NC TraCS/NC State University (NCSU) Office of Research Innovation and Economic Development (ORIED) and the Comparative Medicine Institute (CMI)

Collaborative Translational Research Pilot Grant Program - Request for Applications
Next deadline: October 10, 2017

North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health’s Clinical and Translational Science Awards at UNC Chapel Hill (UNC-CH). NC TraCS is partnering with NCSU’s Office of Research Innovation and Economic Development (ORIED) and the Comparative Medicine Institute (CMI - https://research.ncsu.edu/cmi) to promote interdisciplinary inter-institutional collaborative research teams.

I. Purpose

This 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 translational 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. The PI from each institution should clearly be contributing to the science.

These pilot grant awards are not meant as bridge funding or as supplementary funding for existing projects.

NC TraCS and NCSU are particularly interested in interdisciplinary research that focuses on, but is not limited to, collaborations involving:
- Functional tissue engineering/regenerative medicine
- Development and utilization of large animal models for translational medicine
- Manufacturing and scale up of biomaterials
- Evaluating the potential of naturally occurring disease models for therapeutic discovery
- Development and testing of medical devices
- Improvement of imaging technologies
- Antimicrobial resistance
- Zoonotic diseases
- Tissue-on-chip model systems
- Biomedical data analytics and modeling of clinical/environmental interactions
- Patient data de-identification and cybersecurity
- Biomedical nanomaterials and nanotechnologies
- Next generation drug manufacturing
II. Key Dates

- Informational webinar: Date TBD
- Application Submission Deadline: October 10, 2017
- Selection of Awardees: December 2017

III. Eligibility

Proposed projects must involve a lead investigator (co-PI) from one of the NC TraCS partner institutions (UNC Chapel Hill, RTI International and NC A&T State University) and a lead investigator (co-PI) from NCSU. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment. Also eligible are researchers whose appointment allows them to serve as PI on externally sponsored research projects, for instance UNC-CH researchers holding EHRA non-faculty “research scientist” or “investigator” appointments at UNC’s research institutes and centers. Applicants whose faculty appointment is in the joint UNC/NCSU Department of Biomedical Engineering would represent their “home base” institution, and must have a co-PI from the other institution partnered on this pilot program (NCSU and UNC).

More than one proposal may be submitted by a PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle.

IV. Funding

The research activities at each participating institution will be funded by that institution. NC TraCS and NCSU will each fund up to $25,000 direct costs, for a total of $50,000 per collaborative project. The budget from each site should be equal. Funds will not be subcontracted from one institution to the other.

V. Review Criteria

Applications will be reviewed by the NC TraCS Study Section with involvement of faculty from NCSU. 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

Applicants are strongly recommended to involve a biostatistician in the application development process. The online grant application form will ask for the name of the biostatistician who consulted on
the proposal. Investigators without access to a biostatistician can request support through the NC TraCS Biostatistics Service by emailing nctracs@unc.edu or calling 919-966-6022.

1. Proposals are submitted via the NC TraCS online submission system. To apply:
   • Go to this website and click on “Create New User” (or log in if you already have an account). Proposals must be submitted under the Principal Investigator’s name.
   • The online application system is very intuitive; however, a step-by-step user’s guide is also available. Click here to see the video or read the document.
   • Select the “2017 NC TraCS/NC State Collaborative 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 NC TraCS/NCSU (250 word maximum).
- **B. Research Plan**: The Research Plan should include 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.)
- **C. Budget using PHS 398 Form Pages 4-5**: Each institution's budgets should be prepared on separate form pages but submitted together as a single PDF.
- **D. Budget Justification**: The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
- **E. Proposal Timeline**.
- **F. 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. 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. (no page limit)
- **G. NIH Biosketches for key members of the research team** (as a single PDF). Note the NIH Biosketch format can be found here.
- **H. Resubmission Summary** (if applicable): If your proposal is a resubmission to NC TraCS, provide a summary that details your changes to the original proposal. Include the names of any TraCS advisors you consulted with specifically regarding this resubmission. Applicants are limited to one resubmission per proposal. If an investigator substantially changes and improves a proposal following two unsuccessful TraCS pilot submissions, a determination will be made by a TraCS Research Navigator as to whether that can be submitted as a new proposal. (no page limit; does not count towards 5-page Research Plan page limit).

**VII. Budget Guidelines**

1. The budget period is for 12 months beginning between June 1 and October 1, 2017 and ending no later than September 30, 2018. 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 institutions. Funding will not available until applicable IRB/IACUC documentation is provided to NC TraCS.

2. Budget Guidelines
   A. Grant funds may be budgeted for:
      • Research support personnel
      • 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

   B. Grant funds may not be budgeted for:
      • Salary support for the PI or faculty collaborators
      • 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 federal regulations and requirements regarding the use of CTSA funds. NC TraCS and NCSU 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 allowable direct costs on government-sponsored projects.

VIII. Other Guidelines

1. The NC TraCS Institute is funded through a CTSA grant from NIH’s National Center for Advancing Translational Sciences (NCATS). NCATS requires the review and approval of all TraCS pilot grants involving human subjects research prior to pilot funds being released. Therefore, if your proposal is funded and involves human subjects research, TraCS will require additional documentation to send to NCATS. NCATS expects to complete their review in less than 30 days. The NCATS review can occur concurrently with the IRB review but final NCATS approval is contingent upon IRB approval.

2. Prior to receiving funds, research involving human subjects must have appropriate approvals from the NC State 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 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.
3. NC TraCS pilot program 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. NC TraCS expect 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.

4. 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.

5. Any awardee who leaves his or her position should contact NC TraCS to discuss future plans for the project.