Duke/NC State Translational Research Agreement
Request for Applications 2018-2019
Application Deadline: 11:59 p.m. ET, May 15, 2018

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 NC State’s Office of Research, Innovation and Economic Development (ORIED), as well as NC State’s Comparative Medicine Institute (CMI), to support new inter-institutional collaborative research teams.

Please note that this funding is contingent on the CTSI receiving the Clinical & Translational Science Award (CTSA) renewal from the National Center for Advancing Translational Sciences (NCATS) [the receipt of the notice of award from NCATS is expected May 2018].

I. Purpose

This pilot program is designed to facilitate novel clinical and translational research that applies or accelerates discovery into testing in clinical or population settings. Projects must demonstrate high translational potential with a clear path to subsequent grant support, new company formation, licensing, not-for-profit partnering, or other channels. Population health improvement projects should demonstrate significant stakeholder involvement to move it more globally into broader practice patterns, clinical guidelines, and other applications.

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

- Research that **generates translational discoveries** relevant to human health or disease, regardless of whether the context of the discovery is the laboratory, in animal models or the field.
- Research that **applies or accelerates discovery into testing** in clinical or population settings.
- Development and/or evaluation of the evidence base that **changes practice**.
- Research that investigates how **practice improves health policy, health outcomes, and the health of populations**.

Research areas of interest include, but are not limited to, collaborations involving:

- 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

CTSI and NC State collaborative research awards are not offered as bridge funding or as supplementary funding for existing projects. This program is intended to catalyze new research projects between new or existing research teams.

II. Key Dates

- Application Submission Deadline: **May 15, 2018**
- Selection of Awardees: **June 2018**
- Funding Period: The budget period is for 12 months beginning **July 1, 2018 and ending June 30, 2019**.

4/02/2018
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 representing two or more distinct disciplines. Applicants at each institution must have a full-time faculty appointment.

- Each Duke or NC State faculty member may submit more than one proposal as a Principal Investigator. However, the faculty member is only eligible to receive one award as PI during a given funding cycle. Duke faculty members may not serve as PI on more than one concurrently funded Duke CTSA award, with the exception of the voucher program and NIH supplemental award.

- Duke/NCSU teams whose proposals for the Duke/ NCSU Translational Research Grant were not selected for funding in the June 2017 round may submit a revised application. See VII. Application procedure for more details.

- Interested investigators who need assistance in identifying collaborators at Duke can use Scholars@Duke (http://scholars.duke.edu) or contact either CTSI (ctsfunding@dm.duke.edu) or NC State ORIED (research-development@ncsu.edu).

IV. Funding

Each institution will support the research activities of its investigators. 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.

Funds cannot be carried over from one fiscal year to the next. Requests for no-cost extensions will not be approved.

Note Duke PIs: This award is internally funded and does not need to be routed through ORA.

V. Proposal Preparation

CTSI and NC State 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. Investigators without access to a biostatistician can request support through Duke CTSI Biostatistics Core by submitting a Core Resource Request form or the NC State Biostatistics Service by visiting http://brc.ncsu.edu/consulting.

VI. Selection Process and Review Criteria

Applications will be reviewed by a joint CTSI/NC State 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 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
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Potential for the project to impact broader practice patterns, clinical guidelines, and other applications (if applicable)
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period
VII. Application Procedure

Proposal is submitted via Duke’s MyResearchProposal online submission system.

1. 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.

1. To apply using MyResearchProposal:
   - To apply visit [http://bit.ly/myresearchproposal](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 - Please review this document.
   - Enter Access Code ‘CTSI’ then select the “2018-2019 Duke/NC State Translational Research Grants” funding opportunity and follow the instructions.
   - For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or call 919-668-4774.

2. To apply using PINS:
   - Visit [http://research.ncsu.edu/sparcs/systems-portal/pins/](http://research.ncsu.edu/sparcs/systems-portal/pins/), click on “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.

2. 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 that were previously submitted and not funded will be asked to briefly describe additional data or other changes from the previous proposal.

Proposal sections (except the Abstract) 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 CTSI/NC State (250-word maximum). This section will be direct entry to the application form.

B. **Research Plan**: The Research Plan should follow the standard NIH format: Specific Aims, Significance, Innovation, and Approach. Include where applicable clear evidence of how the proposal meets the review criteria. (5-page limit, using 1-inch margins, single line spacing and a font no smaller than Arial 11, including any tables or figures. References do not count toward the 5-page limit.)

C. **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 NC State budgets should be prepared on separate form pages but submitted together as a single PDF.

D. **Human and/or Animal Subjects Description**: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is 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)

E. **NIH Biosketches** for key members of the research team (as a single PDF) using this format.

**VII. Budget Guidelines**

1. The budget period is for 12 months beginning July 1, 2018 and ending June 30, 2019. Up to $25,000 in direct costs at each institution may be requested and the amount requested from each must be equal as funds will not be subcontracted between Duke and NC State.

2. **Budget Guidelines**
   
   A. Grant funds may be budgeted for:
      - Salary support for the PI or faculty collaborators.
      - Research support personnel
      - Travel necessary to perform the research
      - Small equipment, research supplies and core lab costs, or
      - Other purposes deemed necessary for the successful execution of the proposed project

   B. Grant funds may not be budgeted for:
      - Effort for post-doctoral trainees or fellows on training grant equivalents
      - Capital equipment
      - Office supplies or communication costs, 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. 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. Office of Management and Budget Uniform Guidance sets forth general criteria for determining allowable direct costs on government-sponsored projects. 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 government 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 NC State 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 human subjects must also be approved 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.

Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- 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. CTSI and NC State 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 will be assigned to each funded project. The investigators will 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 (to be provided upon receipt of award) 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 Award Number (to be provided upon receipt of award) 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 (to be provided upon receipt of award). 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.
- 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 and NC State will judge the success of this funding program by tracking (“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 CTSI 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 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

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 funding opportunities.

CONTACT INFORMATION

For additional information on this funding opportunity, please contact Anita Grissom at CTSIfunding@dm.duke.edu or Jonathan Horowitz at research-development@ncsu.edu.