

Duke CTSI Transformative Funding Agreements

REQUEST FOR 2020-2022 APPLICATIONS

Optional Letter of Intent (LOI) Deadline: 11:59 p.m., August 20, 2019

Application Deadline: 11:59 p.m. ET, September 5, 2019

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 supports development and proof-of-concept evaluation of therapeutic agents, biomedical devices, and diagnostic tests designed to address unmet clinical needs. 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 Transformative Funding Agreement provides funding up to \$500,000 to address the T1 valley of death: the gulf between novel clinically motivated research and products that show safety and efficacy in humans ([Coller BS and Califf RM, 2009](#)). This program seeks to provide funding for development of mature research that if successful will attract significant interest for external partnering. **The goal of this program is to enable and accelerate translation of research out of the academic environment** (i.e. new company formation, licensing, or partnership).

Applicants will work toward major milestones (e.g. prototype development, GMP manufacture, GLP toxicology studies, IND submission, completion of Phase I clinical trial) that will enable this translation. Projects must demonstrate stakeholder engagement with a high translational potential. Projects selected for funding will be assigned a translational support team for a run-in period of up to six months to deliver a proposed development path, outsourcing plan, and detailed project timeline before funds are released.

Examples of projects responsive to this application might include, but are not limited to, the following:

- A therapeutic agent that has shown efficacy in animal models but needs funding to complete scale up, pharmacology/toxicology studies and submit IND needed for clinical trials.
- An alpha prototype device with early proof-of-concept data that needs funding to manufacture devices and conduct clinical trials.

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 (CTSA) *UL1TR002553*.

II. Key Dates

- Letter of Intent (Optional): **August 20, 2019**
- Application Submission Deadline: **September 5, 2019**
- Selection of Finalists **December 2019**
- Oral Presentations: **January 2020**

- Final Selection: **March 2020**
- Project Planning Run-In Period: **May – October, 2020**
- Funding Period: **November 1, 2020 - April 30, 2022 (18 months)**

III. Eligibility

- Applicants must have principal investigator status per [Duke's written policy](#). The proposed project should be innovative, high-risk, and high-impact such that if successful, it will attract significant interest for external partnering. Applicants will work toward major milestones that will enable translation out of the academic environment.
- Applicants are encouraged but not required to bring funding partners, matching discretionary or departmental funds, or commitments from other sources to supplement CTSA support and accelerate research or broaden aims. Applicants must show that they have considered collaboration with other NCATS initiatives including Bridging Interventional Development Gaps (BriDGs) and Therapeutics for Rare and Neglected Diseases (TRND) to compress timelines and access available expertise.
- Faculty members may not serve as PI concurrently on the Transformative and Translational Duke CTSI awards.

IV. Funding

The award will consist of up to \$500,000 (direct costs only) with an expected start date of November 1, 2020 and ending no later than April 30, 2022. Only one award may be funded during this award cycle.

Requests for no-cost extensions (carryover) will not be approved.

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. Duke investigators who do not know whether their affiliated department/center/institute has an existing collaborative agreement with the Duke CTSA Methods Core can be connected with an appropriate biostatistician, quantitative, or qualitative methodologist through the Duke CTSI [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 Duke investigator submitting the request does not belong to a group 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. Letter of Intent and Consultation (Optional):
 - We strongly recommend submitting a Letter of Intent with a one-page preliminary proposal via [MyResearchProposal](#).
 - The Duke CTSI Accelerator Operations Group will review the LOI and arrange a consultation meeting with appropriate consultants based on the specific project needs to provide feedback prior to the application submission.
 - Applicants who are resubmitting a proposal that was not funded are highly encouraged to submit an LOI and arrange a consultation.
2. Application Submission: The Review Committee 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.
 - Innovation – The project represents work that is sufficiently patentable and scientifically interesting to attract attention from potential investors or licensors.
 - Approach – The overall strategy, methods and analyses used are well-reasoned and suitable to accomplish the specific aims of the proposal and mitigate the potential associated risks:
 - Technical risk of development (devices), CMC/product risk (drugs) or assay technical risk (diagnostics)
 - Regulatory pathway to approval and regulatory risk
 - Clinical development risk
 - Feasibility – Project scope of work is appropriate for the timeframe and level of funding.
 - Translation – Translational potential of the opportunity presented by the proposed activity including:
 - There is potential for independent external funding with data provided by this award;
 - The project is sufficiently scientifically interesting to attract potential investors or licensors;
 - The commercial potential, either by virtue of market size or unmet need in a smaller

- population can command premium pricing;
 - The competitive landscape, including products in development that might impact the potential to partner or translate the innovation.
 - Level of stakeholder engagement.
 - Students/trainees engagement plan if engaged as part of the research team.
 - Transformative potential – the totality of all of the dimensions supports the transformative nature of the project and addresses an unmet medical need.
3. Oral Presentation: Finalists will be invited to present their proposals during a final selection meeting.
 4. Project Planning Run-In Period: The project selected for funding will undergo a run-in period of up to six months to ensure that all requisite preliminary work is performed before funds are released.

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 Transformative Accelerator Funding Agreements”, and to submit a full application, select the “Duke CTSI Transformative Funding Agreement 2020-2022 – 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:

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 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, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, 1-inch margins.)

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. Intellectual property status, strategy and plan for translation (license, etc.)
3. **Program Timeline:** The timeline should represent the activities to achieve the aims in the specific research grant as well as show the translation of the work covered by the grant through the next logical translational unit(s).

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).

VIII. Budget Guidelines

Please note the following during budget preparation:

1. The budget period is November 1, 2020 through April 30, 2022. 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 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.**
 - 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
4. Grant funds may **not** be budgeted for
- 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, (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, or
 - Indirect costs
5. 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.
6. “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.

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

B. Project Execution

- A Duke CTSI Project Leader will be assigned to each funded project. It is anticipated that the final **grant budget will include up to 20% project leader effort** with any additional required project leader effort being covered by the Duke CTSI.
- The Oversight Committee for the project will include institutional experts in therapeutic development, technology transfer, and commercialization as well as external experts from the pharmaceutical, biotechnology, device, diagnostics, and investment sectors. Projects selected for funding will undergo a run-in period of up to six months to ensure that all requisite preliminary work is performed before funds are released. Key deliverables for the run-in period will include the proposed development path, outsourcing plan, and detailed project Gantt chart.
- Duke CTSI will assign a dedicated team during the run-in including a project manager, a CTSA Regulatory Affairs associate, and an invention manager from the Office of Licensing and Ventures. This team will provide critical expertise in drug and device development, informatics, intellectual property, conflict of interest management, contracts, outsourcing, regulatory affairs, and statistical expertise.
- At the end of the run-in period, the Oversight Committee will meet with applicants to review project aims and preliminary feasibility data and to determine whether to initiate full funding. A committee member will be assigned to each funded project to help develop a long-term funding strategy. Any project that fails to achieve pre-specified deliverables or that meets pre-specified futility endpoints will be reviewed by the Oversight Committee and may be terminated, with residual funds reallocated.
- Investigators agree to work in collaboration with the Oversight Committee, to submit brief written quarterly progress reports to the committee, and present the interim findings of their work at 6 months, 12 months, and final results at 18 months as part of committee meetings.
- 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 PubMedCentral. 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

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, 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 period will be expected to provide updated contact information for future communications.

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 CTSIfunding@duke.edu.

To schedule a consultation, contact **Brittany Sadler** at consultstudio@duke.edu