

Duke-UNC-Chapel Hill CTSA Consortium Collaborative Translational Research Pilot Grants

Request for Applications 2021-2022

Application Deadline: 11:59 p.m. ET, February 23, 2021

The Duke Clinical Translational Science Institute (Duke CTSI) and North Carolina Translational and Clinical Sciences Institute (NC TraCS) are the academic homes of the National Institutes of Health's Clinical and Translational Science Awards (CTSA) pilot funding programs at Duke University and at UNC Chapel Hill (UNC-CH). The Duke CTSI and NC TraCS are interested in promoting inter-institutional collaborations and pilot funds are now available for eligible new investigative teams.

I. Purpose

This pilot program is designed to facilitate novel clinical, population, and 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 collaborating, an evidence base that changes practice or other channels. Duke CTSI and UNC-CH are interested in the following types of translational research projects, with an emphasis on inter-disciplinary collaborations that test generalizable solutions to translational research problems:

- Generates initial or basic discoveries relevant to human health or disease
- Applies or accelerates discovery into testing in clinical or population settings
- Development and/or evaluation of the evidence base that changes practice
- Investigates how practice improves health policy, health outcomes, and the health of populations

Duke CTSI and NC TraCS pilot grant awards are not meant as bridge funding or as supplementary funding for existing grants. **These funds cannot be used to fund grants where the research is conducted outside the United States.**

Teams are encouraged to identify areas in the application where students or trainees may be engaged as part of the research team.

II. Key Dates

- Application Submission Deadline: February 23, 2021
- Selection of Awardees: April 2021
- Funding Period: The budget period is for 12 months beginning between May 1 and July 1, 2021.

III. Eligibility

- Proposed projects must involve a lead investigator from Duke and a lead investigator from UNC-CH. Proposals are encouraged from new teams of investigators from different disciplines. Applicants from Duke must have principal investigator status per the institution's written policy ([Duke Policy](#)) for the entire 12-month funding cycle. Applicants from UNC should have an appointment that allows them to serve as PI on externally-sponsored research projects.
- More than one proposal may be submitted per UNC or Duke Faculty member acting as PI, but the faculty member is only eligible to receive one award from this funding mechanism as PI during a given funding cycle. Duke/UNC-CH teams whose proposals for the Duke-UNC CTSA Consortium Collaborative Translational Research Grant were not selected for funding in previous rounds may submit a revised application.
- Applicants are limited to one resubmission per proposal. See "VII. Application Procedure" for more details.
- Interested investigators who need assistance identifying collaborators at Duke can use Scholars@Duke and
- UNC-CH can use Reach NC (<https://uncch.pure.elsevier.com/en/>) or contact either Duke CTSI (ctsfunding@duke.edu) or NC TraCS (nctracs@unc.edu) for assistance.

IV. Funding

- The research award comprises a 1:1 match between Duke CTSI and NC TraCS. Duke CTSI and NC TraCS will each fund up to \$25,000 direct costs, for a total of \$50,000 per collaborative project.
- Funds will not be subcontracted from one institution to the other. UNC investigators should note that applications for this RFA with Duke do not require a financial match from your Department/School.
- All funds must be expended within one year of the project start date. Requests for no-cost extensions will not be approved.
- Note for Investigators: This award is internally funded and does not need to be routed through ORA (Duke) or OSR (UNC).

V. Proposal Preparation

- Duke CTSI and NC TraCS strongly recommend involving a biostatistician in the application development process. The online application form will ask for the name of the biostatistician who consulted on the proposal.
- Duke Investigators who do not know whether their affiliated department/center/institute has an existing collaborative agreement with the Duke BERD Methods Core can be connected with an appropriate biostatistician, quantitative, or qualitative methodologist through the Duke BERD Methods Core by submitting a [Core Resource Request](#) form. Once a request is submitted, Duke Investigators will be referred to the appropriate collaborative group if an appropriate collaboration model exists. If the investigator submitting the request does not belong to a group that has an established collaboration model affiliated with the Core, or additional methodology expertise is needed, the Core leadership will attempt to identify methodologists with appropriate expertise and collaborative interest/availability. Identifying the appropriate methodologist can be a time-consuming process because the network is large across Duke and the methodologists may have limited availability. Therefore, the Core may not be able to accommodate requests with tight deadlines, especially if there is not an established collaboration to support the work. In all cases, a request for collaboration should identify a Duke funding source for the effort that will be needed and generally should be submitted at least two months prior to a deadline. Because the Core receives multiple requests, this can take much longer for many projects, so we ask that investigators contact the Core as soon as possible.
- UNC Investigators without access to a biostatistician can request support through the NC TraCS Biostatistics Service by submitting a Consult Request form, emailing nctracs@unc.edu, or calling 919-966-6022.

VI. Selection Process and Review Criteria

Applications will be reviewed by a joint Duke CTSI/NC TraCS Study Section. Review criteria will include:

- Significance of the work
- Novelty/innovation of the research idea
- Relevance of the proposed study to translational research
- Applicants are a new 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 both PIs
- 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

VII. Application Procedure

- Proposals are submitted via Duke's MyResearchProposal online submission system.
 - To apply visit <http://bit.ly/myresearchproposal>, click on "Create New User" (or log in if you already have an account). Proposals must be submitted under the Principal Investigator's name.
 - A step-by-step user's guide for applying via the MyResearchProposal software is available [here](#).
 - Enter Access Code 'CTSI' then select the "2021-2022 Duke/UNC-Chapel Hill CTSA Consortium Collaborative

Translational Research Pilot Grants” funding opportunity and follow the instructions.

- For questions concerning MyResearchProposal passwords or system issues, please email myresearchproposal@duke.edu or call 919-668-4774.

B. 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.

C. Proposal sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

1. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI/UNC (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. ***Resubmission Summary** (if applicable): If your proposal is a resubmission to the Duke/UNC-CH CTSI Consortium Collaborative Translational Research Pilot Grant program please provide a summary that details your changes to the original proposal, including detail about any progress that has been made since the original application. This summary has a 3-page limit and does not count towards the 5-page Research Plan limit. Applicants are limited to one resubmission per proposal.
5. **Translation Plan:** The Duke CTSI employs the [Translational Science Benefits Model \(TSBM\)](#) as a framework for planning, demonstrating, and communicating the impact of translational research. NC TraCS has agreed to include this framework for this RFA. 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.
6. **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).
7. **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.
8. Budget with Budget Justification using [PHS 398 Form Pages 4 and 5](#) (combined into a single PDF without a page limit). Section VI 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 UNC-CH budgets should be prepared on separate form pages but submitted together as a single PDF.
9. **Human and/or Animal Subjects:** Institutional Review Board (IRB) or Institutional Animal Care & Use

Committee (IACUC) approval is not required prior to submission but will be required prior to funding. Briefly describe any human and/or animal subject issues. If human subjects are involved, provide a description of their involvement and characteristics, study procedures, materials used in the research, potential risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by the Duke and/or UNC 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 UNC-CH IACUC. (no page limit)

10. NIH Biosketches for key members of the research team (as a single PDF) - [click here for details](#).
11. Relevant Publication (optional; limit to 1 publication)
12. Letters of Support (optional; if more than one, combine into single PDF)

VIII. Budget Guidelines

Please note the following during budget preparation:

A. The budget period is for a 12-month period beginning between May 1, 2021 – July 1, 2021 and **ending no later than June 30, 2022**. Up to \$25,000 in direct costs at each institution may be requested for a total award amount of \$50,000. The budget from each institution should be approximately equal, or the budget justification should explain why this is unfeasible. Funds will not be subcontracted between Duke and UNC. Funding will not be available until approved IRB/IACUC documentation and any required NCATS approvals are provided to Duke CTSI/NC TraCS. See [section IX](#) – Terms of the Award for further information.

B. As part of federal requirements, Duke has an obligation to report effort correctly on sponsored projects. The Duke investigators must include sufficient effort to accurately reflect their effort on the project.

C. The budget period will begin when and the PI indicates everything is in place for the project to begin **but no later than July 1, 2021**. If the PI is not ready to start **by July 1, 2021**, CTSI and NC TraCS reserve the right to withdraw the award. The expectation is that all funds will be expended by the end of the 12-month grant period. At the end of the 12-month project period, any unexpended funds will be retained by CTSI and/or NC TraCS.

D. 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 TraCS 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.”

IX. 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 CTSI and/or UNC-CH IRB. If the research includes animals, the appropriate IACUC animal research forms must 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 and/or NC TraCS prior to funds being released. Human subjects or 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 will also require approval by the National Center for Advancing Translational Sciences (NCATS) prior to receiving funds. The Duke CTSI and NC TraCS will request required documents from the PIs and submit an approval package for each institution to NCATS for review and approval. NCATS says to allow 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 TraCS 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 TraCS 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.
- A Duke CTSI Project Leader and an NC TraCS Advisor will be assigned to each funded project. The investigators are expected to interact regularly with the Duke CTSI Project Leader and NC TraCS Advisor, 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.
- The institutional funds used in our CTSA pilot funding programs may take on the identity of federal funds in this award mechanism and therefore may require to be treated as such with regards to IRB, IACUC, and tech transfer office reporting. NCATS approval is required prior to initiating research involving live vertebrate animals and/or human subjects, and inventions resulting from pilot awards must be reported in iEdison and include UL1TR002553 and UL1TR002489 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 Numbers UL1TR002553 and UL1TR002489. 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 and/or NC TraCS to discuss future plans for the project.

C. Post-Award Reporting

NC TraCS and the Duke CTSI track 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 and NC TraCS will contact investigators annually 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 and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- 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 and applicants are expected to serve as reviewers for future Duke CTSI & NC TraCS funding opportunities.

X. Contact Information

For additional information on this funding opportunity, please contact CTSI Accelerator (CTSI@duke.edu) and/or NC TraCS (nctracs@unc.edu).