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, and is designed to encourage and facilitate novel clinical and translational research in its many forms. Cross-disciplinary basic science research addressing the development of therapies, diagnostics or devices applicable to human disease, clinical research/trials, epidemiological studies, and/or community-based research are considered eligible for these awards. Proposals are encouraged from teams of investigators from different disciplines, institutions and diverse communities.

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.

Proposals in collaboration with community organizations and/or practice-based research networks may focus on research related to improvements to access and utilization of health care, patient-centered outcomes, health information exchange, and culturally competent care. Applications that demonstrate community engagement or utilization of NC TraCS services and research infrastructure in Guilford and Wake counties are encouraged.

Individual investigators may apply for funding to develop new technologies that demonstrate an application or utility, develop a proof-of-concept, or better characterize a technology. If you are interested in funding for this type of research, please request a consult with Carolina KickStart at nctra@unc.edu or 919-966-6022 before submission.
In 2014, NC TraCS introduced 3 Strategic Initiatives aimed at harnessing the existing strengths, energy and expertise of UNC and RTI and offering investigators a no-cost, personalized mentoring program with highly specialized expertise in 3 specific areas of translational research. TraCS is especially interested in proposals with a focus on one of these areas. Click each link to learn more about each Strategic Initiative:

1) **Transformative Technologies (T2)** — proposals utilizing UNC & RTI resources in transformative technologies, including genomic, proteomic, metabolomics and other rapidly developing platforms, to accelerate the discovery of a potential cause or molecular diagnostic of a human disease and to validate the discovery so that it can be moved to the clinic.

TraCS would like to assist investigators to maximize utilization of transformative technologies to accelerate translational discoveries into clinical genomics, biomarkers of disease or targets of drug discovery. Translational scientists often need help with the dizzying array of “-omics” platforms. Consider this scenario: a translational scientist has developed or has access to a well-phenotyped patient population in which genomic, proteomic and/or metabolomic data could be transformative in thinking about that population. Success will require interfaces between the translational scientist, an omics platform and the ability to analyze large data sets. Although ultimately appropriate for external funding, this translational scientist will require significant preliminary data to provide the rationale for further investigation or commercialization. TraCS will help to facilitate efficient utilization of the outstanding genomic, proteomic and metabolomic facilities at UNC and RTI through support from our pilot program.

Another formidable challenge in this area is interpretation of the massive data sets generated with these technologies. Analysis is extraordinarily time consuming, expensive and difficult for individual investigators. Exploiting these and other potentially powerful resources requires a sophisticated informatics and biostatistics infrastructure to aggregate databases and compare individual variant frequencies within a secure workspace. TraCS seeks proposals to build capacity in this regard.

For questions regarding the T2 Strategic Initiative, please contact Program Manager Chris Barker at chris_barker@med.unc.edu.

2) **Drugs, Devices and Diagnostics development (4D)** — proposals to progress innovations through the development process toward an eventual commercial endpoint, being either the launching of a company or licensing to an established company, for investigators that have identified novel and promising drugs, devices or diagnostics.

For questions regarding the 4D Strategic Initiative, please contact Program Manager Andrew Kant at akant@email.unc.edu.

3) **Comparative Effectiveness Research (CER)** — proposals from investigators focused on the study of and dissemination of clinical and translational research in broad populations and the novel utilization of secondary databases or linked databases to conduct Comparative Effectiveness Research.

CER addresses pragmatic questions regarding the optimal approach to preventive, diagnostic and therapeutic interventions when there are multiple options available to patients and providers. Such circumstances are increasingly important as the number of available treatments proliferates. Issues of treatment effectiveness in patient subpopulations are also important as benefit to harm tradeoffs between treatment choices likely vary by these subgroups (e.g., age, sex, comorbidities, and socioeconomic status).
NC TraCS is looking for projects requiring use of secondary databases available at UNC to address a substantive CER question of importance. Implementation of advanced and innovative study designs and/or analytic approaches which reduce the potential for biases (confounding, selection, misclassification, etc.) associated with non-experimental study designs are encouraged. While CER covers a broad range of topics and methods, applicants are encouraged to focus on generating evidence on clinically relevant effects of diagnosis and alternative treatment modalities (e.g., MRI versus CT, surgical versus non-surgical approaches, alternatives to cancer treatments, pharmaceutical therapy versus device, etc.) for a specific indication. The pilot funding is not expected to fully address the problem, rather it should provide sufficient preliminary data which can be used for an external grant submission proposing a larger more sophisticated analysis of secondary data and/or primary data collection to address gaps in our understanding of the problem.

NC TraCS is also interested in supporting applications for funding to develop the infrastructure and identify the resources needed to submit a grant application (e.g., to PCORI or NIH) for a pragmatic trial. Activities may include creating multicenter research teams, identifying and creating stakeholder groups, generating pilot data, and implementing and testing ways to use EMR data to recruit (and follow-up) patients. We expect successful applications to have a high probability of a grant proposal submission for a pragmatic trial within the funding period.

Applicants are strongly encouraged to consult with the CER strategic initiative team in preparing these pilot applications, so as to identify the best resource for a given research question. To do so, please send an email to the following address cer_si@schsr.unc.edu. In the subject line put “CER Pilot Proposal,” and answer the following questions in the body of the email:

1. What is the population of interest?
2. What is the test, treatment, or care delivery approach you wish to investigate?
3. With what alternative will you compare your test, treatment, care delivery system, or policy of interest?
4. Why is this comparison important and of interest to relevant stakeholders?
5. What is the outcome(s) of interest and why is it relevant for stakeholders (e.g., clinicians, patients, payors)?
6. If you will be using secondary data, what database(s) will you examine? If you are unsure, indicate this.
7. If you are interested in developing the infrastructure for a pragmatic trial, what will be the setting for the trial?

For questions regarding the CER Strategic Initiative, please contact Program Manager Abigail Haydon at ahaydon@email.unc.edu.

NC TraCS pilot grant awards are not meant as bridge funds or as supplementary funding for existing grants.

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

More information is available in the Pilot Program FAQ.

**UNC - RTI NC TraCS Pilot Collaboration**

NC TraCS’ CTSA award includes a formal partnership with RTI International, the goal of which is to support high-quality collaborative research between the two organizations. Projects that include RTI and UNC investigators may be eligible for match funds provided by RTI. Investigators may request up to $25,000 to support project activities at UNC and $25,000 to support activities at RTI, so no departmental match would be required for a UNC investigator.
collaborating with an RTI investigator.

**NOTE:** RTI investigators are required to consult with an RTI CTSA financial analyst during the preparation of their proposal budget. Contact Lisa Gehtland (lgehtland@rti.org) or Lori Warren (lwarren@rti.org) for details.

Additional questions about the RTI – UNC collaboration and potential collaborators at RTI or UNC should be directed to Lisa Gehtland (lgehtland@rti.org). Individuals interested in learning more about research expertise at RTI may also visit this website.

RTI is now providing 4 new services that are available to assist if applicable to the research. These include 1) **Metabolomics**, 2) **Early Phase Drug Discovery**, 3) **Drug Development / Regulatory Support**, and 4) **Patient and Caregiver Outcomes in Rare Disease (PCORD) Service** (click each link to learn more about each new service). Investigators considering the use of one of these services must discuss their ideas and needs with the service director listed below, to assure that the application fits the services that can be offered:

- **Metabolomics** – **Dr. Susan Sumner**
- **Early Phase Drug Discovery** – **Dr. Hernan Navarro**
- **Drug Regulatory** – **Dr. Diana Severynse-Stevens**
- **Rare Disease Registry** – **Dr. Don Bailey**

II. Eligibility

The following eligibility criteria should be considered when applying for an NC TraCS pilot grant:

- UNC-CH researchers should hold a faculty appointment. UNC-CH researchers who only hold an adjunct appointment are not eligible to apply.
- Also eligible are UNC-CH researchers whose appointment allows them to serve as PI on externally sponsored research projects, for instance researchers holding EHRA 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 they include a UNC-CH faculty member as a collaborator or co-investigator. RTI International and NC A&T State University are now partners in the CTSA with UNC-CH. Applications submitted by investigators from RTI or A&T must also include an investigator from at least one of the other two partner organizations. Therefore, a proposal from an RTI / A&T team is not required to include a UNC-CH investigator, although this is still strongly encouraged. Proposals that do not include a UNC-CH investigator must have a budget entirely comprised of funds from RTI and A&T.
- 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.
- The proposed research of senior faculty investigators (associate professor level and above) should be a departure from a previous research direction. This must be **clearly evident** in the proposal.

III. 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. For example, a research project with a $10,000 budget would receive $5,000 from NC TraCS matched with $5,000 from the research team’s units. The match must be real dollars and not in “in kind” contributions. Matching funds may not include funds previously committed to the research project. Matching funds must be secured before the proposal is submitted. Since multidisciplinary proposals will be considered highly responsive to this RFA, it is
preferred that matching support comes from more than one school, department, center or partner organization. It is encouraged that entities with their own internal pilot programs use those funds as an NC TraCS pilot matched funding source. Projects that include RTI investigators may be eligible for match funds provided by RTI. A list of potential matching funders can be found at:

NC TraCS provides members with access to research service expertise and applicants are encouraged to utilize those research services where appropriate. NC TraCS staff should be consulted prior to submission to ensure that proposals include accurate budget information for the planned use of NC TraCS services. However, applicants are not required to use NC TraCS services.

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
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
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)

V. 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: The abstract summary of the proposal for use by review committee members and 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 proposal meets the review criteria. (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. 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. Projects involving animal subjects must be reviewed and approved by an IACUC. (no page limit)

7) Letter of Collaboration (if applicable): 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. In addition, Letters of Support may be included if they clearly state a commitment of resources required for the project’s success, for example biobank samples available to the investigator. Generic letters of support are neither needed nor encouraged. (no page limit)

8) 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. (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.

10) 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/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, TraCS reserves the right to retract 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 match organization.

2) For most projects, one budget for the total project, including the match funds, should be submitted. However, for projects with a Co-PI from RTI or NC A&T, please submit a separate budget listing funds to be expended at each institution.

3) 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.

4) 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.

5) Principal Investigators and co-investigators at academic partner institutions are expected to have salary support from their institutions or other funding sources sufficient to allow them time to direct the project and conduct the research. Although funds may not be used for UNC-CH faculty salary support or overhead, requests from academic partners for such support will be considered.

6) 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. 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) 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.

3) If an awardee leaves their position, they should contact NC TraCS to initiate close-out procedures.

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

NC TraCS $5K-50K 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.