

NC TraCS \$5K - \$50K Translational Research Matched Pilot Grant Program Request for Applications (RFA)

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the NIH Clinical and Translational Science Award (CTSA) at UNC Chapel Hill (UNC-CH). Our mission is to accelerate clinical and translational research from health science to discovery to dissemination to patients and communities.

July 2018 Update: Research involving the enrollment of human subjects should discuss in their application how stakeholders will be engaged in the design and conduct of the research. Investigators who would like assistance with this aspect of their project can request a consult from TraCS [Community and Stakeholder Engagement](#) by clicking the “Request a Consult” button.

I. Purpose

The NC TraCS Translational Research Matched Pilot Program facilitates the transfer of research findings to clinical practice in order to improve the health of the people of North Carolina and is designed to encourage and facilitate novel clinical and translational research in its many forms. Applications are encouraged from teams of investigators from different disciplines, institutions and diverse communities.

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.

NC TraCS is interested in 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**.

Investigators may also apply for research funding to **develop new technologies with commercial potential** through the [NC TraCS FastTraCS pilot grant program](#). In addition, faculty seeking funding for activities within an early stage company they have founded can request a consult with [KickStart Venture Services](#) by contacting [Tim Martin](#).

[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 cannot fund pilot grants where the research is conducted outside the United States. More information is available in the [Pilot Program FAQ](#).

II. NC TraCS Partner Institutions and Contact Information

With the 2018 CTSA grant renewal, North Carolina State University ([NC State](#)) joined NC TraCS partners [RTI International](#) and North Carolina A&T State University ([NC A&T](#)) as part of NC TraCS. We are particularly interested in pilot applications from teams of investigators that involve collaborations with faculty and scientists at our partner institutions.

Applicants from partner institutions are strongly encouraged to contact their NC TraCS liaison to discuss their pilot

applications:

- **NC A&T** – 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. Also contact [Raymond Samuel](#), Professor at NC A&T, regarding matching funds or for assistance identifying potential collaborators.
- **RTI** – Contact [Lisa Gehmland](#), CTSA Project Coordinator, with questions about the RTI collaboration and potential collaborators at RTI. **Note** - RTI investigators are required to consult with an RTI financial analyst during the preparation of their application budget. Contact [Lisa Gehmland](#) for details.
- **NC State** - Contact [Jonathan Horowitz](#), Assistant Vice Chancellor, Research Infrastructure, Office of Research, Innovation and Economic Development (ORIED), with questions about the NC State collaboration, including for assistance identifying potential collaborators.

III. PI Eligibility

UNC-CH, NC A&T, RTI and NC State researchers whose appointments allow them to serve as PI on externally sponsored research projects are eligible to apply as PI. This generally means permanent faculty (not adjunct appointments) and includes those with non-faculty appointments like “research scientist” and investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and R01-level funding. For questions regarding eligibility, contact [Mary Beth Cassely](#).

Applicants from NC A&T, RTI or NC State **must include an eligible co-PI from at least one other NC TraCS partner institution**. The required co-PI does not have to be from UNC-CH; however, the inclusion of a UNC-CH co-I/co-PI is strongly encouraged. The budget for grant applications that do not include a UNC-CH co-PI must be comprised entirely of funds from the home institutions of the applicants.

Applications with multiple PIs (“co-PIs”) must identify one PI 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 a departure from a previous research direction, and this new direction must be **clearly evident** in the application.

IV. Pilot Funding and Match Requirement

The total project award comprises a 1:1 match between NC TraCS and match secured by the applicant, for a total award budget of up to \$50,000. Applications that involve research at multiple institutions should include a budget total from each institution that are approximately equal, or else the budget justification should explain why this is unfeasible. Applications that do not involve a UNC-CH co-PI and/or work done on the UNC-CH campus must have a budget comprised entirely of funds from the applicant’s home institutions. In general, research activities at each institution should be funded by that institution. Funds cannot be subcontracted from one institution to the other.

The match must be in real dollars and cannot be “in kind” contributions, funds previously committed to the research project being proposed, or existing grants or contracts. Matching funds must be secured before the application is submitted. Depending on the composition of the research team and the nature of the collaboration, matching funds may be available from one of NC TraCS’ partner institutions. A list of potential matching funders can be found [here](#). Note that matching funds may also come from sources not on this list.

V. Use of NC TraCS Services

NC TraCS offers members a variety of research services and expertise, and applicants are encouraged to utilize those services in pilot grant applications where appropriate. A full list of NC TraCS services can be found [here](#). NC TraCS services that require the investigator to contribute to the cost of the service should be consulted prior to submission to ensure that the application budget includes accurate information. Applicants are **not** required to use NC TraCS

services in their pilot projects. [NC TraCS Research Navigators](#) are available to offer general advice and assistance with applications prior to submission. [Click here](#) to schedule a consultation (choose “Proposal Development” from the menu).

VI. Review Criteria

Applications should be presented in a clear and logical fashion, make a convincing case for the significance of the work, and describe the proposed methods in sufficient detail so an adequate evaluation can be made.

The following review criteria will be considered:

- 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 a commercialization opportunity
- 6) Soundness of the proposed methods
 - 6a) If enrolling human subjects, appropriateness of community/stakeholder engagement plan and recruitment plan
- 7) If a senior level PI, whether the application represents a new research direction
- 8) Feasibility of accomplishing the stated project goals within the 12-month project period
- 9) Utilization of services and resources of NC TraCS (if applicable)
- 10) Focus on one of the 10 NC health priorities identified by NC TraCS (cancer, cardiovascular disease/hypertension, chronic disease management, diabetes, healthcare access, mental health, nutrition, obesity, physical activity, and substance abuse). NC TraCS does not *require* that your application pertain to any of these areas, but it is encouraged.

VII. Application Procedure

NC TraCS very strongly recommends involving a biostatistician in the application development process. The online application form will ask for the name of the biostatistician who consulted on the application.

For investigators without access to a biostatistician, biostatistical support can be obtained through the [NC TraCS Biostatistics Service](#) by completing the “[Request a Consult](#)” form. 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).

For any questions, email nctracs@unc.edu or call 919-966-6022 or 866-705-4931.

Applications must be submitted using the [online system called Foundant](#). Application sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

- 1) **Scientific Abstract:** A summary of the application for use by 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. For studies enrolling human subjects, include engagement and recruitment plans either in this section or in the Human Subjects section (number 8 below). Include where applicable clear evidence of how the application meets the review criteria. 1.5 line spacing, font Arial 11 pt., and 1-inch margins all around. (5-page limit, including tables and figures. References do not count towards the page limit.)

- 4) **Cited References** (No page limit)
- 5) **Budget:** Use [PHS 398 Form Page 4](#) (see Section VIII “Budget Guidelines” below for more details). The total budget should not exceed \$50,000.
- 6) **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources have been requested (see “Budget Guidelines” below). (No page limit)
- 7) **Timeline** covering the 12-month funding period.
- 8) **Human and/or Animal Subjects:** Although Institutional Review Board (IRB) and/or Institutional Animal Care & Use Committee (IACUC) approval is not required at time of submission, the application should 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, study procedures, materials used in the research, potential risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by an IRB, use a single IRB if the project is multicenter, and comply with HIPAA. NC TraCS pilot awards with investigators from multiple institutions will receive assistance from the NC TraCS Regulatory Service in navigating through IRB and IACUC approvals pathways including making use of reliance agreements where possible. If vertebrate animals will 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. Provide assurance that the project will be reviewed and approved by an IACUC. Note that no funds will be released without the requisite approvals in place. (No page limit)
- 9) **NIH Biosketches** for the key members of the research team.
- 10) **Letters of Collaboration** (if applicable): Letters of Collaboration may be included if they clearly state a commitment of resources required for the project’s success, for example biobank samples being made available to the investigator. Generic or non-specific letters of support are not required or encouraged. (No page limit)
- 11) **Resubmission Summary** (if applicable): Resubmission applications should include a summary that details changes to the original application. Include the names of any NC TraCS advisors consulted for the resubmission. *Applicants are limited to two submissions (an original submission and one resubmission) per application. This rule applies even if a portion of the application is resubmitted under another pilot mechanism (i.e., as a Stakeholder Engagement Voucher application or a \$2K pilot application).* If an investigator substantially changes and improves an application following two unsuccessful NC TraCS pilot submissions, he/she should consult with an NC TraCS Research Navigator to determine whether the changes/improvements warrant submission as a new application. *The Resubmission Summary is limited to 3-pages, with 1.5 line spacing, 1-inch margins, and font no smaller than Arial 11.*
- 12) **NIH Summary Statement** (if applicable): Applications that reference an external grant review relevant to the research should include the complete grant Summary Statement.

VIII. Budget Guidelines

- 1) The pilot grant budget covers expenditures of up to \$50,000 for a 12-month period. The budget period will begin when applicable IRB/IACUC/NCATS approvals are received by NC TraCS and the PI indicates everything is in place for the project to begin. If the PI is not ready to start within 4 months of notification of funding, NC TraCS reserves the right to withdraw the award. The expectation is that all funds will be expended by the end of the grant period. At the end of the 12-month project period, any unexpended funds will be retained by NC TraCS and/or returned to the matching entity.
- 2) For most projects, one budget for the total project should be submitted. If matching funds are provided by an entity outside UNC-CH, please include a separate budget listing funds to be expended at each entity. The budgets should be combined into one PDF for uploading. Note the total budget should not exceed \$50,000.
- 3) Pilot grant funds may be budgeted for (1) research support personnel, (2) use of NC TraCS services, including, where applicable, salary support for NC TraCS biostatisticians, biomedical informaticians or other experts, (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.
- 4) Pilot grant funds **may not be budgeted for** (1) salary support for the PI or faculty collaborators (except as noted below in #5), (2) office supplies or communication costs, (3) meals (except for focus groups) or travel, including to conferences, except as required to collect data, (4) UNC-CH IRB fees, (5) professional education or training, (6) manuscript preparation and submission, or (7) indirect costs.

- 5) Funds may not be used for UNC-CH faculty salary support, but requests from TraCS' academic partners (including RTI, NCSU and NC A&T) for such support will be considered. Faculty at partner institutions should communicate with the NC TraCS liaison at their institution (see section II above) regarding local policies regarding research institutes (RTI) or teaching-intensive institutions.
- 6) Expenditures for services outside the PI's home institution will only be allowed if the equivalent service is not available in-house, and such an expenditure will require thorough justification.

IX. 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.
- 3) NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance where necessary. A 6-month interim progress report and a final progress report are required. NC TraCS expects the PI to report the outcomes achieved due to the pilot award over the lifetime of the work, e.g., subsequent external funding, publications, presentations and patents, and to [acknowledge NC TraCS research support](#) where appropriate.
- 4) If an awardee leaves their position, they should contact NC TraCS to initiate close-out procedures.

X. Submission Instructions

NC TraCS \$5K-\$50K pilot grant applications are accepted 3 times per year (see the NC TraCS [website](#) for due dates). Applications will be accepted only through the online [system called Foundant](#). Applications are due by 5:00pm on the due date. After submitting the application, applicants will receive email confirmation that the application was received. Applicants will be notified by email within 12 weeks of the deadline whether their application has been selected for funding. Partner institutions may have internal submission approval processes that should be completed prior to the NC TraCS submission deadline. (See section II for contact information for partner institutions.)