



SCHOOL OF MEDICINE

North Carolina Translational and Clinical Sciences Institute

NC TraCS \$5K - \$50K Translational Research Matched FastTraCS Pilot Grant Request for Applications - Next deadline September 22, 2020

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) at UNC Chapel Hill (UNC-CH). The mission of NC TraCS is to transform clinical and translational research by creating new programs and pathways that make it easier for such research to be performed at UNC-CH and disseminated throughout the state of North Carolina.

I. Purpose

The NC TraCS Translational Research Pilot Program was established to facilitate the transfer of research findings to clinical practice in order to improve the health of the people of North Carolina. This program is designed to promote novel clinical and translational research in its many forms.

This RFA is seeking applications for pilot grants that utilize the FastTraCS (previously 4D) Program. The FastTraCS mission is to accelerate existing and novel healthcare technology towards the marketplace, to ultimately benefit patients in North Carolina and beyond.

Applications for this RFA will be seeking funding to move drug, diagnostic, or medical device-related innovations toward an eventual commercial endpoint, such as the launching of a company or licensing to an established company. Examples of the type of activities this pilot grant intends to fund would include the following:

Therapeutics:

- Studies to validate biological relevance and drugability of a molecular target. The process of target validation identifies and assesses whether a molecular target merits further development in the context of the clinical indication
- Primary and/or secondary functional assay development for library screening, hit identification/selection and/or lead selection
- Optimization of a lead compound using medicinal chemistry, SAR and functional assays
- Biologic development including protein synthesis, antibody synthesis and/or humanization for therapeutic testing
- Absorption, distribution, metabolism, excretion and toxicology studies using a lead compound
- Development and validation of a novel drug delivery system using a model compound
- Development and validation of novel therapeutic modalities, including gene and cell, RNA-targeted or – based therapies

Diagnostics:

- Genomic, proteomic, or metabolomics screening to validate disease-related biomarkers, with a vision for the further development as an LDT, IVD or companion diagnostic
- Conversion of diagnostic platform to clinically relevant and scalable technology/equipment/assay
- Development of novel protocols, tools and/or diagnostics to improve the clinical trial efficacy
- Wearable sensors, mhealth or other Health/IT technology

Medical Devices:

- Design, concept development and prototyping of medical device
- Material, mechanical or electrical testing and validation
- In vitro, animal model or human testing validation

- Human factors testing and engineering

All projects have access to commercially relevant regulatory support through the UNC/RTI Regulatory program. For projects needing preclinical study input, IND-enabling development strategy, IND/IDE gap analysis, predicate identification and/or general regulatory advice, please submit a request through [TraCS Central](#).

Applicants are required to consult with the FastTraCS Program prior to submission; however, applications will be considered post-submission if consultation occurs during the review period. To do so, please send contact Andrew Kant, Associate Director (akant@email.unc.edu).

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

NC TraCS is no longer able to fund pilot grants where the research is conducted outside the United States.

II. NC TraCS Partner Institutions and Contact Information

With the 2018 CTSA 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** – Contact [Andrew Kant](#) with questions about the NC A&T collaboration, including assistance identifying potential collaborators. Applicants from NC A&T also need to contact the A&T Office of Sponsored Programs at divofres@ncat.edu to ensure proper procedures are followed.
- **RTI** – Contact [Lisa Gehtland](#), CTSA Project Coordinator, with questions about the RTI collaboration and potential collaborators at RTI. Learn more about research expertise at RTI at [this website](#). **Note** - RTI investigators are required to consult with an RTI financial analyst during the preparation of their application budget. Contact [Lisa Gehtland](#) or [Jasleen Atwal](#) 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 assistance identifying potential collaborators.

III. 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.

IV. Funding

NC TraCS will award one-year grants of up to \$25,000 which **must be matched with equal funds** from the research team's home schools, departments, centers or partner organizations, for total awards of up to \$50,000. 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 that the applicant already has. If the proposal involves research at multiple institutions, the budget from each institution should be 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 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.

V. Review Criteria

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.

Proposals should be at a stage where the investigator(s) have identified a novel and promising drug target, have validated a novel and relevant biomarker with diagnostics applications or have a novel medical device for diagnosis or treatment of disease.

Collaborative proposals integrating researchers working across two or more areas such as those listed above are encouraged but not required (e.g., development of a novel drug delivery system with the potential of attacking previously undruggable target(s) or integrating target identification and molecular profiling in the area of orphan and neglected disease using innovative animal models for target/drug candidate validation). The potential for progress to commercialization of a drug, device or diagnostic will be a major metric upon which the proposal will be evaluated.

The following review criteria will also be considered:

1. Significance of the work

- a) Does the project address an important unmet medical need or a critical barrier to progress in the field?
- b) How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Innovation with Commercial Potential

- a) Is the innovation novel relative to other current (commercial) approaches?
- b) Does the proposed project have commercial potential to lead to a marketable product, process or service?
- c) Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

3. Commercial Development Pathway

- a) What is the anticipated path that will lead to a commercial product?
- b) What are the scientific and regulatory hurdles along this pathway?
- c) How will this funding move this project along that pathway?
- d) If this project is successful, what are the next steps?

4. Investigator(s) / Team

- a) Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research.
- b) Are the PD/Pis, collaborators, and other researchers well suited to the project?

5. Approach and Soundness of Methodology

- a) Is the proposed project feasible within the one-year project period?
- b) Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

- c) Are potential problems, alternative strategies, and benchmarks for success presented?
- d) If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- e) Feasibility of accomplishing the stated project goals within the one-year project period.

VI. Application Procedure

NC TraCS very strongly recommends involving a biostatistician in the application development process. A large proportion of investigator-initiated 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 (or RTI), biostatistical support can be obtained through the [NC TraCS Biostatistics Service](#) by completing the "[Request a Consult](#)" form.

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 calling 919-966-6022 or 866-705-4931 (toll free).

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 (250 word maximum):** The abstract summary of the proposal for use by review committee members and NC TraCS.
- 2) – Impact (50 word maximum):** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved.
- 3) - Research Plan (5 pages maximum):** 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, includes tables and figures. 1.5 line spacing, font no smaller than Arial 11, and 1- inch margins.
- 4) - Cited References (No page limit).**
- 5) - Budget:** Use [PHS 398 Form Page 4](#) (see Section VI below for more details). For most projects, one budget for the total project, including the match funds, should be submitted. However, for projects with PIs from multiple institutions, please submit a separate budget listing funds to be expended at each institution. The budget should not exceed \$50,000 including the match.
- 6) - Budget Justification (No page limit):** The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Any overlap with existing funding must be addressed in this section.
- 7) - Proposal Timeline (1 page maximum).**
- 8) - Human and/or Animal Subjects (No page limit):** 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. *Please note that neither Institutional Review Board (IRB) nor Institutional Animal Care & Use Committee (IACUC) approval is required prior to submission. However, IRB/IACUC/NCATS approvals must be obtained before funds can be released.* (See Section VIII below for more details).

- 9) - Letter(s) of Collaboration (if applicable – no page limit):** If a proposal has just a sole PI, and that sole PI is not UNC-CH faculty, then the proposal must include a Letter of Agreement from their UNC-CH faculty Co-Investigator (not required for sole PIs from RTI, NC A&T or NC State). Proposals that have Co-PIs do not need a Letter of Agreement if one of the Co-PIs is UNC-CH faculty.
- 10) - Resubmission Summary (if applicable – no page limit):** 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 NC 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 NC TraCS pilot submissions, a determination will be made by an NC TraCS Research Navigator as to whether that can be submitted as a new proposal. (3-page limit).
- 11) - NIH Summary (if applicable):** If your proposal references a prior NIH review, include the NIH reviewer comments.
- 12) - NIH Biosketches for the key members of the research team (4 page maximum each).**

VII. Budget Guidelines

- 1) - NC TraCS pilot grant budgets cover expenditures 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 more than 6 months passes after notification of funding and the PI is still not ready to start, NC TraCS reserves the right to retract 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 match organization.
- 2) - For most projects, one budget for the total project, including the match funds, should be submitted.** However, for projects with PIs from multiple institutions please submit a separate budget listing funds to be expended at each institution.
- 3) - Allowable Items.** Pilot grant funds may be budgeted for:
- research support personnel
 - use of NC TraCS services, including salary support for NC TraCS core faculty, for example biostatistics and biomedical informatics faculty
 - travel necessary to perform the research
 - equipment, research supplies and core lab costs
 - other purposes deemed necessary for the successful execution of the proposed project.
- 4) - Pilot grant funds may not be budgeted for:**
- salary support for the UNC PI or faculty collaborators
 - office supplies or communication costs
 - travel or meals except as required to collect data
 - professional education or training
 - computers or audiovisual equipment
 - manuscript preparation and submission
 - indirect costs.
- 5) - No salary support for UNC-CH principal investigators and co-investigators is allowed.** Although funds may not be used for UNC-CH faculty salary support or overhead, requests from academic partners for such support will be

considered.

VIII. 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) - 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 NC TraCS pilot grants involving human subjects research prior to NC TraCS funds being released. Therefore, if your proposal 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, 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.
- 4) - If an awardee leaves their position, they should contact NC TraCS to initiate close-out procedures.

IX. Submission Instructions

NC TraCS pilot grant applications are accepted 3 times per year (see the NC TraCS [website](#) for exact dates). Applications will be accepted only through the NC TraCS [online system](#). Applications are due by 5:00 p.m. on the due date. Within 24 hours after receiving each application, applicants will receive an email confirmation from NC TraCS. Applicants will be notified by email within 12 weeks of the deadline whether their application has been selected for funding.