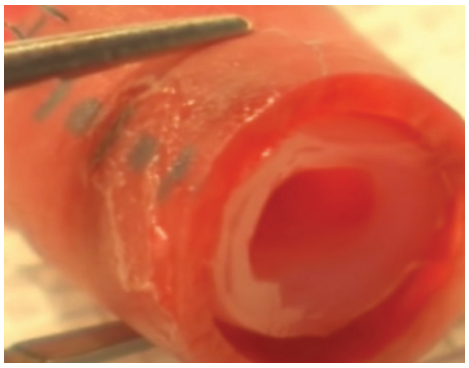
THE FOUR YEAR JOURNEY:
RESEARCH ACCOMPLISHMENTS
FY16-FY19

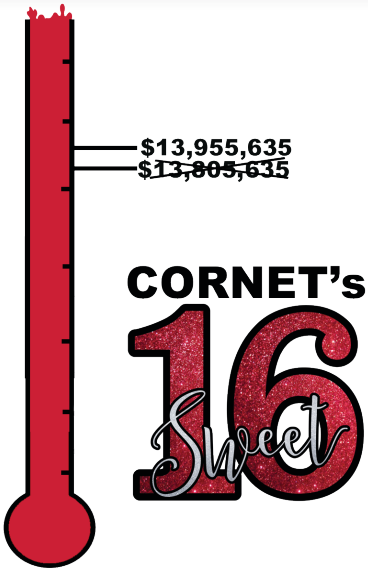
Allocation of Research Space Plan
2016

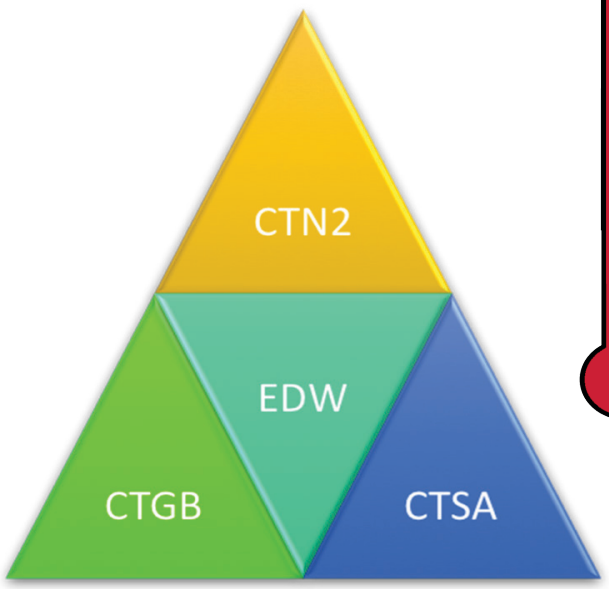


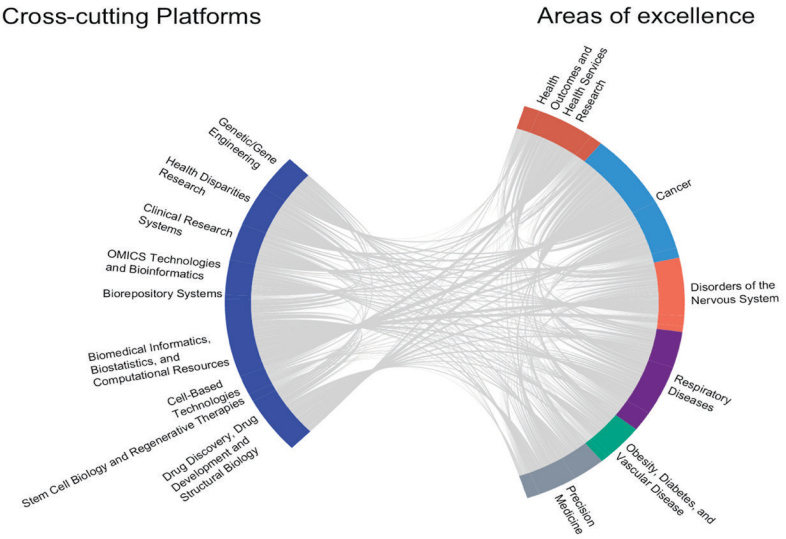
Institutional Research Core Facilities Analysis and Activities Reports

(July 2017-June 2018)

THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER







Legend:
Data sources: Grant proposals and Scopus articles from 2010 to present. Link width: represent the number of authors in common between sub-areas. Area width represents sum of link widths.

THE UNIVERSITY OF TENNESSEE
HEALTH SCIENCE CENTER

OFFICE OF RESEARCH

From the Vice Chancellor

It seems incredible to me that it has been four years since I joined the University of Tennessee Health Science Center, in late July 2015, as Vice Chancellor for Research. Upon my arrival, it was clear that there was a great deal that needed to be accomplished to reach our Institutional Research goals. There needed to be a shared vision for the research enterprise; improvement and sometimes creation of infrastructure; hiring key Associate Vice Chancellors; right-sizing the Office of Research staff; and creating a more interdisciplinary, interprofessional, and entrepreneurial environment.

The first major step was the creation of the UTHSC Operational Strategic Plan for Research (OSPR). Written by UTHSC research faculty leaders from all six Colleges and three campuses, the OSPR provided a shared vision and a five year blue print for implementing that vision. Accomplishing a shared vision requires strong buy-in from stakeholders at all levels, leadership that perseveres in the face of challenges that are inevitable, a mechanism that allows for modifications of the OSPR as opportunities arise, and people who are willing to roll up their sleeves and go to work. We have had all of these elements present in my first four years at UTHSC. Therefore, we have witnessed tremendous Institutional Research Accomplishments in this four year period, which are the focus of this booklet. We, of course, could not list all accomplishments in this short discussion. There have also been wonderful research accomplishments made in individual Colleges and departments, which are not the subject of this booklet.

As you will see in this booklet, the strides that have been made in four years have placed us in a position to realize the UTHSC goal of doubling research in ten years. More importantly, it will allow our UTHSC faculty to accelerate the process of "improving the Health of Tennesseans, the Nation and the Global Community."

This Vice Chancellor for Research and his team will do everything in our power to help the UTHSC Administration and faculty reach these shared goals.

Steven R. Goodman, PhD
Vice Chancellor for Research

Hire of Senior Associate Vice Chancellor for Research and OSPR Planning and Implementation

Dr. Steve Goodman was hired as Vice Chancellor for Research effective July 2015. Dr. Goodman hired Steve Youngentob, PhD, who became Senior Associate Vice Chancellor for Research effective September 2015.

Production of the Operational Strategic Plan for Research (OSPR) began in August 2015 when Dr. Goodman charged an OSPR Committee led by Governor's Chair Robert Williams, PhD, and Dean of the College of Nursing Wendy Likes, PhD, DNSc, ARNP-BC, FAANP.

The OSPR Committee composed of 25 leading researchers from multiple UTHSC departments, Colleges and campuses prepared an outstanding detailed five-year blueprint to grow and strengthen the UTHSC Research Enterprise. The six Areas of Excellence within the plan are Cancer; Obesity, Diabetes and Vascular Disease; Disorders of the Nervous System; Respiratory Disorders; Precision Medicine; and Health Outcomes. The underlying theme of the OSPR is that we will be stronger as a Health Science Center if we build teams of interdisciplinary researchers, who cross Colleges and campuses, and work together on research programs within these Areas of Excellence and their specified Focus Areas.

All sections of the OSPR were vetted multiple times by the OSPR Committee, the Research Council, and the Faculty Senate Research Committee, and the document received final approval from UTHSC Chancellor Steve J. Schwab, MD, on August 22, 2016. Implementation of the OSPR is being led by the VCRs Research Cabinet that is composed of thirty research leaders coming from all six UTHSC Colleges and four campuses.

Dr. Goodman divided the VCR's Research Cabinet into eight Implementation Teams each defining, for their specific area, what portions of the OSPR need to be implemented over the first two years. By the end of FY18, virtually all of the goals set forth by the Implementation Teams had been successfully accomplished.

The Implementation Teams have created a new set of goals for years three and four, and we are now tracking the completion of those goals based on the OSPR.

The CORNET Awards

Shortly after arriving at UTHSC in 2015, Vice Chancellor for Research Steve Goodman created the Collaborative Research Network to provide UTHSC faculty with a new platform to create research partnerships across disciplines, Colleges, Universities and nations. Using an acronym for the Collaborative Research Network (CORNET), Dr. Goodman provided the first CORNET Awards in 2016 based on short peer reviewed proposals from teams of scientists.

Since the inception of the CORNET Awards, funded CORNET collaboratives include:

- **Cross-college:** Bringing together UTHSC faculty from different UTHSC colleges
  - 2016: 47 applications, 9 funded
  - 2017: 41 applications, 6 funded
- **Clinical:** Teaming up UTHSC clinicians with other UTHSC clinicians and/or basic scientists
  - 2017: 29 applications, 4 funded
- **Cross-System:** Creating collaborations between faculty from multiple UT System institutions
  - 2017: UT - Cancer
    - 20 applications, 3 funded
- **Regional:** Facilitating team research between faculty from UTHSC and other Mid-South universities
  - 2016: UTHSC/University of Arkansas for Medical Sciences - Substance Abuse
    - 1 application, 1 funded
  - 2017: UTHSC/University of Arkansas for Medical Sciences - Cancer
    - 10 applications, 4 funded
  - 2018: UTHSC/University of Mississippi Medical Center/Tulane University - Health Disparities
    - 11 applications, 2 funded
- **Global:** Pairing faculty from UTHSC and international universities/hospitals
  - 2017: UTHSC/Harbin Medical University (China) - Cancer, Vascular Disease, Diabetes, and Epidemiology
    - 7 applications, 3 funded
  - 2018: UTHSC/West China Hospital/Sichuan University (China)- Regenerative Medicine
    - 4 applications, 2 funded
  - 2018: UTHSC/Ghana Health Services, Korle-Bu Teaching Hospital, H3Africa/UMC Utrecht, the Netherlands - Preeclampsia
    - 1 application, 1 funded
- **Industry:** Building research relationships between UTHSC faculty and industry partners. Aimed not only at acquiring extramural funding but also spin-off companies, patents, and IP.
  - 2017: UTHSC/UTRF/Southern Research (Birmingham, AL) – Drug Discovery and Development. Aims to launch drug discovery programs that are based on new and unique biology of disease that will fill significant unmet medical needs.
    - 11 submitted, 2 funded

To date, the CORNET Awards have provided over $1.5 million in funding to support new collaborative research teams and their projects.

CORNET ROI CONTINUES TO RISE

CORNET IMPACT

46
CORNET AWARDS GIVEN SINCE 2016

>$2 MILLION
AWARDED FROM ALL PARTNERING INSTITUTIONS

>$1.5 MILLION
AWARDED FROM UTHSC OFFICE OF RESEARCH

16
EXTRAMURALLY FUNDED GRANTS STEMMING FROM CORNET WORK
WORTH ~$14 MILLION

~9 FOLD
RETURN ON INVESTMENT

Phil Cestaro
CTN2 Executive Director

The Clinical Trials Network of Tennessee

CTN2 stands for the Clinical Trials Network of Tennessee, and is the vision of Vice Chancellor for Research Steve Goodman who serves as its President and CEO. CTN2 was created as a site management organization (SMO) to enable UTHSC clinical faculty researchers to design, solicit, and conduct robust statewide clinical trials at multiple partner Hospitals and Practice Plans throughout the State of Tennessee. The goal was to provide new therapies for patient care, research opportunities and education.

We also created CTN2 as a Subsidiary of the University of Tennessee Research Foundation (UTRF) to allow UTHSC to get credit for clinical trials conducted by its faculty.

The Executive Director of CTN2 is Phil Cestaro and the Medical Director is Ari VanderWalde, MD, MPH, MBioeth.

CTN2 also has specialists in contracting and billing, utilizing UTHSC's Enterprise Data Warehouse (EDW), and will often utilize a free standing IRB. It will be able to do business at the speed of Industry.

Just one year into operations, CTN2 has numerous studies both underway and in the pipeline. Two clinical trials are open and enrolling patients: a phase II trial in colon cancer and another building an outcomes registry for heart transplants. More than seven therapeutic studies are preparing to launch: phase I trials in advanced malignancies and oral premalignant lesions; phase II trials in heart failure; and phase III trials in bladder cancer, heart failure, and cardiomyopathy. A separate phase III study is forthcoming in ophthalmology. In addition, CTN2 is spearheading research and data mining projects into the procurement of human biospecimens and post-market surveillance for medical device implants.

The innovative CTN2 network is a unique asset to Tennessee residents, and as CTN2 grows, it will be a boon to public health and health care access. With affiliated practices and hospitals across the entire state, citizens in every region now have the opportunity to participate in CTN2 studies and reap the benefits of clinical research. Historically, Tennesseans have been underrepresented in large-scale studies leading to drug approval. CTN2 also affords state residents potential access to effective medications prior to wide approval.

The Clinical Trials Governance Board

Vice Chancellor for Research Steve Goodman and Chancellor Steve Schwab created the Clinical Trials Governance Board (CTGB) in 2016 as a Federated model to coordinate the multiple Clinical Trials Offices across UTHSC. The goal of the CTGB is to support and grow clinical research by promoting access to resources and opportunities for investigators and faculty throughout the UTHSC system.

CTGB represents established clinical research offices on all campuses and aims to provide a fully integrated model of developing and sharing best practices for clinical research. CTGB coordinates with various Clinical Research Offices to ensure adequate provision of services and resources to all UTHSC affiliated investigators to improve quality, efficiency, and regulatory compliance of the conduct of clinical trials.

The CTGB is led by Ari VanderWalde, MD, MPH, MBioeth (Chair) and Karen Johnson, MD, MPH (co-Chair). Dr. VanderWalde also serves as the Associate Vice Chancellor for Research- Clinical Research.

The broad representation and expertise of the CTGB members can be seen below.

CLINICAL TRIAL OFFICE OR STAKEHOLDER	REPRESENTING MEMBER
Office of Clinical Research	Ari VanderWalde, MD (Chair)
Preventive Medicine Clinical Research	Karen Johnson, MD (co-Chair)
Office of Research	Steven Goodman, PhD
Clinical Research Center	Samuel Dagogo-Jack, MD
CFRI Clinical Research (Le Bonheur)	Dennis Black, MD
Nephrology Clinical Research Unit	Csaba Kovesdy, MD
University Clinical Health	Penny Asbell, MD
College of Dentistry Clinical Research	Franklin Garcia-Godoy, DDS
College of Medicine	Teresa Hartnett, PhD
College of Nursing	Ansley Stanfill, PhD, RN
Center for Biomedical Informatices	Robert Davis, MD
St. Thomas Research Institute (UT Nashville)	Evilio Rodriguez, MD
Erlanger Hospital Research Institute (UT Chattanooga)	Thomas Devlin, MD
University Mecial Center/ UTGSM (UT Knoxville)	Mitchell Goldman, MD

Dr. Ari VancerWalde
CTGB Chair

Dr. Karen Johnson
CTGB co-Chair

The Delta CTSA and TN-CTSI

The UTHSC Research Council approved a new approach for our Clinical and Translational Science Award (CTSA) applications. Led by Vice Chancellor for Research Steve Goodman, we have assembled a Delta Consortium CTSA group that includes UTHSC, Tulane University, and the University of Mississippi Medical Center.

The Delta CTSA proposal is a multi-PI application with PIs coming from each partner Institution. Based on our patient population in the Delta region, the focus of the application is Health Disparities in underserved populations. The UTHSC PIs are Karen Johnson, MD, MPH, and Michelle Martin, PhD. CTN2, the EDW, and the CTGB will all be critical to the application.

Each partner in the Delta Consortium has its own Clinical and Translational Science Institute (CTSI). Drs. Johnson and Martin direct the Tennessee Clinical and Translational Science Institute (TN-CTSI) which has the following goals:

- Innovative research training and career development
- Improve the efficiency and quality of clinical and translational research
- Promote team science
- Partner with the community stakeholders
- Provide pilot funding
- Provide services to promote clinical and translational science
- Maintain the Relationship between CTSA, CTN2, EDW, and CTGB

UTHSC
TENNESSEE CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

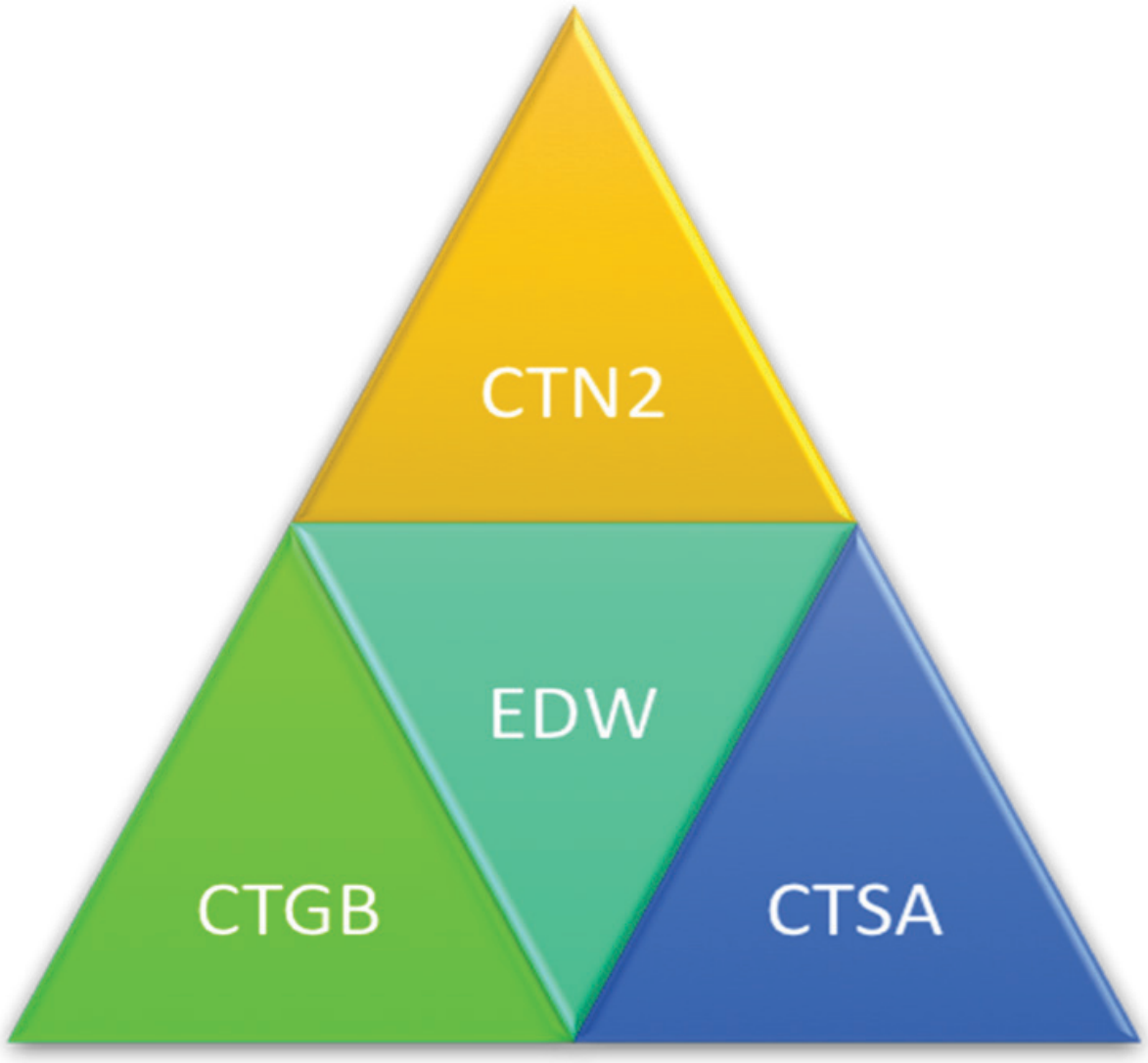
DELTA CTSC
Delta Clinical and Translational Science Consortium

The Enterprise Data Warehouse

Central to the development of our vision for UTHSC Clinical Trials is the development of the Enterprise Data Warehouse (EDW) by Robert Davis, MD, Director of the Center for Biomedical Informatics (CBMI) and Governor's Chair. Dr. Davis is developing the EDW with partner hospitals, who sign a Data Use Agreement with UTHSC, and after approval by our IRB that all data is being handled in a HIPAA compliant manner.

The enormous amount of data being collected in electronic medical records (EMR) creates additional clinical and research value when extracted, transformed and loaded (ETL) in research enterprise data warehouses (EDWs) that extend beyond a single facility's walls. When utilized at scale, this "big data" is currently transforming healthcare nationwide by, for example, enabling providers and researchers to use population data in identifying and preventing diseases, and developing treatments through the conduct of large-scale clinical trials with greater statistical power and precision.

As the reader will surmise from the pages prior, the EDW is the centerpiece for the function of the CTSA, CTN2 and CTGB, and our vision for UTHSC Clinical Trials as shown in the graphic below.



Research Institutes

The OSPR defines Research Institutes and Centers saying, "Research Institutes and Centers are critical to the development of interdisciplinary research at UTHSC. Research Centers will be comprised of faculty from within a Department or across multiple Departments within a College. Research Institutes will be comprised of faculty from multiple Colleges, and often multiple campuses within UTHSC, and may include other institutions. These Research Institutes and Centers are catalysts for interdisciplinary team research leading to large Center and Program Project grant applications and awards."

The following Research Institutes were established during the period of FY16 through FY19:

The Institute for the Study of Host Pathogen Systems (ISHPS) with Colleen Jonsson, PhD, as Director, has synergized infectious disease research among an interdisciplinary group of faculty across the UTHSC enterprise. Dr. Jonsson was recruited to UTHSC to direct ISHPS and the Regional Biocontainment Laboratory (RBL). Recently ISHPS and the RBL has received a $23 million NIH U19 award, with Dr. Jonsson as the PI. The abstract of this impressive award says, "the goal of our U19 Center of Excellence for Encephalitic Alphavirus Therapeutics program is to advance the discovery and development of potent small molecule, replication inhibitors as antiviral drug candidates targeting Venezuelan equine encephalitis virus (VEEV), Eastern equine encephalitis virus (EEEV) and Western equine encephalitis virus (WEEV)."

The Tennessee Clinical and Translational Science Institute, explained in prior pages, is co-led by Dr. Karen Johnson and Dr. Michelle Martin. The TN-CTSI's goals are: "innovative research training and career development, improve the efficiency and quality of clinical and translational research, promote team science, partner with community stakeholders, provide pilot funding, and provide services to promote clinical and translational science."

The Memphis Consortium for Sickle Cell Disease and Classical Hematology Research (MCSCDCHR) is a Consortium without walls, and with representation from all participating institutions: UTHSC, UT-Methodist University Hospital, Regional One Health, and St. Jude Children's Research Hospital. The Goals of MCSCDCHR are: 1) to develop collaborative sickle cell research among all participating Memphis institutions, and 2) to create standardized evidenced-based clinical care across participating institutions that will support clinical and translational research. Dr. Kenneth Ataga, MD, a leading clinical trialist in the area of Sickle Cell Disease was recruited to direct the MCSCDCHR.

The Transplant Research Institute (TRI) (created in 2018) was the vision of James Eason, MD, founder and program director of the UT/Methodist Transplant Institute and professor and chief of the Transplant Division in the College of Medicine at UTHSC, directed by Valeria Mas, PhD. Dr. Mas is director of Transplant Research for the UT/Methodist Transplant Institute and has brought an outstanding Team of Transplant researchers to UTHSC.

The UT Methodist Cardiovascular Institute was created in 2018 to develop world class clinical care in cardiovascular medicine and offer clinical, educational, and research programs in this area. John Jefferies, MD, is co-Director of the Cardiovascular Institute and is responsible for the educational and clinical programs, while Zhongjie Sun, MD, PhD, is another co-Director responsible for the research efforts.

The Memphis Institute for Regenerative Medicine (MIRM) with James Kang, PhD, serving as Executive Director, and Gabor Tigyi, PhD, as Deputy Director, was established in 2017. MIRM has brought together the expertise of the University of Tennessee Health Science Center, the University of Memphis, St. Jude Children's Research Hospital, and Industry Leaders (Revotek, Medtronic, FedEx Biologistics) to perform basic, clinical and translational research in the areas of stem cell biology, 3D bioprinting, tissue engineering, and global transportation of bioprinted tissues. The goal is to translate scientific discovery into new organ repair and replacement therapies for people suffering from organ damage. We have recruited the world leader in production of 3D bioprinted blood vessels, Revotek International, to Memphis, where they are producing blood vessels that will be utilized in the coming months for the first FDA approved human trials of stem cell derived bioprinted blood vessels. The blood vessels are being produced in the Plough Center for Sterile Drug Delivery at UTHSC, and the human trials will be conducted via the Clinical Trials Network of Tennessee (CTN2). Dr. Kang, CEO and Scientific Director of Revotek USA, has been recruited as a part time faculty member at UTHSC, along with his colleague Dr. Wenjing Zhang who is a full time faculty. Currently there are over sixty MIRM members coming from UTHSC, St. Jude Children's Research Hospital, University of Memphis and Industry partners. With money provided by the Memphis Research Consortium, they are focused on four innovative projects:

- *Project One: Novel 3D Biofabrication Methodologies and Manufacturing for Enhanced Tissue Regeneration and Implantable Devices;*
- *Project Two: Cell Interactions with 3D Bioprinted Vessels – Basic and Translational Approaches;*
- *Project Three: Regenerative Strategies in Osteoarthritis Using Adipose-derived Stem Cells; and*
- *Project Four: Gene Editing of Hematopoietic and Cancer Stem-like Cells.*

Entrepreneurship

Vice Chancellor for Research Steve Goodman appointed Dr. Gabor Tigyi as the Associate Vice Chancellor for Research-Industry Relations and Global Partnerships. Some of Dr. Tigyi's accomplishments include: Developing the CORNET with Southern Research, discussed in the previous pages; Developing CORNET grant programs with West China Medical University and monitoring the progress of the CORNETs with Harbin Medical University; helped establish clinical trials of Innolife Ltd. through CTN2; assisted in bringing Revotek Inc. to the Plough Center, led the establishment of a UTHSC Drug Discovery Focus Group; worked on launching the UTHSC-ORNL-Drug Discovery and Development (D3) collaboration; helped to establish the UTHSC Startup Incubator Program, and the competitive awarding of the Innovation lab to UTHSC faculty developing their spin-off companies.

As UTHSC's new Associate Vice Chancellor of Research and Entrepreneurship, Steve Bares, PhD, is responsible for working with UTRF Vice President Richard Magid, PhD, to develop training programs/seminars on intellectual property development, patent filing, and marketing of IP, and the nuts-and-bolts of launching startup companies. Dr. Bares has helped create the Office of Research's new UTHSC LEADS (Launching Entrepreneurial Activities and Discovery in Science) seminar series. Dr. Bares works with faculty to attract grants that drive their entrepreneurial efforts forward. For example, he supported the entrepreneurial and product development portion of the previously mentioned ISHPS U19 award.

Phil Cestaro has taken on the new role of Associate Vice Chancellor of Research and Business Development. At UTHSC, Cestaro helped write the business plan for the Clinical Trials Network of Tennessee (CTN2). He is also Executive Director of CTN2, creating a centralized budgeting and contracting process, and providing business oversight for this 501(c)(3) wholly owned subsidiary of UTRF. Phil Cestaro is also charged with bringing external industry users for our Institutional Research Cores.

Bares and Cestaro also worked alongside Dr. Richard Magid, Dr. Gabor Tigyi, and Dr. Goodman to create the UTHSC Innovation Lab opportunity.

Dr. Gabor Tigyi
AVCR- Industry Relations and Global Partnerships

Dr. Steve Bares
AVCR- Entrepreneurship

Phil Cestaro
AVCR- Business Development

The Office of Scientific Writing

Dr. Goodman established the Office of Scientific Writing in 2017. The Office of Scientific Writing was designed to assist research faculty, postdoctoral fellows, and students in the writing of successful research grants and scientific manuscripts. The office supports the research faculty on UTHSC's Memphis, Nashville, Chattanooga, and Knoxville campuses. The investigator must provide a first draft of a manuscript or Research Proposal portion of a grant application to the Office of Scientific Writing to initiate the process.

The Director of Scientific Writing, Amanda Clarke, PhD, provides investigators with editorial services, as well as assistance with specific aims development; concise project descriptions and project narratives development; and educational resources. The Director also provides expertise for improving the clarity and cogency of manuscripts and grant applications.

The Office of Research Development

In October 2015, Dr. Goodman established the Office of Research Development (ORD) with Lisa Youngentob as its Director. The ORD oversees the announcement and review of all intramural grants, including Bridge Funding, New Grant awards, and CORNET awards. The office also provides targeted information to faculty on available grant opportunities through Elsevier's Funding Institutional platform, and provides grant-consulting services via Hanover Research. This office is also responsible for the announcement and internal review of Limited Submission opportunities.

The Office of Research Communications and Marketing

In March 2016, we opened the Office of Research Communications and Marketing. Sarah Bloch serves as Director. The office increases awareness of the goals and mission of the Office of Research by fostering excitement for creativity, innovation, and scholarship. Mrs. Bloch's team shares valuable information with the UTHSC research community as well as communicates the ways in which UTHSC research shapes knowledge, advances science and technology, and improves the wellbeing of Tennesseans, the Nation, and the world.

Specifically, the office is responsible for producing The Research Rainmaker and all other documents such as the OSPR, Core Business Plans, Allocation for Research Space Plan, CTN2 Plan, etc. It is also responsible for creating and managing the Office of Research's website, social media platforms, and messaging. Moreover, Sarah's team organizes the VCR's Distinguished Lecture Series, Hot Topics in Research, UTHSC LEADS, HSE Grand Rounds, and various other workshops and conferences.

Dr. Aaron Ciechanover, 2004 Nobel Laureate
VCR Distinguished Lecturer, Spring 2018

The VCR's Distinguished Lecture Series

From "basic research," involving the explanation of more fundamental scientific principles, to clinical research, which is distinguished by the involvement of patients, the Office of Research strives to keep the UTHSC community abreast on the world's most pressing research topics. One way we honor this commitment of creating a more robust research environment is by offering educational seminar series such as the VCR's Distinguished Lecture Series.

Designed by Vice Chancellor for Research Steve Goodman, the VCR's Distinguished Lecture Series aims to bring prestigious leaders in the field of biomedical research to the institution so they can share their knowledge and expertise with the university. Invited speakers typically spend two to three days on UTHSC's campus, interacting with faculty and administration, and delivering a scientific lecture.

Since 2016, the Office of Research had the honor of welcoming over twenty prominent investigators ranging in expertise from T0 to T4. Dr. Goodman has hosted members of the National Academy of Science and Aaron Ciechanover, MD, DSc, Israeli Biochemist and 2004 Nobel Prize winner who helped define the mechanisms by which proteins are degraded in our cells.

UTHSC LEADS Seminar Series

In Fall 2017, Dr. Steve Bares and Lisa Youngentob helped to create the Office of Research's UTHSC LEADS (Launching Entrepreneurial Activities and Discovery in Science) Seminar Series. The series is designed to bring successful and engaging entrepreneurial scientists involved in biotech, life sciences, Pharma and device sectors to UTHSC, so that they may relay their "entrepreneurial stories" to our faculty, staff, and students. Specifically, UTHSC LEADS focuses on speakers who have taken an idea from "bench-to-bedside", connecting research done in the laboratory to develop new ways to treat patients.

LEADS has featured four speakers thus far: Samuel E. Lynch, DMD, DMSc, current Chairman and CEO of Lynch Biologics, LLC, who hosted a compelling conversation with a packed auditorium on the successes and struggles of moving research from 'Benchtop to Bedside'; Amy L. Hester, PhD, RN, BC, co-founder of HD Nursing, LLC, whose area of research focuses on falls and injury prediction and prevention across the continuum of care; Todd D. Giorgio, PhD, PE, who spoke on "Academic Research and New Company Formation: Inspirations and Obstacles;" and most recently and most recently Mr. Tim Brahm, Founder of BioD, LLC, and Chief Executive Officer of Ontologix, who spoke on "An Entrepreneur's Journey in Developing and Commercializing Novel Biologic Products: The BioD Story."

Allocation of Research Space Plan

Laboratory space is a valuable and limited resource that is essential to UTHSC reaching research goals. As such, meeting both the current and future needs of the University's biomedical research program required a process for optimal usage of research space.

Under the auspices of the Office of Research, a committee with broad faculty representation developed an Allocation of Research Space Plan, which was subsequently adopted by Research Council in 2016. This plan provided an open and transparent process that now guides the assignment, solicitation, and usage of space based on clear metrics. Key features in determining the allocation of research space to a faculty member are a rolling three-year average of extramural funding, the type and scope of their research, as well as the building where it is conducted. Faculty metrics, in turn, are collectively used to determine a space allocation metric for their respective college.

Working with Andrea Kolen (Space Planning and Utilization) and Lawson Culver (Electronic Research Administration), Dr. Steve Youngentob oversaw the development of a process of bringing together the detailed space, funding, and faculty and staff information required for the determination of the space allocation metrics.

In order to provide continual performance transparency, beginning with the close of FY16, Deans were provided a yearly assessment of the departments in their college's standing relative to the space metrics. Importantly, in order to assure the most efficient and effective alignment of space with the research mission of the campus, the space allocation plan provided for a review, and possible reallocation of space, on a triennial basis. As FY16-18 represented the first three years that research space metrics were monitored and reported to the colleges, with the close of FY18, a draft of the first triennial research space review was written. These drafts were, in turn, provided to the various colleges for their review, and suggested corrections, where applicable.

Experience with the FY16-18 data resulted in a number of modifications to the 2016 plan, and adjustments to the procedures used in calculating the space metrics. The inaugural triennial review data were provided to the Chancellor in early 2019.

Institutional Research Cores

Institutional Research Cores were originally defined by the Operational Strategic Plan for Research as shared resources that are widely used among UTHSC faculty, preferably across multiple Colleges and Departments. In FY 2016, Dr. Goodman appointed Tiffany Seagroves, PhD, to the position of Associate Vice Chancellor for Research– Research Cores. Then seven campus cores were recommended by the Vice Chancellor for Research's Research Cabinet to become institutional core facilities, and this was accepted by the Vice Chancellor for Research. The seven Institutional Research Cores included: the Lab Animal Care Unit (LACU), the Regional Biocontainment Laboratory (RBL), the Molecular Resource Center (MRC), the Flow Cytometry and Cell Sorting Core (FCCS), the Molecular Bioinformatics Core (MBC), the Proteomics and Metabolomics Core (PMC), and the Research Histology Core (RHC). Since that time, a Medicinal Chemistry (MedChem) Core and, in collaboration with the Department of Pediatrics, a Metabolic Phenotyping Mass Spectrometry (MPMS) unit of the PMC have been added.

Using a business model approach, Drs. Seagroves, Youngentob and Goodman established a structured oversight of these core facilities and optimized their operations. Briefly, internal service fees were set based upon market evaluation in which pricing for services were compared among our peer academic institutions and set to be in the bottom-third to bottom-half of internal prices of our peers. Further, the cores are now managed using three-year *pro forma* business plans to develop core budgets, and to use data-based metrics to measure core success on a yearly basis. Each year, Dr. Seagroves, working with core Directors and Business Managers, summarizes core success in an annual research cores performance report.

Creating a Unified Office of Sponsored Programs

One strategic goal outlined in the OSPR was the unification, under the Office of Research, of all existing pre- and post-award functions, as well as additional activities directly related to the research enterprise. This unification process was also focused on both right-sizing the UTHSC office, as well as the development of collaborative sponsored programs offices at the Knoxville, Chattanooga and Nashville regional campuses. In so doing, the UTHSC Office of Research, in conjunction with other newly developed services, would provide support for all activities associated with an agreement, grant or clinical trial life cycle (e.g., identify research funding sources, grant writing, proposal editing services, proposal development and submission, award management, specialized contracting, and compliance).

In May of 2017, sponsored programs staff previously under Finance were transferred to a newly created unified Office of Sponsored Programs (previously Grants and Research Agreements). The campus, in turn, was informed about the consolidation of services and the specific activities that were moved from the Office of Finance to the Office of Research. Briefly, all research related processes previously administered by Sponsored Projects Accounting now fall under the aegis of the unified Office of Sponsored Programs. Further, additional research specific related activities, of note, that have moved to the new unified office include Data Use Agreements, Equipment Release Requests, and Research Agreements.

The unification process crafted by Dr. Steve Youngentob centered around a team-based approach, thereby creating an economy of scale, and providing the opportunity for enhanced communication among personnel, and increasing efficiency. A new and highly experienced Associate Vice Chancellor for Research– Office of Sponsored Programs, Sarah White, EdM, was also hired as well as additional Contracts Administrators and Grants Administrators. The unified office also developed new procedures governing its function. Taken together, these changes have enhanced communication with sponsors and faculty, thereby improving both customer service and performance.

For contracts executed in the first quarter of calendar year 2017, and prior to the unification process and hire of the new Associate Vice Chancellor for OSP, the average number of days to close a contract (across all non-grant instruments) was 81.9 days. At the close of the third quarter of 2019, contract turnaround time, averaged across all instrument types, was 55.9 days. Specific examples underlying the overall performance, for the same time frame, include the execution of Subawards (60.2 vs 65.0), Clinical Trials (176.7 vs 81.1 days) and MTAs (85.1 vs 27.7 days). The obvious improvement in performance notwithstanding, these metrics stand the test relative to outside benchmarks.

Regarding Subawards, the Federal Demonstration Project recently performed an analysis of data provided by 107 institutions. On average, it required 91 days to complete the subaward process. In a similar manner, data from an observational study of contract processing at 29 CTSA sites showed that the time for full execution of a clinical trial was, on average, 103 days.

Finally, a 2011 MTA survey performed by the AUTM Foundation showed that for MTAs processed by academic and non-profit institutions, 29% were completed in >30 days, and 71% were completed in one month or less. Thus, on balance, the unified office has dramatically improved turn-around time and is performing equal to or better than available benchmarks.

Dr. Steve Youngentob
Sr. Associate Vice Chancellor for Research

Sarah White
AVCR- Sponsored Programs

Laboratory Animal Care Unit

The quality of the Laboratory Animal Care Unit (LACU), a critical "Institutional Research Core," was a major infrastructure concern of the Operational Strategic Plan for Research. To remediate this important core, Dr. Steve Youngentob implemented a complete reorganization of its staffing and leadership. With the appointment of a new Director, David Hamilton, DVM, a re-derivation of all standard operating procedures, policies, and staff training practices followed.

A centerpiece of the reorganization process was the new requirement that all husbandry staff achieve a minimum level of AALAS (American Association for Laboratory Animals Science) certification appropriate for their position. The LACU staff are now 100% AALAS certified. Importantly, training toward these industry standard certifications has now become a routine part of the continual proficiency training in LACU. In this respect, the reorganization of the LACU also included the creation and hire of an Assistant Operations/Quality Assurance Manager, and a Training/ Quality Assurance Coordinator. These positions are responsible for the ongoing implementation and assessment of both initial and continued staff training, as well as facility quality assurance monitoring.

In the Spring of 2018, these enhancements to the program led to a three-year re-accreditation of the facility by AAALACi (Association for Assessment and Accreditation of Laboratory Animal Care International) with no mandatory findings for correction.

As part of a continuing program of facility improvement and efficiency, the LACU is training in Lean Six Sigma principles as part of its standard education process. These principles are being applied to specific workflow projects, purchasing practices, and determining other areas for increased efficiencies.

Institutional Biosafety Committee

Led by Mark Miller, PhD, the major accomplishment for the Institutional Biosafety Committee (IBC) was the transition from a paper to an electronic submission platform, using iMedris. This has significantly streamlined the submission and review process.

Dr. Mark Miller
IBC Chair

Research Safety Affairs

In order to facilitate a culture of customer service while promoting a safe research working environment, Dr. Steve Youngentob implemented a complete reorganization of the Office of Reseach Safety Affairs (RSA) leadership and staffing. With the identification and hire of a new Director, Mr. Tim Barton, new standard operating procedures, policies, and campus training practices that previously did not exist were established.

Under the leadership of the new Director, the office also achieved the necessary staffing complement, consisting of a Health Physicist, a Radiation Safety Officer, two Health and Safety Specialists, a Biosafety Officer, and an Administrative Data Coordinator. This overhaul was essential to establishing a viable program that ensured the development and delivery of safety, health, and environmental laboratory management program services directly related to the research enterprise.

To streamline effective safety training on campus, the office developed computer-based learning content for all basic safety courses. These courses are available to UTHSC personnel through Blackboard. To complement this computer-based training, practical hands-on training is now available, using a Mock Laboratory facility designed by Safety Affairs, to promote better learning outcomes among a diverse community of researchers. RSA also implemented the use of the Environmental Health and Safety Assistant database system to manage hazardous chemical inventory, radioactive material inventory, research personnel safety training records, exposure monitoring records and lab safety inspection records on campus.

Two additional key initiates directed at facilitating a culture of customer service were also completed. First, a network of Department Safety Coordinators was developed. These individuals are administrators from within each department that provide researchers and their laboratories with information from Research Safety Affairs, such as updates about new policies, common safety issues, equipment recalls, etc. Second, a new principal investigator and post-doc outreach program was created. This program provides critical safety orientation at the time individuals join UTHSC.

IACUC IMPROVMENTS

13 DAYS

AVERAGE TIME FOR PROTOCOL APPROVAL

With use of rolling Designated Member Review

1 ROUND AT MINIMUM

MANDATORY PRE-REVIEW PRIOR TO SUBMISSION

Fostering collaborative, quality protocols prior to submission

2 MONTHLY MEETINGS

EXPIDITING PROTOCOL REVIEW AND APPROVAL

1 GOAL:

PROMOTE RESEARCH

By enhancing regulatory compliance, and streamlining the submission and review process

Institutional Animal Care and Use Committee

In order to promote research while at the same time enhancing regulatory compliance, Dr. Steve Youngentob shepherded a process in which the Institutional Animal Care and Use Committee's (IACUC) Executive Committee (Drs. Youngentob, Steketee, Hamilton and Ms. Stabenow), in conjunction with the entire committee, made a number of critically needed policy-related and operational changes over the period of this report. First, the IACUC performed an extensive review of all existing policies that cover animal research activities at UTHSC, as well as developed new ones. This activity served two main purposes, namely, to ensure that IACUC policies do not create unnecessary self-imposed burdens on the research community, and to provide researchers with clear regulatory guidance related to their animal research activities. In addition, the IACUC initiated major procedural changes in the submission and review process of animal use protocols. The goal of these changes was to decrease the time required to obtain an approved IACUC protocol, and streamline the submission and review process in a manner consistent with that goal.

All newly proposed animal-related activities are now required to undergo, at least, one round of mandatory pre-review, prior to submission. Essential to this pre-review process, assigned reviewers and subject matter experts now interact collaboratively with investigators, in order to foster the development of a quality protocol prior to submission.

Further, the IACUC implemented the use of two IACUC meetings per month (i.e., every two weeks), and added the use of a rolling Designated Member Review (DMR) (i.e., two assigned reviewers who act on behalf of the committee), as a possible mechanism for protocol review. In this latter respect, for protocols that are nominated for DMR the committee is immediately polled for their approval rather than waiting to the next convened meeting.

The result of these cultural and functional changes has exceeded expectations, reducing the average time for protocol approval from 9.3 weeks to 13 days.

Three additional key improvements have been: (a) the removal of a cap on the number of additional non-USDA regulated animals that may be requested, during the three-year approval period of a protocol (each request must be scientifically justified); (b) the ability to develop SOPs that are reviewed and approved by the IACUC, thereby, eliminating the need to provide details during protocol development; and (c) the change to the iMedris protocol submission platform, along with the development of a new streamlined protocol submission form. This streamlined form now focuses on only the essential details required by regulatory bodies for the IACUC to determine the acceptability of a proposed animal use study.

In Conclusion

We are proud of our Institutional Research progress over the past four years. Changing a culture is never easy. It requires great creativity and will power, buy-in from the vast majority of stakeholders (Administration, Faculty, Staff and Students); a dedicated Office of Research Staff; the willingness to "stay the course" with the nimbleness "to change course" when opportunities arise. We were blessed with all of the above which allowed us to provide a clear Research Vision, a platform that allows successful implementation.

When I delivered my Research Town Hall presentation on September 26, 2016 on the UTHSC Operational Strategic Plan for Research, I had a slide entitled Underlying Principles which said:

1. Our mission, vision, and metric of doubling UTHSC funding will only be accomplished if we think institutionally when it comes to research;

2. the way to think institutionally is to increase collaboration among departments, colleges, and campuses when creating interdisciplinary and inter-professional research teams around focused areas; and

3. that we need to provide these interdisciplinary research teams with an infrastructure and the resources that will make them successful.

All of these ring true today, and the VCR and Office of Research Associate VCRs and Staff have dedicated ourselves to these Underlying Principles for the past four years. This booklet is a testament to the success of the combined efforts of the UTHSC Research Community and the Office of Research.

Steven R. Goodman, PhD
Vice Chancellor for Research

THE UTHSC IMPACT

The University of Tennessee Health Science Center (UTHSC) was founded in 1911. Our vision is to be the preeminent public research and teaching university linking the people of Tennessee to the nation and the world.

UTHSC improves human health through education, research, clinical care and public service. Offering a broad range of postgraduate and selected baccalaureate training opportunities, the main campus is located in the heart of the Memphis Medical District and includes six colleges – Dentistry, Graduate Health Sciences, Health Professions, Medicine, Nursing and Pharmacy. UTHSC educates and trains cohorts of medicine, pharmacy and health professions students – in addition to medical residents and fellows – at its campuses in Knoxville, Chattanooga, and Nashville. Patient care, professional education, and research also are carried out at more than 100 clinical and educational sites across Tennessee.

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