

CTSI Clinical and Translational
Science Institute

Annual Report

FY18



A NEW SEASON —

I am pleased to present another year of excellent work by the Clinical and Translational Science Institute (CTSI).

This past year has been a productive one for the CTSI as we strive to provide excellent research infrastructure across our institution. As always, I am impressed by the breadth and reach of the CTSI, but most importantly, the tremendous faculty and staff responsible for leading our programs and services. I have highlighted below a few of our notable accomplishments and I invite you to look at our many achievements in our FY18 annual report.

FY18 began with significant recruitment initiatives. Under Dr. Gary Rosenthal's leadership, the CTSI coordinated the recruitment of Dr. Metin Gurcan from The Ohio State University. Dr. Gurcan leads the new Center for Biomedical Informatics (WFBMI). I invite you to learn more about Dr. Gurcan and the WFBMI on page 9.

Our new Director of Sponsored Programs, Sara Stanley, was recruited from New York University School of Medicine. Under Ms. Stanley's leadership, the Office of Sponsored Programs (OSP) has continued its improvement initiatives in collaboration with the Research Operations Committee. OSP also reduced account set-up times by five days compared to FY17 with an average set-up time of 12.5 days.

The Office of Clinical Research, the Institutional Review Board, and the Office of Sponsored Programs, initiated a "60-Day Challenge" for industry-sponsored clinical trial activation. To date, five departments and sections have enrolled in this challenge and achieved an average of 54 days to activation as compared to historical trends of approximately 150 days. Read more about the 60-Day

Challenge on page 6. Additionally, I am proud to report that the Regulatory Affairs and Research Integrity Office improved our ClinicalTrials.gov compliance from 22% in FY17 to over 99% compliance.

This year marked the start of our fourth year of CTSA funding and many accomplishments towards our Academic Learning Health System goals. As a designated CTSA hub, we are able to build national research collaborations that enhance local research resources. A few notable examples are our inclusion in the Mid-South PCORnet Clinical Data Research Network (Informatics) and the Appalachian Translational Research Network (Community Engagement). We supported two additional KL2 scholars and provided pilot funding support to several research teams across the institution, including initiating a targeted Clinician Planning Grant that provided protected time and resources to support clinicians interested in developing research projects.

Additionally, we submitted a CTSA renewal application in May, proposing to extend the Learning Health System framework by integrating academic goals of T0-T4 discovery, translation, and scholarship. We call this evolved vision the Academic Learning Health System (aLHS) and are excited to have an opportunity to further develop this framework with renewed funding. Lastly, I invite you to visit our new space on the fourth floor of Bailey Power Plant where our administration, finance, community engagement, and informatics offices now reside.

My sincere gratitude goes to all faculty and staff who lead and support these tremendous CTSI initiatives.

Sincerely,

Donald A. McClain

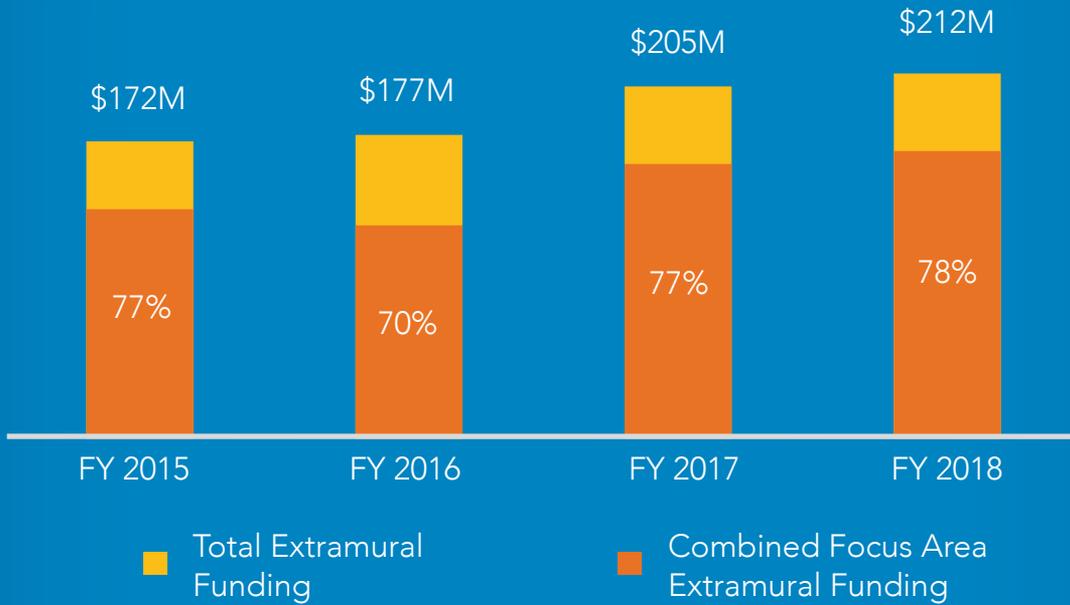
Dr. Donald McClain, MD, PhD
DIRECTOR AND PRINCIPAL INVESTIGATOR

CONTENTS —

Welcome Letter	2
Research Funding	3
KL2 Scholars	4
Community Tour	5
60-Day Challenge	6
FY18 At A Glance	7
Pilot Program	8
A Conversation with Dr. Metin Gurcan	9
Special Populations Ambassadors	9
Research Studio Q&A	10
A Look At Us	11
Educational Offerings.....	11
Quality Improvement Showcase.....	11

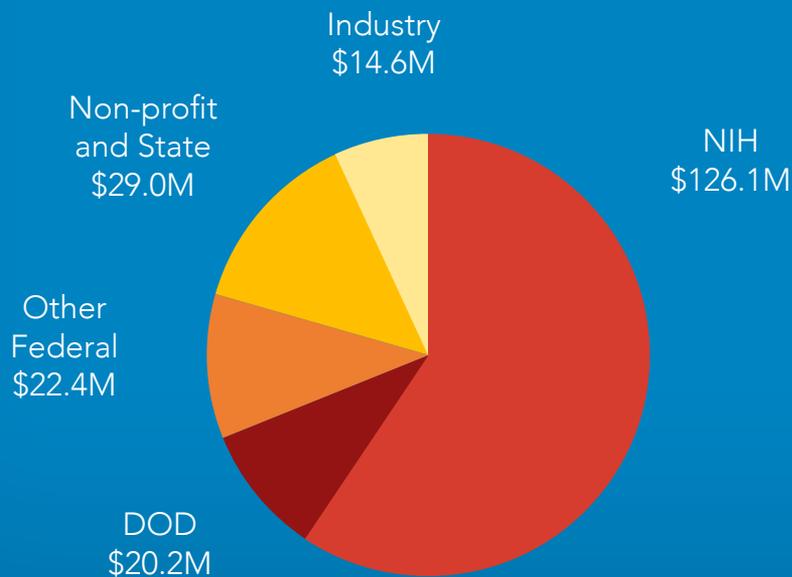
FY18 RESEARCH FUNDING

Extramural Funding



Wake Forest's research focus areas include: Cancer, Diabetes, Obesity, and Metabolism, Aging and Alzheimer's Disease, Cardiovascular Sciences, Neurosciences, and Regenerative Medicine.

Funding by Source



MEET OUR KL2 SCHOLARS —

The KL2 Mentored Career Development Program 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.

Applications for the KL2 Scholars Program are accepted in the fall of each year.

For more information, contact us at CTSI@wakehealth.edu

In 2018, the CTSI welcomed four new KL2 scholars:



Erin Barnes, MD
INTERNAL MEDICINE –
INFECTIOUS DISEASES

IMPROVING IDENTIFICATION OF INJECTION DRUG USE ASSOCIATED ENDOCARDITIS IN THE HEALTH RECORD

The study of injection drug use endocarditis (IDU-IE) has been limited by the ability to reliably and efficiently identify these cases in the electronic medical record. This project will explore combining a wide variety of administrative codes and patient characteristics through logistic regression with an approach examining the free text of physician notes. Dr. Barnes will develop, validate, and deploy an efficient case identification and data extraction tool for IDU-IE so that meaningful analysis can result in evidence-based treatment.



Amber Brooks, MD
ANESTHESIOLOGY

DEVELOPMENT OF BEHAVIORAL eHEALTH TREATMENT FOR OBESE, OLDER ADULTS WITH CHRONIC LOW BACK PAIN

Treatment of pain with opioid and non-opioid medications in older adults is often limited due to the higher prevalence of side effects in this population. Behavioral treatment programs are a viable non-pharmacological therapy approach for addressing pain conditions in older adults. The purpose of this study is to develop a three-part eHealth Platform that will identify patients likely to benefit from behavioral treatments and deliver tailored communications via the myWakeHealth portal.



Deepak Palakshappa, MD
GENERAL INTERNAL MEDICINE

THE EFFECT OF FOOD INSECURITY ON OBESITY TREATMENT AND OUTCOMES

Although prior studies have evaluated if food insecurity leads to increased weight and obesity, little is known about how food insecurity affects individuals who are obese. The goal of this study is to determine if food insecurity is an independent risk factor for developing medical comorbidities from obesity and advance the understanding of how food insecurity impacts obesity management.



Jaime Speiser, PhD
PUBLIC HEALTH SCIENCES –
BIostatISTICS

RANDOM FOREST METHODOLOGY FOR LONGITUDINAL OUTCOMES IN AGING.

This work is being developed to improve decision support tools for predicting dynamic changes in mobility disability over time in a geriatric population. Accurate predictions of mobility disability will aid in decisions about care (e.g. whether assisted living is needed) and have the potential to improve quality of life in older adults (e.g. implementing preventative interventions), thereby lessening the burden of disability.



“What will you do differently in practice or recruitment as a result of what you’ve seen today?”



Keena Moore and DeWanna Hamlin

COMMUNITY TOUR: PAINTING A DEEPER PICTURE

Every day over 2,000 members of our community come to Wake Forest Baptist Health as patients or participants in research. As clinicians and researchers, how many of their stories do we know? Are we familiar with the neighborhoods where they live? Do we know the obstacles they encounter in accessing our care? Through the day-long Community Tour, the CTSI’s Program in Community Engagement aims to provide an expanded understanding of communities in Winston-Salem that see the greatest disparities in health.

“We might stop at a grocery store to show how limited access to healthy food really impacts people’s overall health and why,” says Keena Moore, CTSI Community Health Educator. Mrs. Moore and DeWanna Hamlin, Community Research Associate, plan and host the tours in collaboration with community partners. The tour tells the history of Winston-Salem and uses social determinants of health to guide the discussion.

Since 2015, the Program in Community Engagement has hosted seven tours for 71 faculty, administrators, and staff. Tours include an introduction session, a guided



tour of the community, lunch provided by a local food bank with speaker presentations, and a post-tour debrief. Ample opportunities for reflection and discussion are provided. The six-hour tour includes approximately five stops for conversations with staff at local community agencies, highlighting resources and protective factors that promote resilience.

While the concept is not new, the small group size (tours are limited to 12 participants), full day immersion, and the fact that participants exit the bus to interact with community-based organizations and local establishments set the CTSI’s Community Tour apart from other institutions. The goal is to educate our researchers and clinicians, raising awareness of the barriers in the

community, and asking the question: “What will you do differently in practice or recruitment as a result of what you’ve seen today?”

The Program in Community Engagement offers a tour in the spring and fall of every year.

If you are interested in participating, please email Keena Moore at krmoore@wakehealth.edu

60-DAY CHALLENGE

In 2016, the average time from receipt of industry-sponsored regulatory documents to clinical trial activation was 150 days.

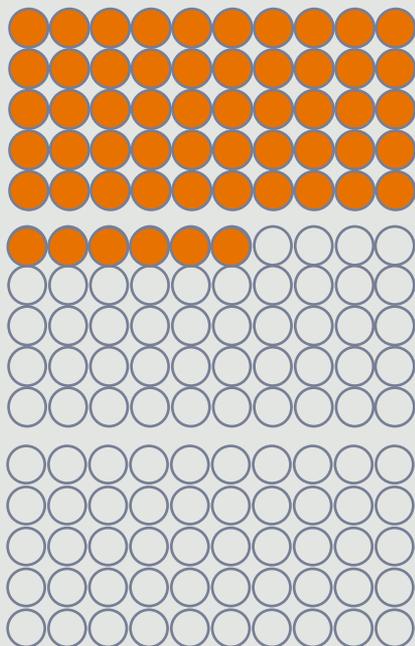
Motivated by concerns that process inefficiencies and redundancies were delaying clinical trial initiation to the detriment of our patients, the CTSI implemented a program in early 2018 called the 60-Day Challenge—the goal being to initiate all industry trials within 60 calendar days.

This required a complete process redesign to eliminate redundancy, decrease hand-offs, and increase coordination.

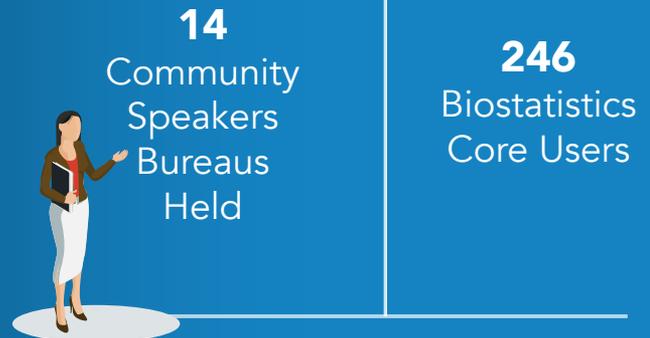
In FY18, **14 studies** across five different departments/sections participated in this opt-in program, with **11 completing the challenge** in under 60 calendar days, for a 79% completion rate and an **average of 56 days to completion**.

AVERAGE DAYS TO COMPLETION: 56

(COMPARED TO 150 IN 2016)



FY 2018 At A Glance



As of 2018,
3+ million
Unique patients in the
Translational
Data Warehouse



3,627
Participation
requests
through Be Involved
clinical studies website



CLINICAL
RESEARCH UNIT
VISITS

5,624

MENTOR
ACADEMY
PARTICIPANTS

12 Mentors of
68 Mentees

DATA USERS

253



DOCUMENTS
EDITED

116 Grants
57 Manuscripts

STUDENT SCIENCE
OUTREACH
PARTICIPANTS

441

10,086

Animals cared for by
Animal Resources
Program Staff



95

Studies supported
by the Study
Coordinator Pool

FY18 CTSA award amount
(from the NIH)

\$3,996,841

119

Team Science
event attendees

306 **vervet**
183 **rhesus**

monkeys
in research cohort



20

**Special Populations
Vouchers Issued**

(for total award amount of
\$27,803)

23

Studies supported
by the Network
Research Team

FY18 Special Populations Enrollment

Older Adults:
2,356

Pediatric:
599

Underrepresented
Minorities:
1,858



TRANSLATIONAL PILOT PROGRAM —

The CTSI's Translational Pilot Program solicits, reviews, and awards pilot grants to produce and rigorously test novel tools and methods that bridge translational gaps and overcome barriers impeding the pace of research translation.

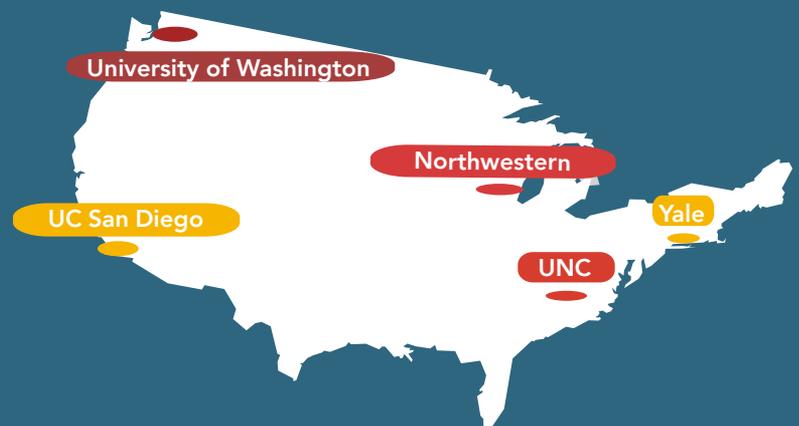
The Pilot Program supports three pilot mechanisms: Ignition Funds, which are released monthly, and Open and Targeted pilot awards, which are released in the fall of each year. Ignition funds are smaller, rapid-access awards designed to help teams maintain momentum on feasibility projects. The annual Open and Targeted awards are designed to support larger translational research projects that test generalizable solutions.

In March of 2018, the CTSI released a new funding opportunity designed to increase the number of competitive applications led by clinicians. This new mechanism, the Clinician Planning Grant, offers 5% effort for the investigator over a 6-month time frame. Investigators are given priority access to CTSI resources and receive guidance from the Pilot Program Leaders. The goal is to produce a competitive proposal for a future CTSI pilot grant with a learning health system focus. Three clinicians were awarded planning grants in 2018.

FY18 pilots awarded to research faculty
9 for a total of \$294,000

Ignition funds awarded and amount
16 for a total of \$82,879

Nonhuman Primate Feasibility Projects: 5



Since CTSA funding began in FY16, the Pilot Program has awarded a total of \$2,113,338, resulting in

a 13:1 return on investment



A Conversation with Dr. Metin Gurcan

Dr. Metin Gurcan joined Wake Forest Baptist Health (WFBH) in 2018 as the inaugural director for the Center for Biomedical Informatics (WFBMI), after serving as Professor of Biomedical Informatics and Pathology at The Ohio State University. He is the founder of the Clinical Image Analysis (CIA) Lab, and his research focuses on the development of computer vision and artificial intelligence techniques to detect and diagnose diseases from medical images.

Describe your mission and vision for WFBMI:

Our mission is to contribute to WFBH evolution as an academic learning health system and to foster better health throughout our nation by advancing and promoting informatics research, service, and education. Our top priorities are the patients and

families who are impacted by our work. All of our decisions are driven by how our research, inventions, and discoveries can promote positive outcomes.

What attracted you to WFBH?

I was captivated by our institution's commitment to being an academic learning health system, and its appreciation for the important role biomedical informatics plays in implementing this vision. I also was impressed by the collaborative nature of WFBH departments, and the earnest excitement around partnering to improve health.

What are WFBMI's goals for 2019?

The Center will have three goals: catalyze, discover, and educate. We will work with CTSI toward achieving these goals, with a focus on recruitment and growing our Center membership, and will explore synergistic opportunities to support WFBH through informatics-related activities and projects.

Become a WFBMI Center member. Email wfbmi@wakehealth.edu



Dr. Metin Gurcan



SPECIAL POPULATIONS RESEARCH AMBASSADORS PROGRAM —

To increase representation of special populations in research throughout the institution, the Maya Angelou Center for Health Equity and CTSI's Integrating Special Populations Program developed the Research Ambassador Program. The program was piloted in December 2017 to share knowledge and equip Research Coordinators to be empowered to serve as ambassadors for under-represented populations in research studies.

Ambassadors meet quarterly to discuss community-engaged research, recruitment, and cultural sensitivity topics. The meeting is a time for ambassadors to identify barriers faced by under-represented populations and to discuss opportunities and initiatives that will support special populations research and studies. Leaders of the program hope that those who participate will gain a greater sense of knowledge of cultural barriers and a better understanding and appreciation

“
prepared and empowered to serve as ambassadors

for the value of community and interdisciplinary partnerships.

The Research Ambassadors Program encourages institutional collaborations that will lead to improved health outcomes and has done so with the Program in Community Engagement, Language Services, and Regulatory Affairs.

RESEARCH STUDIO Q&A —

Dr. Weiner shares his experiences in a Research Studio that helped him prepare for a P50 grant from the National Institute on Alcoholism and Alcohol Abuse (NIAAA).

Briefly describe your research.

We have known the mechanisms of action for other drugs of abuse for many years and that knowledge has not really led to effective treatments for those addictions. I began to think that a more important question might be: what are the brain mechanisms that make some individuals or populations more vulnerable to addiction in the first place? To address this question, my lab established a rodent model to study vulnerability to alcohol use disorder and developed a research program focused on identifying the neurobiological mechanisms responsible for vulnerability and resilience to this disease.

Describe the project you presented during the Research Studio.

I began to collaborate with other researchers at WFSM with an interest in addiction vulnerability and together we developed the only translational research program employing rodent, non-human primate, and human subjects to study individual differences in vulnerability to alcohol addiction. Recently, we decided to attempt the daunting task of applying for a P50 Center grant from the NIAAA. These grants are highly competitive and very difficult to obtain. There are only 20 NIAAA Centers in the United States and the only way to be awarded one is to unseat one of the existing Centers—no easy feat!

Why were you interested in participating in a Research Studio?

A key requirement of P50 Center grant applications is to convey to the review committee that the Center projects



“The Research Studio experts provided invaluable comments that helped us to more clearly highlight how all our projects were linked and poised to significantly advance our field.”

Dr. Jeffrey Weiner



are highly integrated and not just a collection of “stand-alone” projects. Although we knew that our projects were well-integrated, we really wanted an objective set of experts to review our grant to make sure that we were properly communicating the many integrative elements of our application.

How did the Research Studio influence your project?

The Research Studio experts provided invaluable comments that helped us to more clearly highlight how all our projects were linked and poised to significantly advance our field. Our

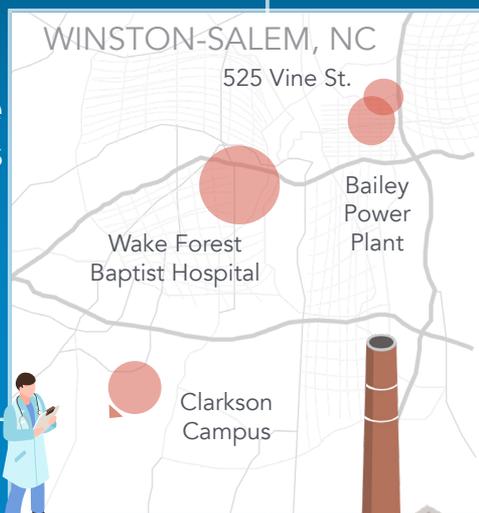
revised Overview, and our research projects, were favorably reviewed by the NIAAA study section, and we were awarded this Center grant on our first attempt. Center integration was perceived as a major strength of our application, an outcome that was facilitated by the feedback we received during the Research Studio.

Research Studios are open to all WFBH faculty. To schedule a Research Studio, please visit the CTSI website and complete a **Service Request Form.**

A LOOK AT US IN 2018

Office Locations

Total Employees
215



New Administrative Home:

Bailey Power Plant

Wake Forest Innovation Quarter, Winston-Salem, NC



CTSI EDUCATIONAL HIGHLIGHTS —

	FY18 PARTICIPANT TOTALS:
Medical Student Research Program	60
Research Systems Training	142
Human Research Protection Program Training	257
CTSI Seminar Series	241
Research Administration & Finance Training	177
Animal Training	317
REDCap Training	122



Quality Improvement Showcase

The Quality Improvement (QI) Showcase is a forum to highlight outstanding QI projects designed and implemented by Medical Center trainees, including residents, fellows, medical students, and graduate students, or early career faculty, as either individual or team efforts.

In collaboration with Dr. Mitchell Sokolosky, Associate Dean for Graduate Medical Education, the CTSI hosted the third annual QI Showcase on May 3, 2018. The showcase included **34 posters** with oral presentations from the top four projects.

The award for QI Project of the Year went to Lynsey Watry, MD (pictured), Melanie Marsh, MD, and Anna Verenes, MD for their project, Pediatric Resident Initiated I-PASS Implementation.

CTSI Clinical and Translational
Science Institute

Your partner
in research.