The Duke Translational Research Institute (DTRI) is the academic home of the National Institutes of Health’s Clinical and Translational Science Awards (CTSA) pilot funding program. The DTRI accelerates translational research, from discovery to preclinical and human trials, and on to implementation into practice or commercialization. DTRI supports 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 DTRI Translational Research Pilot Funding Agreements provide funding up to $100,000 (direct costs only) to support novel clinical and translational research in its many forms. 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 considered eligible for these awards. 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. Proposals from teams of investigators from different disciplines are encouraged.

DTRI is interested in the following types of translational research projects:

- Research that generates initial discoveries relevant to human health or disease, regardless of whether the context of the discovery is the laboratory 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.

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) UL1TR001117.

II. Key Dates

- Letter of Intent (Optional): September 15, 2015
- Application Submission Deadline: October 30, 2015
- Selection of Finalists and Oral Presentations: January 2016
- Final Selection: February 2016
- Funding Period: May 1, 2016 - April 30, 2017
III. Eligibility

- Proposals must be submitted by Duke regular rank faculty. Researchers who only hold an adjunct appointment are not eligible to apply.
- Ranks lower than regular-rank assistant professors such as post-doctoral trainees, medical instructors and/or fellows are not eligible to serve as PIs, but are eligible to serve as co-investigators and play a prominent role in conducting the project.
- Non-Duke faculty may be named as co-investigators if they have a separate aim that will be funded by their local CTSA (Duke will not issue subcontracts to other institutions under this award).
- 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 on more than one concurrently funded Duke CTSA pilot award, with the exception of the Core Facility Voucher and NIH Supplemental Award Programs.

IV. Funding

Each award will consist of up to $100,000 (direct costs only) with an expected start date of May 1, 2016 and ending on April 30, 2017. 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.

V. Selection Process and Review Criteria

1. Letter of Intent (LOI) and Consultation (Optional):
   - We strongly recommend submitting an LOI with a one-page preliminary proposal. Please submit via email to dtripilots@dm.duke.edu.
   - The DTRI 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. 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.
   - Approach – Methods and analyses used are well-reasoned and suitable to accomplish the specific aims of the proposal.
   - 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 presented by the proposed activity.
3. Oral Presentation: Finalists will be invited to present their proposals during a final selection meeting.

VI. Application Procedure

DTRI strongly recommends involving a biostatistician in the application development process and including biostatistical 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, biostatistical support can be obtained through the Duke CTSA Biostatistics Core. The core provides an initial 1-hour consultation upon request at no cost.

DTRI utilizes the MyResearchProposal online application software to submit applications. To apply

- Select the “DTRI Translational Research Pilot Funding Agreements 2016-2017” funding opportunity and follow the instructions.

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 DTRI (250-word maximum).
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 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
VII. Budget Guidelines

Please note the following during budget preparation:

1. The budget period is May 1, 2016 through April 30, 2017. 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 translational research pilot agreement involves significant programmatic involvement, and investigators must include sufficient effort to accurately reflect their leadership on the project.
3. Grant funds may be budgeted for
   - salary support for the PI or faculty collaborators
   - research support personnel
   - 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
   - subcontracts to other institutions
   - effort for post-doctoral trainees or fellows on training grant equivalents
   - capital equipment
   - office supplies or communication costs, including printing
   - meals or travel, including to conferences, except as required to collect data
   - professional education or training
   - computers or audiovisual equipment
   - 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. DTRI 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. Project Execution

Investigators agree to work in collaboration with the DTRI Pilot Program Leadership Committee, submit brief written quarterly progress reports to the committee, and present the interim findings of their work at 6 months and final results at 12 months, as part of committee meetings. Proposed aims of funded projects may be changed, added or deleted during the funding period, pending Investigator and DTRI Pilot Program Leadership Committee review and agreement. Funding amount may be modified pending Investigator and DTRI Pilot Program Leadership Committee agreement. Projects must complete in the 12-month period; no-cost extensions will not be granted.

A DTRI Project Leader will be assigned to each funded project. Investigators will meet with their DTRI Project Leader during the March-April project run-in period to review project plans and ensure projects are ready to start May 1st. The investigators will interact regularly with the DTRI 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 DTRI and other key resources.

B. Post-Award Reporting

The DTRI 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 DTRI 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
- 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.
The DTRI pilot funding program is supported by the Duke CTSA. 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 UL1TR001117. 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. Awardees are expected to serve as reviewers for future DTRI funding opportunities.

MORE INFORMATION

For additional information on this funding opportunity, please contact Vonda Rodriguez, PhD at dtripilots@dm.duke.edu.