Duke/UNC-Chapel Hill CTSA Consortium Collaborative Translational Research (T1/T2) Pilot Grants - Request for Applications

The Duke University Translational Medicine Institute (DTMI) and North Carolina Translational and Clinical Sciences Institute (NC TraCS) are the academic homes of the National Institutes of Health’s Clinical and Translational Science Awards (CTSA) at Duke University and at UNC Chapel Hill (UNC-CH). DTMI and NC TraCS are interested in promoting inter-institutional collaborations and pilot funds are now available for eligible new investigator teams.

I. Purpose

This T1/T2 pilot program is designed to encourage and facilitate novel clinical and translational research that applies or accelerates discovery into testing in clinical or population settings. Cross-disciplinary basic research addressing the development of therapies, diagnostics or devices applicable to human disease and clinical research/trials are areas of interest 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.

DTMI and NC TraCS pilot grant awards are not meant as bridge funds or as supplementary funding for existing projects.

II. Key Dates

- Application Submission Deadline: October 31, 2014
- Selection of Awardees: December 2014
- Funding Period: The budget period is for 12 months beginning between January 1 and May 1, 2015 and ending no later than April 30, 2016

III. Eligibility

Proposed projects must involve a lead investigator from Duke and a lead investigator from UNC-CH. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment.

More than one proposal may be submitted per UNC or Duke faculty member acting as PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle. Duke faculty members may not serve as PI on more than one concurrently funded Duke CTSA Collaborative (including the Duke/UNC-Chapel Hill Collaborative) or Transformative pilot award.

Interested investigators who need assistance identifying collaborators at Duke or UNC-CH can use the Reach NC tool (http://reachnc.org/) or contact either DTMI or NC TraCS for assistance.

IV. Funding

The research activities at each participating institution will be funded by that institution’s CTSA. DTMI and NC TraCS will each fund up to $25,000 direct costs, for a total of $50,000 per collaborative project.
Funds will not be subcontracted from one institution to the other. DTMI and NC TraCS anticipate funding two projects in this initial round. UNC investigators please note that for this RFA with Duke you are not required to have a Department/School match.

CTSA funds are not allowed to be carried over from one fiscal year to the next, therefore requests for no-cost extensions will not be approved.

V. Review Criteria

Applications will be reviewed by a joint DTMI/NC TraCS 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
- Level of community engagement (if applicable)

VI. Application Procedure

DTMI and NC TraCS strongly recommend 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. For investigators without access to a biostatistician, biostatistical support can be obtained through the DTMI Biostatistics Core by emailing dtripilots@dm.duke.edu or the NC TraCS Biostatistics Service by emailing nctracs@unc.edu or calling 919-966-6022.

1. Proposal is submitted via the DTMI Foundant online 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 Principal Investigator’s name.
   - A step-by-step user’s guide for applying via the DTMI Foundant software is available - Please watch applicant tutorial or review this document.
   - Select the “2015-2016 Duke/UNC-Chapel Hill CTSA Consortium Collaborative Translational Research (T1/T2) Pilot Grants” funding opportunity and follow the instructions.

Proposal 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 DTMI/NC TraCS (250 word maximum).
B. 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 towards the 5-page limit. 1.5 line spacing, font no smaller than Arial 11, 1-inch margins.)

C. Budget with Budget Justification using PHS 398 Form Pages 4 and 5 (combined into a single PDF with no 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 UNC-CH budgets should be prepared on separate form pages but submitted together as a single PDF.

D. Proposal Timeline.

E. Human and/or Animal Subjects: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission. 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 UNC 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 UNC-CH IACUC. (no page limit)

F. NIH Biosketches for the key members of the research team (combined into a single PDF).

VII. Budget Guidelines

1. The budget period is for 12 months beginning between January 1 and May 1, 2015 and ending no later than April 30, 2016. Up to $25,000 in direct costs at each institution may be requested and the amount requested from each must be equal as funds will not be subcontracted between Duke and UNC. Funding will not available until applicable IRB/IACUC documentation is provided to DTMI/NC TraCS.

2. Budget Guidelines
   A. Grant funds may be budgeted for:
      - salary support for the PI or faculty collaborators (Duke only)
      - research support personnel
      - travel necessary to perform the research
      - equipment, research supplies and core lab costs, or
      - other purposes deemed necessary for the successful execution of the proposed project

   B. Grant funds may not be budgeted for:
      - salary support for the PI or faculty collaborators (UNC only)
      - 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
C. Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to government regulations and requirements regarding the use of CTSA funds. DTMI and NC TraCS reserve the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal. Office of Management and Budget Circular A-21 sets forth general criteria for determining the allowability of direct costs on government sponsored projects. The Duke General Accounting Procedure (GAP) 200.320 http://finance.duke.edu/accounting/gap/m200-320.php 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 government sponsored project.

VIII. Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke and/or UNC-CH 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 DTMI or NC TraCS 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.

2. DTMI and NC TraCS 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. DTMI and NC TraCS expects the PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.

3. 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 Numbers UL1TR001117 and UL1TR001111. 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.

4. If an awardee leaves their position, they should contact DTMI or NC TraCS to discuss future plans for the project.