North Carolina TraCS Institute Pilot Grant Program
Planning Grants for Extramural Funding Opportunities
Program Guidelines

> *PLEASE NOTE the new requirement for biostatistical consultations for all Planning Grant applications. See "Section VI: Application Procedure" for details.*

The North Carolina TraCS Institute is the academic home of the NIH Clinical and Translational Science Award (CTSA). The mission of NC TraCS is to transform all activities relating to clinical and translational research by creating new programs and pathways that make it easier for research to be conducted.

Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community.

I.   Purpose

The NC TraCS Planning Grants aim to stimulate UNC-CH investigators to serve as Principal Investigators for awards such as Center grants or P series program project grants. This grant mechanism intends to reduce the barrier for faculty who may conceive of these large-scale proposals, but never move forward because of the daunting process of applying for and carrying out these complex studies. In addition to having scientific merit, these grants must demonstrate interdisciplinary involvement among investigators.

Planning Grants may be up to 18 months in duration, and up to $100,000 in CTSA funding/match may be requested. An email of intent must be submitted to TraCS Pilot Program Director Mary Beth Cassely (marybeth_lister@med.unc.edu) for approval prior to the submission of an application. Planning Grant applications can be submitted at any time.

NC TraCS is no longer able to fund pilot grants where the research is conducted outside the United States. Proposals with a foreign component must be discussed with a TraCS Research Navigator prior to submission - click here to schedule a consultation (choose "Proposal Development" from the menu).

II.   Eligibility

Faculty members with a primary appointment at UNC-Chapel Hill may serve as principal investigators (PIs). Co-PIs are allowed, although one person must be identified as the primary contact. SPA and EHRA non-faculty staff members are not eligible to apply.

III.   Funding

The NC TraCS Institute will make awards of up to $50,000 that must be matched with equal funds from participating schools, departments, centers or partner organizations, for total awards of up to $100,000. Match fund sources must represent funds not previously committed to the PI or project. The number and amount of the awards depend upon the quality of the proposals received and the availability of funding. Since multidisciplinary proposals are highly prized, it is encouraged that matching support comes from more than one school, department, center or partner organization. A list of schools, departments, centers and partner organizations that have already committed matching funds can be found on the NC TraCS website.

V.   Review Criteria

Applications will be evaluated based on scientific merit and innovation. It is the applicant's responsibility to present the proposal in a clear and logical fashion, to make a convincing case for the significance of the work and to present sufficient detail about the proposed methods so that an adequate evaluation of the proposal can be made. The following review criteria will be considered:

1) Potential for the project leading to future external funding or potential for the project to lead to commercialization opportunity
2) Novelty/Innovation of the research idea
3) Genuine multidisciplinary teamwork integral to the application
4) Relevance of the proposed study to translational research
5) Significance of the work
6) Feasibility of accomplishing stated project goals within 18-month project period
7) Soundness of the proposed methods
8) Level of community engagement (if appropriate)
9) Potential for contributing to or fostering further research in the area

VI.   Application Procedure

NC TraCS very strongly recommends involving a biostatistician in the application development process. A large proportion of investigator-initiated clinical studies have major statistical deficiencies that can generally be easily addressed. To increase the likelihood of funding of translational research grants and to accelerate the initiation of grants, a biostatistician should be engaged early in the proposal 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 through their Department or Center, biostatistical support can be obtained through the NC TraCS Biostatistics Service by emailing nctracs@unc.edu or calling 919-966-6022 or 866-705-4931 (toll free). It's strongly recommended to contact them at least 3 weeks prior to the proposal deadline.

For cancer-related research, please contact the Lineberger Comprehensive Cancer Center for biostatistical support (email: LCCC_BIOS@med.unc.edu).

Applications must be submitted using the NC TraCS online system. 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 NC TraCS. (250 word maximum)

2) Impact: Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved. (50 word maximum).

3) 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 towards the 5-page limit. 1.5 line spacing, font no smaller than Arial 11, and 1-inch margins.)

4) Budget: Use PHS 398 Form Page 4 (see Section VI below for more details).

5) Budget Justification: The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. (no page limit)

6) Proposal Timeline.

7) Human and/or Animal Subjects: Although 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 will be involved in the research, 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 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 an IACUC. (no page limit)

8) Letter of Collaboration (if applicable): PIs who are not UNC Chapel Hill faculty members must include a letter of agreement from their UNC-CH faculty member collaborator or co-investigator. (no page limit)

9) 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. (3-page limit, 1.5 line spacing, font no smaller than Arial 11, and 1-inch margins)

10) NIH Biosketches for the key members of the research team. Please note the new NIH Biosketch format as of May 2015 – click here for details.

11) NIH Summary (if applicable): If your proposal references a prior NIH review, include the NIH reviewer comments.

VII.   Budget Guidelines

Grant budgets are to cover expenditures for an 18-month period. Expenditures may begin at any time after the award date, and must be expended within 18 months of the award date. The expectation is that all funds will be expended by the end of the grant period. TraCS staff will work closely with you throughout the grant period to monitor progress and, where necessary, provide mentoring. A 6-month interim progress report and a final progress report will be required. NC TraCS will expect the PI to report whether or not the pilot funding contributed to new external funding.

Grant funds may be budgeted for (1) personnel (administrative or research personnel, including biostatisticians), use of NC TraCS services, travel (necessary to the performance of the research), equipment, research supplies or core lab costs, and other purposes deemed necessary for the successful execution of the proposed project. Grant funds are **not available** for PI or Co-Investigator salary, professional education or training, or indirect costs.

The level of funding for this RFA is not intended to support investigator or faculty salaries. Principal Investigators and Co-Investigators are expected to have salary support from their organizations or other funding sources sufficient to allow them time to direct the project and conduct the research.

VIII.   Other Guidelines

1) Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CH IRB, and research involving animals must have the appropriate IACUC approval. 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. 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) The NC TraCS Institute is funded through a CTSA grant from NIH's National Center for Advancing Translational Sciences (NCATS). NCATS requires that they review and approve all NC TraCS pilot grants involving human subjects research prior to funds being released. If your application is funded and involves human subjects research, NC TraCS will require additional documentation to send to NCATS. NCATS expects to complete their review in less than 30 days, and grants determined to be "minimal risk" are approved in a few days.

IX.   Submission Instructions

There are no specific deadlines for the TraCS Planning Grants. Applications may be submitted at any time. Applications will be accepted only through the NC TraCS online system. Within 24 hours after receiving each application, applicants will receive an email confirmation from NC TraCS. Applicants will be notified by email within 8 weeks of the deadline whether their application has been selected for funding.