

NC TraCS Translational Science Methods & Process Awards Pilot Request for Applications (RFA) – Next deadline March 24, 2020

PLEASE NOTE the new requirement for biostatistical consultations for all Translational Science Methods & Process Awards 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 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 and disseminated throughout the state of North Carolina.

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.

The NC TraCS Pilot Grant 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, and is designed to encourage and facilitate novel clinical and translational research in its many forms. Proposals are encouraged from teams of investigators from different disciplines, institutions and diverse communities.

I. Purpose of RFA & Examples of appropriate projects

Recently the National Center for Advancing Translational Sciences (NCATS), the funding source for NC TraCS, has begun encouraging CTSA pilot programs to institute mechanisms to support research that will advance translational science, the discipline focused on understanding and addressing the scientific and organizational challenges underlying each stage of the translational process.

For this RFA, NC TraCS is interested in projects which develop, test and/or disseminate new methods and best practices in translational research including implementation science. These projects **must be** developed in collaboration with one of the [NC TraCS Resources and Services](#). The project should be either applicable to a number of ongoing or planned projects at NC TraCS partner institutions (UNC, RTI, NC A&T, and NC State) or potentially developed into a collaborative effort across 3 or more CTSA's.

Examples of the type of projects appropriate for this special RFA include:

Development of biostatistical and epidemiological methods that overcome specifically identified limitations and enhance the validity and accuracy, scope or speed of clinical or translational research

Development of novel methods for clinical study design, informed consent of research subjects, or research subject recruitment

Development and implementation of innovative community engagement methods and technologies that demonstrably increase the efficiency and effectiveness of intervention development and deployment, and measurement of their effects on improving health outcomes.

Educating and training the translational research workforce through collaborative initiatives.

Adapting technology and methodology that are shown to be successful in other domains to address challenges in clinical and translational research.

Innovative methodologies that address translational research roadblocks e.g. development and testing of novel biological assays and novel outcome measure development.

[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. Proposals with a foreign component must be discussed with a TraCS Research Navigator prior to submission - [click here](#) to schedule a consultation.

II. Eligibility

- UNC-CH applicants should hold a faculty appointment.
- Also eligible are UNC-CH researchers 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](#).
- Members of NC TraCS-affiliated academic partner institutions and community organizations are eligible if they include a UNC-CH faculty member as a collaborator or co-investigator.
- Teams of multiple PIs are encouraged, although one person must be identified as the main contact with primary responsibility for the research project and the disposition of project data.

III. Funding

NC TraCS will award one-year grants of up to \$50,000. For this RFA, matching funds are **not** required, though evidence of in-kind investment or matching funds from research partners is strongly encouraged. Applicants should consult with the appropriate TraCS service or resource program manager to determine whether TraCS resources, staff or faculty should be included in the budget.

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. In general, research activities at each institution should be funded by that institution. Funds cannot be subcontracted from one institution to the other.

IV. 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 be considered:

- 1) Significance of the work to **advance translational science methods and processes**.
- 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) If a senior level PI, whether the application represents a new research direction
- 8) Feasibility of accomplishing the stated project goals within the one-year project period
- 9) Level of community engagement (if applicable)
- 10) Utilization of services and resources of NC TraCS

V. 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 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. 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 (toll free).

Applications must be submitted using the NC TraCS [online pilot submission system](#). Proposal sections (except the Abstract) will be uploaded as individual PDF files. The application sections are:

- 1) Scientific Abstract: The abstract summary of the proposal for use by review committee members and NC TraCS (250 word maximum).
- 2) Impact: Discuss 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. Include where applicable clear evidence of how the proposal meets the review criteria and how the project will be generalizable. (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.)
- 4) Budget: Use [PHS 398 Form Page 4](#) (see Section VI below for more details).
- 5) Budget Justification: The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Be sure to thoroughly justify any funds which need to be spent outside of UNC or RTI. (no page limit)
- 6) Proposal Timeline
- 7) Human and/or Animal Subjects: Although Institutional Review Board (IRB) approval is not required prior to submission; briefly describe any human 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. (no page limit)

8) **REQUIRED:** Letter of Collaboration from an NC TraCS service or resource (no page limit)

In addition, 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.

9) 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.)

10) 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.

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

VI. Budget Guidelines

1) NC TraCS pilot grant budgets cover expenditures for a 12-month period. The budget period will begin when applicable IRB 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, 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.

2) Pilot grant funds may be budgeted for (1) research support personnel, (2) use of NC TraCS services, including salary support for NC TraCS staff or 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) Pilot grant funds may **not be budgeted** for (1) salary support for the PI or faculty collaborators, (2) office supplies or communication costs, (3) meals 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) Any funds being spent outside of UNC or RTI should be thoroughly justified in the Budget Justification section.

VII. Other Guidelines

1) Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CH IRB. 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 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 6-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. Submission Instructions

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.