Duke CTSI Translational Accelerator Research Funding Agreement
REQUEST FOR 2021-2022 APPLICATIONS
Optional LOI Deadline: 11:59 p.m. ET, December 02, 2020
Application Deadline: 11:59 p.m. ET, January 12, 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) 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 and health equity, 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 anticipates funding for up to 3 awards, with grants not exceeding $125,000 per award (only direct costs allowed) to support novel 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 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) are eligible for these awards. Proposals from teams of investigators from different disciplines are encouraged.

For this funding opportunity announcement, 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 **generates translational discoveries** relevant to human health or disease.
- 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.

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): **December 02, 2020**
- Application Submission Deadline: **January 12, 2021**
- Selection of Finalists and Oral Presentations: **February-March 2021**
- Final Selection: **April-May 2021**
- Project Planning Run-In Period: **May – June 30, 2021**
- Funding Period: **July 1, 2021** – **June 30, 2022**

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.
- Previously submitted proposals to this funding mechanism not previously selected for funding may be resubmitted as a revised application. See Section VII. *Application procedure* for more details.
- More than one proposal may be submitted per 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.
- 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 $125,000 (no indirect costs or F&A allowed) with an expected start date of July 1, 2021 and ending on June 30, 2022. The Duke CTSI Translational Accelerator awards are not meant as bridge funding or as supplementary funding for existing projects. **Requests for no-cost extensions (carryovers) will only be approved by the Program Committee and CTSI Director under extraordinary circumstances.** 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 Procedure below). The LOI must list the specific aims, collaborators, anticipated budget, and translational relevance of the project.
   - The Duke CTSI Project Office will review the LOI 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 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 CTSA Biostatistics, Epidemiology and Research (BERD) Methods Core can be connected with an appropriate biostatistician, quantitative, or qualitative methodologist through the Duke CTSI 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 or department 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 must be submitted at least 6 weeks 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.

VI. Selection Process and Review Criteria

1. LOI and Application Submission: Applicants are encouraged to submit an LOI with a **one-page** preliminary proposal. Please submit the LOI via MyResearchProposal (see Section VII LOI and Application Procedure below). The LOI must list the specific aims, collaborators, anticipated budget, and translational relevance of the project. 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.
   - Students/Trainees engagement plan if engaged as part of the research team.
   - Level of stakeholder engagement
2. Oral Presentation: Finalists will be invited to present their proposals during a final selection meeting.
3. 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 here.
- Enter Access Code **'CTSI'** then to submit a LOI, select the **"LOI - Duke CTSI Translational Accelerator Funding Agreements"**, and to submit a full application, select the **"Duke CTSI Translational Accelerator Research Funding Agreements 2021-2022– CTSA 3.0"** funding opportunity and follow the instructions.
- For any 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:

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

C. 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).

D. 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 #s 1, 2, 3, 5-8) will be uploaded as individual PDF files. The application sections are:

1. **Project Narrative**: Describe the relevance of this research to public health in, at most, three sentences.

2. **Translational Impact Statement**: Describe how the proposed collaborative project, if successful, will have impact on the field of translational science, or human health, or will result in an intermediate outcome linked to health impact (250 word maximum, equivalent to 1,500 characters including letters, spaces, punctuation, special characters, etc.)

3. **Scientific Abstract:** The abstract summary of the proposal for use by review committee members and Duke CTSI (500 word maximum, equivalent to 3,000 characters including letters, spaces, punctuation, special characters, etc.).

4. **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, with explanation of unmet clinical need
    b. Innovation
    c. 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)*
    d. Timeline & table of quarterly milestones to be achieved
    *Renewal applications should report progress against the original plan.

5. **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.

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. **Equity in Research Plan**: Applicants must indicate ways in which the research will ultimately increase health equity (where applicable). The Duke CTSI centers Equity as one of our integral

organizational values and goals. We seek to fund proposals that clearly align with this commitment. Specifically, Applicants should indicate ways in which the proposed research applies an "equity lens" to their work, which could include but is not limited to, advancing health equity through disparities research, proactive and rigorous recruitment planning to ensure appropriate representation of diverse participants or samples in the study, ensuring broad applicability of the innovation to the entire population, authentically engaging community stakeholders to shape the work, or inclusion of under-represented and minority students or trainees in the research program. We encourage applicants to set up a free consultation with the CTSA Equity in Research Core by contacting Sabrena Mervin Blake at sabrena.mervin-blake@duke.edu

9. **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 budget and updated budget justification using the PHS 398 budget forms. 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.

10. **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)

11. **NIH Biosketches** for key members of the research team (as a single PDF) - click here for details.

12. One copy of a relevant publication (no page limit; optional).

13. Letters of Support (optional)

VIII. Budget Guidelines

Please note the following during budget preparation:

a. The budget period is for 12 months beginning July 1, 2021 through June 30, 2022. No indirect or F&A costs are awarded; the awardees receive direct costs only.

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.

c. Grant funds **may** be budgeted for:
   i. Salary support for the PI or faculty collaborators
   ii. Research support personnel
   iii. Student stipend and tuition and fees **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. The amount of tuition expenses allowed is commensurate with the level of student effort on the project.

   iv. Travel necessary to perform the research
   v. 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.)
   vi. Other purposes deemed necessary for the successful execution of the proposed project.

d. Grant funds may **not** be budgeted for:
   i. General consumables (**NOTE:** Project specific general consumable supplies are allowable, however supplies that are typically allocable across multiple projects or for lab-wide use are unallowable.)
   ii. Foreign components, as defined in the NIH Grants Policy Statement
   iii. Effort for post-doctoral trainees or fellows on training grant equivalents
   iv. Capital equipment
   v. Office supplies including printing and postage or communication costs (excludes project specific teleconference charges)
   vi. Meals or travel, including to conferences, except as required to collect data
   vii. Professional education or training
   viii. Computers or audiovisual equipment
   ix. Cell phones
   x. Manuscript preparation and submission
   xi. Indirect costs
   xii. F&A

e. 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.

f. 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 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.

- o Research involving 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 PIs and submit a regulatory package to NCATS for review and approval.
- o Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- o Investigators agree to work in collaboration with the Duke CTSI Accelerator to monitor progress and when necessary, provide assistance. Quarterly and final progress reports will be required. Investigators will present the interim findings of their work at six months and final results at 12 months, if requested. The investigators are expected 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. 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 be completed in the 12-month period; **no-cost extensions will not be granted**.
- o Investigators will meet with their Duke CTSI Project Leader during the project run-in period to review project plans and ensure projects are ready to start July 1st. **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**.
- o 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 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.
- o 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.
- o 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 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 period will be expected to provide updated contact information for future communications.

Awardees and applicants will be asked to serve as reviewers for future Duke CTSI funding opportunities.

X. Contact Information

- For additional information on this funding opportunity, please contact **Dr. Tarun Saxena** at CTSIfunding@duke.edu
- To schedule a consultation, contact **Brittany Sadler** at consultstudio@duke.edu