

Duke CTSI Translational Accelerator Research Funding Agreements

REQUEST FOR 2019-2020 APPLICATIONS

Application Deadline: 11:59 p.m. ET, November 8, 2018

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) funding program. The Duke CTSI accelerates translational research, by resourcing discovery to preclinical research and human trials, through to implementation into practice and commercialization. Duke CTSI accelerates translational research not only by providing funding, but also by promoting investigator collaboration, encouraging innovation, providing project management assistance, and providing access to resources/services in a collaborative and service-oriented fashion.

I. Purpose

The Duke CTSI Translational Accelerator Research Funding Agreement provides funding up to \$150,000 (direct costs only) to support novel clinical, population, and translational research that applies or accelerates discovery into testing in clinical or population settings. Projects must demonstrate stakeholder engagement and high translational potential 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. Cross-disciplinary scientific research addressing the development of therapies, diagnostics or devices applicable to human disease, clinical research/trials (excluding Phase 2 or beyond), epidemiological studies, and/or community-based research are eligible for these awards. Proposals from teams of investigators from different disciplines are encouraged.

Duke CTSI is interested in the following types of translational research projects, with an emphasis on inter-disciplinary collaborations that test generalizable solutions to translational research problems:

- 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 impacts how practice improves health policy, health outcomes, and the health of populations.

The primary source of funding is from Duke's National Institutes of Health (NIH), National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Award UL1TR002553.

II. Key Dates

- Letter of Intent (Optional): September 20, 2018
- Application Submission Deadline: November 8, 2018
- Selection of Finalists and Oral Presentations: February 2019
- Final Selection: March 2019
- Project Planning Run-In Period: March – April, 2019
- Funding Period: May 2, 2019 - May 1, 2020

III. Eligibility

- Applicants must have principal investigator status per [Duke's written policy](#).
- Researchers holding an adjunct appointment are not eligible to apply.
- Non-Duke faculty may be named as co-investigators if they have a separate aim that will be funded by their local CTSA or other funding sources.
- More than one proposal may be submitted per faculty member acting as PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle.
- Faculty members may not serve as PI concurrently on the Transformative and Translational Duke CTSI awards.

IV. Funding

Each award will consist of up to \$150,000 (direct costs only) with an expected start date of May 2, 2019 and ending on May 1, 2020. Requests for no-cost extensions (carryovers) will not be approved. Funded projects are eligible to re-apply for renewal in subsequent years and, if selected, receive funding for up to two cycles.

Note: This award is internally funded and does not need to be routed through the Duke Office of Research Administration (ORA).

V. Proposal Preparation

1. Letter of Intent (LOI) and Consultation (Optional):
 - We strongly recommend submitting an LOI with a one-page preliminary proposal. Please submit LOI via MyResearchProposal (see Section VII LOI and Application Submission below).
 - The Duke CTSI Project Office will review the LOIs and arrange a consultation meeting with appropriate consultants based on the specific project needs to provide feedback prior to application submission.
 - Applicants who are resubmitting previous proposals that were not funded are highly encouraged to submit an LOI and arrange a consultation.
2. Duke CTSI strongly recommends involving a biostatistician early in the application development process and including biostatistics support in the budget where necessary to ensure success. The online application form will ask for the name of the biostatistician who consulted on the proposal. For investigators without access to a biostatistician, biostatistics support can be obtained through the [Duke CTSI Biostatistics Core](#) by submitting a [Core Resource Request form](#). The core provides an initial 1-hour consultation upon request at no cost.
3. Duke CTSI recommends a consultation with the [Duke CTSI Community Engagement Core](#) to identify opportunities to include stakeholder engagement in the project, if appropriate.

VI. Selection Process and Review Criteria

1. LOI and Application Submission: A Review Committee comprised of researchers, clinicians, and experts in translation will perform a detailed review of the applications and select the finalists. The Review Committee will consider the following criteria when reviewing and scoring applications:
 - Significance – The novelty, uniqueness and impact of the opportunity presented by the proposal; opportunities that provide generalizable solutions to translational research problems are highly encouraged.
 - Approach – The overall strategy, methods and analyses used are well-reasoned and suitable to complete value recognition studies and proposed specific aims.
 - Feasibility – Project scope of work is appropriate for the timeframe and level of funding.
 - Collaboration – Collaboration of investigators provides complementary skills and expertise.
 - Translation – Translational potential of the opportunity including intellectual property, strategy for partnering and follow-on support where needed to advance the proposed activity.
 - Level of stakeholder engagement
 - Oral Presentation: Finalists will be invited to present their proposals during a final selection meeting.
2. Project Planning Run-In Period: The project selected for funding will undergo a run-in period of up to two months to ensure that all requisite preliminary work, including IRB, animal use, and other institutional and NCATS approval are obtained before funding.

VII. LOI and Application Procedure

Duke CTSI uses the MyResearchProposal online application software to submit applications.

- 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 - Please review this [document](#).
- Enter Access Code ‘**CTSI**’ then select the “LOI - Duke CTSI Translational Accelerator and Transformative Funding Agreements” to submit an LOI and to submit a full application, select the “Duke CTSI Translational Accelerator Research Funding Agreements 2018-2019” funding opportunity and follow the instructions.
- For any questions concerning MyResearchProposal passwords or system issues, please contact Anita Grissom or Lesia O’Hara at myresearchproposal@duke.edu.

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

1. Project Title, Brief Description, and Amount Requested
2. Co-Investigators: Name, rank, department, and area of expertise

3. General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, ongoing sources of funding, intellectual property, relevant citations).
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:

1. Scientific Abstract: The abstract summary of the proposal for use by review committee members and Duke CTSI (4,000 characters maximum including letters, spaces, punctuation, special characters, etc.).
2. Research Proposal (5-page limit, including tables and figures. Use 1-inch margins, single line spacing, and font no smaller than Arial 11. References do not count towards the 5-page limit.)
Research proposal should address the following:
 - a. Explanation of unmet clinical need
 - b. Table of quarterly milestones to be achieved
 - c. Research plan to achieve milestones (include preliminary data where helpful)
 - i. Include stage of the project/product
 - ii. Include preliminary data where helpful (not required)
 - iii. Renewal applications should report progress against the original plan
 - d. Strategy and plan for successful translation
3. 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. Finalists selected for oral presentations will be required to submit a detailed NIH budget and updated budget justification. This award is internally funded and does not need to be routed through (ORA); Duke CTSI will route final budgets to departments for review and approval.
4. 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, 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 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 the Duke IACUC. (no page limit)
5. NIH Biosketches for key members of the research team (as a single PDF) - [click here for details](#).
6. One copy of a relevant publication (no page limit).

VII. Budget Guidelines

Please note the following during budget preparation:

1. The budget period is May 2, 2019 through May 1, 2019. No indirect or overhead costs are awarded; the awardees receive direct costs only.
2. 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.
3. 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
 - tuition and fees
 - 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
4. Grant funds may **not** be budgeted for
 - general consumables
 - foreign components, as defined in the [NIH Grants Policy Statement](#)
 - 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, or
 - indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to government regulations and Duke requirements regarding the use of CTSA funds. Duke CTSI reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal. 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 IRB and NCATS. The Duke CTSI will request required documents from the PI and submit a regulatory package to NCATS for review and approval prior to the funding start date. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Investigators agree to work in collaboration with the Duke CTSI Translational Accelerator, submit brief written quarterly progress reports, and present the interim findings of their work at six months and final results at 12 months. Duke CTSI may terminate and reallocate residual funds for any team failing to submit required written reports in a timely manner. Proposed aims of funded projects may be changed, added or deleted during the funding period, pending Investigator and Duke CTSI Program Leadership Committee review and agreement. Funding amount may be modified pending Investigator and Duke CTSI Program Leadership Committee agreement. Projects must complete in the 12-month period; no-cost extensions will not be granted.
- Investigators will meet with their Duke CTSI Project Leader during the March-April 2018 project run-in period to review project plans and ensure projects are ready to start May 2nd . 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 UL1TR002553 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 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.
- Any awardee who leaves his or her position should contact Duke CTSI to discuss future plans for the project.

C. Post-Award Reporting

The 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 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.

CONTACT INFORMATION

For additional information on this funding opportunity, please contact Tarun Saxena at CTSI@duke.edu.