



SCHOOL OF MEDICINE

North Carolina Translational and Clinical Sciences Institute

NC TraCS \$5K - \$50K Translational Research Matched FastTraCS Pilot Grant Request for Applications

The North Carolina Translational and Clinical Sciences (NC TraCS) Institute is the academic home of the National Institutes of Health Clinical and Translational Science Award (CTSA) at UNC-Chapel Hill. 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-Chapel Hill and disseminated throughout the state of North Carolina.

Special Emphasis: NC State ASSIST & UNC Translational Research Collaborations

NC TraCS and the Center for Advanced Self-powered Systems of Integrated Sensors and Technologies (ASSIST) at NC State are seeking highly innovative proposals that address high-impact unmet clinical needs using NC State's ASSIST-developed technologies. The goal of this Special Emphasis is to match UNC providers' expertise of clinical challenges and unmet needs, with engineering faculty at ASSIST seeking to develop novel technology applications.

ASSIST, along with NC TraCS, is extending an open invitation to UNC faculty, NC TraCS partners, and UNC Health providers to join a virtual Technology Showcase hosted by ASSIST. Participants will hear brief presentations on various tech and invited to breakout discussions to explore idea. It will be held on **Monday May 3, 2021 @ 12PM-2PM**. Up to 10 ASSIST-sponsored technologies and recording will be made available for those not able to attend. Register at ncsu.zoom.us.

Technology examples include, but are not limited to (additional information on ASSIST at assistcenter.org):

- Self-powered wearable biomonitoring devices (e.g., cardiac, respiratory, activity level)
- Sensors integrated into textiles/apparel
- Implantable diagnostics
- Non-invasive biomarker monitoring (e.g., skin patch for sweat or interstitial fluid)
- Gaseous/volatile sensor platforms

Any teams preparing to submit, either as part of existing collaborations or newly formed, may reach out to the contacts listed below for more information.

UNC | Andrew Kant (akant@email.unc.edu), Associate Director, FastTraCS

NC State | Adam Curry (adam.curry@ncsu.edu), Innovation Ecosystem Director

Note: Participation in the virtual technology Showcase is strongly encouraged, though not a requirement to submit.

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.

II. Appropriate Research Topics

Applications for this RFA will be seeking funds to develop biomedical technologies aimed at eventual commercial milestones, such as the launching of a company or licensing to an established company. Technology examples include, but are not limited to wearable devices, non-invasive sensors, combination devices, remote patient monitoring, continuous biomarker monitoring, pathogen surveillance/detection and more.

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

Note: If research is planned to be conducted outside the United States, please contact NC TraCS prior to submission to ensure the research plan is in compliance with NIH and other federal guidelines.

III. NC TraCS Partner Institutions and Contact Information

With the 2018 CTSA renewal, North Carolina State University ([NC State](#)) joined [RTI International](#) and North Carolina A&T State University ([N.C. A&T](#)) as members of the NC TraCS partnership. We are particularly interested in pilot applications from investigative teams drawn from multiple partner institutions.

Applicants from partner institutions are strongly encouraged to contact their respective **NC TraCS Liaisons** to discuss their pilot applications:

- **UNC-Chapel Hill & N.C. A&T** – Contact [David Carroll](#), Director, Team Science NC TraCS' Team Science service with questions about the N.C. A&T collaboration, including assistance identifying potential collaborators.
- **RTI** – Contact [Lisa Gehmland](#), 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 additionally required to consult with an RTI financial analyst during the preparation of their application budget. Contact [Lisa Gehmland](#) or [Jasleen Atwal](#) for details.
- **NC State** - Contact [Adam Curry](#), Innovation Ecosystem Director, ASSIST Center or [Jonathan Horowitz](#), Assistant Vice Chancellor, Research Infrastructure, Office of Research, Innovation and Economic Development (ORIED).

IV. Investigator Eligibility

UNC-Chapel Hill, N.C. 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 N.C. 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-Chapel Hill. The budget for grant applications that do not include a UNC-Chapel Hill co-PI must be composed 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.

V. 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 funds 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. If the distribution of work precludes this, the PI should explain why equal funds distribution is unfeasible in the Budget Justification section. Applications that do not involve a UNC-Chapel Hill co-PI and/or work done on the UNC-Chapel Hill campus must have a budget comprising funds from the applicant’s home institutions only. In general, research activities at each institution should be funded by that institution. Funds cannot be subcontracted from one institution to the other.

VI. 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.

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.

VII. Application Procedure

Applicants are **required** to consult with FastTraCS staff prior to submission; however, exceptions will be considered post-submission within the review period. To schedule a consultation, please [Submit a Request](#) to meet with Andrew Kant, Associate Director.

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) must 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 (250 word maximum).
- 2) - **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. **Please note required text formatting:** 1.5 line spacing, font no smaller than Arial 11, and 1-inch margins all round.
- 3) - **Cited References (No page limit).**
- 4) - **Budget:** Use [PHS 398 Form Page 4](#) (see Section VIII 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 FastTraCS Pilot Grant budget should not exceed \$50,000, including the match; however, NC TraCS encourages use of additional funding sources are available to support the project beyond matching funds.
- 5) - **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.
- 6) - **Proposal Timeline (1 page maximum).**
- 7) - **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 and/or IACUC approvals must be obtained before funds can be released. (See Section IX below for more details).

- 8) - Letter(s) of Collaboration (if applicable – no page limit):** If a proposal has just a sole PI, and that sole PI is not UNC-Chapel Hill faculty, then the proposal must include a Letter of Agreement from their UNC-Chapel Hill faculty Co-Investigator (not required for sole PIs from RTI, N.C. 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-Chapel Hill faculty.
- 9) - Resubmission Summary (3 pages maximum):** 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 (ie, two submissions total). 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.
- 10) - NIH Summary (if applicable):** If your proposal references a prior NIH review, include complete review with reviewer comments.
- 11) - NIH Biosketches for the key members of the research team (4 page maximum each).**

VIII. Budget Guidelines

- 1) - NC TraCS pilot grant budgets cover expenditures for a 12-month period.** The budget period will begin when applicable IRB/IACUC documentation is provided to 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-Chapel Hill principal investigators and co-investigators is allowed.** Although funds may not be used for UNC-Chapel Hill faculty salary support or overhead, requests from academic partners for such support will be considered.

IX. Other Guidelines

- 1) - Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-Chapel Hill 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.
- 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.

X. 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.