



North Carolina TraCS Institute \$2K Pilot Grant Program Request for Applications (RFA)

Due to uncertainty around COVID-19, a new application section asks applicants to specifically discuss the feasibility of their timeline and their ability to complete the work under the current restrictions.

Purpose

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health Clinical and Translational Science Award (CTSA). The express purpose of the NC TraCS \$2K Pilot Program is to support the generation of preliminary data that will enable researchers to compete for external funding. To this end, TraCS provides small grants of up to \$2,000 to assist clinical and translational researchers in implementing a proposed study or moving a research project forward by providing rapid access to funds that will support almost any aspect of promising and innovative translational research.

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. Eligible projects must be translational in nature. This includes clinical trials, epidemiological studies, community-based research, and cross-disciplinary basic science research addressing the development of therapies and diagnostics applicable to human disease. Basic science projects must be translational in nature.

Priority will be given to projects done in North Carolina, particularly research focused on one of the 10 health priority areas identified by TraCS through a series of meeting with community groups (cancer, cardiovascular disease/hypertension, chronic disease management, diabetes, healthcare access, mental health, nutrition, obesity, physical activity, and substance abuse).

A consultation with a TraCS Research Navigator is available for any applicant who would like to discuss their project and \$2K application. [Click here](#) to schedule a consultation (choose "Proposal Development" from the menu).

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

TraCS pilot grants do not support research that is conducted outside the United States.

Due to uncertainty around COVID-19, a new application section asks applicants to specifically discuss the feasibility of their timeline and their ability to complete the work under the current restrictions (see UNC website: ["Updated Guidance for Research Activities in response to COVID-19"](#)). Applicants should assure reviewers that the proposed work is allowable and achievable under the current restrictions. This is a new and important review criterion.

Who is Eligible to Apply as PI?

* UNC-CH researchers whose appointments allow them to serve as PI on externally sponsored research projects are eligible to apply as PI. In practice, this restricts UNC-CH eligibility to permanent faculty, non-faculty researchers, postdoctoral trainees, medical residents, clinical fellows, and doctoral students.

* Applicants from NC A&T, RTI or NCSU are eligible to apply as PI but must include an eligible co-PI or co-Investigator from at least one other TraCS partner institution (UNC-CH, NC A&T, RTI, or NCSU). The required co-PI/co-I does not have to be from UNC-CH; however, the inclusion of a UNC-CH co-I/co-PI is strongly encouraged. Applicants from NC A&T need to contact the A&T Office of Sponsored Programs at divofres@ncat.edu to ensure proper procedures are followed.

* Members of community organizations and practice-based research networks who are collaborating with UNC investigators are eligible to apply as PI.

Applications may have multiple PIs (“co-PIs”) although one PI must be identified as the main “contact PI”, with primary responsibility for the administrative aspects of the pilot award.

NC TraCS encourages applications from junior investigators. Senior faculty PIs (Associate Professor and above) may apply, however they must demonstrate that the proposed work is a departure from a previous research direction, and this new direction must be **clearly evident** in the application.

Non-faculty applicants are required to include a faculty mentor on their application. If the grant is funded, mentors must sign a document in which they agree to the following responsibilities:

- (1) Provide guidance, encouragement, support, and direction to the PI to ensure the project is completed on time, and, where appropriate, ensure the results are published and the data used for the submission of subsequent extramural grants;
- (2) Review interim and final progress reports prior to submission to TraCS;
- (3) Become PI of the \$2K grant if a mentored PI leaves UNC before the grant ends, and assume responsibility for completing the project and ensuring the funds are used appropriately;
- (4) Accept responsibility for reporting to TraCS any future results (publications, grants, etc.) that result from the TraCS-funded pilot if a mentored PI leaves UNC after the grant has ended.

Doctoral students should note that work aimed solely at finishing a dissertation project is not eligible for this award. In the section addressing future funding plans, doctoral students should make a clear case for how the data generated will also support the research of their mentor or faculty collaborator(s), including specifically how the project will contribute to future extramural funding opportunities for UNC-CH faculty. Bear in mind that, while doctoral students and postdocs are eligible for \$2K pilot funding, they may not be eligible to apply for subsequent external (e.g., NIH) funding. Therefore, future funding plans should include individuals who are eligible to apply for such funding, e.g. faculty mentors or collaborators.

Funding and Budget

Each award will provide up to \$2,000 to investigators to perform translational and clinical studies. Grant budgets are to cover expenditures for a 12-month period. Funds will be released after any required IRB/IACUC approval documentation has been provided to TraCS and any documents required by NIH for human subjects research (see “Regulatory Requirements” below) have been approved. The expectation is that all funds will be expended by the end of the grant period. TraCS staff will work closely with awardees throughout the grant period to monitor progress and, where necessary, provide mentoring. A six-month interim and a final progress report are required.

Budget requests are encouraged for the use of TraCS Institute core services and UNC suppliers and service providers, including UNC core research facilities. See information about TraCS Services and Resources [here](#). When preparing an application, it is highly recommended that applicants consult with TraCS experts for guidance on budgeting fees for the work to be done.

Pilot grant funds may be budgeted for (1) research support personnel, (2) use of TraCS services, including salary support for TraCS core faculty such as biostatistics and biomedical informatics faculty, (3) travel necessary to perform the

research, (4) equipment, research supplies, and core lab costs, or (5) other expenditures deemed necessary for the successful execution of the proposed project.

Pilot 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.

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. Requests for faculty salary from TraCS' *academic partner institutions (NC A&T, RTI or NCSU)* will be considered.

Review criteria

A review committee will examine each application for:

- ☐ Significance of the work
- ☐ Novelty/innovation of the research idea
- ☐ Soundness of the methods
- ☐ Relevance of the proposed work to translational research
- ☐ A genuine multidisciplinary team and/or new collaboration being formed
- ☐ If a senior level PI, whether the application represents a new research direction
- ☐ Potential for the project to lead to future external funding or a commercialization opportunity
- ☐ Feasibility of the project goals being accomplished within the one-year project period
- ☐ **NEW:** Feasibility of the project goals being accomplished within the COVID-19 restrictions

“Applicants are limited to two submissions (an original submission and one resubmission) per application. *This rule applies even if the application is resubmitted under another pilot mechanism (i.e., as a Stakeholder Engagement Voucher application or as a \$5-50K pilot application).* Resubmissions should include a “Resubmission Summary” section, detailing amendments and improvements to the original application.”

Regulatory requirements for TraCS pilot grants

Although a full protocol and IRB/IACUC submission are not required at the time of application submission, funds will not be released until any required UNC-CH IRB/IACUC/NCATS approvals have been granted. Applications to UNC’s IRB must list a UNC faculty member as PI.

TraCS is funded through a CTSA grant from the NIH National Center for Advancing Translational Sciences (NCATS). NCATS requires review and approval of all TraCS pilot grants involving human subjects research prior to TraCS funds being released. Therefore, funded grants involving human subjects research will need to provide TraCS with 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.

Application procedure

The application is available to complete online [here](#). Application deadlines are [monthly](#). Applications are due by 5:00 p.m. on the due date. Notification of awards will be made generally within 5 weeks of the due date. Applicants will be notified by email whether or not their application is selected for funding.

Tips for writing a successful application

1. The “Research Methods” section (maximum 3,750 characters including spaces or about 500 words) corresponds to the “Approach” section of an NIH application. Describe how you will perform your study with as much detail as possible. The reviewers are drawn from a wide range of scientific disciplines. Therefore, avoid (or define where necessary) technical jargon or specialized abbreviations or acronyms. Pitch your narrative toward a more general audience than you might for a more specialized NIH Study Section. Your first goal is clarity. The reviewer needs to understand what you’re proposing to do in order to get excited by your project.

Pay particular attention to the biostatistical aspects of your project, if statistical analysis is applicable, as an inadequate data analysis plan frequently weakens an otherwise competitive application. Describe and justify the number of subjects and the statistical analyses that you will apply to your data. If necessary, consult with the [TraCS Biostatistics Service](#).

Address timelines and feasibility. *You* may be confident that you can complete your work in a year, but the reviewers don’t know that. For example, address how long it will take to recruit the study cohort. Cite numbers.

2. The maximum allowable budget is \$2,000, to be expended over a maximum of one year. Justify your budget. Don’t just provide a one-line budget asking for \$2,000 for any given resource. Provide a realistic estimate of costs. The overall project budget may exceed the \$2,000 award limit; however, the source for the extra required funds must be specified. If the overall project budget is substantially greater than the \$2,000 award, explain how the TraCS pilot award is essential to the completion of this project, and why the other funding source is insufficient to complete the project.

3. Please remember that this is a Pilot award, intended to generate data to support future external funding, and not simply to support a terminal project. It is very important to describe where this work is going. Assuming the work is successfully completed, what is the next step? An external grant application? Commercialization? Be as specific as you can, while understanding that such plans for future funding can change over time and with changing circumstances. The goal is to demonstrate to the reviewers that there *is* a plan. Doctoral students or postdocs, who may not be eligible to apply for subsequent federal funding, should describe a future funding plan that includes their funding-eligible mentor or collaborator.