The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the NIH-funded Clinical and Translational Science Award (CTSA) of UNC and serves as the central translational and clinical research resource for UNC. NC TraCS’ three overarching goals are: (1) to prepare and empower members of the academic community, health care providers, and citizens to participate in translating discoveries into health advances for individual patients and populations; (2) to provide the advice and resources necessary to design and execute innovative, worthy clinical and translational research projects; and (3) to ensure that the institute’s most promising discoveries and results rapidly become solutions to important statewide and global health problems. These goals are accomplished by maintaining a seamless network of connections among 18 cores: Biostatistics, Clinical Research Ethics, Clinical & Translational Research Center (CTRC), Community Academic Resources for Engaged Scholarship (CARES), Comparative Effectiveness Research, Core Lab Facilities & Resources, Early-Phase Drug Discovery, Education, FastTraCS, Information and Data Science (IDSci), Integrating Special Populations, Pilot Program, Proposal Development, Recruitment, Regulatory, Research Coordination & Management Unit (RCMU), Team Science, and Trial Innovation Network (TIN). Each core provides special expertise, unique research facilities, and the tools necessary to support research, from discovery to translation. All cores are multidisciplinary, share goals and missions, and are closely connected by TraCS Central, which develops, maintains, and tracks NC TraCS requests and initiatives.

UNC was awarded $58.1 million from the NIH in 2018 to renew its five-year CTSA for the third cycle. With the new award, UNC will broaden its reach across the state with outreach efforts touching each of North Carolina’s 100 counties. Over the last funding period, NC TraCS worked with over 350 practices, 130 community-based organizations, 88 percent of other CTSA hubs, and numerous non-CTSA universities through pilot awards or other initiatives. The Institute provided leadership for a number of high-impact multi-center clinical trials in HIV, diabetes, obesity, cancer, and pregnancy, among others.

Since 2013, NC TraCS has included a research partnership with ***RTI International (RTI)*** to support joint translational research projects, and develop best practices to train, support, and retain a diverse clinical and translational research workforce. UNC’s CTSA also includes ***North Carolina A&T State University (NC A&T)***, collaborating with UNC and RTI on initiatives to strengthen NC A&T’s clinical and translational research resources and its workforce. For its third award cycle, ***North Carolina State University*** joined the UNC CTSA as a full partner. NC TraCS is governed by some of UNC’s and RTI’s most accomplished scientists and clinicians with extensive experience in each of the five domains of NC TraCS–translational, clinical, basic, and population sciences research, and operations. Its directors are **John Buse, MD, PhD**, and since July 2020, **Nicholas Shaheen, MD, MPH**, who replaced **Timothy Carey, MD, MPH**. Dr. Carey will continue to chair the NC TraCS Pilot Program Study Section and participate in informatics and mentoring.

Capitalizing on the joint research strengths at UNC and its partner institutions, NC TraCS has also created three strategic initiatives to focus on three research foci that typically have proven to be stumbling blocks for translational researchers. The strategic initiatives are (1) *Transformative Technologies-* next-generation technologies that will transform clinical research and practice, (2) *Comparative Effectiveness Research –* comparative effectiveness research studies to provide definitive evidence of the benefits and harms of tests and treatments in the real-world community setting, and (3) *Drugs, Devices and Diagnostics Development (4D)-*resources dedicated to accelerating drug, device, and diagnostic development. All resources, services, and initiatives are multidisciplinary, share goals and missions, and collaborate with one another and with RTI. Finally, as one of about 70 medical research institutions in the national CTSA Consortium, NC TraCS works to improve the effectiveness, efficiency, and safety of clinical and translational research conducted across the country.

***\*\*Optional – below are descriptions of a few of the cores that can be included if applicable to the proposal\*\****

The *Biostatistics Core* provides timely, state-of-the art biostatistical collaboration for study design and analysis. The core offers daily walk-in hours for short-term, faculty-level input on statistical design or analysis, and provides more detailed consults for external grant and all NC TraCS pilot grant submissions. With the IDSci, the core co-manages the TraCS Clinical Research Data Management System (CRMS).

*NC TraCS Regulatory Core*: The goal of Regulatory Core is to provide education and assistance to investigators and study personnel early in the research process to assure conformity with regulatory and institutional requirements. Advocacy for the rights of the research participant is another important focus and resources are available to support their rights and wellbeing. The Regulatory Core strives to make compliance a seamless, coordinated process by partnering with investigators to: (1) incorporate regulatory compliance and subject safety at the earliest stages of research planning, (2) simplify adherence to good clinical practices and streamline the research process, and (3) provide oversight programs that enable investigators to conduct research successfully and safely.

*Affiliated Centers*: NC TraCS collaborates with several campus-wide centers to promote various aspects of professional development. The UNC Center for Faculty Excellence (http://cfe.unc.edu), for example, provides campus-wide support for faculty development. This includes course redesign support, workshops for faculty, introductions to new teaching approaches and technologies, and one-on-one consultations. Of particular relevance to this application are the Mentoring Lecture Series, the Core Skills Program for Faculty Leadership, and – for trainees – the PI Development Lecture Series and the Seminar Series for Early Career Faculty Development. Similarly, the UNC Center for Bioethics (http://bioethics.unc.edu) hosts regular conferences and special events focused on various aspects of clinical and research ethics. The Clinical Ethics Grand Rounds and the Research Ethics Ground Rounds are held every 1-2 months and offer state-of-the-art discussions about contemporary ethical challenges.

*Recruitment Services* were established in 2009 to assist researchers with subject recruitment and retention. The primary goal of Recruitment Services is to assist individual investigators and research teams in meeting their targeted enrollment goals. Recruitment Services provides web based recruitment tools including an internet based volunteer engagement and study listing system called Join the Conquest. In addition, individual consultation on protocol feasibility, strategies, tactics and educational webinars are available.

NC TraCS Recruitment Services connects researchers with resources from across the UNC-CH campus, local community and state to achieve recruitment goals. For example, the office conducts feasibility assessments and collaborates with the Carolina Data Warehouse-Health (CDW-H) to help the investigator identify appropriate patient populations internally for potential study enrollment. In addition, the Office connects investigators with the National Recruitment Registry: ResearchMatch.com, a CTSA Consortium effort that provides a national registry of individuals willing to participate in clinical studies.

*The Trial Innovation Network (TIN)\** is a collaborative initiative within the CTSA program composed of three key organizational partners: the CTSA hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC).The multi‐disciplinary TIN Hub Liaison Team leads scientific, training, and implementation aspects of the network and helps investigators utilize all local CTSA resources for initiating multi-center clinical. They use experience and knowledge of the local environment to innovatively operationalize the network for UNC, tailoring general network plans into more specific action plans.

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