

**CTSI** Your Partner  
In Research

## Clinical & Population Scientists



The Clinical and Translational Science Institute (CTSI) facilitates innovative clinical and translational research at the Wake Forest School of Medicine. We have developed a variety of tools and services designed to support your research and career development.

**Explore our available services and see how we might help you!**  
**Visit [ctsi@wakehealth.edu](mailto:ctsi@wakehealth.edu).**

## FUNDING OPPORTUNITIES

*Do you have an idea for a novel technology or want to test the feasibility of a novel approach?*

The CTSI offers a number of funding opportunities to accelerate your research goals.

Programs available include:

**Translational Pilots:** One-year awards of up to \$40,000 to support novel projects that bridge translational gaps. Within a typical year, the CTSI will fund 8 to 10 awards. Investigators should anticipate the release of new RFAs in August of each year.

**Ignition Funds:** Rapid-access awards of up to \$5,000 to help maintain momentum on feasibility projects. Ignition funds are issued every month.

**KL2 Program:** Scholars receive salary support and other expenses for two years for support of educational and research needs. More information is listed under Education.

### Request a Service!

To request any of our services, please complete our Service Request Form by selecting "Request Services" at [ctsi.wakehealth.edu](https://ctsi.wakehealth.edu). Services are open to all faculty.

## EDUCATION

*Interested in furthering your research expertise or improving your grant-writing skills?*

The CTSI offers education opportunities focused on enhancing clinical and translational research knowledge and skills.

Opportunities include:

**Translational Research Academy:** The Translational Research Academy is a two-year program focused on education, mentoring, networking and research support to enhance the career development and success of early career faculty with significant effort devoted to research. A new cohort is selected in the early fall of each year.

**KL2 Program:** Scholars receive 75 percent salary support for two years and up to \$35,000 per year to support educational and research needs. Scholars become members of the CTSI Translational Research Academy and participate in diverse educational, networking and mentoring opportunities. The CTSI funds 1 to 2 new KL2 scholars each year.

**Research Education Seminars and Courses:** The CTSI provides live and "Ready When You Are" online educational opportunities designed to enhance knowledge and skills in conducting effective research.

Access a list of educational offerings and training materials at [ctsi.wakehealth.edu](https://ctsi.wakehealth.edu).

## COMMUNITY ENGAGEMENT

The Program in Community Engagement (PCE) facilitates collaboration among community members, health care providers and translational scientists through scheduled events and consultation services. PCE faculty and staff are available to assist with the following:

- Entree to community organizations
- Brokering relationships between investigators and community members
- Project design and development
- Implementation and evaluation of community-engaged programs and projects

## CLINICAL RESEARCH UNIT (CRU)

*Do you need support to conduct clinical research?*

The CRU provides dedicated clinical space, patient care, bionutrition and specimen processing for approved studies.

Support for clinical studies includes:

- **Dedicated Research Space:** 14 exam rooms, procedure room, metabolic kitchen and CLIA-certified specimen processing laboratories.
- **Patient Care:** Research nurses and technicians conduct procedures for studies with pediatric, adult and geriatric patients.
- **Bionutrition:** Research dietitians and technicians provide food service, nutrition assessments and nutrition education.
- **Specimen Processing:** Technicians provide specimen processing with an emphasis on eliminating pre-analytical variation.
- **Dry Ice:** Available for research study needs. Dry ice can be used within or outside of the CRU.

## STUDY COORDINATOR POOL

*Need help with the management of clinical studies?*

Our Study Coordinator Pool offers reliable, experienced research staff to assist in the day-to-day management of clinical research studies. Coordinators are available to:

- Prepare and submit IRB applications and consent forms, prepare and maintain regulatory binders, develop study documents, and assist in negotiation and preparation of budgets.
- Recruit and screen participants, conduct study visits, collect data, draw and process specimens, and track finances.
- Act as a liaison between study teams and sponsors.

**For more information or questions, please contact [ctsi@wakehealth.edu](mailto:ctsi@wakehealth.edu).**

## CLINICAL TRIALS OFFICE (CTO)

*Would you like help developing a budget or a visit schedule for your clinical trial?*

The CTO facilitates all stages of clinical trial management, including budget development, study initiation and protocol implementation, study coordination, and data and regulatory management.

The CTO also performs Medicare Coverage Analysis and facilitates billing the study sponsor on your behalf for non-federal studies.

## RECRUITMENT/FEASIBILITY

*Do you need to identify a feasible participant cohort based on your research criteria?*

Our Recruitment Unit can help determine the feasibility of your research project, identify qualifying patients through our Translational Data Warehouse, and provide consultations and support to reach participants.

## INTEGRATING SPECIAL POPULATIONS

*Interested in engaging particular populations for research participant recruitment?*

An important component of the CTSI mission is to facilitate the inclusion of older adults, children and underrepresented minorities (special populations) in clinical studies and increase the opportunities for those populations to participate in research. We will work with you to better understand the needs of special populations and assist with recruitment and enrollment.

## ADMINISTRATIVE SERVICES

*Need administrative support for you research?*

Our goal is to support you throughout the research process as you seek funding, manage awards and prepare manuscripts.

### Services include:

**Grant Editing:** The CTSI provides professional medical editing and writing services to all investigators. We can help with grant preparation, editing and guidance, application resubmissions, and the development of letters of support, biosketches and other supporting documents.

**Grant Management Core:** Our finance staff is available to provide post-award support to manage all aspects of grant account activity and maintain fiscal compliance. There is a fee for all investigators utilizing this service.

**IND/IDE Navigation:** The CTSI supports a full-time navigator to facilitate IND/IDE applications by offering in-depth advisory consultations to improve investigators' ability to meet FDA requirements.

## AFFINITY GROUPS

*Interested in getting more involved in the future of research at Wake Forest?*

The CTSI sponsors affinity groups to engage and support investigators in the areas such as **Implementation Science**. Visit [ctsi.wakehealth.edu](https://ctsi.wakehealth.edu) for more information.

## BIostatistical SUPPORT

*Need expert consultation on your research design?*

The Biostatistics, Epidemiology and Research Design (BERD) Program provides investigators with clinical research design and interpretation expertise, including education in research design and analysis. BERD offers pre-award and post-award support to all faculty.

**Pre-award:** Support includes hypothesis development, statistical methods and sample size estimation. Pre-award support is free to all faculty on the condition that post-award support be included in the grant budget.

**Post-award:** Support includes data entry and management, data analysis, interpretation, and preparation of results for publications and presentations. Post-award support is billed on an hourly basis.

BERD also offers drop-in consultation hours to all faculty free of charge (visit [ctsi.wakehealth.edu](https://ctsi.wakehealth.edu) for available hours).

**Clinical Research Methods Short Course:** BERD sponsors a short course that introduces participants to research study design. Course topics include methodological issues, statistics, sample size and power, and data synthesis.

## RESEARCH STUDIOS

*Would you like to enhance the quality of your research, foster advances in research and clinical practice, increase publications or generate new hypotheses?*

When you request a Research Studio, CTSI faculty and staff will assist in developing a multi-disciplinary panel of experts to participate in a guided roundtable discussion focused on your needs and goals.

Each 90-minute session will include a facilitator and key experts, and conclude with verbal and written feedback to investigators.

## NONHUMAN PRIMATE PROGRAM

*Do you need access to nonhuman primates and primate facilities for your research?*

The Nonhuman Primate Program offers state-of-the-art facilities to conduct animal research, as well as funding opportunities and access to nonhuman primate data and tissues.

- **Facilities:** Animal radiology suite, clinical pathology laboratory, diagnostic and experimental necropsy laboratory, diet preparation laboratory, mobile imaging platform, molecular biology laboratories, nursery suite and surgery facilities.
- **Feasibility Awards:** The Program offers awards to investigators with projects focused on the translation of data from nonhuman primates to diseases of human relevance. The objective is to facilitate the collection of pilot data from nonhuman primates in support of applications for extramural funding. Applications are accepted on a rolling basis. For more information, please contact [primates@wakehealth.edu](mailto:primates@wakehealth.edu).
- **Primate Data and Tissue Repository:** Investigators may request access to nonhuman primate data and tissues for research purposes. Repository inquiries should be directed to [primates@wakehealth.edu](mailto:primates@wakehealth.edu).

## TRANSLATIONAL IMAGING

*Do you need access to imaging resources for your research?*

The Translational Imaging Program (TIP) offers shared resources to all faculty seeking research imaging services. Shared resources include:

- 3T MRI
- 7T MRI
- CT
- PET/CT
- MicroPET/CT
- MEG
- Custom radiotracer development
- Animal anesthesia and other animal research procedures

Visit [ctsi.wakehealth.edu/Translational-Imaging-Program](https://ctsi.wakehealth.edu/Translational-Imaging-Program) for scan rates and additional information.

## BIOMEDICAL INFORMATICS

*Do you need access to data or programming assistance?*

CTSI staff can assist in querying clinical data, managing your research data via REDCap and building applications to enhance your research projects.

### Services include:

**i2b2 and the Translational Data Warehouse:** Our analysts can query clinical data for cohort identification and pull detailed data for approved research projects. Available data includes demographics, diagnoses, procedures, medications, lab results, vitals, and visit details from the medical record.

**REDCap:** A secure, web-based application for building and managing online surveys and databases. It enables rapid project development, provides users with complete autonomy and control of a project, and directly exports data to common statistical packages. Access to REDCap is free to all WFBH employees. CTSI staff will build REDCap projects for a fee. For questions, please contact [ctsiredcap@wakehealth.edu](mailto:ctsiredcap@wakehealth.edu).

**Programming:** Do you have advanced data collection needs beyond REDCap's capabilities? Our experienced programmers can help assess your technical needs and build custom applications and tools.

**Clinical Informatics Short Course:** The CTSI offers a 16-hour short course with the goal of introducing participants to the core content of clinical informatics.

**For more information or questions, please contact [ctsi@wakehealth.edu](mailto:ctsi@wakehealth.edu).**



## Are you an Early Career Investigator or Non-Faculty Researcher?

The Principal Investigator (PI) or the Co-Principal Investigator (Co-PI) of the study must meet one of the criteria to be designated as **Early-Career**:

- Faculty with a rank of Assistant Professor or lower who have never been the PI or Co-PI of an extramural research award exceeding \$100,000 in direct costs per year; OR
- Individuals currently supported by a career development award (e.g. K23, K08); OR
- Active CTSI Translational Research Academy members

**Non-Faculty Researchers** are individuals that can be listed as the Project Lead or, more specifically, the Principal Investigator of an IRB protocol, but are not classified as Faculty. A non-faculty researcher is an individual who is in departmental administration or a departmental staff member. Individuals that might meet this definition include:

- Resident
- Fellow
- Physician Assistant
- Nurse Practitioner
- Pharmacist
- Physical Therapist (DPT)
- Nurse Researcher
- Research Associate
- Physician

## CTSI PROGRAMS

Learn more about the CTSI and its programs! For more information about any of the programs below, visit [ctsi.wakehealth.edu](http://ctsi.wakehealth.edu).

- Biomedical Informatics
- Biostatistics, Epidemiology & Research Design (BERD)
- Collaboration and Team Science
- Evaluation and Continuous Improvement
- Integrating Special Populations
- Implementation Science Affinity Group
- KL2 Career Development Program
- Nonhuman Primate Program
- Mentor Academy
- Participant & Clinical Interactions
- Participant Identification & Recruitment
- Program in Community Engagement
- Regulatory Knowledge and Support
- Translational Imaging
- Translational Pilot Program
- Translational Workforce Development

## CTSI Administration

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## Cite & SUBMit

Publications supported by WF CTSI must cite the CTSA Grant number (UL1TR001420) and, by law, be submitted to PubMed Central. For instructions, review the NIH Public Access Policy at [publicaccess.nih.gov](http://publicaccess.nih.gov).

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