

NEW Clinical and Translational Science Institute (CTSI)
Request for Applications for
Translational Science Pilot Award

Overview

This RFA calls for projects that are very different from those that have been funded previously under the CTSA Pilot Program. One project will be funded and will receive up to **\$40,000** in direct costs.

Purpose

The purpose of this RFA is to support new and innovative research relevant to **Translational Science**. Proposed projects must be focused on translational science, i.e. focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. The intent of the award is to explore possible innovative new leads or new directions for established investigators, stimulate investigators from other areas to lend their expertise in research in clinical and translational science, and provide initial support to establish proof of concept. Translational research projects, i.e., project focused on crossing a particular step of the translational process for a particular target or disease, will not be considered.

Definitions:

- ‘Translation’ is defined by NCATS/NIH as the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.
- ‘Translational research’ (TR) is defined by NCATS/NIH as the endeavor to traverse a particular step of the translational process for a particular target or disease.
- ‘Translational science’ (TS) is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. TS is disease-agnostic.

Whereas translational research focuses on the specific case of a target or disease, translational science is focused on the general case that applies to any target or disease; advances in translational science are the focus of this RFA. A key tenet of translational science is to understand common causes of inefficiency and failure in translational research projects (e.g., incorrect predictions of the toxicity or efficacy of new drugs, lack of data interoperability, ineffective clinical trial recruitment). Many of these causes are the same across targets, diseases, and therapeutic areas; therefore, advances in translational science will increase the efficiency and effectiveness of translational research to enhance health, lengthen life, and reduce the burdens of illness and disability. Like any other science, translational science seeks to elucidate general operative principles to transform translation from an empirical, phenomenological process into a predictive science. The application of scientific and operational innovation and strategies to improve the efficiency and effectiveness of all research is at the heart of developing, demonstrating, and disseminating the science of translation.

An example – for illustration only – may help clarify the distinction between TR and TS. An investigator who wishes to test whether a particular drug improves outcomes in diabetes will need to recruit sufficient underserved participants; this is a TR problem and will be addressed from the standpoint of effectiveness for the drug’s effects and the diabetes community, using established recruitment methods. By contrast, an investigator who wishes to understand the fundamental underlying barriers to recruitment for clinical trials generally, and test an intervention directed at those hypothesized causes and mechanisms, is engaging in TS. To test the hypothesis, the TS investigator may choose a use case that may in fact be the same as that used by the TR researcher – in this example a drug for diabetes – but the question to be answered is primarily whether the TS innovation accomplishes full recruitment of the desired underserved population more effectively and efficiently.

Examples of studies that would be responsive:

- Development of new research methodology and/or new technologies/tools/resources that will advance clinical and translational science and thus increase the efficiency and effectiveness of translation e.g., collaborative structures; integration of project management; incentives/credit for team science; incentives/credit for health improvements; education/training (scientific and cultural); biomarker qualification process

- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock
- Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
- Dissemination of effective tools, methods, processes, and training paradigms
- Feasibility/proof of concept studies to support future clinical and translational science projects
- Projects that demonstrate how technology can be used to facilitate rollout of new clinical processes
- Understanding what is similar across diseases to help develop multiple treatments at a time
- Development of models that better predict a person's reaction to a treatment
- Data-related improvements and tools, e.g., data interoperability; Electronic Health Records for research; data transparency/release;
- Clinical research improvements and tools, e.g., clinical trial networks; clinical outcome criteria (e.g., patient-reported outcomes); clinical diagnostic criteria; contemporary clinical trial designs; single Institutional Review Board (IRB) implementation; regulatory science; streamlining processes; shortening time of intervention adoption
- Clinical study recruitment improvements and tools, e.g., identification, recruitment, engagement and/or retention of populations and/or subpopulations in clinical trials and studies
- New tools for community and stakeholder engagement
- Methods to better measure impact on health (or lack thereof).

Specific projects that would be considered responsive:

- Development of an analytic approach to better understand physician use of Epic-based Best Practice Advisories (BPA) and how many “alerts” must fire before a provider responds. These data could be used to inform a de-implementation approach or alternative approach to getting providers to engage in evidence-based interventions.
- [A Review of Novel Uses of REDCap in Clinical and Translational Science](#)
- [Use of Live Community Events on Facebook to Share Health and Clinical Research Information with the Community: An Exploratory Study](#)
- [Development of Marketing Materials for the NJACTS Integrating Special Populations Core](#)

Examples of non-responsive studies:

- Investigation of patient outcomes or health care provider behaviors in a specific subspecialty
- Test of implementation strategies for a specified intervention
- Early development of new therapy/technology for treatment of a single disease
- Test of new interventions in disease X with a rationale that it will generalize to disease Y

Whatever tool, method, strategy, that is developed, tested, disseminated, etc. needs to be “broadly” useful – i.e., beyond advancing a disease-specific research agenda (focused on a particular intervention, disease, metabolic process, etc.) to be responsive to this RFA.

No pilot data is necessary to apply for this RFA, however supporting data from the recent literature is appropriate if available.

Funding

One project will be funded and will receive up to **\$40,000** in direct costs. 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.

Eligibility

These awards are open to all faculty with a rank of instructor or higher across the Atrium Health Enterprise including Atrium Health, Atrium Health Navicent, and Wake Forest Baptist Health, including Wake Forest

School of Medicine. Wake Forest University faculty and all CTSI affiliated institutions with a Wake Forest co-investigator are also invited to apply.

Clinician scientists, interdisciplinary teams that represent a combination of clinicians and basic scientists, adult and pediatric researchers and/or junior and senior investigators are all strongly encouraged to apply. Project teams comprised of researchers from multiple Regions and Markets (e.g. one investigator from Charlotte and one from Winston-Salem) are also strongly encouraged to apply.

The CTSI will allow a Co-PI structure if the PIs include both a skilled researcher and clinician with expertise relevant to the project.

Additional Information:

- Projects already submitted as CTSI or other intramural Pilot Proposals are eligible, but must incorporate reviewer feedback and must be responsive to this specific Translational Science Pilot Award RFA.
- Only one proposal may be submitted per faculty member serving as PI or co-PI.
- CTSI KL2 scholars whose KL2 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.

Key Dates

Date	Detail
01/05/22, 11:59 pm	Letter of Intent (LOI) Deadline
01/21/22	Investigators Invited for Full Application
02/28/22, 11:59 pm	Full Application Deadline
04/25/22	Selection of Awardees
05/31/22	If applicable, completed materials sent to NCATS for approval (Appendix I)
07/01/22	Project Start Date
06/30/23	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. She 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).

Application Procedure

1. Letter of Intent Deadline: 01/05/22, 11:59 pm

Letters of Intent (LOI) (1 pages max) require the following:

- A brief abstract.
- A clear statement of how the proposed study will improve Translational Science.
- 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 CTSI faculty. Reviewers at this stage will be looking for whether proposed projects are 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 01/21/22.

2. Full Application Deadline: 02/28/22, 11:59 pm

Investigators invited to apply will receive an e-mail by 01/21/22 with a link to submit a full by **02/28/22**.

Applications received after 02/28/22 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
- Consecutively numbered pages

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
- Research Plan:
 - Significance
 - Innovation
 - Approach
 - Study Team
- Study milestones and anticipated outcomes (e.g. publication, presentation, grant submission, patent) with timeline (see [Appendix II](#) for examples)

References (no page limit)

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 consult with Issis Kelly Pumarol at jkellypu@wakehealth.edu for support and to discussion timelines. The timelines can impact your full project timeline and should be considered in the project plans.
- Protection of Human Subjects

- 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 CTSI DSMB Administrator, Issis Kelly Pumarol, at ikellypu@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.
- 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.

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), a Dean-appointed committee of selected expert faculty, using NIH review criteria and scoring. Budgets will be reviewed by both CTSI Administrators and IRSC for appropriateness. There will be separate review discussions for clinical science and basic science proposals.
3. Final award approval will be at the recommendation of CTSI Leadership.

Reviewers will use the [NIH Scoring system](#) and procedure: 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 and feasibility, with clear milestones
5. Generalizability: Likelihood the innovation will be broadly applicable and impact translational research or delivery of care
6. A reporting plan, whether the study yields positive or negative results
7. 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 07/01/22 and ending 06/30/23. Up to \$40,000 in direct costs may be requested.

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
- 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).

Specific Deliverables

- Participation in the study initiation meeting
- A formal progress report at 6 months
- 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 Britney Patterson at britjack@wakehealth.edu.

Appendix I: 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 05/31/22 (if an investigator is not ready to submit to NCATS by 05/31/22, their project timeline will not 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 04/25/22.
- 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 II: 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

References

1. IOM (Institute of Medicine). Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press; 2012.
2. IOM (Institute of Medicine). The CTSA program at NIH: Opportunities for advancing clinical and translational research. Washington, DC: The National Academies Press; 2013. p.36
3. IOM (Institute of Medicine). The Learning Healthcare System: Workshop Summary. Olsen L, Aisner D, McGinnis JM, eds. Washington, DC: National Academies Press; 2007.
4. NIH (National Institutes of Health) / NCATS (National Center for Advancing Transactional Sciences. Translational Science Spectrum. NCATS 2015: <https://ncats.nih.gov/translation/spectrum>