

Duke-NCCU-CTSI Consortium Collaborative Translational Research Award

REQUEST FOR 2022-2023 APPLICATIONS

Optional Letter of Intent Deadline: 11:59 p.m., March 4, 2022

Application Deadline: 11:59 p.m. ET, April 5, 2022

The Duke Clinical and Translational Science Institute (Duke CTSI), the academic home of the National Institutes of Health's Clinical and Translational Science Awards (CTSA) pilot funding programs at Duke University, is partnering with North Carolina Central University (NCCU) to support inter-institutional collaborative research projects.

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 sustainability and development to move into clinical practice, generate new clinical guidelines, or other applications via subsequent grant support, not-for-profit partnering, an evidence base that changes practice, or other channels.

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

- 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**.
- 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 communities.
- Research that applies or accelerates discovery into testing in clinical or population settings.

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

- Community-based research
- Clinical outcomes/ health services research
- Behavioral health
- Social determinants of health
- Translational research ready for the NCCU Biomanufacturing Research Institute and Technology Enterprise (BRITE) and Biomedical/Biotechnology Research Institute (BBRI).

Duke CTSI and NCCU 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. Projects **developing new collaborative science teams** with investigators from both Duke and NCCU are encouraged. Projects that promote health equity, advance evidence-based guidelines into health practice, or evaluate population outcomes are highly encouraged.

II. Key Dates

- Optional Letter of Intent (LOI): **March 4, 2022**
- Application Submission Deadline: **April 5, 2022**
- Selection of Awardees: **April/May 2022**
- Funding Period: The budget period is for 12 months beginning **July 1, 2022 – June 30, 2023**

III. Eligibility

- Proposed projects must involve a lead investigator from Duke and a lead investigator from NCCU. Proposals by cross disciplinary new teams of investigators are encouraged. Applicants at each institution must have a principal investigator status per the specific institution's written policy ([Duke policy](#); [NCCU policy](#)).
- More than one proposal may be submitted per NCCU 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-NCCU teams whose proposals for the Duke- NCCU Translational Research Grant were not previously selected for funding may submit a revised application. See VII. Application procedure for more details.
- Submission of LOI (see section VI. For submission instructions).

IV. Funding

The research activities at each participating institution will be funded by the Duke CTSI. The Duke CTSI will fund up to \$50,000 per award.

The Duke NCCU 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 the Office of Research Administration (ORA). However, we strongly recommend that you include your grants team in the preparation of this proposal budget.

V. Selection Process and Review Criteria

1. Applications will be reviewed by a joint Duke CTSI-NCCU study section. Review criteria will include:
 - Significance of the work
 - Novelty/innovation of the research idea
 - Relevance of the proposal 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 the collaborators
 - Potential for the project to lead to future external funding 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

- Students/trainees engagement plan if engaged as part of the research team

VI. Application Procedure

The proposal is submitted via Duke's MyResearchProposal online submission system.

- To apply visit <http://bit.ly/myresearchproposal>, click on "Create New Account" (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 - Please review this [document](#).
- Enter Access Code 'CTSI' and select "LOI 2022-2023 Duke-NCCU CTSI Consortium Collaborative Translational Research Award", **OR** for the application, select "Application 2022-2023 Duke-NCCU CTSI Consortium Collaborative Translational Research Award", and follow the instructions.
- For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or 919-668-4774.

Applicants will enter general project information via the web-based form:

1. Project Title, Brief Description, and Amount Requested
2. Investigator Information: Name, rank and department.
3. General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).
4. Resubmissions: Applications previously submitted and not funded will provide a brief description of additional data or other changes from the previously submitted proposal.

Letter of Intent (Optional)

- A. Brief overview of specific aims (limit of 500 words)
- B. Summary of proposed research design/approach (Limited to 1 page not including references, Arial 11 font, 1-inch margins, and single space.):
 - a. What is innovative about this project?
 - b. Expected significance and impact of the project from a translational science perspective.
- C. High level draft budget (e.g. 10% salary support, 90% supplies and equipment usage fee)

Full Application

Proposal sections (except A, D-F) will be uploaded as individual PDF files. The application sections are:

- A. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI/NCCU (500-word maximum). This section will be direct entry to the application form.
- B. **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.
- C. **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
- D. ***Resubmission Summary** (if applicable): If your proposal is a resubmission to the Duke-NCCU 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.
- E. **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 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.
- F. **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).
- G. **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.
- H. **Budget with Budget Justification** using the Duke NCCU Budget and Budget Justification form (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 NCCU budgets will be uploaded separately using the specified budget form noted on the application.**
- I. **Human and/or Animal Subjects:** Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission but IRB approval 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, 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 NCCU 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 NCCU IACUC. (no page limit)
- J. **NIH Biosketches** for key members of the research team (as a single PDF) - [click here for details](#).
- K. Relevant Publication (optional; limit to 1 publication)
- L. Letters of Support (optional; if more than one, combine into single PDF)

VII. Budget Guidelines

1. The budget period is for 12 months beginning July 1, 2022 and ending June 30, 2023. Up to \$25,000 in direct costs at each institution may be requested. No indirect costs will be awarded for the Duke teams. NCCU teams should calculate indirect cost based on the 34% negotiated rate of the requested direct expenses on the appropriate budget form (found [here](#)). Funding will not be available for human and/ animal work until applicable IRB and/ IACUC documentation, is provided to Duke CTSI/NCCU. See [section VIII](#) – Terms of the Award for further information.
2. 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.
 - 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 (excludes 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 (Duke Applicants only)
 - 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 NCCU 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 \(GAP\) 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 CTSI and/or NCCU IRB. If the research includes 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 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 animal 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 from the Duke PIs and submit a regulatory package to NCATS for review and approval **if required**.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Duke CTSI and NCCU staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. Quarterly and final progress reports will be required. Duke CTSI and NCCU 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 Duke and NCCU 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 grants *UL1TR002553* notice of grant awards 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 **may be** required prior to initiating research involving 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 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 *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 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 & NCCU funding opportunities.

IX. Contact Information

For additional information on this funding opportunity, please contact the Program Officer, Dr. Eman Ghanem at (CTSIfunding@duke.edu).