
    a. Include the supplemental funding 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.