NC TraCS - IMPROVING HUMAN HEALTH AWARDS
Request for Applications (RFA)
Next deadline October 18, 2016

I. Background:

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health’s 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, our partner institutions, the state and worldwide.

II. Purpose:

The purpose of the “Improving Human Health” pilot funding mechanism is to support research with high potential to accelerate the development of novel therapeutics/diagnostics with the goal of improving human health. As these awards are individually the largest investment of NC TraCS funds to date, we strongly encourage investigators to work with the NC TraCS “Strategic Initiatives” as their advice and support may be critical for successful applications.

This RFA is focused on funding high impact projects such as:

- 4D Strategic Initiative (Drug, Device Diagnostic Development) - Drug/device development projects which are poised to identify a preclinical lead or series/device for eventual entry into specific IND/IDE-enabling preclinical studies;
- T2 Strategic Initiative (Transformative Technologies) - Biomarker/diagnostic development with the specific objective of advancing the technology to the point that it can be clinically implemented at UNC or beyond within ~2 years coupled with a proposed path for further dissemination;
- CER Strategic Initiative (Comparative Effectiveness Research) - Project is likely to result in substantial policy or guideline modification or groundbreaking areas of externally-funded research.

III. Eligibility:

- Applicant must hold a UNC-CH faculty appointment. Adjunct faculty are not eligible to apply as PI.
- Also eligible are UNC-CH researchers whose appointment allows them to serve as PI on externally sponsored research projects, for instance researchers holding EPA non-faculty “research scientist” or “investigator” appointments at UNC’s research institutes and centers.
- Members of NC TraCS-affiliated academic partner institutions and community organizations are eligible if a UNC-CH faculty member is a collaborator or co-investigator on the project. Interested RTI researchers should contact Don Bailey (dbailey@rti.org) to discuss a potential application.
- 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.

IV. Funding

NC TraCS will award 18-month grants of up to $100,000, with no match required. The budget period will commence upon notification of the award, so teams must be poised and ready to begin the work at the time they submit the proposal.
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.

IV. Review Process/Criteria

A 2-step accelerated review process will be followed to ensure promising projects are funded as soon as possible. Applications will be assigned for review by a team that consists of a subset of the TraCS Study Section and regulatory, commercialization and external industry experts. Written critiques and suggestions will be provided back to the investigative team and then each applicant whose application has been scored as highly meritorious will briefly present their proposal and any responses to the written reviews to TraCS leadership and have an opportunity to respond to questions about their proposals. The most promising project(s) felt to have high potential for rapid clinical implementation or advancement through the translational process will be notified of funding, which may be contingent upon a revised proposal being submitted.

Examples of proposals relevant for this RFA can be found in Section IX.

The following review criteria will be considered:

i. Potential for the project to lead to meaningful clinical impact in 2 years, such as entry into IND-enabling preclinical studies and/or a commercialization opportunity, or modification of clinical care guideline or protocol.

ii. Significance of the work

iii. Novelty/Innovation of the research idea

iv. Relevance of the proposed study to translational research

v. Regulatory strategy

vi. Soundness of the proposed methods

vii. Feasibility of accomplishing the stated project goals within the eighteen-month project period

viii. Thoughtful and feasible development pathway beyond the 18-month project period (provide brief letters of support as needed).

Please contact TraCS if you have a project that you feel might be relevant for consideration.

V. Application Procedure

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: The abstract summary of the proposal (250 word maximum).

2) Research Plan: The Research Plan should follow the standard NIH format: Specific Aims, Significance, Innovation, and Approach. Include where applicable clear evidence of how the proposal meets the review criteria. It is strongly recommended that investigators receive consultation with experts in regulatory science and commercialization and robustly address these issues in the proposal and letters of support from TraCS or other experts available to the applicant. (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.)

3) Budget: Use PHS 398 Form Page 4 (see Section VI below for more details).

4) 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)

5) Proposal Timeline

6) Human and/or Animal Subjects: Although Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission; 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. Provide assurance that the project will be reviewed and approved by the UNC IRB and comply with HIPAA. Projects involving animal subjects must be reviewed and approved by an IACUC. (No page limit)

7) Letter of Support (if applicable): Letters of Support may be included if they clearly state a commitment of resources required for the project’s success. Generic letters of support are neither needed nor encouraged. 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 or NC A&T). Proposals that have Co-PIs do not need a Letter of Agreement if one of the Co-PIs is UNC-CH faculty.

8) Resubmission Summary (if applicable): If your proposal is a resubmission to NC TraCS, please provide a summary that details your changes to the original proposal. Applicants are strongly encouraged to schedule a free consultation with a TraCS Research Navigator to discuss reviewer feedback and brainstorm improvements to the proposal. 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. (no page limit; does not count towards 5-page Research Plan page limit).

9) 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.

VI. Budget Guidelines

1) NC TraCS pilot grant budgets cover expenditures for an 18-month period. The budget period will begin immediately upon notification of the award. At the end of the 18-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 core 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) computers or audiovisual equipment, (6) manuscript preparation and submission, or (7) indirect costs.

4) Any funds being spent outside of UNC, RTI or NC A&T 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. If the research includes animals, the appropriate IACUC animal research forms must also be 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 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) NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and, where necessary, provide assistance. A 6-month and 12-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 discuss a strategy.

VIII. New requirements for funded pilot grants

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 TraCS pilot grants involving human subjects research prior to TraCS funds being released. Therefore, if your proposal is funded and involves human subjects research, TraCS will require additional documentation to send to NCATS. NCATS expects to complete their review in less than 30 days. The NCATS review can occur concurrently with the IRB review but final NCATS approval is contingent upon IRB approval.

IX. 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.

X. Proposal Examples

The examples below are not meant to be exclusive, or indicate that a proposal incorporating these examples would be approved. We do want to stress that given the relatively large amount of funds allocated, we are looking for proposals that are ambitious and that will either be ready for application in practice or a large scale multi-site test at the end of 18 months.

Transformative Technologies (T2) Strategic Initiative

- Characterization of biomarker candidates in appropriate clinical context to address unmet needs in diagnosis, following treatments or as surrogate endpoints in clinical trials
- Establish assay/test performance characteristics to validate accuracy and performance of test
- Demonstrate the potential for new analytic platforms (such as genetic, proteomic, epigenetic, etc.) to detect pre-clinical disease states amenable to early intervention

Drugs, Devices and Diagnostics Development (4D) Strategic Initiative

Drugs

- Lead identification including structure activity relationship studies, physicochemical profiling and in vitro ADME.
• Lead optimization efforts which may include medical chemistry efforts to improve potency/selectivity, in vitro pharmacokinetics and stability testing.
• Early toxicological studies which may include initial dose-ranging studies, genotoxicity testing and CYP450 inhibition.

Devices
• Clinical trial benchmarking studies for medical devices against comparable or predicate devices.
• Development of quality system design controls to be included in a future IDE submission.
• Optimization and development of performance specifications, operating parameters and design specifications/schematics.

Note: Investigators may refer to the following FDA Guidance, “Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies”.

Comparative Effectiveness Research (CER) Strategic Initiative
• Developmental work for a multi-site pragmatic trial, conducted in practice settings, testing a health policy, treatment, or test.
• Secondary data analysis sufficiently robust to provide evidence that would change current guidance regarding a test, treatment or health policy.
• Developmental work for establishment of a test or condition specific multi-site cohort to determine the effectiveness of a treatment (drug, device or policy).