

CTSA Consortium Multi-Institutional Collaborative Translational Research Pilot Grants Request for Applications

PLEASE NOTE the new requirement for biostatistical consultations for all Multi-Institutional pilot grant applications. See “Section V: Application Procedure” for details.

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health’s Clinical and Translational Science Award (CTSA) at UNC Chapel Hill (UNC-CH). NC TraCS is interested in promoting inter-institutional collaborations among CTSA’s and has made pilot match funds available for eligible teams of researchers using the guidelines below.

Please note these instructions only pertain to a UNC faculty member gaining support from the UNC CTSA for a multi-CTSA pilot award. Each CTSA has their own process and so you must consult with your collaborators at other institutions regarding those procedures.

I. Purpose

This program is designed to encourage and facilitate novel clinical and translational research in its many forms. 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. Cross-disciplinary basic science research addressing the development of therapies, diagnostics or devices applicable to human disease, clinical research/trials, epidemiological studies, and/or community-based research are considered eligible for these awards.

We are also accepting proposals for the following types of translational research projects:

- Research that generates initial or basic 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.
- Individual investigators may apply for funding to develop new technologies that demonstrate an application or utility, develop a proof-of-concept, or better characterize a technology. If you are interested in funding for this type of research, please request a consult with Carolina KickStart at nctracs@unc.edu or 919-966-6022 before submission.

[This article](#) is a useful reference titled “Recommendations for Planning Pilot Studies in Clinical and Translational Research.”

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

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

Proposed projects must involve investigators at two or more institutions with an active CTSA. Applicants at each collaborating institution must have a full-time faculty appointment at their CTSA institution.

Investigators should note that NC TraCS has a separate annual opportunity for Duke & UNC-CH collaborators to submit pilot grant applications, therefore a proposal with just Duke & UNC-CH investigators cannot apply through this mechanism. For more information on this other annual opportunity, email mbcassely@med.unc.edu.

III. Funding

The research activities at each participating research site will be funded by that institution's CTSA and the funds provided by NC TraCS must be expended by the UNC applicant. Each CTSA will contribute an equal amount of funds to the project. Funds will be transferred between CTSA's. Because each institution decides how much funding will be devoted to their multi-CTSA pilot program, the amount of funding available will vary depending on the institutions of the investigators involved in an application. It is anticipated that funds in the range from \$10,000 to \$25,000 direct costs per participating institution may be available for these collaborative projects. Investigators should contact their own institutions' CTSA leaders to determine the level of support being provided for the collaborative pilot grants.

Funds may be used for any research purpose other than faculty salary support. Typical expenses include laboratory supplies, small equipment, patient costs, consultants, or support for pre/postdoctoral students, technicians, or research assistants. Awards are not transferable to any other institution.

The award period at each of the participating CTSA institutions will depend on the policies of the respective institutions. Because CTSA funds are not generally allowed to be carried over from one fiscal year to the next, a variety of approaches may be considered to permit a sufficiently long award period at each of the institutions participating in a collaborative project. These may include using non-NIH funds for part or all of an award or funding the first and second portions of the award period with NCATS funds from consecutive fiscal years.

IV. Review Criteria

Applications will be reviewed by the NC TraCS Study Section. Review criteria will include:

- 1) Significance of the work
- 2) Novelty/Innovation of the research idea
- 3) Relevance of the proposed study to translational research
- 4) Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research
- 5) Potential for the project to lead to future external funding or to a commercialization opportunity
- 6) Soundness of the proposed methods
- 7) Feasibility of accomplishing the stated project goals within the one-year project period
- 8) Level of community engagement (if applicable)

V. 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).

There are no set deadlines. Before submitting a collaborative pilot grant application, the applicant at each institution is required to obtain approval for submission from his/her parent institution CTSA pilot grant program director.

1. To obtain NC TraCS support, complete the [CTSA Multi-Institutional Pilot Grants Preliminary Request For Approval](#) and submit to: marybeth_lister@med.unc.edu. UNC CTSA leadership will review the submission and inform you if the UNC CTSA is supportive of the project.
2. Once all CTSA's involved have approved a specific project, the investigators write the full proposal and each submits that to their own CTSA for review and approval. At UNC that grant should be submitted using the NC TraCS [online system](#). 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 (250 word maximum).
 - B) Impact: Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (50 word maximum).
 - C) 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.)
 - D) Budget: Use [PHS 398 Form Page 4](#) (see Section VI below for more details).
 - E) Budget Justification: The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. (no page limit)
 - F) Proposal Timeline.
 - G) 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)

H) 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)

I) 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)

J) [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.

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

VI. Budget Guidelines

1) NC TraCS grant budgets cover expenditures for a 12-month period. The expectation is that all funds will be expended by the end of the grant period. The budget period will begin when applicable IRB/IACUC/NCATS documentation is received by NC TraCS and the PI indicates everything is in place for the project to begin. If more than 6 months passes after notification of funding and the PI is still not ready to start, TraCS reserves the right to retract the award.

2) Grant funds may be budgeted for (1) research support personnel, (2) use of NC TraCS services, including salary support for NC TraCS core faculty, for example biostatistics and biomedical informatics faculty, (3) travel necessary to perform the research, (4) equipment, research supplies and core lab costs, or (5) other purposes deemed necessary for the successful execution of the proposed project.

3) Grant funds may **not be budgeted** for (1) salary support for the PI or faculty collaborators, (2) office supplies or communication costs, including printing, (3) meals (except for focus groups) or travel, including to conferences, except as required to collect data, (4) professional education or training, (5) manuscript preparation and submission, or (6) indirect costs.

4) Principal Investigators and co-investigators at academic partner institutions are expected to have salary support from their institutions or other funding sources sufficient to allow them time to direct the project and conduct the research.

VII. Other Guidelines

1) Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CH IRB. If the research includes animals, the appropriate IACUC animal research forms must also be filed and 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.

- 2) NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and, where necessary, provide assistance. A six-month interim progress report and a final progress report will be required. NC TraCS expects the PI 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) If an awardee leaves their position, they should contact NC TraCS to initiate close-out procedures.

VIII. New requirements for funded pilot grants

The NC TraCS Institute is funded through a CTSA grant from NIH's National Center for Advancing Translational Sciences (NCATS). NCATS recently instituted a new policy requiring the review and approval of all TraCS pilot grants involving human subjects research prior to TraCS 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, and grants determined to be "minimal risk" are approved in a few days.

IX. Submission Instructions

There are no specific deadlines for the Multi-Institutional 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.