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.

2017 Update: NC TraCS is particularly interested in proposals focused on opioid misuse and addiction, one of the state’s most significant health problems.

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 TraCS 4D 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.

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 2017 CTSA renewal, North Carolina State University (NC State) joined 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 Meriel Parker, NC A&T Director of Life Science Research, with questions about the NC A&T collaboration, including assistance identifying potential collaborators.
• 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 Lasleen 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. 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 R01-level funding.

Applicants from NC A&T, RTI or NC State **must include an eligible co-PI or co-investigator from at least one other NC TraCS partner institution.** The required co-PI/co-I does not have to be from UNC-CH, however, the inclusion of a UNC-CH co-I/co-PI is strongly encouraged.

Faculty at other academic institutions and members of community-based organizations are eligible to apply if they include an NC TraCS partner institution faculty member as a Co-PI, co-investigator or collaborator.

Applications may have multiple PIs (“co-Pis”) although one PI must be identified 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 the applicant’s home schools, departments, centers or partner institutions, for a total award budget of up to $50,000. All funds must be expended within **one year** of the project start date. 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. 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 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.

### 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 that an adequate evaluation of the application can
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
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) Level of community engagement (if applicable)
10) Utilization of services and resources of NC TraCS (if applicable)
11) 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. 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) **Research Plan:** The Research Plan should include Specific Aims, Significance, Innovation, and Approach. 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.)
3) **Cited References** (No page limit)
4) **Budget:** Use PHS 398 Form Page 4 (see Section VII “Budget Guidelines” below for more details). The total budget should not exceed $50,000.
5) **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources have been requested (see “Budget Guidelines” below). (No page limit)
6) **Timeline** covering the 12-month funding period.
7) **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. TraCS pilot awards with investigators from multiple institutions will receive assistance from TraCS Regulatory Service in navigating through IRB and IACUC approvals paths 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)

8) **NIH Biosketches** for the key members of the research team.

9) **Letters of Collaboration** (if applicable): Applications with a single PI who is **not** from one of the NC TraCS partner institutions (UNC-CH, NC A&T, RTI or NC State) must include a Letter of Collaboration from their NC TraCS partner institution faculty co-investigator. In addition, 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)

10) **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 one resubmission per 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. (No page limit).

11) **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 documentation is provided to NC TraCS and the corresponding PI indicates everything is in place for the project to begin. If the corresponding PI is not ready to start within 4 months of notification of funding, NC TraCS reserves the right to withdraw the award. 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. 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.

4) Pilot grant funds may not be budgeted for (1) salary support for the PI or faculty collaborators (except as noted above in #3), (2) office supplies or communication costs, (3) meals or travel, including to conferences, except as required to collect data, (4) UNC-CH IRB fees, (5) professional education or training, (6) computers or audiovisual equipment, (7) manuscript preparation and submission, or (8) indirect costs.

5) Funds may not be used for UNC-CH faculty salary support, but requests from academic partners for such support will be considered. Faculty at partner institutions should communicate with the NC TraCS liaison at their institution regarding local policies (see section II above) regarding research institutes (RTI) or teaching-intensive institutions.

6) Any funds being spent outside of the PIs’ home institution(s) should be thoroughly justified.

**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 generally completes their review in 21 days or less. The NCATS review can occur concurrently with IRB review but final NCATS approval is contingent upon IRB approval.

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 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 Foundant system. Applications are due by 5:00 p.m. on the due date. Within 24 hours after receiving each application, applicants will receive email confirmation that the proposal 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.