

Duke-NC State Translational Research Agreement

Request for Applications 2021-2022

Application Deadline: 11:59 p.m. ET, June 3, 2021

The Duke Clinical & Translational Science Institute (CTSI), the academic home of the National Institutes of Health's Clinical and Translational Science Awards (CTSA) pilot funding program at Duke University, is partnering with North Carolina State University (NC State) Office of Research and Innovation (ORI) and NC State Comparative Medicine Institute (CMI), to support inter-institutional collaborative research teams.

I. Purpose

This pilot program is designed to facilitate collaborative and novel translational research that applies or accelerates discovery into testing in clinical or population settings. Projects must demonstrate stakeholder engagement and a high translational potential with a clear path for continued development to move into clinical practice, generate new clinical guidelines, or other applications via subsequent grant support, new company formation, licensing, not-for-profit partnering, an evidence base that changes practice, or other channels.

Duke CTSI and NC State are interested in the following types of translational research projects:

- Projects **developing new collaborative science teams** with investigators from both Duke and NC State.
- Research that generates translational discoveries relevant to human health or disease, regardless of whether the context of the discovery is the laboratory, individuals or the community.
- Research that applies or accelerates discovery into testing in clinical or population settings.
- Development and/or evaluation of the evidence base that changes clinical practice.
- Research that investigates how practice improves health policy, health outcomes, and the health of populations.

Potential areas of concentration are listed below; however, collaborations are not limited to these specified areas.

- Medical textiles and biomaterials
- Large animal model-based translational medicine
- Manufacturing of biomaterials and scale-up
- Personalized biomedical sensor platforms
- Epidemiology of environmental toxicant exposure

Duke CTSI and NC State grant awards are **not meant** as bridge funding or as supplementary funding for existing projects. Awards will promote the development of programs that advance translational science aims while also developing or nurturing productive collaborative scientific teams spanning both institutions. Teams are encouraged to identify areas in the application where **students or trainees** may be engaged as part of the research team.

The primary source of Duke funding is from the National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award (UL1TR002553) and NC State.

II.Key Dates

- Application Submission Deadline: June 3, 2021
- Selection of Awardees: August-September 2021
- Funding Period: The budget period is for 12 months beginning October 1, 2021 and ending September 30, 2022.

III.Eligibility

- Proposed projects must involve a lead investigator from Duke and a lead investigator from NC State. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment and have principal investigator status per the specific institution's written policy ([Duke policy](#); [NC State policy](#)).
- More than one proposal may be submitted per NC State or Duke Faculty member acting as PI, but the faculty member is eligible to receive only one award as PI from this funding mechanism during a given funding cycle.
- Duke/NC State teams whose proposals for this program were not previously selected for funding may submit a revised application. See Section VI. "Application Procedure" for more details.
- Interested investigators who need assistance in identifying collaborators at Duke can use Scholars@Duke or contact Duke CTSI (ctsifunding@duke.edu). Interested investigators who need assistance in identifying collaborators at NC State can use ResearchGate or contact ORI at research-development@ncsu.edu.

IV.Funding

- Each institution will support the research activities of its respective investigators. Duke CTSI and NC State will each fund up to \$25,000 direct costs, for a total of \$50,000 per project. Up to one award will be made per funding cycle. Funds will not be subcontracted from one institution to the other.
- The Duke-NC State awards are not meant as bridge funding or as supplementary funding for existing projects. **Requests for no-cost extensions will not be approved.**
- **Note for Duke Investigators:** This award is internally funded and does **not** need to be routed through Office of Research Administration (ORA).

V.Review Process and Evaluation Criteria

Applications will be reviewed by a joint Duke CTSI-NC State Study Section. Evaluation criteria will include:

- Significance of the work
- Novelty/innovation of the research idea
- Relevance of the proposed study to translational research
- Applicants are a multidisciplinary team who have not previously published or been awarded grants together in this area of research OR the work represents a significant change of research direction for the collaborators
- Potential for the project to lead to future external funding or to a commercialization opportunity or an evidence base that changes practice
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period
- Level of stakeholder engagement
- Trainee/student engagement plan if including trainees/students

VI. Application Procedure

- Proposals must be submitted via Duke’s MyResearchProposal online submission system as well as NC State’s Project Information and Navigation System (PINS) submission system.
- **To apply using MyResearchProposal:**
 - Click [here](#) to access MyResearchProposal and logon or choose “Create New User” to apply. Proposals must be submitted under the Duke Principal Investigator’s name.
 - A step-by-step user’s guide for applying via the MyResearchProposal software is available - Please review this [document](#).
 - Enter Access Code ‘CTSI’ then select the “Duke-NC State Translational Research Grant Application 2021 - 2022” funding opportunity and follow the instructions.
 - For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.
- **To apply using PINS:**
 - Visit <http://research.ncsu.edu/sparcs/systems-portal/pins/>, click on “Log into PINS” and then “Create a new proposal” and submit under the NC State co-Principal Investigator’s name. Select “Duke/NC State Translational Research Grant” as the Direct Sponsor of this funding opportunity.
 - Applicants will enter general project information via the web-based form:
 - Project Title, Brief Description, and Amount Requested
 - Investigator Information: Name, rank and department.
 - General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).
 - Resubmissions: Applications that were previously submitted and not funded will be asked to briefly describe additional data or other changes from the previous proposal.
- **The application sections are** (Note: Only sections 2,3, 7-11 will be uploaded as individual PDF files):
 1. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI/NC State (500-word maximum). This section will be direct entry to the application form.
 2. **Specific Aims:** 1-page limit, including tables and figures. References do not count toward the 1-page limit; single line spacing, font no smaller than Arial 11, with at least 0.5-inch margins.
 3. **Research Plan:** The Research Plan should follow the standard NIH format with the following **mandatory sections** (5-page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, with at least 0.5-inch margins). Include where applicable clear evidence of how the proposal meets the review criteria.
 - Significance & Background, with explanation of unmet clinical need
 - Innovation
 - Approach, Methods, and Analysis (include [if applicable] stage of the project/product, hypotheses, design, procedures, sample recruitment, methods/measures, potential pitfalls and alternatives, benchmarks for success, facilities/environment plan, and data management and analysis plan)*
 - Timeline & table of quarterly milestones to be achieved
 4. **Translation Plan:** CTSI employs the Translational Science Benefits Model ([TSBM](#)) as a framework for planning, demonstrating, and communicating the impact of translational research. Applicants must choose a total of up to 5 Indicators of the TSBM that are germane to the proposal and specifically address how the proposed work will have an impact on the chosen TSBM Indicators [More details in the Application]. Using the TSBM, the applicant must identify primary impact indicators **and** clearly

delineate the strategy and plan for successful translation, commercialization plan (if applicable); define what translation means in the context of the proposed project; and describe how translational success and impact can be evaluated and measured.

5. **Stakeholder Engagement Plan:** The applicant must clearly outline relevant stakeholders; strategies to engage with them; and delineate stakeholder-relevant outcomes (i.e., outcomes relevant to patients, consumers, families, practitioners, administrators, and/or policymakers).
6. **Student Engagement Plan:** The applicant must outline the roles and responsibilities of the mentor, mentoring activities, research areas of engagement, etc. if students are part of the research team.
7. **Budget with Budget Justification:** (using PHS 398 Form Pages 4 and 5 with no page limit). Section VII below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Duke and NC State budgets and budget justifications will be uploaded separately.
8. **Human and/or Animal Subjects Description:** Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is encouraged but not required prior to submission. Briefly describe any human and/or animal subject issues. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the Duke and/or NC State IRB and comply with HIPAA. If vertebrate animals are to be used, provide a description of the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Projects involving animal subjects must be reviewed and approved by a Duke and/or NC State IACUC (no page limit).
9. **NIH Biosketches** for key members of the research team (as a single PDF) using this format.
10. Relevant Publication (optional; limit to 1 publication)
11. Letters of Support (optional; if more than one, combine into single PDF)

VII. Budget Guidelines

Please note the following during budget preparation:

- A. The budget period is for 12 months beginning October 1, 2021 and ending September 30, 2022. Up to \$25,000 in direct costs at each institution may be requested. The amount requested from each institution must be equal as funds will not be subcontracted between Duke and NC State. Funding will not be available until applicable IRB or IACUC approved documentation, if applicable, is provided to Duke CTSI/NC State and subsequent NCATS approval.
- B. Budget Guidelines
 - a) Grant funds **may** be budgeted for:
 - Salary support for the PI or faculty collaborators
 - Research support personnel
 - Student stipend and tuition **if not** covered by other funding mechanisms. **NOTE: Teams are encouraged to identify areas in the application where students or trainees may be engaged as part of the research team**
 - Travel necessary to perform the research
 - Small equipment, research supplies and core lab costs (NOTE: Project specific research supplies are allowable, however supplies that are typically allocable across multiple projects or for lab-wide use are unallowable. See Section B below for additional information)
 - Other purposes deemed necessary for the successful execution of the proposed project

- b) Grant funds may **not** be budgeted for:
- General consumable supplies (**NOTE:** Project specific general consumable supplies are allowable, however supplies that are typically allocable across multiple projects or for lab-wide use are unallowable.)
 - Effort for post-doctoral trainees or fellows on training grant equivalents
 - Capital equipment
 - Office supplies or communication costs (excluding project specific teleconference charges), including printing and postage
 - Meals or travel, including to conferences, except as required to collect data
 - Professional education or training
 - Computers or audiovisual equipment
 - Cell phones
 - Manuscript preparation and submission
 - Indirect costs
 - Subcontracts to other institutions
 - Foreign components, as defined in the [NIH Grants Policy Statement](#)
- c) 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. Duke CTSI and NC State reserve the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal.
- d) The general criteria for determining allowable direct costs on federally-sponsored projects is set forth in [2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards \(The Uniform Guidance\)](#). The Duke [General Accounting Procedure \(GAP\) 200.320](#) is a resource to determine whether or not a particular cost item would be considered an allowable direct cost for budgeting and/or charging on a federally sponsored project.

VIII. Terms of the Award

A. Approvals Required Prior to Funding Start Date

- Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke and/or NC State IRB. If the research includes live vertebrate animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to Duke CTSI prior to funds being released. Human subjects or live vertebrate animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.
- Research involving live vertebrate animals and/or human subjects may also require approval by the National Center for Advancing Translational Sciences (NCATS) **prior** to receiving funds. The Duke CTSI will request required documents, which includes IRB and/or IACUC **approval** letters, from the Duke PIs and submit a regulatory package to NCATS for review and approval. NCATS requires up to 30 days for their review.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Duke CTSI and NC State 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. Duke CTSI and NC State expect PIs to report annually, for up to 5 years post-award, the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
- A Duke CTSI Project Leader will be assigned to each funded project. The investigators are required to interact regularly with the Duke CTSI Project Leader, who will work with the investigators to manage projects, report progress relative to planned milestones, and serve as a resource to identify and fulfill unmet project needs via the Duke CTSI and other key resources.
- Duke's CTSA grant Award Number UL1TR002553 notice of grant award included both federal funding and our institutional commitment. The institutional funds used in our CTSA pilot funding programs take on the identity of federal funds in this award mechanism and therefore should be treated as such with regards to IRB, IACUC, and tech transfer office reporting. NCATS approval is required prior to initiating research involving human subjects, and inventions resulting from pilot awards must be reported in iEdison and include UL1TR002553 as the source of federal funding.
- 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 Award Number UL1TR002553. 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. After your publication is accepted, [click here](#) for a guide to complying with the NIH Public Access Policy
- Any awardee who leaves his or her position should contact Duke CTSI to discuss future plans for the project.

C. Post-Award Reporting

- Duke CTSI tracks significant events ("translational units") required to translate a scientific discovery from laboratory, clinical or population studies into clinical or population-based applications to improve health by reducing disease incidence, morbidity and mortality. The Duke CTSI will contact investigators annually, for up to 5 years post award, to determine if any translational units have been achieved as a result of this award. Examples include:
 - Abstracts/presentations, manuscripts, published guidelines
 - Follow-on funding (e.g., grants, SBIR/STTR, angel and venture capital investment)
 - Milestones achieved in animal models, manufacturing and toxicity campaigns
 - Regulatory meetings and filings (e.g., 510K, IDE, IND, BLA, NDA)
 - Initiation of appropriate clinical studies
 - Improved diagnosis or treatment of disease
 - Implementation in clinical practice or community
 - Translation of models to other geographical areas
 - Translation of models to other therapeutic areas
 - Clinical outcomes in practice and communities
 - Clinical guideline or guidelines updated
 - Agreements with partners and strategic collaborators to translate more broadly
 - Commercialization (e.g. new intellectual property, patent applications, license, commercial partnerships, start-up company)

- Direct-to-consumer interactions (e.g. apps)
- When requested, all awardees will be expected to provide updates of publications and other translational units that originated from the award. Awardees that leave the institution within in 5-years post award will be expected to provide updated contact information for future communications.
- **Awardees and applicants are expected to serve as reviewers for future Duke CTSI and NC State funding opportunities.**

IX. Contact Information

For additional information on this funding opportunity, please contact the Program Officer, Dr. Tarun Saxena, at CTSIfunding@duke.edu or Dr. Jonathan Horowitz at research-development@ncsu.edu