

Duke-NC State Collaborative Translational Research Grant

Request for Applications 2022-2023

Application Deadline: 11:59 p.m. ET, June 14, 2022

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
- Manufacture and scale-up of biomaterials
- Personalized biomedical sensor platforms
- Epidemiology of environmental toxicant exposure

Duke CTSI and NC State grant awards are **not intended** as bridge funding or as supplementary funding for existing projects. Awards will support the development of projects 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 may come from Duke's National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award (UL1TR002553) or the Duke School of Medicine and NC State. Awards are contingent upon funding.

II. Key Dates

- Application Submission Deadline: June 14, 2022
- Selection of Awardees: July/August 2022
- Funding Period: The budget period is for 12 months beginning October 1, 2022 and ending September 30, 2023.

III. Eligibility

- Proposed projects must involve a lead investigator from Duke and a lead investigator from NC State. Proposals by cross disciplinary new teams of investigators are encouraged. 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 only eligible to receive one award per funding cycle from this Duke CTSI pilot funding mechanism.
- 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. Funds will not be subcontracted from one institution to the other.
- Awards are contingent upon funding.
- 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). However, we strongly recommend that you include your grants team in the preparation of this proposal budget.

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
- Translational potential of the opportunity as it pertains to proposed area of research
- 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 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 Collaborative Translational Research Grant” as the Direct Sponsor of this funding opportunity.
 - You will upload a **single** PDF file that contains **all** of the relevant grant components requested in MyResearchProposal below.
- **To apply using MyResearchProposal:**
 - Click [here](#) to access MyResearchProposal and logon or choose “Create New Account” 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 platform is available [here](#).
 - Enter Access Code ‘CTSI’ then select the “Duke-NC State Collaborative Translational Research Grant Application –2022-2023” funding opportunity and follow the instructions.
 - For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.
- Applicants will enter general project information via MyResearchProposal:
 - Project Title, Brief Description, and Amount Requested
 - Investigator Information: Name, rank, and department.
 - 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:** Duke 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 five 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. **DRAFT Budget with Budget Justification** using [PHS 398 Form Pages 4 and 5](#) (combined into a single PDF with no page limit). Initial submissions are approximate and do not need institutional approval. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. This **does not need to be routed through (ORA); Duke CTSI will route approved budgets to departments for review and approval.**
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, 2022 and ending September 30, 2023. 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 (F&A or G&A)
 - 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 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.

Project Execution

- Duke CTSI and NC State staff will work closely with funded team(s) 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 require PIs to report annually, for up to five 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 Duke and NC State 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 **may** include 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 **may** be required prior to initiating research involving live vertebrate and/or human subjects, and **only** 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 **may be required to** 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.

B. 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 five years post award, to determine if any translational units have been achieved as a result of this award. Examples include:
 - Abstract 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)
- Selected TSBM indicators as applicable to the project
- 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. Eman Ghanem, at CTSI funding@duke.edu or Dr. Jonathan Horowitz at research-development@ncsu.edu.

You can request a consult with the Duke CTSI team by clicking [here](#).