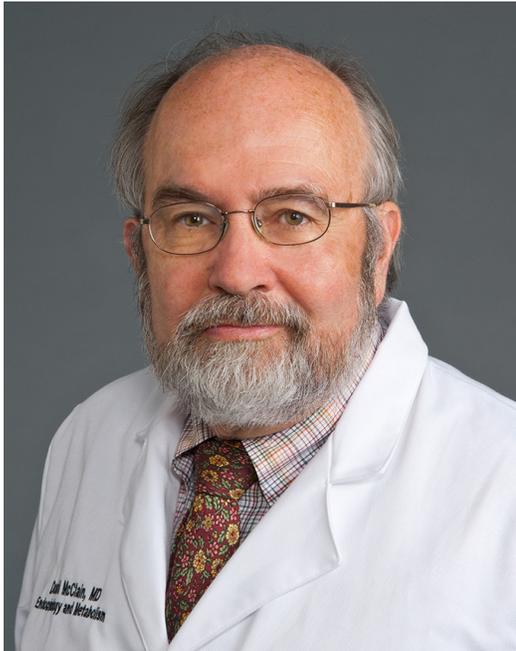


Wake Forest Clinical and  
Translational Science Institute

# Annual Report

## FY17



## MESSAGE FROM THE DIRECTOR

### — *Dr. Don McClain*

I am pleased to present the Clinical and Translational Science Institute (CTSI) FY17 annual report. In my first year of serving as the leader of the CTSI and Principal Investigator for our CTSA grant, I have thoroughly enjoyed working with the CTSI faculty and staff and have been impressed by the hard work, dedication and collaborative spirit of the team. As an organization responsible for providing the overall administrative infrastructure, services and tools, and education and training to support our research faculty and staff, the CTSI has had a successful and productive year.

We have seen strong growth in our extramural funding portfolio in FY17 reaching \$205M; a significant increase from \$177M in FY16. Our commitment to our research focus areas has proven successful. Aging/Alzheimer's, Cancer, Cardiovascular, Diabetes/Obesity/Metabolism, Neurosciences, and Regenerative Medicine accounted for \$159M, or 77 percent of our extramural research funding.

The Office of Clinical Research, in partnership with the Comprehensive Cancer Center, ITS, and several key contributors from our Departments and Centers, implemented a new Clinical Research Management System—Wake Integrated Solution for Enterprise Research (WISER). This provides our institution with a single solution for regulatory, billing, biobanking sample management, and data management for all clinical studies conducted at Wake Forest.

The Office of Sponsored Programs engaged an outside consultant to review its processes and procedures; examine structure and staffing levels; and guide development of service level agreements. In response, OSP has initiated a series of improvement initiatives that will allow it to carry out its mission: to support and advance our research community through partnerships and education, while ensuring quality, accuracy, and compliance.

The Office of Regulatory Affairs and Research Integrity, along with many external partner institutions, launched the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB process to facilitate the NIH single IRB Policy. Additionally, I am very proud to report the IACUC and Animal Resources Program collaborated to successfully apply for re-accreditation from the AAALAC with no major findings or mandatory changes. We have been continuously accredited for 51 years, which is the second longest streak of consecutive accreditation in the country.

Through the efforts of the Education Program team, a new cohort of Translational Scholar and Mentor Academies were initiated with a total of 30 research faculty participating in these programs, including the addition of a KL2 research scholar. The Education team also developed several online interactive training modules and worked closely with all the offices and programs across the CTSI and with institutional partners to conduct seminars, trainings and support short course activities in Research Methods and Biomedical Informatics.

I have highlighted above just a few of the many accomplishments the CTSI has achieved over the course of the year but I invite you to read our full report and learn more about our initiatives and the diverse, talented, and caring group of people across the CTSI with whom I have the great privilege to work.

Sincerely,

Dr. Donald McClain, MD, PhD

DIRECTOR AND PRINCIPAL INVESTIGATOR

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# CTSA COLLABORATIONS

An important part of the national CTSA program is the collaboration of institutions to speed the translation of research discovery into improved patient care. As a CTSA designated institution, we are fortunate to be involved in many regional and national collaborations that support this initiative.



**A**  
**UNC-Chapel Hill, Duke, RTI International**

Funded CTSA Innovation Award for the Early Check Collaborative, which provides early screening and detection for genetic disorders such as Fragile X.

Funded CTSA Supplement for the Regulatory Guidance for Academic Research of Drugs and Devices (REGARDD) initiative.

**B**  
**UNC-Chapel Hill, Duke, Medical University of South Carolina**

Established the Carolinas Collaborative Data Network, a data resource that harmonizes EHR data of participating institutions to expedite clinical research and quality improvement studies.

Funded two pilot projects through the Carolinas Collaborative.

**C**  
**Harvard, Washington University, Boston University, Morehouse, UC Davis, UT Houston**

Funded PCORI Clinical Data Research Network, the Scalable Collaborative Infrastructure, a diverse and collaborative patient-centered network.

**D**  
**University of Kentucky**

Co-sponsored opioid-focused pilot award aimed at addressing health issues identified by the Appalachian community.

**E**  
**Rockefeller University**

Collaborated with Rockefeller University to implement a pilot study (Research Participant Perception Survey) to better understand the experiences of individuals who participate in research studies.

**F**  
**Columbia, UC Denver, Mayo Clinic, NYU, Northwestern, UC San Diego, Yale, University of Washington, Duke, UNC-Chapel Hill**

Awarded funds to conduct 10 nonhuman primate feasibility studies with other CTSA designated institutions.

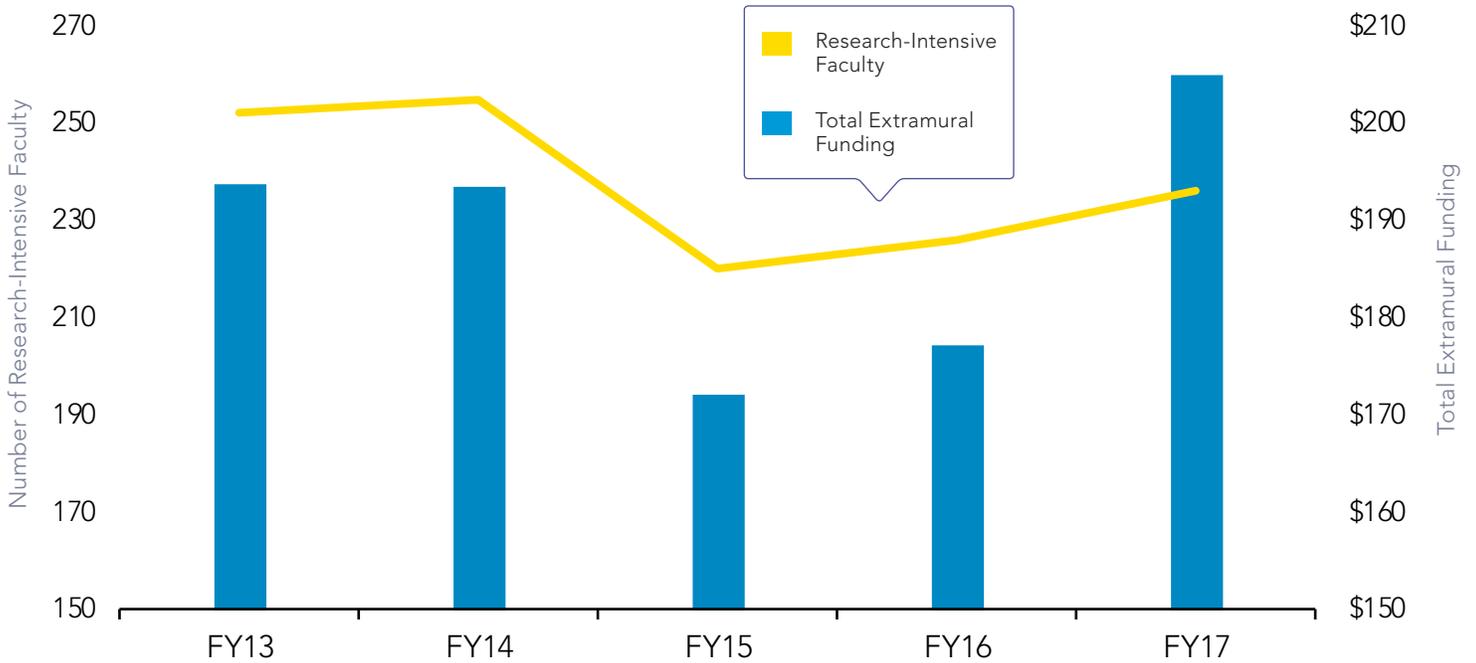
**G**  
**University of Iowa**

Participated in "The Science of Health Equity" summit at the University of Iowa where where Wake Forest presented on promoting health equity through community engaged research.

# RESEARCH FUNDING

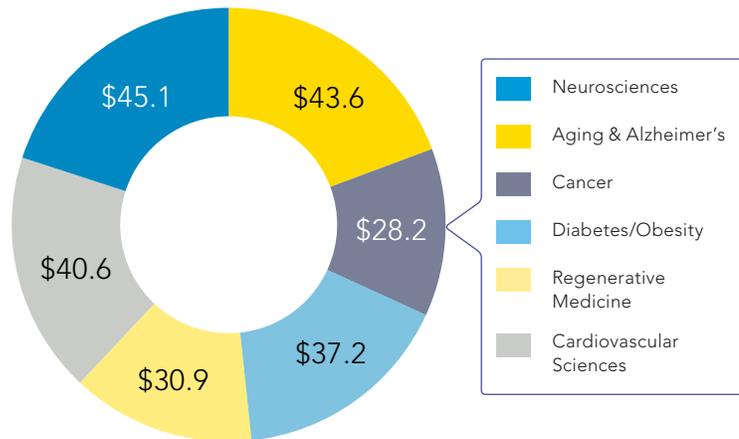
## Total Extramural Funding and Number of Research-Intensive Faculty

Dollars are in millions. Research-intensive faculty is defined as faculty with 50 percent or greater research effort.



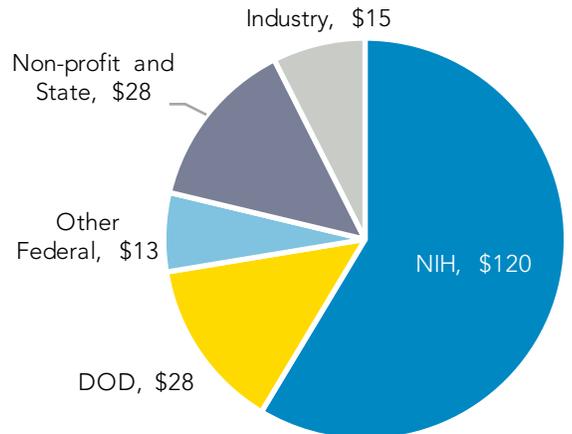
## Research Focus Area Award Volume

Dollars are in millions. Award volume measures projects with a funding period start date within the fiscal year. Depending on the nature of the research, awards may be included in more than one focus area.



## FY17 Funding by Source

Dollars are in millions. Total FY17 extramural funding was \$205 million.



## Q&A WITH DR. KATE CALLAHAN, Pilot Award Recipient

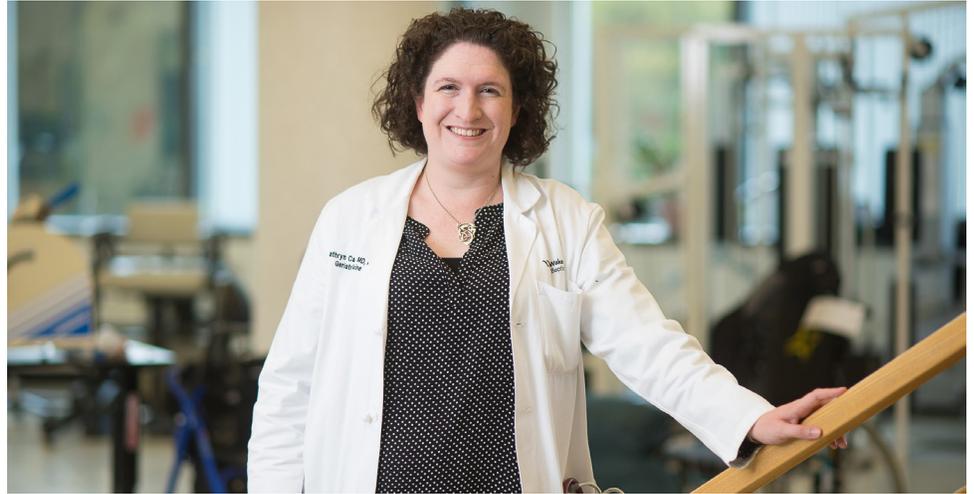
Dr. Callahan's pilot project, "Promoting Active Living in Aging: Innovation in Primary Care," is changing the way we care for the older population.

### Please describe your project.

Despite research showing that physical activity preserves mobility and reduces falls, few older adults in primary care practice are screened for mobility impairment or counselled on the value of physical activity. This pilot study implemented a physical function screening for older adults across three diverse primary care practices. The project randomized older adults to a) a video about physical activity and their personal risk for losing mobility, or b) a video about healthy eating. We then measured participants' perceptions of their mobility and attending a session on community-based physical activity.

### How did the pilot impact the delivery of care and demonstrate the qualities of a Learning Healthcare System?

The project increased awareness of mobility problems and how subtle they can be, and increased awareness of community-based resources for



promoting physical function. The study also allowed us to create patient-friendly materials to communicate risk of losing mobility; such materials were not previously available. Lastly, the study enabled us to implement the 4-meter gait speed test in a clinical practice setting. The test is consistently used in research and a major predictive tool for mortality and morbidity.

### How did the study incorporate the principles of community-based participatory research and what impact did this have on the research?

Members of our patient advisory board reviewed all patient-facing materials, including videos, handouts, scripts, and materials for the physical activity session. This changed some of our language, particularly our explanations.

We also had input from physicians, nurses and medical assistants which led to significant changes in the structure and flow of the intervention. There are challenges with obtaining consent in community-based participatory research. The Institutional Review Board worked with us and with the practice sites to develop a video-based consent process that was easy to implement and has the potential to positively impact other projects in the future.

### Now that your pilot has ended, what are your plans for expanding upon this research?

This fall I am applying for a Paul B. Beeson Emerging Leaders Career Development Award in Aging using data from the pilot study.

## Translational Pilot Program Statistics

10

Pilots

\$370,000

Amount Awarded\*

20

Ignition Funds

\$109,400

Amount Awarded

\*This amount includes joint funding provided by the Center on Diabetes, Obesity and Metabolism, the J. Paul Sticht Center on Aging and Rehabilitation, the Comprehensive Cancer Center, and the Alzheimer's Disease Core Center. A total of \$80,000 was provided in joint funding.

## FACULTY CAREER DEVELOPMENT

The CTSI is devoted to supporting the career development of Wake Forest researchers and offers three faculty development programs. Applications for these programs are accepted in the fall of each year.



### Mentor Academy

The Mentor Academy is a six-month program that provides training and support for mid-career faculty to enhance their knowledge and skills in both research- and career-related mentoring. Academy members receive five percent salary support during the six-month program period.

The second cohort of the Mentor Academy was held from January-June, 2017. Twelve mid- and senior level faculty and one staff member from Wake Forest Innovations participated. In 2016 we expanded the eight-hour, evidence-based curriculum to a 20-hour curriculum held over 10 sessions. The curriculum includes six major competencies: 1) maintaining effective communication; 2) aligning expectations; 3) addressing understanding; 4) addressing equity and inclusion; 5) fostering independence; and 6) promoting professional development.

### Translational Research Academy

The Translational Research Academy is an education and research support program to enhance the career development and success of early-career clinical and translational researchers. Faculty who have a significant effort devoted to research are eligible to become Academy Scholars. The Academy provides education and leadership development training, research support services, mentoring and networking opportunities. Each Academy Scholar receives preferential access to CTSI services and can use many CTSI services, including the Clinical Research Unit and Study Coordinator Pool, at no charge.

The 2016 cohort began in February and included 19 members from 15 different departments. The 2017 cohort began in June and includes 17 members from 12 different departments.

### KL2 Career Development

The KL2 Mentored Career Development Award provides two years of support for early-career research faculty to build clinical and translational research skills and competencies under the guidance of skilled multi-disciplinary mentoring teams. KL2 Scholars receive salary support, priority access to all CTSI resources, including biostatistical and research design support, study coordinators and research navigators at no charge.

In 2016, the CTSI funded three KL2 Scholars: Roy Strowd, MD; Jillian Urban, PhD; and Zachariah McIver, DO. The CTSI funded an additional KL2 Scholar, Kenneth Kishida, PhD, in April of 2017. All KL2 Scholars are part of the Translational Research Academy and actively participate in its ongoing and diverse educational, networking and mentoring opportunities.

CTSI KL2 Scholars receive 75 percent salary support for at least two years, up to \$35,000 per year to support educational and research needs, an individual development plan, and a multi-disciplinary mentoring team.

## Meet our KL2 Scholars

Roy Strowd, MD

Neurology

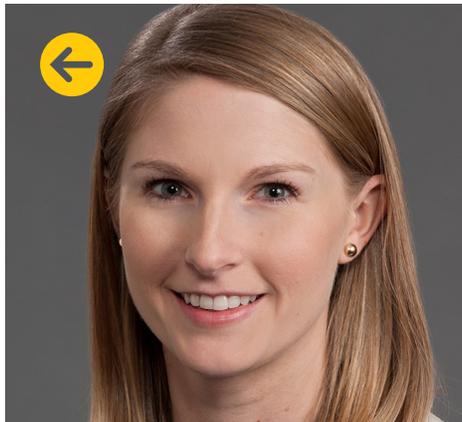
Determining the Competence of the Immune System of the First Year of Therapy in Patients with Malignant Glioma: A Battery of Quantitative, Qualitative, and Functional Measures of Immune Readiness



Jillian Urban, PhD

Biomedical Engineering

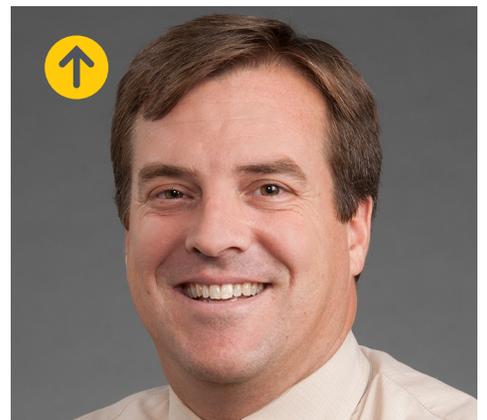
Cumulative Exposure to Subconcussive Impacts on Youth Football Athletes



Zachariach McIver, DO

Hematology/Oncology

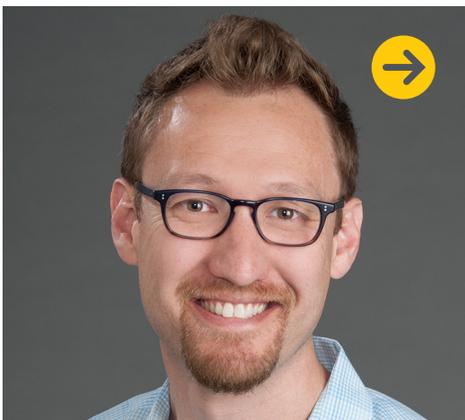
Photodepletion Techniques to Prevent Graft-versus-Host-Disease (GVHD) in Hematopoietic Stem Cell Transplantation



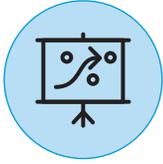
Kenneth Kishida, PhD

Physiology/  
Pharmacology

Neurobiology of Dopamine and Serotonin Signaling During Social Exchange in Humans



# SERVICES IN THE SPOTLIGHT



## Clarkson Campus Outreach

NONHUMAN PRIMATE SIGNATURE PROGRAM

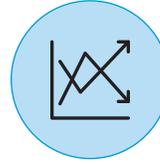
The Clarkson Campus regularly offers campus visits to local students, industry sponsors and outside institutions, as well as other outreach activities aimed at introducing students to biomedical research and medical careers. A typical visit includes a presentation by a faculty member and a tour of the campus, with the highlight being the vervet colony. Since the CTSA was awarded in 2015, over 650 students have visited the campus.



## Special Populations Support

MAYA ANGELOU CENTER FOR HEALTH EQUITY

Health equity services in research meet the health needs across diverse populations, increase knowledge, and assure the efficacy of preventative interventions. CTSI services include research participant navigation; consultation and language services; health equity education; and a voucher program which supports the accrual of special populations. Nine studies have used our research services, resulting in 105 participants being recruited and retained.



## Biostatistical Support

BIostatISTICS, EPIDEMIOLOGY, AND RESEARCH DESIGN

The CTSI offers research design and interpretation expertise, including education in research design and analysis. Statistical consulting office hours are available to all faculty, staff, and students and are offered three days per week. Statisticians are also available to provide pre-award and post-award support for research studies. In FY17, the CTSI provided 66 total office hour consultations and provided biostatistical expertise to 82 studies.



## Research Studios

COLLABORATION AND TEAM SCIENCE

Research Studios are sessions where institutional experts in particular research fields participate in a guided roundtable discussion to provide feedback to the faculty participant on his/her research idea or grant project. Research Studios are available to faculty at all levels. In FY17, the CTSI hosted 12 research studios with a total of 59 studio participants (PI, study team members, experts and moderators).

## CTSI Educational Offerings

Providing high quality and diverse educational opportunities for faculty and staff conducting research at Wake Forest is a core component of the CTSI. The following trainings and events were offered in FY17.

Topic	Number of Unique Attendees
CTSI Seminars	152
Animal Trainings	288
Human Research Protection Program Trainings	92
Responsible Conduct of Research Orientation	16
CRMS/WISER Training	217
REDCap Basics and Advanced Class	126
Research Administration and Finance	260
Medical Student Research Program	104
Other Research-Related Training (K Writers' Series, ad hoc, etc.)	52

## SERVICES IN NUMBERS

6,292

CLINICAL RESEARCH UNIT VISITS

1,027

REDCAP USERS

DATA ACCESS USERS

320

GRANTS EDITED

153

MANUSCRIPTS EDITED

80

STUDIES SUPPORTED BY CTSI  
STUDY COORDINATORS

96

INVESTIGATIONAL  
DRUG/DEVICE  
CONSULTATIONS

69

STUDY PARTICIPATION REQUESTS  
THROUGH BE INVOLVED

6,403

## COMMUNITY ENGAGEMENT SPOTLIGHT: DR. JULIE LINTON

Effective advocacy is inspired by compassion, informed by data, and moved forward through hard work and collaboration. Dr. Julie M. Linton is an emerging leader committed to creating a national, regional and local culture of health that includes children in immigrant families. As a pediatrician and the granddaughter of immigrants, Linton has dedicated her career to clinical care, education, advocacy and scholarship to promote health equity for children in immigrant families.

Through community-based collaborations with the public health department, non-profit organizations and city government, and emerging local and national leadership, Linton seeks to build a culture of health among children and families in our community. In recognition of her efforts and dedication, she was recently selected to be in the second cohort of the Robert Wood Johnson Culture of Health Leaders program.

“I have learned from partners who appreciate my passion and training as a physician. They have shared knowledge and insight that complements areas where I lacked training and experience.”

Linton’s research is supported by the CTSI’s Program in Community Engagement (PCE) via a community engagement internship. The PCE sponsors one- and two-year internships for faculty members (with 10 percent paid effort) to familiarize themselves with how community organizations function, the obstacles they encounter and how community-engaged research



can best be implemented. Linton began her internship in 2015 to work with community-based organizations that support the health of children in immigrant families.

Linton has been involved with extensive local and national efforts

to move this initiative forward. At the community level, she partnered with other health care providers, the local health department, the primary refugee resettlement organization, and others to form the Forsyth County Refugee Health Collaborative. This collaborative seeks to address issues for a complex and distinct subset of the immigrant population—

newly-arrived refugees. Linton and the collaborative developed a successful algorithm to connect all refugees in the community with a medical home.

“I have learned from partners who appreciate my passion and training as a physician,” Linton remarks. “They have shared knowledge and insight that complements areas where I lacked training and experience.”

Among the lessons she learned from her partners were the need for strategic planning for new organizations, patience with challenges related to frequent staff turnover in community-based settings, and the importance of assigning clear tasks and accountability for them.

Linton has since been invited to develop and chair the Health Sub-Committee for Building Integrated Communities for the City of Winston-Salem.

# FY17 AT A GLANCE

## 33 | Research Core Facilities

604 protocols approved by the IRB

162 protocols approved by the IACUC

# 209 Employees

## 337

early-career faculty users



Number of individuals who used at least one CTSI service:

# 2,878



## 19

Community Tour participants



## \$3,996,924

2016 CTSA funding (from NIH)



17 unique animal species cared for by our staff



## 862

active multi-site clinical research projects

## 44

Clinical Research Methods Short Course participants



## 21

Clinical Informatics Short Course participants



# CTSI

Your partner in research.