

Duke-RTI Collaborative Translational Research Grants
Request for Applications 2021-2022
Mandatory Letter of Intent: 11:59 p.m. ET, May 20, 2021
Invitation for Full Application Deadline: 11:59 p.m. ET, August 05, 2021

The Duke Clinical and Translational Science Institute (Duke CTSI) is 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 the Research Triangle Institute International (RTI) to support new inter-institutional collaborative research teams.

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 will advance solutions by applying discoveries generated during research in the laboratory, and in preclinical studies in the areas of medicinal chemistry, computational chemistry, High Throughput Screening (HTS) and assay development, in vitro absorption–distribution–metabolism–excretion–toxicity (ADMET) and pharmacology and *in vivo* pharmacokinetics in clinical or population settings.

Duke CTSI and RTI are interested in the following types of translational research projects that foster collaboration between the two institutions:

- 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.

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

- **Mandatory** Letter of Intent (LOI): **May 20, 2021**
- Invited LOI Presentation/Consultation: **June-July, 2021**
- Invited Application Submission Deadline: **August 05, 2021**
- Selection of Awardees: **September 2021.**
- Funding Period: The budget period is for 12 months beginning October 1, 2021 – September 30, 2022

III. Eligibility Requirements

- Proposed projects must involve a lead investigator from Duke (full-faculty appointment) and a lead investigator from RTI. Proposals are encouraged from new teams of investigators from different disciplines. **A RTI investigator will be identified to collaborate on invited applications following the LOI presentation.**
- More than one proposal may be submitted by a Duke Faculty member acting as PI, but the Duke Faculty member is only eligible to receive **one** award as PI from this funding mechanism during a given funding cycle.
- Submission of mandatory LOI (see section VII. For submission instructions).
- Completion of proposal presentation to CTSI and RTI for selected LOI applicants. **Upon conclusion of the**

presentation you will be connected with a RTI investigator to collaborate on Full Application Submission, if invited.

IV.Funding

- The research activities at each participating institution will be funded by the Duke CTSI and RTI. The Duke CTSI and RTI will fund up to \$50,000 per award (\$25,000 per institution).
- Duke CTSI and RTI grant awards are not meant as bridge funding or as supplementary funding for existing projects. Requests for no-cost extensions will not be approved.
- The primary source of funding is from the National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award UL1TR002553 (Duke) and RTI internal research and development funds.

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

V.Review Criteria and Selection Process

Mandatory Letters of Intent (LOI), LOI presentations and invited full Applications will be reviewed by a joint Duke CTSI-RTI 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.
- Soundness of the proposed methods.
- Feasibility of accomplishing the stated project goals within the one-year project period.
- Students/trainees engagement plan if engaged as part of the research team

VI.Letter of Intent and Application Procedure

- The mandatory Letter of Intent (LOI) will be 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 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 "Letter of Intent (LOI) Duke-RTI Collaborative Translational Research Grants 2021-2022" opportunity and follow the instructions.
 - For questions concerning MyResearchProposal passwords or system issues, please contact myresearchproposal@duke.edu or 919-668-4774.
 - Note: Applicants invited to submit full applications will receive an email notification when the full application is accessible. Unsolicited full proposals submitted will not be reviewed.

- 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.).

 - **Letter of Intent (Mandatory)** – To be uploaded as a PDF file and includes the following sections (2-page limit, including tables and figures. References do not count toward the 2-page limit; single line spacing, font no smaller than Arial 11; 1-inch margins)
 - Brief overview of specific aims
 - Summary of proposed research design/approach:
 - What is innovative about this project?
 - Expected significance and impact of the project from a translational science perspective.
 - High level draft budget (e.g. 10% salary support, 90% supplies and equipment usage fee)

 - **Invited Full Application 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 Duke CTSI/RTI (250 word maximum).
 - 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.
 - a. Significance & Background
 - b. Innovation
 - c. Approach, Methods, and Analysis (include hypotheses, design, procedures, sample recruitment, methods/measures, potential pitfalls and alternatives, benchmarks for success, facilities/environment plan, and data management and analysis plan)
 - d. Timeline & table of quarterly milestones to be achieved
- *Renewal applications should report progress against the original plan.
- D. 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.
 - E. 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).

- F. **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.
- G. **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 RTI budgets and budget justifications will be uploaded separately.
- H. **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 RTI 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 RTI IACUC (no page limit).
- I. NIH Biosketches for key members of the research team (as a single PDF) - [click here for details](#).
- J. Relevant Publication (optional; limit to 1 publication)
- K. 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. Funding will not be available until applicable IRB/IACUC documentation is provided to Duke CTSI/RTI.
- B. As part of federal requirements, Duke has an obligation to report effort correctly on sponsored projects. The investigators must include sufficient effort to accurately reflect their effort on the project.
 - 1. 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
 - 2. 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](#)
3. 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 RTI reserve the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal.
 4. 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 RTI 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 or RTI 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 may require approval by the National Center for Advancing Translational Sciences (NCATS) prior to receiving funds. The Duke CTSI and RTI will request required documents from the PIs and submit a regulatory package for each institution to NCATS for review and approval.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Duke CTSI and RTI 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 RTI 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 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 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 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 their 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 5 years post-award completion 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 funding opportunities.

IX. CONTACT INFORMATION

For additional information on this funding opportunity, please contact the Program Officer, Dr. Tarun Saxena at CTSIfunding@duke.edu