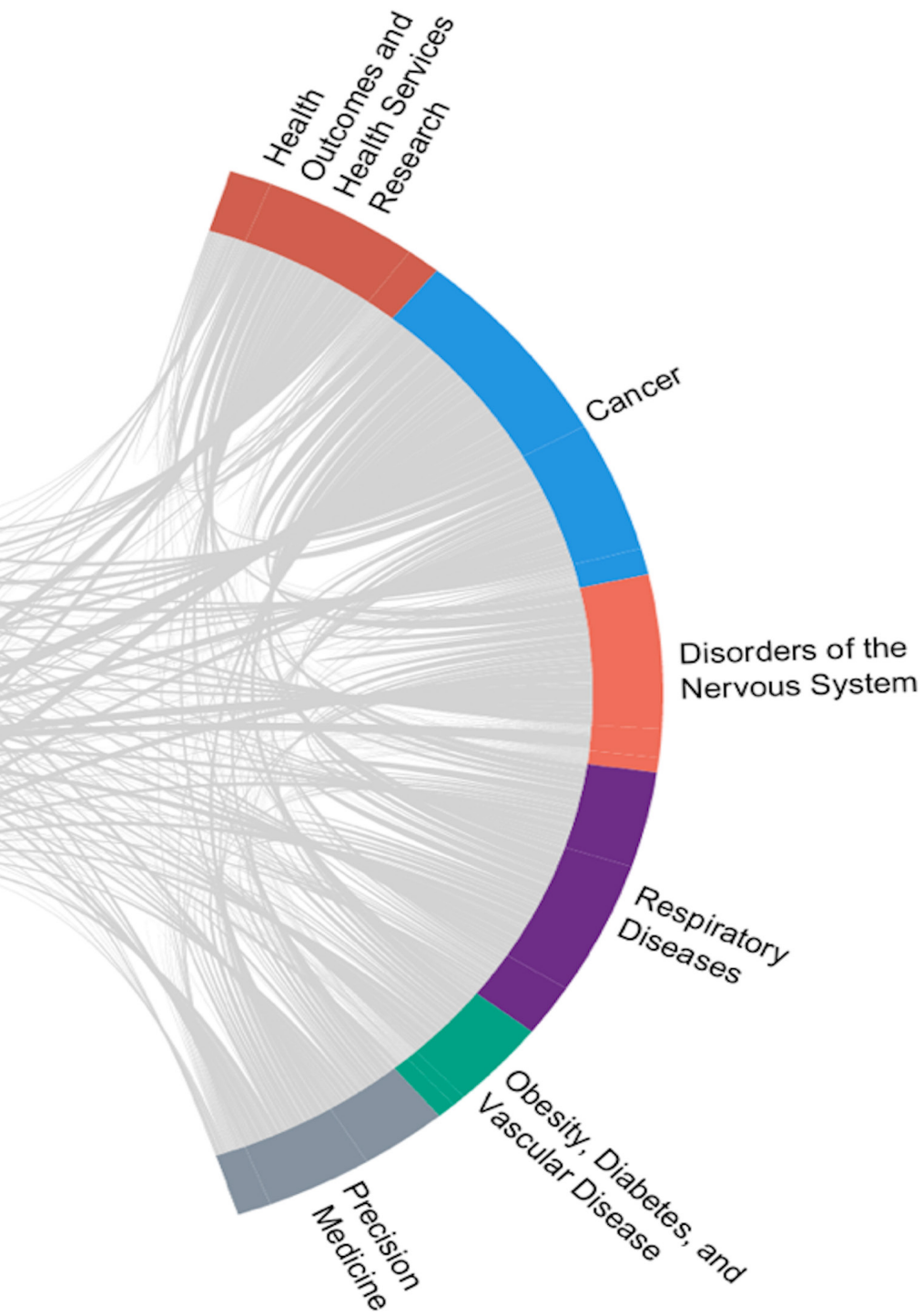
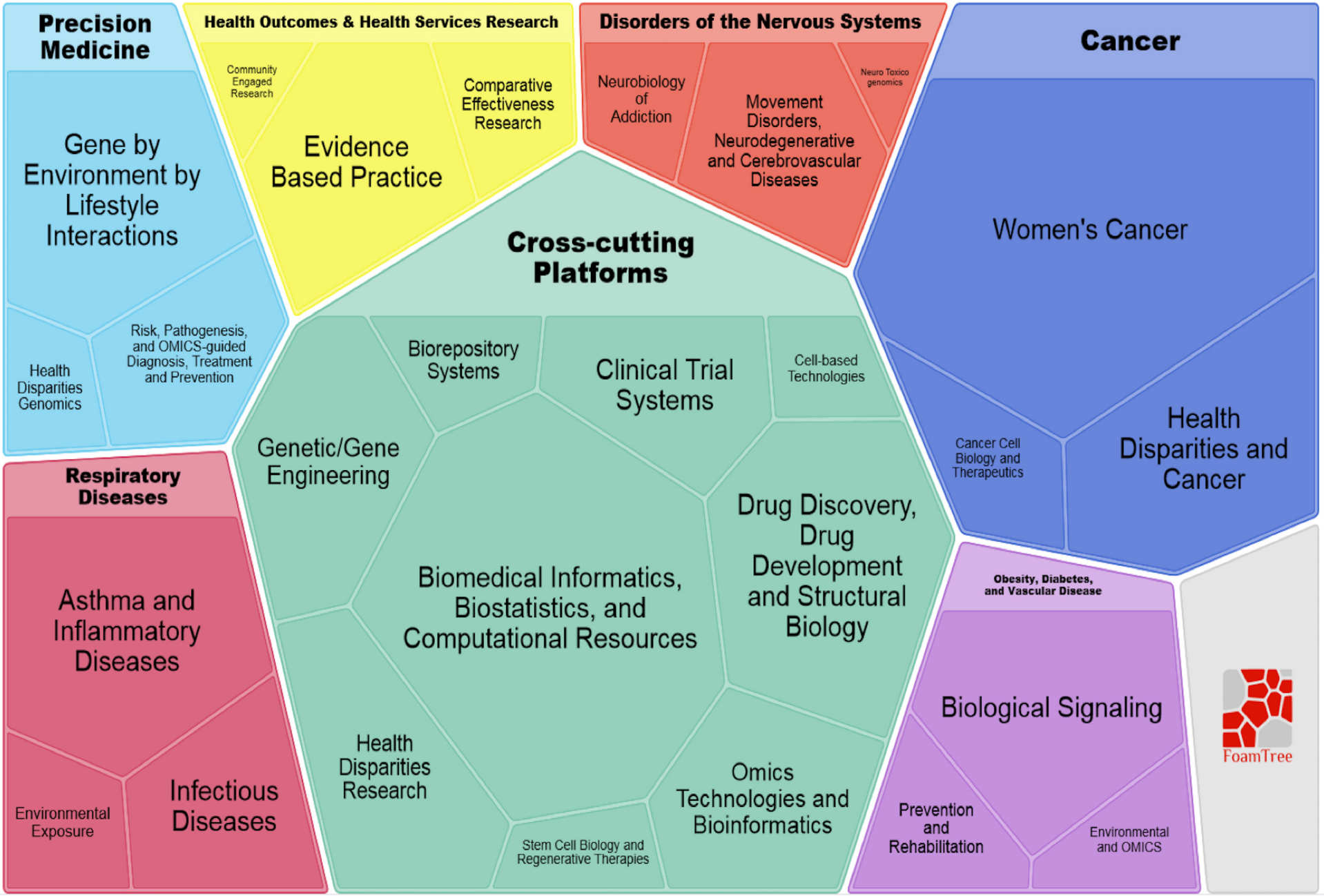
Areas of excellence



Operational Strategic Plan for Research

THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER



Legend:

Data sources: Grant proposals and Scopus articles from 2010 to present. Area size: represents the number of authors associated with each topic.

Node color: represents topic area. Areas of Excellence and the Cross-cutting platform labels are in bold.

Operational Strategic Plan for Research

Vision:

To become a world-class, interdisciplinary, and research-intensive health science center

Mission:

To cultivate and support scientific discovery, innovation, commercialization, and economic growth within the University of Tennessee Health Science Center and the State of Tennessee, with the dedication to improve the health of Tennesseans, the Nation, and the Global community.

Approved August 22, 2016

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1. Introduction

The University of Tennessee Health Science Center (UTHSC) has four campuses in Memphis, Knoxville, Chattanooga, and Nashville with research conducted at each. At UTHSC in Memphis there are six Colleges (Dentistry, Graduate Health Sciences, Health Professions, Medicine, Nursing, and Pharmacy) each of which has research as part of its mission. Therefore, the committee that wrote this Operational Strategic Plan for Research (OSPR) was composed of research leaders representing multiple UTHSC campuses and all Colleges. In addition, we had broad representation within the committee in terms of areas of research; and experts in basic, translational and clinical research. Furthermore, the writing groups that prepared the OSPR were composed of faculty within the OSPR committee, and subject matter experts from the UTHSC research faculty community, at large.

UTHSC is the leading State institution for research on the causes, treatment, and prevention of diseases. Our research mission is linked with a mandate to train health care professionals and to provide state-of-the-art clinical care across the State. We strive to do better and aim to be competitive at the highest levels. This 2016 Operational Strategic Plan for Research lays out a pragmatic and ambitious course of action that will systematically strengthen and grow research at UTHSC, and that will harmonize our work with our partner institutions over the next five years. The keys to success: Effective collaboration, efficient resource pooling, aggressive adoption and development of new methods and technologies, will all be described within.

Our efforts in writing this OSPR benefited greatly from work over the last decade, which had defined major Areas of Excellence and key areas for growth. The dynamic nature of biomedical research means that much of this plan is new, and radically redesigned. For example, rapid technological advances and intense competition now demand an emphasis on sophisticated and expensive core facilities operated by highly trained researchers. Large shifts in funding now encourage bench scientists, clinicians, and data scientists to work together intimately. This Plan calls for focused growth in the major Areas of Excellence described in the next sections. However these areas cannot stand alone, they need to work together using cross-cutting technologies and methods of analyses, encompassing studies of single molecules to large human populations. These Areas of Excellence must be intricately linked by bridges and frameworks to create an enhanced interdisciplinary environment.

The Plan has also been influenced strongly by major innovations and changes at the National Institutes of Health (NIH), our single largest source of funding for both basic and clinical research. There are several major new NIH initiatives on health care

disparities and effectiveness, on human brain diseases and cancer, and on the new fields of precision medicine, genomics, imaging, and "big data" science. Over the next five years, UTHSC will pivot toward some of these major federal initiatives (see *Turning Discovery into Health*: The 2016-2020 NIH Strategic Plan: https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf). You will see several examples in the pages that follow. At the same time, NIH and other funding agencies are demanding more complete data sharing, and higher levels of research integrity, fiscal and ethical oversight, and tighter compliance to ensure that resources are used to the fullest advantage. What this means is that the administrative support for high-powered research is becoming more complex and more crucial to success. To be a premier research institution demands not only highly qualified researchers and considerable resources, but also proficient administration. We need to make smart decisions that strengthen current efforts, and that catalyze new cross-cutting programs with high impact and growth. The pages that follow highlight much of our team's work to address these challenges, with an emphasis on building a consensus vision of how to move forward with, and improve research on all campuses and in all colleges.

The OSPR provides six UTHSC Areas of Excellence, some of which are current areas of strength, and others are emerging areas where we feel that it is important to develop strength. For each Area of Excellence, the OSPR describes three Focus Areas with details concerning needed expertise amongst potential future faculty hires, required core facilities and other needed infrastructure. The OSPR then goes on to describe, in detail, nine Cross-cutting Platforms which provide technologies and resources needed for the success of most, if not all, of the Areas of Excellence and Focus Areas. The document then describes how we should proceed with collaborations internally and externally; the infrastructure that is needed to make our faculty successful; Research Institutes and Centers which will be essential for the development of large interdisciplinary team oriented grant proposals such as program project and center grants; and finishes with what metrics and dashboards we will use to measure that success.

Health care and biomedical research are now woven together in ways that are having significant economic impact. For example, cutting-edge genetic testing and imaging is now part of standard health care. UTHSC research teams are engaging to an increasing degree with health care systems, corporate partners, non-profit agencies, state and local governments. We have special responsibilities to the citizens of the state of Tennessee. With local and state support, we will strive towards making Tennessee a powerhouse in medical research. The Memphis Research Consortium is just one concrete example. We have powerful partners across the State—from The Oak Ridge National Laboratory to St. Jude Children's Research Hospital, and from our sister campuses to our major hospital partners, such as Methodist Le Bonheur Healthcare System, Memphis Veterans

Administration, and West Cancer Center. We are poised to do great things. This Strategic Plan is intended to help define the pertinent processes and directions we need to implement to achieve our ambitious goals.

This plan is intended to be used as a guide for researchers and administrators over the next five years. The faculty and administrators who contributed to this plan recognize that we need to be prepared to make rapid operational changes, to seize or make opportunities, from the level of individual researchers to entire colleges. What will be critical in forging change is the development of a process that gains the trust of researchers and administrators of all ranks. Our most important resources are our people, and they need to be part of an organization that encourages participation in decisions, allows personal growth, and engenders long-term career satisfaction.

2. Integration Across Missions

Teaching, Patient Care and Service

Scholarly activity/research, teaching, patient care, and service are all UTHSC recognized faculty activities. Deliberate and thoughtful integration of each activity with the others maximizes outcomes of the individual activities. With this understanding, principles of and opportunities for integration between research and the other activities were considered and the main points are summarized below. Action steps to initiate or stimulate progress are included wherever possible.

Principles and opportunities for integration between research and teaching:

1) All UTHSC trainees should receive early exposure to and fundamental instruction in research. Those interested in research should be provided a mentor or support to pursue research. A “grow our own” strategy is productive as a number of current faculty were former students. In addition, our trainees who frequently stay in our region/state should complete their training predisposed to and supportive of the research mission. Deans should initiate a review of curricula to insure more openings of research training and avenues to obtain more in-depth research experience. The Office of Academic, Faculty and Student Affairs should coordinate sharing of the research curricula among associate deans.

2) Dual degree programs such as an MD and PhD, DNP and PhD, PA and PhD, PharmD and PhD, and DDS and PhD should have publicized pathways with clear requirements. For each program (a) deans should oversee the creation and distribution at orientation of an information sheet with contact information, and (b) this same information should be on the Office of Research website.
3) College undergraduate and high school students interested in research should be connected with UTHSC faculty. Programs should be administered directly or jointly with colleges by the Office of Research and promoted on a webpage.
4) Creation of new programs that, upon completion, award a research-related master's or a specified certificate would further support faculty research development. The Office of Research in collaboration with the College of Graduate Health Science should work to establish such programs.
5) As a Health Science Center we should support scholarships as it relates to education. The Office of Academic, Faculty and Student Affairs should coordinate such efforts.

Principles and opportunities for integration between research and patient care:

1) Ongoing efforts to obtain a CTSA (Clinical and Translational Science Award) should continue, and if practical, be broadened. A CTSA will help to increase the number of health care provider-scientists at UTHSC.
2) Ongoing efforts such as the CORNET (Collaborative Research Network) Awards should continue. This program provides pilot funding for collaboration of researchers among colleges and campuses.
3) Renew efforts to support collaboration of basic scientists and clinicians modeled after CTSA. Pilot funding, for example a BASS CLARINET (Basic or Population Scientist - Clinician Researcher Integrated Network) Award, should be supported by the Office of Research.
4) Barriers exist for some faculty in conducting research at local hospitals. For example, for PhDs to have access to patients in the clinical settings. The Chancellor and Vice Chancellor for Research should work with hospitals to reduce these barriers.
5) Faculty who obtain part of their salary from a university-affiliated practice should be allowed to put their entire salary on grant proposals. For example, a clinician with $150,000 supported by a practice plan and $50,000 supported by a college would record a total compensation on a grant proposal of $196,000 (NIH maximum) with 25% grant effort supporting $50,000 rather than 25% of $50,000 or $12,500 in extramural support. The Vice Chancellor of Finance and the Vice Chancellor for Research should be charged with achieving this new policy.

6) Clear and publicized policies should exist for faculty health care providers who wish to have more protected time to do research. “Cost-sharing” between grant/philanthropic/other sources of support and college support of salary/time should be addressed in this policy. College deans should oversee formation of policies.
7) Clinical fiscal support from hospitals that go to the Chancellor should be used to support the research strategic plan in all colleges. The Chancellor should consider how each college can specifically and significantly contribute to aspects of the strategic plan and fund accordingly.
8) Clinicians should be supported in their use of the patient population they serve to support clinical investigation. Strategies and mechanisms to assist them should be established through the UTHSC Clinical Trials Governance Board, discussed later in this document, which would present recommendations to the Vice Chancellor for Research and the UTHSC Research Council.
9) Efforts to establish a biorepository and the precision medicine initiative should be supported.

Principles and opportunities for integration between research and service:

1) Senior scientists should promote junior colleagues for service on national committees, grant study sections, editorial boards, and board membership of foundations. They should (a) identify who currently serves on various national and regional committees, (b) identify junior faculty who are qualified and wish to serve on these committees, and (c) connect senior and junior colleagues.
2) Researchers are encouraged to initiate and participate in public and private national and community health organizations and fund raisers related to their areas of research. Examples include joining health support organizations and linking UTHSC with outreach programs (i.e. walks, bike races etc.). This outreach should be catalyzed by the Office of Research and supported, were possible, by various UTHSC units, departments and colleges.
3) Advocacy for community health, such as programs with the YMCA that are led by our faculty, should be recognized, encouraged, and supported.

3. Translation of Research

T_0 through T_4

Translational research seeks to move scientific discoveries along a 'virtual path' from the basic science laboratory to human (clinical) testing to general practice/real world settings. Using this framework, research projects generally fall into one of five categories (Table 1).

Table 1. The Full Spectrum of Translational Research

Type of Translational Research	Exemplified by
T0: Basic scientific discovery	• Pre-clinical approaches to investigate: pathway, pathophysiology or inform treatment approach
T1: Translation to Humans	• Phase 1 trial of novel agents • Significance of specific genes in cancer pathogenesis and therapy
T2: Translation to Patients	• Phase 2, 3 Clinical Trials • Pragmatic Clinical Trials
T3: Translation into Practice	• Phase 4 Clinical Trials • Health Services or Clinical Outcomes Research
T4: Translation to Population Health	• Population-level outcome studies • Social determinants of health

Why is the full spectrum of Translational Research important?

The ultimate goal of NIH is "turning discovery into health". Every component in the translational pathway is critically important to attaining that ultimate goal of human health. There are many places along that pathway where connections fail and translations are not made. Evidence suggests that even when we know how to improve health and health care, it is difficult to translate that knowledge into care delivery. Jencks et al. (2000) examined 1997 – 1999 Medicare claims and found that many Medicare

beneficiaries did not receive recommended care. For example, only 11% of Medicare patients hospitalized for pneumonia were screened for pneumonia immunization status before discharge; 69% of Medicare enrollees with diabetes received an eye exam within the recommended two-year period.[1] Research across the T0 to T4 spectrum will support UTHSC's mission of improved health for citizens of Tennessee, our region and the U.S. There is also great interest from a variety of funding sources to support the full spectrum of research.

Where are we strong? Where do we need to grow?

UTHSC has traditionally been strong in T0 research, with some strengths in T1 and T2; we have fewer strengths in T3 and T4, although a few key individuals, plus recent hires create numerous opportunities for growth (Table 2).

Table 2. Areas of Strength and Opportunities for Growth

Translational Research	Current Strengths	Growth Opportunities
T0: Basic scientific discovery	• Physiology • Pharmacology • Pediatrics	• Genetics/Genomics, Proteomics, Metabolomics
T1: Translation to Humans	• Pediatrics, COP	• Drug discovery
T2: Translation to Patients	• Preventive Medicine • Pediatrics	• Pragmatic Clinical Trials • Conditional Trials
T3: Translation into Practice	• Gen Internal Med	• Implementation, evaluation of innovative clinical programs to improve health outcomes
T4: Translation to Population Health	• Preventive Medicine • Center for Biomedical Informatics	• Research leveraging EHR (Electronic Health Record) data warehouses, registries, other population data

[1]Jencks SF, Cuerdon T, Burwen DR, et al. Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels. *JAMA.* 2000;284(13):1670-1676. doi:10.1001/jama.284.13.1670.

Connections and Synergies

The spectrum of translational research is all about connections, and not missing the connections in translating discoveries along the pathway of improving the health of populations. At UTHSC, some researchers have natural connections with each other, and some connections have been fostered through joint appointments, cross-departmental/college/centers/institutes, collaborative forums, and shared resources; examples of these are outlined in Table 3. To enhance translational research across the spectrum, additional investments should be made in "connection disciplines" (e.g. epidemiology, genetics, informatics) and connector opportunities (pilot funding).

Table 3. Examples of Existing Connections and Synergies and Opportunities for Growth

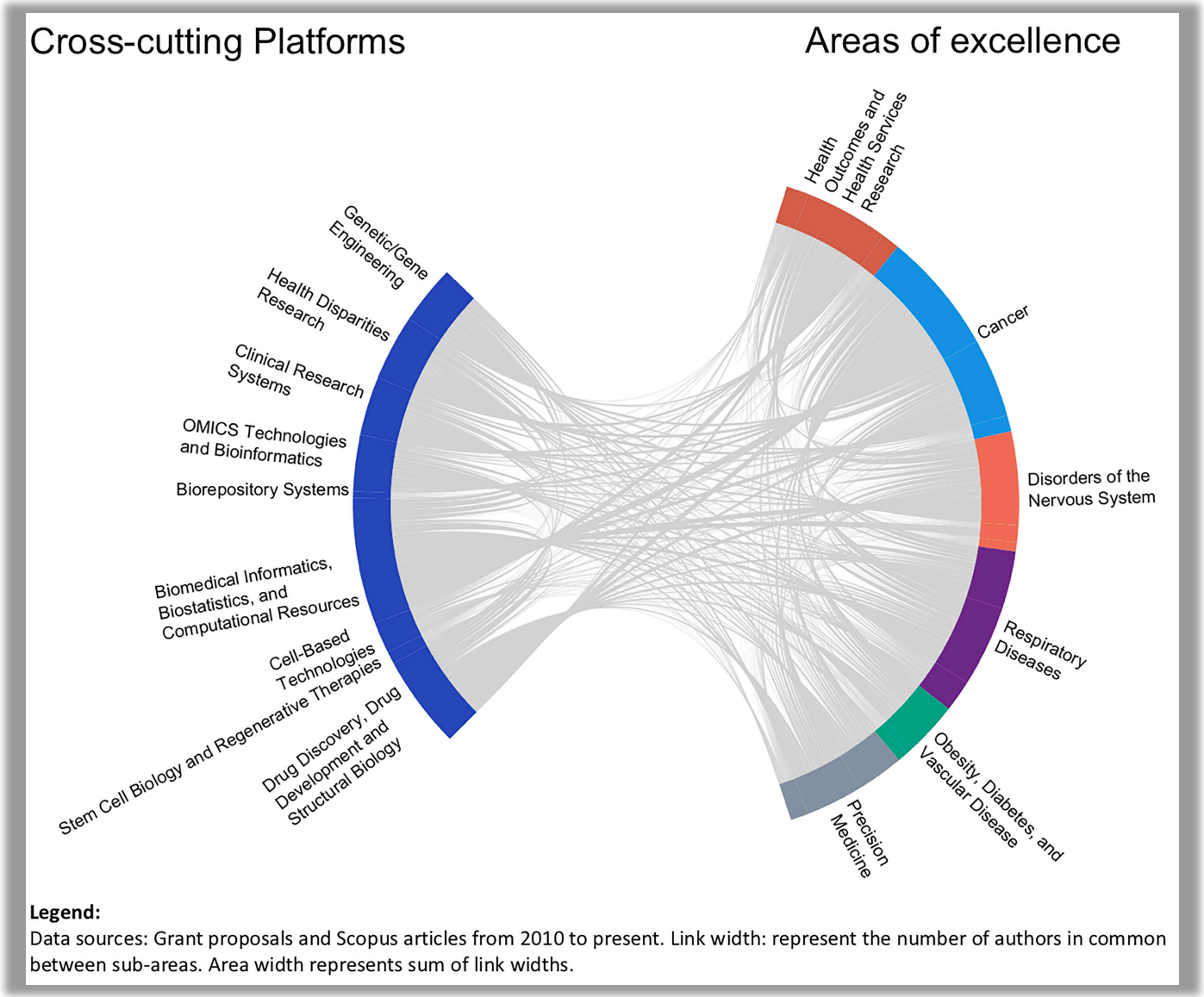
Current Connections/Synergies	Concrete Examples	Opportunities for Growth
Joint Faculty Appointments	Physiology/Peds COP/Peds Medicine (GIM)/Prev Med	Additional joint hires
Cross-Departmental Centers/Institutes	Neurosciences Institute iRISE	Institutes in new interdisciplinary areas
Connecting Disciplines	Epidemiology Genetics Informatics	Additional hires, Infrastructure investments (e.g. data warehousing, biobanking)
Collaborative Forums	SPARKs, Health Systems Research Conference DOME conference	Additional transdisciplinary conferences to support range of research: idea generation, work-in-progress to polished product
Collaborative Grants	CORNET iRISE pilot awards	Additional awards to support connections and synergies

Institutional Impact

The burden of chronic disease in our region, and the need to address health disparities, demand that we develop comprehensive research programs across the translational research spectrum. In addition, translational research across the spectrum of T0 to T4 is where significant grant opportunities lie, providing us the best opportunity to realize our goal of doubling research funding within 10 years.

4. Areas of Excellence and Focus Areas

The Operational Strategic Plan for Research Committee, through substantive discussions, identified six broad Areas of Excellence which represent current and emerging areas of research strength at UTHSC. As these



Areas of Excellence were intended to be broad in scope, while resources are finite, the committee then determined three Focus Areas for each. These are described in detail in this section. In the following section 5, we discuss the crosscutting-platforms which are required to support the Areas of Excellence and Focus Areas. The Areas of Excellence, Focus Areas and Cross Cutting Platforms were presented to the Faculty Senate and the Research Council for review and suggested revisions, and approval of the Chancellor prior to our commencing with the writing of sections 4 and 5.

(A) Disorders of the Nervous System

Introduction

Our goal is to build on current disease-oriented research strengths and develop new, clinically significant research programs. Although distinct, these areas overlap in their long-term objectives of understanding the mechanisms driving, and identifying potential cures for, injury- and disease-induced nervous system disorders. Indeed, many of the valuable areas for faculty recruitment outlined below fit in multiple focus areas as well as cross-cutting strategic interests in several colleges. Consequently, future investments in the specific technologies and new faculty hires suggested here are expected to both synergize the three proposed areas and enhance collaborative efforts across UTHSC. Common objectives include: (a) the discovery, localization and functional analysis of genes and epigenetic factors responsible for these disorders; (b) the identification of genetic, biological and environmental risk factors; (c) common molecular and cellular events that mediate susceptibility: these include, but are not limited to, oxidative stress, mitochondrial dysfunction, inflammation, transcriptional dysregulation, defective cell-signaling and protein misfolding and aggregation; (d) identification of novel molecular targets and drug development; (e) the development of simple model systems for understanding the origins and nature of complex neurological disorders; and (f) the development/incorporation of computational neuroscience methods to understand CNS physiology, pathophysiology and response to intervention. Focused investment in these research areas will lead the way towards new and innovative approaches to preventing and treating neurological disorders. In addition, there is high potential for collaborative bench to bedside research, both within and across these topics of investigation. To accomplish this goal, strategic hires should emphasize inter-professional research teams.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Movement Disorders, Neurodegenerative and Cerebrovascular Diseases
(2) Neurobiology of Addiction
(3) Neuro-Toxicogenomics

Focus Areas for Investment

(1) ***Movement Disorders, Neurodegenerative and Cerebrovascular Diseases:*** Understanding the pathogenesis of movement disorders, as well as neurodegenerative and cerebrovascular diseases, represents a major interest area of both the National Institutes of Health and various private research foundations. Currently, there exists a substantial group of basic and clinical researchers across UTHSC colleges and the VA with diverse expertise in neurosciences, as they relate to the development and manifestation of a number of these high prevalence diseases. In the areas of movement disorders and neurodegenerative diseases, these include Alzheimer's disease and Dementia, Parkinson's disease, Huntington's disease, Traumatic Brain Injury, Multiple Sclerosis, Dystonias, and the natural consequence of aging on memory and cognition. In cerebrovascular diseases, there are key research strengths related to the distinct disruption of the brain circulation (microcirculation, in particular), the neurovascular unit and the blood brain barrier. Some examples include micro-infarctions in Alzheimer's disease and other vascular dementias, ischemic and hemorrhagic stroke.

Valuable Areas for New Hires: • Neurotoxicology; • Systems neurobiologist/mouse model development; • Cell biologist/*in vitro* studies; • Inflammation and the neurovascular unit; • Molecular/cell biologist in neuron-glial signaling; • Clinical Alzheimer's disease specialist; • Neuroregeneration; • Clinician scientist(s) in any of the foregoing areas; • Neurorehabilitation

(2) ***Neurobiology of Addiction:*** The behavioral and cognitive processes underlying addictive behaviors and the neurobiological processes responsible for these effects are not well understood. Even less understood are the antecedent factors and individual differences associated with increased risk of drug initiation behaviors and continued abuse. UTHSC has a diverse faculty with expertise in the neurosciences, pharmacology, molecular genetics and epigenetics and pharmaceutical sciences as it relates to the development and manifestation of a number of addictive disorders. These include

the mechanisms of compulsive cocaine use and addiction, genetic and environmental factors influencing alcohol consumption and differential susceptibility to alcohol, FASDs (Fetal Alcohol Spectrum Disorders), caffeine-alcohol interactions, perinatal abstinence syndrome, and the complex interactions between social, genetic and sensory factors in regulating drug abuse behavior.

Valuable Areas for New Hires: • Optogenetics/chemogenetics; • Simple organism model systems; • Clinician scientists in addiction; • Genetics of individual differences in drug initiation, dependence, relapse, etc; • Computational neuroscience; • Disruption of the neurovascular unit/cerebral circulation by drugs of abuse

(3) Neuro-Toxicogenomics: Investigations of the nervous system in response to specific environmental exposures represents an important topic of overlap with the above focus areas. Understanding the shared mechanisms or common biological pathways leading to complex neurological diseases such as inflammation, epigenetic modifications and oxidative stress will be critical for the development of diagnosis and treatment strategies. In this regard, the definition of environmental exposures has expanded well beyond the original notion of just chemical pollutants. A more contemporary view held by the National Institute of Environmental Health Sciences includes both internal and external exposures from a variety of non-traditional sources, such as the microbiome, infectious agents, altered nutrition and even stress. The untoward consequences of such varied exposures can occur at different developmental epochs across the life-span, and often from the interaction of several insults, leading to different outcomes. Thus, susceptibility and outcomes are fundamentally important questions. There is a growing genomics platform at UTHSC that is focused on the potential adverse effects of environmental exposures. The current expertise in basic cellular and systems neurobiology, systems genomics, and the availability of newly developed genetic reference populations of mice at UTHSC all advocate that a research focus area that should be developed is neuro-toxicogenomics. Research into the traditional environmental exposures such hydrocarbons, metals, pesticides, herbicides, etc, will be important areas of study. However a strong component of this research should emphasize the non-traditional environmental stressors, such as those related to early nutrition and the microbiome.

Valuable Areas for New Hires: • Epidemiologist with expertise in population/systems genetics; • Pharmacogenetics; • Epigenetics; • Environmental toxicology; • Nutrition and the epigenome/microbiome

Institutional Impact and Deliverables

The Disorders of the Nervous System Area of Excellence provides a framework for enhancing “team science”, not only within and across the focus areas of investigation, but across colleges and institutions. The importance of this conceptual deliverable should not be underestimated, as the unifying themes that have been described will foster economies of scale, thereby providing the scientific nimbleness to address questions too large for any single investigator. Moreover, it provides the depth and breadth of intra-professional research teams that can address questions spanning the spectrum of basic science, to health disparities and prevention, to drug discovery and treatment. In this respect, we anticipate the creation of interdisciplinary Research Institutes, the development of interdisciplinary Program Projects and Center Grants. The afore mentioned would be expected to make extensive use of institutional Research Core facilities and of all basic and clinical science research components of UTHSC. Our success in achieving these goals will be set forth in a number of quantifiable variables that include, but are not limited to: (a) number of submitted grants; (b) number of funded proposals; (c) increases in extramural funds; and (d) the number of publications and their scientific impact.

Specific Technical Foundations to be Developed for the Above Focus Areas: • Behavioral phenotyping facility(s) for rats and mice that are within the vivarium; • Facility for simple organism model systems (e.g. zebra fish, xenopus, etc.)

Technical Foundations to be Developed that Cross Research Areas of Excellence: • DREADDS (Designer Receptors Exclusively Activated by Designer Drugs) and optogenetics; • Cryo-EM for small molecule structural imaging; • Super resolution light microscopy; • Small animal functional imaging systems such as fMRI, PET or SPECT

Technical Foundations to be Expanded that Cross Research Areas of Excellence: • Flow cytometry; • Histology core; • Omics

Synergies and Collaborative Potential

The strategy outlined above focuses on an approach that programmatically coordinates clinical and basic neuroscience research, with the goal of encouraging the development of translational and clinical projects. Importantly, the Disorders of the Nervous System Area of Excellence provides a critical branding/marketing tool necessary for establishing collaborative

initiatives that transcend traditional institutional boundaries and scholarly disciplines at a local, regional, national and international level. Branding and marketing "who we are" will also be essential for partnering with industry. Finally, the defined focus areas above notwithstanding, the collaborative culture emphasized in our approach, will increase synergies with other areas of excellence in this document, providing immense opportunity for scientific growth. For example, addictive disorders such alcoholism can be linked to the development of specific cancers and metabolic disorders.

(B) Cancer

Introduction

The overall goal of the strategic plan pertaining to cancer is to develop a path to become an NCI-designated cancer center within the next 5–10 years. The development of the role of the associated UT-West Institute for Cancer Research is of primary importance, and will allow for it to be the vehicle through which all cancer research is conducted, awarded and funded. It is envisioned that UT-West Cancer Center will guide the further development of substantial laboratory, translational, clinical, and population-based research activities.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Women's Cancer
(2) Health Disparities of Cancer
(3) Cancer Cell Biology and Therapeutics

Focus Areas for Investment

(1) ***Women's Cancer:*** Both basic and clinical research at UTHSC have a strong focus on women's cancer. UTHSC and the West Cancer Center have strong track records in the funding and conduct of basic and clinical research in breast cancer. There remain opportunities to further the development and growth of expertise relating to gynecological cancers, including ovarian, endometrial, and cervical cancers. These types of cancer contribute a significant disease burden both regionally and nationally, and for which already exist significant clinical expertise within the cancer center. Within breast cancer, there

is a need for the development of greater focus on subsets beyond triple-negative breast cancer, such as endocrine-resistant and hormone receptor positive cancers. It is essential for us to create both breast cancer and gynecological malignancy groups of clinicians and scientists, with a focus on understanding the following:- the determinants of disease; the creation and development of therapeutic novel approaches; prognostic, diagnostic and therapeutic biomarkers; and the measurement and determination of health-related outcomes in these diseases.

Valuable Areas for New Hires: • Investigators with a focus on drug design and development; • Hires who specialize in validation of drug targets; • Cancer immunologists

(2) Health Disparities of Cancer: The primary focus areas of cancer inequities are racial and socioeconomic disparities in cancer outcomes. Research in this area must span all types of investigations, including genomic, clinical, and population-based approaches that can help to identify and modify factors associated with prognosis, as well as predict responses to therapeutic interventions. Given the racial and socioeconomic demographics of the region, investigations in health disparities is of primary importance at UTHSC. Current research within both the Cancer Research Building (CRB) and the Department of Preventive Medicine has begun to develop studies in cancer disparities, but further development of formal programs, including specific training and funding opportunities, are needed. It is our goal to develop internal training grant programs that support graduate and post-doctoral students. In addition, we will begin tracking data necessary for competitive NIH training grants, to make UTHSC competitive for institutional (T32) awards, with a focus on diversity-based recruitment and training related to diversity health. There is the need to integrate with researchers within the other research focus areas in order to understand disparities in co-morbid diseases and their role in cancer outcomes. Furthermore, there is the need to increase engagement of at-risk communities, to educate about best practices in cancer prevention and treatment, and to encourage participation in epidemiology studies and clinical trials.

Valuable Areas for New Hires: • Health disparities expertise and program building in the areas of oral cancer, lung cancer and prostate cancer; • Development of further epidemiologic expertise in colorectal cancer and lung cancer; • Hires with expertise in bioinformatics and biomedical informatics are needed to categorize and catalogue, and investigate cancer disparities across the genome and the population of the Mid-South

(3) Cancer Cell Biology and Therapeutics: Abnormal gene regulation and gene expression are critical components of cancer growth and progression. The role of the tumor environment, including immune components, are emerging as increasingly important determinants of malignancy and potential therapeutic interventions. Strengths in cancer cell biology currently exist within the university, but design and development of new therapies has not yet emerged. It is a major goal to develop novel experimental therapeutics to combat metastatic diseases and translate "home-grown" therapies into clinical trials.

Valuable Areas for New Hires: • Strengthening the base of cancer cell biology expertise, including investigators with a focus on factors that influence tumor progression and metastasis, and factors that lead to therapy resistance; • Develop a program in drug discovery and development; • Hires with expertise in molecular pharmacology, translational science, and early-phase clinical research; • Expertise in cancer immunology and immunotherapy

Institutional Impact and Deliverables

Currently, investigators across campus are engaged in cancer research, with a center in the UT Cancer Research Building (CRB). Built in 2007, the CRB contains 32 research laboratories with state-of-the-art equipment in a 90,000 ft^2 facility. Current research being conducted in the CRB focuses on such diverse topics as the role of hypoxia in cancer cell growth, hormone sensitivity and manipulation in breast and prostate cancer, the role of micro-RNAs in melanoma and glioma, and others. The CRB allows for substantive interactions among investigators across specialties, representing the Colleges of Medicine, Pharmacy, and Dentistry, and within the College of Medicine includes investigators from the Departments of Pathology, Internal Medicine, Surgery and Orthopedics. Additional laboratory space is available for new hires, and to cancer researchers from any college or department at UTHSC.

As interdisciplinary collaborations between scientists and clinicians are under-developed, an immediate term goal is to undertake initiatives which specifically bridge these interactions. Prompt development of shared resources, centralization and enhancement of cross-campus awareness of current research activities in cancer is essential. This would include development and leverage of internal intramural resources, to support submission of multiple PI (MPI) and program-project grants, by partnering between basic and clinical investigators, and across departments, colleges, and local institutions. A critical intramural need toward this end includes the creation of an oncology tissue biorepository, annotated to electronic health records, with a focus on collection of blood samples and tumor specimens. The biorepository should be readily

accessible to both clinical and basic researchers for genomic and protein-based analyses. Additionally, there is a need to develop interdisciplinary, specific cancer working groups across all colleges. These groups will cooperate to create translational cancer program strengths among the basic scientists, clinicians, and outcomes researchers. Current strengths are breast, colorectal, and central nervous system cancers and melanomas. Aspirational areas for growth include: (a) oral; (b) pancreatic; (c) gynecological; (d) prostate; (e) lung; and (f) young-adult cancers.

Specific Technical Foundations to be Developed for the Above Focus Areas: • Intramural support is needed for pilot project grants and for shared common equipment. Our goal is to improve the graduate training program in cancer and developmental biology, and to address proactively the impact that the new SJCRH doctoral program may have on recruitment of PhD students to the CRB track, and to the placement of graduate students in UTHSC-based laboratories; • Reinvigorate the CRB seminar series by increasing funds to support the seminar series, which are needed to recruit distinguished external speakers; • Enhance communication with the local community and the region, and position UT-West Cancer Center as the leader in research for adult cancers through improved marketing and business development. This can lead to further philanthropic income through the UT-West Institute for Cancer Research, further development of community partnerships, and increased patient engagement in clinical trials, all of which can serve to provide funding for many of the activities described above.

Technical Foundations to be Developed that Cross Research Areas of Excellence: • Creation of a Tissue Biorepository, including readily-accessible access to basic scientists, and the investment in newer technologies for genomic analysis; • Creation of a bioinformatics and biomedical group devoted to cancer research and outcomes.

Technical Foundations to be Expanded that Cross Research Areas of Excellence: • Renewal of the West Cancer Center funded xenograft core and creation of a Patient derived Xenograft (PDX) core, including humanized mouse models in which to test immunotherapies; • Update of the animal bio-imaging facility to include additional modalities such as X-ray or PET imaging; • Update of the Flow Cytometry and Cell Sorting facility to enable analysis at the single-cell level and simultaneous measurement of RNA, cell surface proteins, and intracellular proteins.

Synergies and Collaborative Potential

We aspire to develop cancer-site focus areas of expertise that can integrate across schools, departments, and research expertise. An example of such a collaborative group could be a focus in Oral Cancer Research and Administration. The responsibility for oral cancer research, training professionals, and informing the public, falls in a gap between the medical and dental professions. The goal of this group would be to bridge the gap through a multi-disciplinary plan of research, education and outreach. Research would include investigation into the causes of oral cancer, including the role of viruses, tobacco and alcohol use; evaluating the significance of new trends in oral delivery of pharmacoactive substances such as e-cigarettes and vaporizers; improving methods of early diagnosis, including identifying tumor biomarkers and using saliva as a diagnostic fluid; studying in vitro models of oral cancer progression and tissue invasion; examining the genomics of oral cancer and epigenetic factors. Outreach could include collaborations within the community engaging the young and those at most risk in the future, and recognizing the high incidence and mortality of oral cancer among African-Americans and smokeless tobacco users as health disparities which are especially relevant to Memphis and the Mid-South region.

(C) Respiratory Diseases

Introduction

Respiratory diseases are leading causes of preventable morbidity and mortality worldwide. The Memphis metropolitan area and the State of Tennessee are particularly affected by chronic respiratory issues including asthma, chronic obstructive pulmonary disease, sleep apnea and manifold infectious diseases that impact the respiratory tract and exacerbate these co-morbidities. UTHSC features numerous investigators whose work falls within the umbrella of respiratory diseases; there are also strengths in infectious and inflammatory diseases that are cross-cutting and interact with other research areas. The overall goal of the strategic plan pertaining to respiratory diseases is to embrace common research themes, invest and strengthen the environment for conducting bench to bedside to community research in this area, and build on existing programs to develop increased depth and synergy across the institution. Currently, there are significant strengths in the College of Pharmacy within the domains of anti-infective discovery, resistance and pharmacodynamics, particularly regarding fungal and bacterial infections. There are also strengths within the College of Medicine in the domains of pathogenesis, anti-infective agents and vaccine development, particularly regarding respiratory pathogens. These areas of expertise synergize

with existing programs in inflammation and immunology, where pulmonary fungal and respiratory virus models are used to explore asthma and other inflammatory diseases. Sleep medicine is a cross-cutting program embracing the Colleges of Nursing, Medicine and Dentistry. Sleep disorders produce a wide array of sequelae in and among themselves and are also associated with asthma, obesity, type 2 diabetes and other chronic illnesses including respiratory diseases. Finally, the role of the environment, including fungal exposures, air pollution and other side effects of the natural and built environment, is a growing area that impacts all of these diseases. It is proposed as an aspirational focus area for further development.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Infectious Diseases
(2) Asthma and Inflammatory Diseases
(3) Environmental Exposure

Focus Areas for Investment

(1) ***Infectious Diseases:*** There exists a substantial institutional expertise within the College of Pharmacy and Medicine, in addition to robust animal models for infectious diseases that are utilized routinely, and a strong pipeline of antiviral drugs established in collaboration with industry. Together with the unique capabilities of the Regional Biocontainment Laboratory (RBL), this institutional expertise and resources provides a rich environment for further growth in anti-infective research, including drug discovery and development.

(2) ***Asthma and Inflammatory Diseases:*** Currently, there is substantial basic and clinical expertise in asthma, inflammatory diseases, and related co-morbidities. Basic, clinical and translational investigation spans areas such as development of fungal and viral-induced asthma, obesity as an inflammatory disorder and its genetic and dietary basis and its overlap/association with a unique asthma phenotype, hypersensitivity pneumonitis and the intersection of sleep disorders, asthma and obesity. There is a strong clinical and community program within asthma centered on a high risk asthma clinic, pulmonary function laboratories including infant pulmonary function testing (PFT) facilities and strong bronchoscopy expertise. The CHAMP (Changing High Risk Asthma in Memphis through Community Partnership) program extends these

studies into the home and provides overlap with environmental exposures, particularly in regards to fungal-induced allergic asthma.

*(3) **Environmental Exposure:*** Currently, there is strong expertise in the area of exposure to combustion derived particulate pollution and induction/exacerbation of inflammatory diseases of the lung. There is also research in the area of hypersensitivity pneumonitis. However, there is little breadth to these programs at present.

Valuable Areas for New Hires: Unmet needs and valuable areas for future recruitment that would benefit all three focus areas listed above include:- • Recruitment of research intensive faculty with a focus on anti-infective medicinal chemistry; • Pulmonary drug delivery; • Academic sleep medicine; • Advanced bronchoscopy; • Clinical pharmacogenomics; • Fungal pathogenesis

Institutional Impact and Deliverables

It is expected that these investments will yield a number of deliverables. In the short term, hires in these key target areas should lead to rapid increases in extramural funding. We will develop research databases in areas such as sleep disorders, asthma, and respiratory infections. We will participate in the response to the global threat of emerging treatment-resistant infections as defined by WHO and the 2015 summit of G7 leaders. In the longer term, focused research in these areas should allow for greatly increased funding through development of larger collaborative efforts, including instrument, center and training grants, or a portfolio of mentored career development grants. A strong translational base in these areas will allow us to compete for NIH supported clinical trials and industry funding. Metrics to follow, include programmatic revenue from NIH and industry, and improvements to patient outcomes in target areas such as childhood asthma. This will have a broad institutional impact through national recognition of UTHSC as a center for respiratory disease research excellence, which will in turn improve trainee recruitment in these areas, strengthening the overall pipeline. We envision that investment and development in these areas over the next five years will result in creation and extramural funding of multi-disciplinary programs in areas such as: (a) Asthma and Allergic Diseases Cooperative Research Center (U19-Research Program, Cooperative Agreements); (b) Consortium for Food Allergy Research Leadership Center (UM2-Program Project or Center with Complex Structure Cooperative Agreement); (c) Center for Excellence on Environmental Health Disparities Research

(P50-Specialized Center Grants); and (d) Children's Environmental Health and Disease Prevention Research Center (P50-Specialized Center Grants).

Specific Technical Foundations to be Developed for the Above Focus Areas: • Centralized mouse PFT core laboratory (with sophisticated plethysmography and aerosol delivery capabilities); • Mouse/human rheometry core

Technical Foundations to be Developed that Cross Research Areas of Excellence: • Increased support for Center(s) devoted to respiratory diseases with administrative resources for large multi-disciplinary research initiatives; • Continuous investment in many areas that would benefit multiple investigators within the overall umbrella of clinical and translational research; • Improvements to the animal facilities; • Investment in structural biology; • Expanding sequencing and bioinformatics capabilities; • Recruitment of clinician scientists interested in respiratory disease-related research; • Recruitment and/or training of personnel at many levels, to support Center or Institute concepts for multi-disciplinary research programs, extending from basic science to clinical cohorts.

Technical Foundations to be Expanded that Cross Research Areas of Excellence: • Improved high throughput drug screening capabilities are required to support Focus Area 1 (Infectious Diseases).

Synergies and Collaborative Potential

There is particular overlap with resources and expertise in respiratory tract infections, pharmacodynamics, and drug discovery at St. Jude Children's Research Hospital, which strengthens this Focus Area 1. Synergies are expected to expand with the development of cross cutting efforts in Drug Discovery, Drug Development and Structural Biology, OMICS Technologies and Bioinformatics, Biorepository Systems, as well as institutional resources at the Center for Molecular Biophysics at Oak Ridge National Laboratory and the Institute for Biomedical Engineering at UT Knoxville. With the institutional plan to develop the RBL as a site for study of toxicant effects and toxico-genomics, and with the substantial overlap with asthma and other chronic respiratory diseases, this will become a natural area for synergistic growth.

(D) Obesity, Diabetes, and Vascular Disease

Introduction

UTHSC currently supports a wide range of clinical and community research programs addressing obesity, diabetes, and vascular disorders. These chronic conditions are particularly prevalent in the Mid-South and are associated with significant health disparities. Therefore we are well positioned to become a nationally recognized citadel of excellence and global leader in cardiometabolic research. The overarching goal of this Area of Excellence is to increase understanding of the environmental, behavioral and biological processes (e.g. genetic, demographic, chemical, or molecular) that lead to the development and progression of obesity, diabetes, and cardiovascular disorders. The vision is to enable discovery and development of strategies for the prevention and management of obesity, diabetes, and cardiovascular disease, and in doing so, improve quality of life and survival. Incorporated in this overall vision, is the ultimate goal of eliminating disparities across the spectrum of cardiometabolic disorders through collaboration and synergies with other research focus areas.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Biological Signaling: Signaling, energetics, stress, inflammation and hormonal function/ dysfunction
(2) Environmental and OMICS: Influences on health and disease across the lifespan, focusing on the built and internal environment, social determinants, and disparities
(3) Prevention and Rehabilitation: Prevention, recovery and reversal of degenerative disorders using innovative clinical, cellular, molecular, pharmacological and behavioral approaches

Focus Areas for Investment

(1) ***Biological Signaling:*** Biochemical and electrical signaling are key areas of research for diabetes, metabolic disorders, and cardiovascular diseases. There are a number of funded UTHSC investigators in basic, clinical and translational science pertinent to this focus area. However, this focus area could be strengthened through targeted new hires (described in detail below), and by creating a Center or Institute to increase collaboration among the diverse pool of investigators.

Valuable Areas for New Hires: • Signal transduction expert with broad interest in hormonal signaling in brain and peripheral tissues; • Cardiometabolic molecular biologist; • Clinical and basic science researchers in diabetes, obesity and energetics; • Basic science and clinical researchers in heart failure and cardiovascular disease

(2) Environmental and OMICS: The following influences from the built and internal environments increase susceptibility to diabetes, obesity, and cardiovascular disease:- (a) dietary and physical activity behavior; (b) toxins; (c) air quality and small particulate pollutants; and (d) microbial flora. Oxidative stress, inflammation, endocrine disruption, socioeconomic status, and disequilibrium in energy balance foster the development of cardiometabolic disorders. The integration of these biobehavioral factors with emerging insights in the OMICS sciences is a promising approach that could expand knowledge considerably. Investment in this area would facilitate growth, foster synergies, and drive the development of quality and value metrics based on genomics and big data. Currently, investigators focusing on this research area are scattered across various colleges and departments. To strengthen this research base, and to facilitate interaction and collaboration, targeted new hires are needed.

Valuable Areas for New Hires: A framework of faculty with expertise and protected time to expand research focusing on the following areas:- Toxins and the built environment; • The internal environment (including the microbiome); • OMICS influences and informatics across the lifespan; • Epidemiology and social determinants of health and disparities

(3) Prevention and Rehabilitation: The focus areas of obesity, diabetes, and cardiovascular disease belong to the broad classification of degenerative disorders. The overall objective of this focus area is to prevent or reverse the underlying processes of degeneration. Unraveling the mechanisms of degeneration is crucial to the discovery of rational interventions. Requisite knowledge areas include: (a) cellular, molecular, and vascular biology; and (b) metabolic and behavioral pathways. The translation of basic research findings depends heavily upon having clinical scientists with adequate protected time and data from value-based precision medicine and informatics research. Currently, there is a limited base of investigators engaged in Prevention and Rehabilitation research. A core of investigators from basic science to clinical disciplines, with expertise that spans from bench to sidewalk is needed. Additionally, a platform for interaction and collaboration among investigators (e.g., Center or Institute) would strengthen its impact.

Valuable Areas for New Hires: A core of faculty with expertise and protected time to expand research focusing on the following areas:- • Basic science of wound healing and tissue repair; • Precision medicine and predictive sciences; • Big data research, informatics, outcomes analysis; • Basic/clinical research in kinesiology, neuromuscular, and rehabilitative sciences; • Lifestyle intervention for prevention and treatment of cardiometabolic disorders

Institutional Impact and Deliverables

Each of the research focus areas (Biological Signaling, Environmental and OMICS, and Prevention and Rehabilitation) would be assessed according to the following four criteria: (a) Evidence of a successful launch of new research initiatives in the areas of research pertinent to the fields of obesity, diabetes and cardiovascular disease; (b) Demonstration of successful collaboration and synergies across UTHSC entities; (c) Award of extramural funding in pertinent areas; and (d) Communication of novel research findings in scientific conferences and publications in peer-reviewed scientific journals.

Specific Technical Platforms to be Developed for the Above Focus Areas: • Platform for complete dissection of signal transduction across biological systems; • In vivo human physiological protocols; • Facility/resources for quantitation, visualization and assessment of beta-cell function, insulin action, body composition, and brown fat expression.

Technical Platforms to be Developed that Cross Research Areas of Excellence: • fMRI, PET/SPECT; • Small rodent models for use in biobehavioral, metabolic and vascular biology protocols.

Technical Platforms to be Expanded that Cross Research Areas of Excellence: • ELISA, hormone assays; • Flow cytometry; • Mass spectrometry; • OMICs

Synergies and Collaborative Potential

Within UTHSC, there are well-established units in the Colleges of Medicine, Pharmacy, Dentistry, Nursing, and Health Professions with research activity in Obesity, Diabetes, and Cardiovascular Disease. Additional opportunities exist at the Church Health Center, Urban Child Institute, Christ Community Center, UTHSC-affiliated hospitals, the University of Memphis, UT Research Foundation, and Tennessee Health Department. Regionally, there are potential opportunities for creative collaborations with UTHSC campuses in Nashville, Knoxville and Chattanooga; Vanderbilt University and Meharry

Medical Center; Oak Ridge National Laboratory; Universities of Arkansas and Mississippi; and Washington University in St. Louis.

(E) Precision Medicine

Introduction

Precision Medicine seeks to customize healthcare with decisions, practices, and/or products tailored to the individual, and to maximize treatment and prevention effectiveness by taking into account individual variability in genes, environment and lifestyle. The greatest progress to date is currently in pharmacogenomics, where targeted therapy is being researched and developed for anticoagulation, hypertension, asthma, and cancer, to name just a few. Initiatives at Vanderbilt, Cornell-NY Presbyterian, Geisinger, Intermountain, and Harvard demonstrate the large investment being made in precision medicine by academic centers across the country. We have the opportunity to play an important role in the Precision Medicine Initiative (PMI) by enrolling subjects representative of the inner city African-American population of Memphis. This group has a high burden of chronic disease: it ranks nationally near the bottom in areas of health and wellness across the lifecycle, including infant mortality, heart disease, stroke, cancer, diabetes, and obesity. National precision medicine efforts can be supported, enhanced, and expanded through a robust Memphis/Shelby County Precision Medicine Initiative. The initiative should include active participation from medical care systems and congregational health centers able to address racial disparities in genomic health research, in addition to laying the groundwork for delivering precision medicine and tailored interventions to these same groups. Components of such a PMI include: (a) biobanking; (b) genomic sequencing and other “omics”; (c) bioinformatics and biomedical informatics; and (d) health care practitioners trained to deliver personalized health care at the bedside. To date, progress includes: (a) the Le Bonheur Children’s Hospital Pediatric Research Database (comprised of children only); (b) a nascent Methodist-wide data warehouse (including both adults and children); and (c) a new DNA biorepository (children only). Efforts to scale are underway, and will include: (a) a tissue biorepository (of adults and children); (b) enrollment of adults (selected groups) in the DNA biorepository; and (c) community education efforts. In addition, to become national leaders in precision medicine, we can link hospitals in Chattanooga, Knoxville (with their east Tennessee Appalachian population), and Nashville to the DNA biorepository and establish data warehouses for each hospital partner – thereby enabling a statewide PMI that will benefit the citizens of Tennessee and our research mission.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Risk, Pathogenesis and OMICS-guided Diagnosis, Treatment and Prevention
(2) Interaction Between the Human Genome and the Environment
(3) Disparities in Health Genetics and Genomics

Focus Areas for Investment

*(1) **Risk, Pathogenesis and OMICS-guided Diagnosis, Treatment and Prevention:*** Francis Collins has noted that the concept of precision medicine is entering a new phase of knowledge acquisition and evidence application. The promise of precision medicine has been dramatically improved by the accelerating development of large-scale biologic databases (such as the human genome sequence) in concert with large-scale patient phenotype databases (such as the research databases found in CTSA sites, PCORNET, and the Sentinel Initiative). In addition, there are new powerful technologies and methods for characterizing patient's proteomics, metabolomics, and genomics, and with newly developed computational tools for analyzing large sets of data. The next generation of medicine will be devoted to applying rigorous evidence-based approaches to studying the clinical impact of new precision medicine approaches, and then using these findings to influence clinical practice.

Valuable Areas for New Hires: • Pharmacogenomics; • Metabolomics (to utilize Orbitrap mass spectrometer in the Proteomics and Metabolomics Core Facility, PMC); • Biomedical informaticians for EMR (electronic medical record) phenotyping at-scale

*(2) **Interaction Between the Human Genome and the Environment:*** There is substantial interest in the study of how human genetics influences interactions with the environment to alter or modulate disease processes. The NIH has recently partnered with the Environmental Protection Agency to fund 5 new research centers to address the interplay between the human genome and the environment, with the goal of improving health in communities overburdened by pollution and other environmental factors. We are particularly well situated to take advantage of the interest shown by the NIH and others in this research direction. The CANDLE study (Conditions Affecting Neurocognitive Development and Learning in Early Childhood) has been assembled to investigate: (a) the separate and combined effects of the mother's prenatal actions; (b) the home

environment and childhood experiences; (c) the exposure to potentially harmful toxins; and (d) the genetic make-up of the child on his/her brain development from birth to three years of age. In addition, a subject that is rapidly growing in importance is the microbiome and its utility as a diagnostic tool in precision medicine, both from the standpoint of disease susceptibility and response to treatment, including pharmaco-microbiome interactions.

Valuable Areas for New Hires: • Epidemiologist and/or Genetic epidemiologist and/or geneticist; • Toxicogenomics specialists; • Microbiome specialists

(3) Disparities in Health Genetics and Genomics: Some, such as T. Frieden, Director of the CDC, have argued that 'your zip code is more important for your health than your genetic code'. Others have countered that both the zip code and genetic code are substantial, independent, and interrelated contributors to health (M. Khoury, CDC Office of Public Health Genomics). Eventually advances in 'omics' could worsen health disparities, if such new evidence is not equally collected from, studied in, and applied equally to all racial and ethnic groups in the United States. As such, it is important for us, to address the needs for research capacity enabling research into causes of and solutions to disparities in health genetics and genomics.

Valuable Areas for New Hires: • Epidemiologist and/or health disparities researcher (health services trained)

Note: Underpinning all these hires is the front-end investment necessary to establish the infrastructure of the biorepository efforts, which will be critical to our ultimate success in Precision Medicine.

Institutional Impact and Deliverables

A fully functional and robustly populated biorepository will make us one of only a few institutions in the country with this type of resource. Linking the biorepository with the Enterprise Data Warehouse (EDW) will allow senior and junior faculty, as well as graduate students and postdocs, to carry out cutting edge research in a quicker fashion. The PMI, BIG and EDW will be critical infrastructure attributes making us more attractive to faculty candidates. Furthermore, developing vigorous collaborative efforts between UTHSC, the UT systems around the state, and Oak Ridge National Laboratory (ORNL) has

the potential to be transformative for research here, and will make possible more robust participation in large national initiatives led by NIH, PCORI, FDA, CDC and AHRQ, as well as with industry led clinical trials.

Specific Technical Foundations to be Developed for the Above Focus Areas: • A substantial investment for computing resources (both analytic and storage) will be necessary to maximize use of the Biorepository; • Training in bioinformatics and biomedical informatics will be key to future physician scientists. Both GGI (Genetics, Genomics and Informatics) and CBMI (The Center for Biomedical Informatics) need faculty time to produce and teach these skills; • Development of methods and processes for curating large scale genomic information for clinical application, and developing best practices for acting on significant genetic findings; • CLIA (Clinical Laboratory Improvement Amendments) certified genomics facility (including a Illumina HiSeq 4000 and 1-2 NextSeq 550 NGS (next-generation sequencing) systems (for whole genome sequencing, whole exome sequencing, NIPT testing); • One to two Affymetrix GCS 3000Dx microarray systems (for Chromosomal copy number variation); • One to two MiSeqDx or Ion S5 NGS systems (for targeted gene sequencing); • One to two Illumina iScan or Affymetrix Gene Titan microarray systems (GWAS-level SNP microarrays for quick and cheap population screening); • Orbitrap software investment to capitalize on its diverse capabilities (e.g., software to support Lipidomics research/analysis).

Technical Foundations to be Developed that Cross Research Areas of Excellence: • Full development of the Methodist Le Bonheur Healthcare (MLH) Enterprise Data Warehouse (EDW) enabling in-depth electronic phenotyping of patients for research or provision of precision medicine; • Full development of an Enterprise Data Warehouse (EDW) for all UT affiliated medical center patients (including UT Chattanooga, UT Knoxville and UT Nashville) thus enabling in-depth electronic phenotyping of patients for research or provision of precision medicine.

Technical Foundations to be Expanded that Cross Research Areas of Excellence: • A fully functioning biorepository that collects multiple biospecimens over time on all MLH-UTHSC patients, and integrates genomic and other -omic data seamlessly with longitudinal data within the EDW.

Synergies and Collaborative Potential

Our faculty in this area have many collaborations with other institutions that can be leveraged to increase the visibility of our research efforts, and increase synergies with other institutions. We can perform a wide range of important studies on precision medicine with our collaborators in the following institutions: (a) ORNL; (b) Veterans Administration; (c) St. Jude Children's Research Hospital (SJCRH); (d) West Cancer Center; (e) University Medical Center in Knoxville; (f) the University of Tennessee at Chattanooga (UTC); and (g) Erlanger in Chattanooga.

(F) Health Outcomes and Health Services Research

Introduction

We have demonstrated a strong commitment to health outcomes and health services research (HSR). Assisting these areas, we have multiple centers, departments, graduate programs, and data registries. In the past five years, top researchers in these areas brought in over $29 million in funded research and published over 250 papers. Training is an additional area of strength. UTHSC faculty mentor students at the Master's and PhD level in: health policy, health systems pharmacy management, health informatics, epidemiology, and pharmaco-economics. Research in these areas is supported by several systems available on campus including: (a) the Enterprise-Wide Data Warehouse (EDW); and (b) RedCap, a web-based data and survey management application, the University of Tennessee at Chattanooga (UTC) and the University of Tennessee College of Medicine Chattanooga (UTCOMC) have collaborated in forming Research Interest Groups (RIGs) between the two campuses to ensure growth and development of biomedical and biobehavioral research capacity and partnering.

As part of this Strategic Plan, we propose three research focus areas for future investment:

(1) Comparative Effectiveness Research: a methodology designed to provide evidence on the effectiveness, benefits, and harm of differing treatment options.

(2) Evidence-based Practice: the integration of clinical expertise, best research evidence, and patient values into the decision making process for patient care.

(3) Community-engaged Research: designed to foster collaborations between researchers and communities in addressing local health and health care challenges.

Focus Areas for Investment

(1) ***Comparative Effectiveness Research:*** A number of centers and departments across our network have developed a body of grant funded comparative effectiveness research initiatives. These include the Memphis-based Departments of Medicine and Preventive Medicine, focusing on therapeutic outcomes and the impact of health policy changes, respectively. The Center for Health System Research Improvement (CHSI) focuses on applied research, evaluating primary care and community-based health care delivery innovations. The Department of Clinical Pharmacy studies medication therapy management programs and medication adherence. The College of Nursing focuses on intervention outcomes and caregiver research. Faculty at UTCOMC and UTC study improvements in functional outcomes, weight management, and rehabilitation. The University of Tennessee Medical Center (UTMC) conducts research on outcomes, neonatal monitoring devices, and medication delivery. Health outcomes and HSR support faculty by providing data management and analytical expertise for studies based on the United States Renal Data Systems and the national VA research database, managing CHSI, and hosting a health systems research conference.

Valuable Areas for New Hires: • Senior health policy faculty for the Institute for Health Outcomes and Policy (IHOP); • Health informatics faculty with data science skills for the Health Informatics PhD track in IHOP; • Health care delivery innovations research faculty with quality improvement skills

(2) ***Evidence-Based Practice:*** Emphasis on evidence-based practice will help improve patient care. Several departments have exhibited a strong commitment to this area by conducting research on evidence-based medicine/practice, these include: (a) the Departments of Medicine; (b) Preventive Medicine; (c) Pediatrics; and (d) the Colleges of Nursing and Pharmacy. Faculty have supported this area by hosting the Diabetes Wellness and Prevention Coalition (DWPC), a practice-

based research and quality improvement network of over 35 practices. However, this area needs to be expanded in terms of research focus and support for faculty to engage in evidence-based practice, by offering dedicated salaried time.

Valuable Areas for New Hires: • A senior clinician-investigator with experience in developing evidence-based research networks

*(3) **Community-Engaged Research:*** We have the potential to improve health of the West, Middle, and East regions of the state through improved patient care and community-engaged research. Several centers, including the Center for Health System Improvement and the new UT-West Cancer Center for Community Health Improvement are contributing to this area through patient-centered outcomes research/community-engaged research. UTHSC's Clinical Translational Science Institute (iRISE) also has a community engagement core with a mandate to connect investigators with community organizations and facilitate Community-Engaged Research in this area can be supported by existing and developing new disease-specific registries, including the Diabetes Wellness and Prevention Coalition Registry.

Valuable Areas for New Hires: • Senior leader for UTHSC Master's Program in Epidemiology. UTHSC needs faculty to head and develop an MD/MPH program and a HSR/patient-centered outcomes research fellowship program for clinicians

Institutional Impact and Deliverables

We must recognize that training in informatics (both bioinformatics and biomedical informatics) and research methods are essential to our ability to remain competitive. UTHSC's first priority in recruiting key faculty should be to commit the necessary resources: (a) infrastructure; (b) faculty; and (c) trainee time. A robust database infrastructure will allow graduate students and postdocs to conduct research that can be completed within a shorter time-frame than traditional research. Furthermore, available infrastructure will strongly support research in clinical departments (i.e. medicine, nursing, and health professions), allowing us to attract and train talented clinicians. Developing mechanisms to improve care quality and patient outcomes will help our clinical partners build a reputation for excellence, bringing value to them and enhancing their position locally and nationally; this will make us preferred collaborators for future endeavors.

Specific Technical Foundations to be Developed for the Above Focus Areas: • Develop a single, UTHSC-wide policy on HIPAA compliance; • Support healthcare quality improvement through support of HIPAA-compliant applications and evidence-based research; • Support faculty to engage in evidence-based practice by offering dedicated salaried time; • Support expansion and development of the DWPC practice-based research and quality improvement network.

Technical Foundations to be Developed that Cross Research Areas of Excellence: • Support collaboration between research methodologists, informaticists, health care delivery research, and clinical domain experts; • Support for expansion and development of the DWPC practice-based research and quality improvement network.

Technical Foundations to be Expanded that Cross Research Areas of Excellence: • Financially support a UTHSC-wide plan for computational infrastructure; • Creation of a secure, centralized, HIPAA-compliant population data warehouse across our campuses to facilitate linkages of databases, enhance collaboration, facilitate resource sharing, support registry development, cohort identification, and strengthen our competitive position for grant applications.

Synergies and Collaborative Potential

Our faculty currently have collaborations with other institutions that can be leveraged to increase synergies and the visibility of our research efforts. Notable collaborators include: (a) Methodist Le Bonheur Healthcare; (b) Regional One Health (ROH); (c) West Cancer Center; (d) the Memphis VA Medical Center; (e) University Medical Center in Knoxville; (f) Erlanger Health System in Chattanooga; (g) St Thomas in Nashville; (h) Diabetes Wellness and Prevention Coalition participating practices; and (i) the Knoxville VA Medical Center. Institutes and Centers focused on HSR, such as IHOP, CBMI, and CHSI can facilitate collaborators participation in HSR across the entire UTHSC system.

5. Cross-cutting Platforms

(A) Drug Discovery, Drug Development and Structural Biology

Introduction

One of the major goals of biomedical research is the translation of basic scientific knowledge into new medications that can be used as therapeutic interventions to prevent or treat medical conditions. A drug discovery initiative arises because there is a disease or clinical disorder, without suitable therapeutics available, and this lack of effective treatment is thus an unmet clinical need. These therapeutic interventions include chemically defined small molecule drugs, as well as biologics such as antibodies, vaccines or other biotechnologically-derived therapeutic proteins. The development of new therapeutic entities and their effective use is relevant to or intertwined with all six research Areas of Excellence at UTHSC.

The drug discovery process is at the scientific or preclinical level in most instances and development is comprised of a defined set of consecutive steps. Drug discovery includes the identification of a druggable target (target identification), the target validation and prioritization among alternatives, the identification of compounds that modulate the target, and the identification of lead compounds with favorable properties for drug development, thereby considering 'freedom to operate' with regard to unclaimed intellectual property space. In turn, drug development comprises lead optimization, including early de-risking strategies with regard to intrinsic toxicity and off target effects, followed by assessment and optimization of ADME (absorption, distribution, metabolism, and excretion) properties, drug-likeness, and *in vivo* acute and chronic toxicity in preclinical species. Clinical development that follows the preclinical stage is addressed in the Clinical Trials platform.

Current Status of Drug Discovery, Drug Development and Structural Biology at UTHSC

We have an established track-record in drug discovery and development activities by individual faculty across multiple colleges, particularly in the Colleges of Medicine and Pharmacy. A large fraction of the intellectual property disclosed and patented at UTHSC through the University of Tennessee Research Foundation (UTRF) is related to drug discovery and development.

Multiple investigators at UTHSC in different departments and colleges have pursued drug discovery and development projects to varying stages of development. Some of these projects have led to licensing of disclosed IP, the formation of spin-off companies and advancement into clinical development. In addition, there are many investigators at UTHSC that have experience and expertise in certain aspects of the drug development process, including the in-depth biological processes associated with many diseases, and the translation of small molecule hits for druggable targets into lead compounds that can be tested in animals and humans. A core facility, that provides GLP and CLIA level analytical services and biospecimen storage for samples from preclinical and clinical trials, has been established by a UTHSC investigator.

Particular clusters of expertise include: (a) investigators in target identification and validation, medicinal chemistry, biopharmaceutics, pharmacodynamics, pharmacokinetics, drug delivery sciences; (b) AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) accredited animal facilities with extensive veterinary support; (c) NMR and high resolution and triple quadrupole mass spectrometry equipment; and (d) the Plough Center for Sterile Drug Delivery. Nevertheless, most investigators have not been formally trained in drug discovery, development or regulatory sciences, and there are currently no coordinated efforts in facilitating and supporting individual drug discovery and development projects at the institutional level.

Required Growth of Drug Discovery, Drug Development and Structural Biology at UTHSC

An essential step in strengthening the drug discovery and development enterprise at UTHSC is to provide institutional structure and support in this area, particularly for investigators that are new to the process and usually have only expertise in one or a few development steps. In the short term, this should be facilitated by the formation of an institutional board that (a) provides guidance, training, and feedback to investigators on how to navigate and advance a project through the drug development process and pursue funding opportunities and IP protection; (b) provides training in data mining that aids in identifying, selecting and prioritizing potential disease targets; (c) provides training opportunities for investigators, research staff and trainees in drug development and regulatory sciences; (d) provides and coordinates institutional core facilities in support of drug discovery and development activities; (e) provides researchers an avenue for discussions with commercial entities to translate their discoveries into medications; and (f) provides support services for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant submissions.

In the long term, the formation of a campus-wide institute in support of these activities should be considered as the optimal tool to bolster Drug Discovery and Development. Such an institute would serve the different colleges and academic units and establish UTHSC as a regional and national leader in this area.

Furthermore, emphasis should be put on the development of several key areas in the drug discovery and development processes. Key hires are needed in areas that currently are lacking and/or are perceived as bottlenecks, and in areas that connect and complement existing facilities and expertise. These include (a) structural biology expertise combined with molecular modeling and molecular dynamics, a crystallography core, and computational drug discovery to facilitate target validation, hit-to-lead development and lead optimization; (b) medicinal chemistry-based lead optimization that is integrated with *in silico* drug design and provides the bandwidth to address the synthetic chemistry bottleneck; (c) bioanalytical core facilities that provides GLP level analytical services for samples from preclinical and clinical trials; and (d) pharmacokinetics and pharmacodynamics core laboratory that would also provide basic animal models for toxicokinetic evaluation of drug candidates. This core could be named the Experimental Therapeutics Core Laboratory, which caters to all campus and off campus (fee-for-service) entities, and could also provide these services to the Cancer Drug Discovery group.

Synergies and Collaborative Potential

A strategic self-study should identify collaborative opportunities with the cancer drug discovery program, the newly created Center for Addiction Medicine, and emerging structural biology investigations at UTHSC. A strategic alliance with the UT/Oak Ridge National Laboratory Center for Molecular Biophysics and the UT Supercomputer Facility should be developed with direct access and dedicated computing time to UTHSC investigators. We should also seek to develop an alliance with high-throughput facilities in the region, such as Southern Research Institute in Birmingham and Cincinnati Children's Hospital. In addition, a closer partnership with UTRF, CirQuest Labs, and Memphis Bioworks Foundation should be pursued to provide increased access to IP and legal expertise surrounding drug discovery, and to investors and entrepreneurial opportunities.

The Drug Discovery, Drug Development and Structural Biology platform can not only be relevant for every research Area of Excellence, but should also have cross-talk/interactions with the Omics, Biorepository, and Biomedical Informatics platforms during the drug development phases. After successful development of candidate drugs at the preclinical level, there would

be a natural feed directly into the clinical trials platform. This would also provide an additional cross-link between the College of Pharmacy and the rest of the campus.

(B) Stem Cell Biology and Regenerative Therapies

Introduction

The overall goal of the strategic plan is to establish a research group focusing on stem cell biology and regenerative therapies in the next 5-10 years. This group includes existing PIs on UTHSC's campus and those at the University of Memphis (UM), Memphis VA Medical Center, St. Jude Children's Research Hospital and Le Bonheur Children's Hospital. The role of this group is expected to connect with other basic, translational and clinical research areas that can benefit from the expertise of this group. For example, stem cell biology research may connect with cancer stem cell research; regenerative therapies can support clinical research in areas of tissue engineering and regeneration.

To direct future growth, the following four research focus areas are proposed:

(1) Stem cell biology on multipotent and pluripotent stem cells
(2) Tissue engineering and scaffolding science
(3) Translational and preclinical small and large animal models for tissue engineering
(4) Clinical trials and treatments using tissue regeneration concepts

Current Status of Stem Cell Biology and Regenerative Therapies at UTHSC

In 2015, a Stem Cell Interest Group (SCIG) on UTHSC's campus was established with ~30 members from UTHSC, UM and St. Jude. The Group meets once a month with members or invited non-members giving seminars. The expertise of the members includes stem cell biology, cancer biology, bone biology, material science, regenerative therapeutics, cell-based clinical therapies and clinical grade cell processing technologies. There may be other PIs on UTHSC's campus or at neighboring research centers working in this area who are not yet connected. Interdisciplinary collaborations between scientists and clinicians are underdeveloped in this area.

The current discipline is supported by various facilities including Flow Cytometry, Microbiology, Immunology and Biochemistry Confocal Microscope, Molecular Resource Center, Viral Vectors, Nanostring nCounter Gene Expression Analysis, and Laboratory Animal Care Unit and facilities.

Required Growth of Stem Cell Biology and Regenerative Therapies at UTHSC

There is an unmet need for investigators focusing on cutting-edge stem cell research covering pluripotent and multipotent stem cells.

It is our aim to hire 1-2 PIs who can direct a Current Good Manufacturing Practice (cGMP) facility capable of producing clinical grade therapeutic cells for trials and treatment. The PIs should have previous experience in operating a cGMP facility. Within the next 5 years, this facility should be installed, or in place, such that clinical trials and treatments can commence. In the next 10 years, phase I & II clinical trials should be ongoing or completed, and cell-based therapy should be performed in various clinical settings at UTHSC or the affiliated hospitals.

The use of iPSC (induced pluripotent stem cell) lines will be an asset for organ module integration into human-on-a-chip technology. Fibroblasts from an individual could be reprogrammed into iPSC lines, which can then be differentiated into renewable cell sources for all major organ tissues. Human-on-a-chip technology will allow a robust model for personalized drug responses, which could provide valuable insight into an individual's reaction to specific treatment regimens and compound tolerability. More in-depth knowledge could be gained with regard to various population differences, including genetics, gender and demographics. Even in special cases, such as patients with rare diseases, tissue samples could be obtained and examined to learn about mechanism and potential therapeutics. Future use: The MPS (microphysiological systems) Program will produce organ modules as deliverables used for drug discovery and screening. However, the potential for MPS platforms could be utilized in many areas of research, including countermeasures, the microbiome, responses to toxins, infectious diseases and in conjunction with clinical trials.

The establishment of a website for Stem Cell Biology and Regenerative Therapies as well as with other groups or disciplines is required. This will facilitate interactions between researchers within and outside of the campus. The website should also allow postdoc and PhD students to participate and organize seminars to enhance learning/training processes.

Synergies and Collaborative Potential

- One important facility that requires establishment, is the clinical grade cell processing core or cGMP. This facility may be integrated into the Plough Center or a new facility may be created for this purpose. This facility is indispensable for mounting clinical trials or treatments.
- St. Jude has two cGMP facilities and the Directors there are the members of this SCIG who can provide input and assistance for establishing cell-based technologies collaboration or platforms.
- The CRB and West Caner Center are in collaboration on cancer research and treatments. One potential direction is cell-based therapy for various tumors, which can be supported with a cGMP facility.
- cGMP facility will also be welcomed by other faculty who are developing treatments that are non-stem cell based approaches (e.g. DNAzyme therapy).

(C) Cell-Based Technologies

Introduction

Cell-based methods are a vital component of biomedical and clinical research. These methods include well known *in vitro* assays, flow cytometry and cell sorting, bead-based multiplex assays, novel 2D- and 3D-culturing methods, and advanced microfluidic methods. Cell-based methods complement both cell-free and *in vivo* approaches, and are commonly used to quantify cell types, rates of proliferation, metabolism, rates of apoptosis, responses to infectious agents and toxins, cell signaling and secretion, and biophysical properties and interactions among cells. Cell-based methods reduce the need for animals in research, particularly in toxicology and drug screening. They provide efficient ways to (1) study mechanisms of cell function, (2) discover biomarkers and new drugs, (3) evaluate toxicity, (4) test therapies, and (5) regenerate tissues and organs. These technologies exploit many cell types: primary cells, stem cells, immortalized cell lines, genetically engineered cells and reporter lines.

We have diverse capabilities in cell-based methods that are now widely distributed across campuses. We review strengths and opportunities for growth, and provide several recommendations to improve our capabilities. Two recommendations of paramount importance are to upgrade core equipment, and to consolidate our resources for more efficient joint use.

Current Status of Cell-Based Technologies at UTHSC

Several cores at UTHSC support cell-based technologies (see *Core Summary*) including: (a) Flow Cytometry Facility; (b) Molecular Resource Center; (c) Viral Vector Core; (d) Bioengineering & Biomaterials Testing Core; (e) NanoString Core; and (f) the Regional Biocontainment Laboratory.

Flow cytometry and cell sorting are particularly critical. There are seven systems on the main campus used by ~50 teams of investigators. The UTHSC Flow Cytometry Facility has a 3-laser, 9-color LSR II flow cytometer and a 4-laser, 12-color FACSAria II sorter. The Department of Pediatrics has a 6-color Sony SH-800 sorter that can sort into tubes and microtiter plates, as well as two flow cytometers—an 8-color BD FACSCanto II and a 12-color BD LSRFortessa cell analyzer. The Regional Biocontainment Laboratory is equipped with a FACSAria II. The Department of Ophthalmology has a FlowSight imaging flow cytometer that combines cytometry with 20x confocal images of cells. We also have laboratories with the expertise in small-scale manual cell separation using magnetic cell isolation, applicable to any species or sample and compatible with whole blood or cell suspensions. UTHSC's Knoxville and Chattanooga locations do not currently have instruments of the types above for research use.

Complementing the flow sort systems, the UTHSC main campus has both Fluidigm C1 and NanoString nCounter systems. They can be used in combination with flow sorters and sequencers and to analyze RNA and DNA sequence of single cells.

The three systems in the main Flow Cytometry Core, the Fluidigm and NanoString systems are open to all UTHSC investigators. Other equipment may be accessible but is now mainly dedicated to particular teams of investigators. The number of core technicians (currently one in the Flow Cytometry Facility) may become a bottleneck.

Required Growth of Cell-Based Technologies at UTHSC

An essential step in strengthening the cell-based technology platform at UTHSC is an upgrade of major equipment. We recommend that the main campus flow cytometry and cell sorters be upgraded in 2016–2017 so that investigators have access to state-of-the-art technologies. The FACSAria sorter needs to be upgraded to the now standard 5-laser system. The cytometer needs to be replaced with a new 3- or 4-laser system— a Sony 6800 or equivalent.

We would also benefit from the purchase of new equipment. We recommend both an open-access Luminex 200 system (www.luminexcorp.com/clinical/instruments/luminex-100200/) and Seahorse cell metabolism system (www.seahorsebio.com) in the Flow Sort Facility. Robotics systems may be needed to increase capacity.

Note: The Flow Cytometry Facility provides strong scientific and technical support but expanded use may require new personnel.

It is recommended that the Flow Cytometry Core and key personnel be moved closer to the Molecular Resources Center, the Proteomics and Metabolomics Core, the Fluidigm C1 System, and the NanoString nCounter system. Spatial integration will improve use of current resources.

To enhance interactions, we recommend networking among investigators across departments, colleges, and campus by establishing a quarterly SPARKs meeting and seminar series with a technical focus on Cell-Based Analytic Methods.

To improve translational impact of research programs we should establish a clinical cell processing core as part of a Current Good Manufacturing Practice facility (cGMP). Such a facility could extend the reach of our programs and lead to early stage clinical trials.

Synergies and Collaborative Potential

- Cell-based technologies are critical to most Areas of Excellence and complement our other research platforms. This platform is used intensively by investigators who study immune function and infectious diseases. We need to reach out to these communities across campuses and the state.
- The Regional Biocontainment Facility will benefit immensely from enhancements of high-throughput cell assays that enable high-throughput analysis of pathogens and toxicants. The RBL has current Good Laboratory Practice (cGLP) capabilities in an ABSL-3 (Animal Biosafety Level-3) suite with access to large cohorts of genetically variable mice.
- Single-cell omics is now practical and is having an impact in cancer biology, developmental biology, epigenetics, and gene expression analysis. Tight coordination with the Stem Cell Biology and Omics platforms is vital.

- Synergies will occur more easily if equipment and experts are brought together. We need a one-stop shop for all campuses.
- Expand collaborations with St. Jude Children's Research Hospital, Oak Ridge National Laboratory, and our hospital systems partners, and obtain input and assistance in improving our cell-based technologies and platforms.
- Expand collaboration in cancer stem cell-based technologies with the West Cancer Center under the Precision Medicine initiative.
- Combine cell-based assays with more sophisticated and integrated informatics and computational workflows to enhance reliability, replicability, and efficiency.
- Integration of these platforms with a centralized tissue biorepository will foster new insights into disease-related research.

(D) Biomedical Informatics, Biostatistics and Computational Resources

Introduction

To provide support for all of the Areas of Excellence and their Focus Areas, we need to acquire cutting-edge computational resources and biomedical informatics support systems including physical infrastructure and software capabilities. In addition, UTHSC needs to build its workforce of trained data scientists, and develop efficient means of completing inter- and intra-organizational agreements for data use agreements, data transfers, contracts and business associate agreements. This will enable the acquisition of data for research studies, and support: (a) data warehouse creation, maintenance and use; (b) registry and database creation; (c) production of multiple common data models; (d) data analysis, visualization and querying; (e) appropriate study design and statistical analysis plans; and (f) development of novel statistical methods and software. Biomedical Informatics capabilities need to include computational resources (physical infrastructure), as well as expertise (faculty and staff) in: (a) predictive analytics; (b) natural language processing; (c) semantic ontology; (d) analysis of streaming (physiologic) data, genomic data, image data, pathology data; and (e) analysis of HL7, claims, and other administrative data. Biostatistics capabilities need to include HIPAA-compliant computational resources, as well as faculty and staff with expertise in: (a) clinical trials; (b) causal inference from large-scale and observational data; (c) statistical genetics; and (d) statistical analysis of omic-data. Expertise and support for these activities and areas are critical for ongoing and future basic, translational, clinical, and population health research.

Current Status of Biomedical Informatics, Biostatistics and Computational Resources at UTHSC

The Center for Biomedical Informatics (CBMI) and the Le Bonheur Children's Hospital Office of Biomedical Informatics (OBI) currently maintain registries including: (a) the PRD (Pediatric Research Database) and CERNER HealthFacts; (b) the Methodist South Diabetes Wellness and Prevention Registry; and (c) the MLH/WCC/UTHSC Breast Health Data Registry. The Department of Preventive Medicine currently maintains a large claims data warehouse, housing Medicare and TennCare claims, as well as hospital discharge data from the Hospital Cost and Utilization Project (HCUP). Work on the research Enterprise Data Warehouse (rEDW) and the Biorepository for Integrative Genomics is in its initial stages. Databases for studies are produced in REDCap, Unity, Intellitrial, FileMaker Pro, and analytic programs including R, Python, Stata, SPSS, and SAS. Visualization and query capabilities are provided via Tableau and will soon include i2b2 and D3. Data for ongoing registry work is stored in the OHDSI Common data model compliant with NIH and PCORI recommendations. Physical infrastructure includes: (a) a VNX Storage-26 TB mirrored; (b) encrypted Storage Attached Network (SAN); (c) a closed Dell Cluster for the Digital DNA Data Repository; (d) an open (CBMI managed) cluster for virtual machines running CBMI data management resources; and (e) a (Preventive Medicine managed) cluster for analysis of high-dimensional data. Current biomedical informatics expertise includes: (a) data mining; (b) visual analytics; (c) predictive analytics; (d) natural language processing; (e) semantic ontologies; (f) data standardization; and (g) harmonization. Planning is underway for real-time analytics of HL7 and streaming (physiological) data and integration of image data of various modalities, (radiology) into the rEDW using HTML5 technology and DeepZoom Image (DZI) software applications.

We are home to biostatistics expertise in clinical trials, observational data, statistical computing, Bayesian analysis, statistical genetics, and high-dimensional data. The BERD (Biostatistics, Epidemiology and Research Design) unit also provides access to research methods in study design and data analysis. Current expertise includes: (a) biostatistics; (b) epidemiology; (c) GIS systems; and (d) bioinformatics.

Required Growth of Biomedical Informatics, Biostatistics and Computational Resources at UTHSC

A robust computational infrastructure, capable of supporting a range of research applications, is essential to the future of our research. There are two critical functionalities necessary: (a) the ability to securely store and share large amounts of

biomedical data for multiple projects and (b) the capacity to provide the computational platform for the statistical analysis of large datasets and complex methods.

Also essential for research progress is an integrated approach to HIPAA compliance and an analytic platform supporting integration of data such as: (a) “omics”; (b) “clinical/health/healthcare”; (c) “environmental”; (d) “behavioral”; (e) “drug knowledge data”; and (f) “patient-reported outcomes”. Data needs to be appropriately formatted with strict adherence to modern security and privacy preserving, HIPAA-compliant workflows/protocols are also required.

Current software needs for data wrangling and analysis include: (a) Pentaho kettle/spoon and Talend (enterprise versions for ETL data operations); (b) noSQL; and (c) tranSMART (or its equivalent, for integration of genotype-phenotype queries into the rEDW). Natural Language Processing (NLP) software such as: (a) Apache cTakes (clinical Text and Knowledge Extraction System); (b) MedEX; (c) MetaMap; (d) cleartk (computational language and education research toolkit); and (e) ConText. For statistical analyses, a Stata server license is needed to support multiple users, multiple cores, and large datasets.

Large scale databasing and data processing capabilities, to include NoSQL and Hadoop databasing for large scale dynamic non-structured data processing are needed. Furthermore, there are current critical needs for more ‘data miners/data integrators’ to meet the rapidly growing needs of our research community. We recommend hiring analysts and system administrators to handle big data, including the rEDW and big data platforms like Hadoop/NoSQL and data analysis using SAS/SQL. System and database administrators are specifically needed for big data systems who are able to oversee multiple clusters as well.

Moreover, hardware to include centralized flexible IT infrastructure with computational capacity to support the rEDW, genomics platforms, clinical trials management, and statistical analysis is needed. Capacity to ramp up computing power (RAM/local memory) and HIPAA-compliant data storage, is and will remain critical. IT support to perform frequent routine backups for data stored locally (e.g. c drive back-ups for workstation computers). Increased data transfer speed for cores (e.g. MRC; Proteomics, etc. with at least 10 GB) is also essential. For biostatisticians (and campus researchers) there is a pressing need to securely store, share, and archive data in a HIPAA-compliant system.

We recommend the creation of training programs (MS/PhD/post-doctoral) in clinical informatics, data sciences, and application of computational algorithms to clinical data. The Health Informatics and Information Management (HIIM) department's PhD program in Health Informatics needs to be expanded as well.

Special expertise is needed in natural language processing, signal and image processing, ontologies, machine learning, visualization, statistical integration of diverse data sources, causal inference from observational data, and genome-phenome meta-data analysis. Informatics capabilities for storing, analyzing and integrating pathology and laboratory data are also critical needs.

An effectively managed, centralized biostatistics unit, that includes both faculty and staff, can better position UTHSC for recruiting in a competitive environment, foster efficient use of resources, better support our educational mission, and facilitate specialization to support particular areas of excellence and focus areas. To strengthen ties with other departments and colleges, biostatistics faculty should maintain secondary appointments in departments of major collaborators and adequate supporting resources should be available across campus locations (e.g. staff biostatisticians or data analysts).

Finally, consolidated office infrastructure (even if virtual) housing CBMI, CFRI OBI, HIIM and Preventive Medicine (Biostatistics, Epidemiology, Health Services & Policy Research) would add momentum for a critical mass of science, resources and personnel.

Synergies and Collaborative Potential

- A more robust computational infrastructure, available to investigators across our campuses, is necessary to support current science, and will naturally support collaborations as investigators are able to share the same environment.
- Data scientists provide natural linkages across multiple departments and colleges. They can facilitate collaboration and resource sharing by identifying shared interests and needs.
- Strong biomedical informatics and biostatistics will be critical to drive genomics to the bedside, and to perform gene/omics-disease studies.
- The data repository and computational infrastructure will enable small-scale pilot research projects using one-time data snapshots as well as large-scale research projects involving on-going data collection.

- There are multiple opportunities to create synergies with local and regional training programs, including data science programs at UT Knoxville and St. Jude Children's Research Hospital. In addition, there are under-utilized opportunities for data analyses with all of our clinical partners.
- Biorepository and Integrative genomics DNA repository, collecting DNA of consented patients from LBH expected to produce 2000 samples in year one and expanding to outpatient centers in subsequent years.
- Predictive analytics will be a major growth area in clinical research, sourcing partners in all UTHSC colleges by supporting computerized, practical clinical decision-making.
- Biostatistics methods researchers to work with basic, translational, and clinical researchers to identify statistical challenges and develop robust analytic solutions.

The systems proposed above, by including HIPAA compliant data management and storage processes, regulatory compliance, would position UTHSC for a range of national trials, including FDA, NIH, pharma, etc.

(E) OMICS Technologies and Bioinformatics

Introduction

To provide support for all of the Areas of Excellence and their Focus Areas we need a cutting-edge omics platform with broad competence in genomics, transcriptomics, proteomics, metabolomics, metagenomics, epigenomics, interactomics, and bioinformatics. Expertise and support for this omics stack is critical for ongoing and future basic, translational, and clinical research, as well as for diagnostics of human disease at all UTHSC campuses.

Current Status of OMICS Technologies and Bioinformatics at UTHSC

Current next-generation sequencing (NGS) systems available in Memphis include Ion Protons and Ion Personal Genome Machines (PGMs) in the MRC and an Illumina MiSeqDx in the Le Bonheur Hospital clinical laboratory, provide several service including:- Limited whole exome sequencing, targeted gene panel NGS for single nucleotide polymorphism (SNP), insertion or deletion (indel) detection/quantification, DNA methyl-seq of affinity purified samples, limited RNA-seq of whole transcriptomes, and smallRNA-seq of whole microRNAomes. Current microarray systems include an Affymetrix GCS 3000

and an Illumina iScan in the MRC, enabling genome-wide genotyping, chromosomal copy number variant (CNV) analysis, global promoter and DNA methylation analysis, and transcriptome/microRNAome expression analysis. Expertise exists for most of these capabilities, but could be expanded for CNV analysis, particularly in a clinical setting, and for DNA methylation analysis.

The Vice Chancellor for Research has created a new Proteomics and Metabolomics Core which is equipped with a Thermo Scientific ORBITRAP FUSION LUMOS Mass Spectrometer with a nanospray ionization source. This top of the line instrument, with two HPLCs for proteomics and metabolomics, is excellent for analysis of proteomes and metabolomes. We have recruited a Core Director with substantial past experience to UTHSC.

The recent hire of a Director of the new Molecular Bioinformatics core (mBio), in conjunction with the installation of a user-friendly interface for whole genome analysis, the publically available GALAXY tool suite, has been essential to bioinformatics analysis at UTHSC. There is now ample opportunity to expand this core with additional personnel to assist in pipelines for omics analysis and interactomics.

Required Growth of OMICS Technologies and Bioinformatics at UTHSC

A strong bioinformatics core, additional bioinformatics faculty and user-friendly resources in bioinformatics will be essential to our growth across all Areas of Excellence. In the near future, massive amounts of sequence and expression data from specific disorders, as well as evolving areas of translational research in cancer and precision medicine, will require expertise in the handling and manipulation of extremely large clinical datasets. These efforts, in addition to decreased costs for genome scale sequencing, will produce an influx of data on campus at both the clinical biospecimen and basic research levels. Areas for growth include: (a) additional computational power, sequence analysis software and storage capacity on campus; (b) an influx of bioinformatics expertise including a graduate degree program and additional synergy with the University of Memphis Bioinformatics, and Computer Science programs; (c) additional regional collaborations with SJCRH, Hudson Alpha, Washington University and/or Vanderbilt University; and (d) campus wide education efforts to bring the level of translational and basic research involving bioinformatics and omics up to speed with other institutions.

The addition of a Chief of Clinical Genetics, other new faculty in the Department of Genetics, Genomics, and Informatics, the initiation of a general population DNA Biorepository by the Department of Pediatrics, and similar efforts by several other departments, requires essential areas of omics growth on campus. This growth includes introduction of whole genome sequencing capability, greater capacity for whole exome sequencing, the development of validated disease-based NGS panels, CNV analysis capabilities for use in clinical diagnosis of inherited disorders and large-scale clinical genomics research, and establishment of a CLIA-approved Clinical Genomics Laboratory. Moreover, this expansion goes well beyond the clinic, into basic, translational and clinical research, and will generate the volume of data necessary to develop an enterprise data warehouse that incorporates both omics and clinical data. This is a resource that will not only enable investigation of causative genes in many disorders affecting the local population, but will improve patient care by developing the capability to incorporate actionable omics findings into the electronic medical record (EMR).

The expansion of NGS systems into whole genome-seq will also provide the capability for whole genome DNA methylation-seq, as well as RNA-seq at much greater depth. These technologies will greatly increase basic research capabilities, advanced discovery, and will provide a competitive advantage for grant funding and new faculty recruitment. An initial CLIA facility should have a minimum of one HiSeq4000 NGS system, one NextSeq550 NGS/Array system, one or two MiSeqDx NGS systems, and possibly one Affymetrix GCS3000Dx Array system. This configuration would permit the sequencing of up to 400 to 800 whole genomes and 5,000 to 10,000 whole exomes per year, plus up to 5,000 to 10,000 targeted NGS disease panels, 5,000 Chromosomal Copy Number Arrays, 5,000 NIPT tests, and 5,000 transcriptomes and microRNAomes. These NGS systems would also provide microbiome analysis capabilities. This will require additional staffing with the requisite expertise in omics and bioinformatics, and initial seed funding for sample analysis.

Our state-of-the-art Proteomics and Metabolomics Core Facility will do an excellent job of covering the needs of our current UTHSC research community. With the expansion of the use of proteomics and metabolomics analysis of clinical samples, over the next five years, additional mass spectrometry equipment will be required within a CLIA-certified laboratory. The VCR has substantial expertise in interactomics, and can assist the deans in recruitment of computational biologists with expertise in creating and analyzing integrated interactomic data.

We will need, as part of the UTHSC omics platform, the capacity to analyze microbiomes. While determining whether this capability should be developed as a future UTHSC Institutional Research Core, the Vice Chancellor for Research is

developing a Cores partnership with UAB which will allow our faculty to outsource this work in the near term to their Core facility.

Synergies and Collaborative Potential

- Strong bioinformatics teams will be critical in ongoing collaborations with biorepositories across UTHSC—one example being the BIG (Biorepository for Integrative Genomics) program in Pediatrics at Le Bonheur Children's Hospital.
- Tumor typing by NGS is the current state-of-the-art technology in cancer research, requiring intense bioinformatics and genomic support. Ongoing programs including collaboration with West Cancer Center and the Department of Surgery need to be expanded.
- More accurate pharmacogenomics and pharmacoproteomics, involving all of our Areas of Excellence, will benefit drug evaluation programs across all colleges and campuses.
- The development of a Saliva Research Center where samples are stored for omics analyses will be critical for both clinical diagnosis and research.
- We have a unique opportunity to expand our platforms in collaboration with teams of computer scientists at UT Knoxville and Oak Ridge National Laboratory (ORNL). We have unrivaled, but still unexploited access to world-class supercomputers at the UT-ORNL Joint Institute for Computational Sciences.
- All of these broader analyses can be applied to basic research in model systems (mice, flies, yeast, etc.) using whole genome approaches that require bioinformatics expertise.
- Cross discipline omics stack projects that begin at the clinic with a group of cases sharing a genomic lesion have proven to promote research synergy across campus at other institutions.

(F) Biorepository Systems

Introduction

Precision medicine is an approach to the prevention and treatment of disease that takes into account differences in genes, environment, and lifestyle to personalize recommendations by health care professionals. The field of medicine is moving

rapidly towards an era where quality care will have to be individualized to best serve our patients. However, a major roadblock exists: the lack of clinical and genetic data available from disadvantaged populations. In the Mid-South, African-Americans and rural populations of several races and ethnicities contribute substantially to the burden of chronic disease and the associated costs of healthcare. Unfortunately, these populations have been severely under-represented in genetic studies and particularly in clinical trials of drugs, making precision medicine and the associated improvements in outcomes and costs unachievable at present. As an example, promising new drugs for common conditions such as asthma or high blood pressure, which may have worked well in a homogenous group of middle-class research subjects, may not work in minority and other disadvantaged populations or may even be harmful. An initial step towards the realization of this care pathway is to collect health data and genomic information on disadvantaged populations so that all persons in this region can benefit from advances in healthcare. In concert with the construction of enterprise data warehouses and associated clinical databases (cf. Computational Resources), UTHSC needs a broadly representative, comprehensive biorepository for DNA, and a second biorepository for tissues of various types, that is focused on areas that are identified by the Operational Strategic Plan for Research.

Current Status of Biorepository Systems at UTHSC

Currently, numerous biorepositories of various sizes exist at UTHSC, and our partner institutions in the UT system, mostly to support individual Investigators or Programs. To more broadly address the needs of the research community, in 2015 a Health Genomics Laboratory was founded, in partnership with Le Bonheur Children's Hospital (LBCH), to collect and analyze DNA samples from patients including under-represented minorities and children with chronic health conditions. This Biorepository and Integrative Genomics Initiative (BIG) was designed to allow large-scale collection of DNA from a broad and diverse population of children in West Tennessee. These samples are linked to personal health data through creation of a data warehouse derived from the electronic medical record. Currently thousands of DNA samples have been banked, and collection and accessioning is ongoing. Many existing biorepositories can be linked to centralized resources to take advantages of scale and the advanced systems that have been created, allowing automated accessioning, storage, retrieval, and data linkage. However, some specialized biorepositories (e.g., PBMCs in vaccine studies which require liquid nitrogen storage) may be unsuitable for a centralized facility, and some investigators may not wish to take advantage of centralization because the aims of their personal bio-banking programs would not benefit.

Required Growth of Biorepository Systems at UTHSC

In order to properly support the broad range of research at UTHSC, several initiatives must be undertaken. These include: (a) integration of existing DNA biorepositories into BIG, where desired and practical; (b) scale up BIG to include adult participants from aligned hospitals (e.g., Methodist University Hospital) and from the community; and (c) develop a parallel, central biorepository for other biosamples with similar storage, accessioning, and data linkage capabilities. The tissue biorepository should be able to handle a wide variety of inputs, including: (a) saliva; (b) hair; (c) placenta; (d) fat cells; and (e) surgical specimens.

We must also integrate existing tissue biorepositories into this nascent UTHSC tissue biorepository, where desired and practical, and extend the scope of both central biorepositories to other hospitals in the UT system and generally across the State of Tennessee; provide support for and linkage to other biorepositories outside of the central ones at UTHSC.

Furthermore, as technologies mature, costs stabilize, and funding becomes available, we must convert the DNA biorepository into a data biorepository by performing next generation genomic analyses, using some or all of the available samples, and recruit new investigators in all focus areas of the Strategic Plan who will make use of the biorepository resources.

Synergies and Collaborative Potential

- The availability of clinical materials (or genomics and other data derived from those clinical materials) linked to a clinical database will provide substrate for research across the T0-T4 spectrum and in all of the focus areas for research defined by this Strategic Plan.
- This initiative will provide synergies within the Institution and between UTHSC and other entities both within the UT system and with our partners (e.g., University of Memphis, Oak Ridge National Laboratories).
- Biorepository Systems will be tightly linked with other cross-cutting platforms such as Drug Discovery, Biomedical Informatics, OMICS technologies, Clinical Trial Systems, Health Disparities Research, Genetic Engineering, and Computational Resources. It will be absolutely essential for our journey into Precision Medicine over the next decade.

(G) Clinical Research Systems

Introduction

The Clinical Trials Governance Board (CTGB) at UTHSC will be developed as a fully integrated model of developing and sharing best practices for clinical research through institution-wide offerings. The primary goal of CTGB is to support and grow clinical research by promoting access to resources and opportunities for investigators and faculty throughout the UT system. CTGB will support clinical research trials, as well as research efforts to further translate findings from clinical trials more broadly for adoption into our communities. The establishment of the CTGB should facilitate acquisition of increased research funding from industry, nonprofit, and governmental sources in order to conduct top quality and high impact research. CTGB will coordinate with the various Clinical Research Centers to ensure adequate provision of services and resources to all UT affiliated investigators for the following:- To improve quality, efficiency, and regulatory compliance of the conduct of clinical trials (interventional or observational research); enhance the institution's ability to achieve its research mission. As clinical research is defined as any research involving human subjects, the scope and breadth of CTGB must support the conduct and facilitation of research involving human specimens, translational research, Phase I-IV interventional research, and observational studies. Therefore, it is of primary importance that CTGB foster an environment in which researchers can work together in a team approach to develop products and solutions for health problems applicable to patients and our community. Established clinical research offices (e.g. Office of Clinical Research, Clinical Research Center, Children's Foundation Research Institute, Preventive Medicine, College of Dentistry) as well as future additional resources throughout the UT system, would benefit from the development of this model.

Current Status of Clinical Research Systems at UTHSC

A number of clinical research offices currently exist at UTHSC including: (a) the Clinical Research Center (CRC), which provides space and resources for government-sponsored projects, particularly those with a focus on diabetes and metabolism; (b) the Preventive Medicine Clinical Research Facilities (PMCRF), which supports clinical research of all types including interventional trials and observational epidemiologic and preventative research activities; (c) the Le Bonheur Children's Foundation Research Institute (CFRI) which provides a comprehensive infrastructure for pediatric clinical

research; (d) the College of Dentistry Clinical Research Center; and (e) the UT Office of Clinical Research (OCR), which supports investigator training and facilitates conduct of trials funded by industry and non-profit entities.

Each office has a different focus and different infrastructures specific to that focus. Integration of the offices is only now beginning to occur through the CTGB. Additionally, each office has various degrees of funding and revenue sharing with investigators, departments, and the institution. These currently range from overhead sharing, to flat fees for space needs, to fee-for-service models. This creates an environment of confusion for investigators. Moreover, the institution does not provide integrated clinical trial expertise in contracts and budgeting, and limited space exists for clinical trial activities. There is no universal tool for invoicing and managing clinical trials in real time, and there are no system-wide strategies and systems for recruiting research subjects or research staff. There are also no campus-wide services to provide for clinical trial medical writing, database systems, or support outside the UTHSC campus itself. Integration between university and hospital partners is poor, as a result many investigators at UTHSC are unable to conduct research with hospital partners due to a lack of understanding of the role of non-physician researchers.

Statewide, the university is unable to keep up with the demand of its investigators for clinical research support. For example, the University of Tennessee College of Medicine Chattanooga has recently been forced to contract with an external contracted research organization (CRO) to perform study support. This is a very expensive and therefore limiting solution, and indicative of a system-wide failure of our current infrastructure to support and encourage clinical research activity. However, great strides have been made in the last few years with the funding and development of the OCR on a university level, which has begun to provide this level of support to all clinical investigators with funded projects at the UTHSC campus, including: (a) provision of research nurses; (b) direct contracting; (c) budgeting support; (d) research space; and (e) adoption of a clinical trials management system. Furthermore, the recent creation of CTGB promises to address many of these outstanding issues.

Required Growth of Clinical Research Systems at UTHSC

To support the level of volume and coordination required within this Operational Strategic Plan for Research, significant investment for growth is necessary in the multiple areas. The first area of growth is financial support of clinical trial services. All clinical trials programs that are undergoing growth tend to spend more on infrastructure than they recoup. Additionally,

given the reimbursement models for non-profit or industry based research, compensation for trial services provided often does not occur for months to years after the service has been provided (and the personnel and infrastructure cost has been incurred). As such, significant investment must be taken for growth, and we propose a model by which this cost can be recouped through a financing plan, by which the trial offices are enabled to make investments that will have long-term financial reward.

Secondly, the creation of the CTGB allows for networking and sharing of best practices across Clinical Research Offices, as well as encouraging a staffing model that takes advantage of resources across groups. Creation of a statewide network will also allow for externally facing activities which will advertise the university as a valuable partner for clinical research among funding agencies and academic partners.

In addition to grants and contracting support, additional support is needed for investigators to support grant submissions, IRB submissions, ensure regulatory compliance, foster industry partnerships, and help provide resources for subject recruitment and enrollment. Recruitment will be managed through creation and management of a system-wide recruitment tool, which will require at least one FTE from the Department of Biomedical Informatics, as well as the cost needed to set up this system. Enrollment will be managed through adoption of a single Clinical Trial Management System across research offices. Contract and budgeting support will be supported through the OCR which works closely with both UTHSC and the Methodist Hospital System to streamline clinical trial activities, including CDAs, CTAs, and relationships with industry. Investment is needed for clinical trials data management systems, which could include RedCap and should be facilitated through interaction with the Division of Biostatistics and the Department of Biomedical Informatics. Relationship building and education of Methodist Hospital System leadership must be performed to facilitate credentialing and encouragement of non-physician investigators. Finally, medical writing support is needed to facilitate clinical grant applications and dissemination of research results.

Furthermore, faculty, trainees, students, and staff should have access to formal instruction in clinical and translational research. Programs already exist through the Department of Preventive Medicine, which provide either a Master's degree in epidemiology or an online certificate in clinical research. However, no training program for research staff and personnel exists on campus. Development of a research rotation within the College of Nursing, availability of clinical research internships for PhD and other students, and formal educational opportunities through the OCR and Department of Preventive

Medicine should be made readily available. This will allow for potential investigators and staff, with an interest in pursuing a career in research, to gain training at a significantly reduced cost.

Considering the expansive role of the CTGB and the OCR in education, training, and provision of trial services to all potential investigators on campus, resources should be provided to the CTGB and OCR to allow for rapid growth and responsiveness to investigator needs on campus. These needs include the rapid turnaround and resource provision to expand trial services, and study personnel on demand for investigators with funded projects. The OCR can aid in the development of new investigators with the ultimate aim of facilitating physician scientists applying for federal academic level grants, which can then be performed with the support of the appropriate Clinical Trial Unit on campus. A flexible staffing model with oversight from CTGB should be provided to allow for sharing of resources across clinical trial units as needed.

Finally, a limited number of clinics, across campus currently accommodate those with clinical research needs and resources, should be provided to allow for adequate space in clinical research units (CRC, OCR, etc.), to meet demand, as well as to provide research services directly in physician practices. This will include both expansion of resources available at Methodist University Hospital, development of resources among partner institutions including the Veterans Administration and other campuses, as well as training and dispersal of research nurses into individual practices to support clinical investigators. Additionally, dedicated trial services must expand to include Phase I capabilities (which would include dedicated clinical research laboratories and research pharmacies), as well as capabilities to perform pharmacokinetic studies and tissue-based studies requiring specimen processing and collection. These services and space should be integrated to provide comprehensive research support across the life cycle spanning from pediatrics to geriatrics.

Synergies and Collaborative Potential

- Clinical research systems will support all of the Areas of Excellence in this Strategic Plan, with significant inroads already made in cancer (West Cancer Center), respiratory diseases (CFRI), endocrine and metabolic diseases (CRC), and cardiology (OCR).
- This platform will directly support and define research dedicated to researching health-care disparities. Through both the prioritization of such studies, throughout all clinical trial units, as well as direct support in epidemiologic and observational studies through PMCRF.

- Clinical research systems will work closely to ensure appropriate synergy with the biorepository function in provision of both regulatory support and tissue procurement services.
- Integration with biomedical informatics will serve to enhance database building, creation of trial networking capabilities, observational research, and patient recruitment tools.
- Collaboration with laboratory scientists in designing and implementing translational research programs will be essential in the creation of a fully integrated T1-4 model of research across the university.

(H) Health Disparities Research

Introduction

The health disparities research platform addresses the overarching goal of Healthy People 2020, which is to eliminate health disparities among segments of the population, including differences that occur by gender, race or ethnicity, education or income, disability, geographic location, or sexual orientation. Our focus is on integrating a 'disparities sensitivity' among all research/investigative efforts across all units and within each of our designated research areas.

Current Status of Health Disparities Research at UTHSC

Addressing and investigating health disparities has been a priority for us. Efforts thus far have included a number of strategies to engage this cross-cutting research platform. One such strategy has been the formation of centers/collaboratives such as the Consortium for Health Education, Economic Empowerment and Research (CHEER), a community-based participatory health disparities research center funded by the National Center for Minority Health and Health Disparities. An example of a more specialized center is the UT-West Cancer Center for Innovation in Health Equity Research, a recently established Center that addresses health equity in cancer care in the Mid-South. Another strategy to address health disparities by the UTHSC is the hiring of faculty and staff who represent diverse backgrounds and research interests across the UTHSC landscape. Finally, we have sought to promote health disparities research through its immediate access to diverse populations, and through unique community partnerships across the three major regions of West, Middle, and East Tennessee.

Required Growth of Health Disparities Research at UTHSC

Some essential steps for growth of this platform include integration of health disparities research within teaching, patient care, and service. It is important for our students and trainees to receive instruction in health disparities research throughout their training. Courses, clinical experiences, and outreach opportunities will include opportunities for health disparities research.

Translational studies across diverse populations need a higher priority at UTHSC. Recruitment of subjects into translational studies should consist of the broadest cross-section of patients and/or participants, representing disparate populations. This requires establishing and maintaining effective collaborations and partnerships with local clinics, hospitals, community- and faith-based organizations, and public health centers to affect policy and decision making.

Moreover, because neurodegenerative, cerebrovascular, and movement disorders are more prevalent among low income and minority populations, efforts to address such disparities in nervous system research should become a priority for our network. Included is research that addresses addictions with its strongly associated cultural, racial, and ethnic determinants.

Studies identifying the biologic and behavioral determinants associated with poorer cancer outcomes among persons representing diverse racial/ethnic and socioeconomic backgrounds need to be conducted. Strategic hiring of key scientific personnel representing clinical epidemiology, health psychology, and genomics are necessary to carry out such studies, while taking full advantage of the UTHSC's access to multiple at-risk populations in the Memphis/Delta, as well as in the Appalachian regions of the state.

In addition, significant health disparities have been identified among these health outcomes. The investigation of disparity-driven health determinants needs to be integrated into our research efforts, including any variability in signaling and recognition, the interaction of environmental factors and OMICS, and culturally sensitive and inclusive approaches to the prevention and rehabilitation from these outcomes. Such teams require research skills in genetic epidemiology, molecular biology, social and behavioral science, econometrics, and public health.

Precision medicine research efforts across UTHSC units should address disparities by: (a) 'omics-guided' diagnosis, treatment, and prevention; (b) an understanding of gene-environment-lifestyle interactions in a variety of cultural/social contexts; and (c) investigations into the interaction of social/behavioral determinants of health, health genetics, and genomics.

Finally, health disparities need to be addressed and integrated in the areas of comparative effectiveness research, evidence-based practice, practice-based evidence, and community-engaged research. Such a focus is necessary to improve healthcare delivery, maximize the impact of prevention, treatment, and health improvement interventions among underserved populations.

Synergies and Collaborative Potential

- Facilitate health disparities research collaborations across the UTHSC campuses, departments, and research focus areas, which include: (a) The Institute for Research, Innovation, Synergy and Health Equity (iRISE); (b) the Clinical and Translational Science Awards (CTSA) program; (c) the UT-West Cancer Disparities Center; (d) the UTHSC Research Data Center; (e) UT Chattanooga's SimCenter; (f) Tennessee Data Center; and (g) the Joint Institute for Computational Science (UTK/ORNL).
- Expand our research focus areas to include health disparities/social determinants of disease in collaboration with community partners, both governmental and non-governmental agencies such as: (a) Shelby County, Knox County, and Hamilton County Health Departments; (b) Southeast, East, and West Tennessee State Health Department Regional Offices; (c) Le Bonheur Children's Hospital, Knoxville Children's Hospital, and Children's Hospital at Erlanger; and (d) Congregational Health Network, Lifespring Community Health, Urban Child Institute, The Siskin Children's Institute, and the Center for Addiction Research.
- This platform will also maximize the formation of cross disciplinary research teams that practice team science, and community-based participatory research in addressing the complexities of health disparities across each of the research focus areas.

(I) Genetic/Gene Engineering

Introduction

CRISPR/Cas and related technologies (Talen, Zinc fingers, Mega-TALS) have the promise to rapidly transform medicine over the next decade by making safe and easy gene editing possible. Currently, use of CRISPR/Cas is mostly effective in *in vitro* systems, but proof of principle in animals and humans has been accomplished. The limitations that still need to be overcome are mainly in the areas of delivery (both in targeting of the correct cells and in efficiency of deletion / alteration) and in further reducing off-target effects. It is also currently easier to knock-out than knock-in desired traits. Nevertheless, the pace of progress is rapid and it is predictable that we will be engaged in clinical trials in humans at UTHSC within the next five years. This will likely take a staged approach, with basic discoveries been made in vitro, followed by pre-clinical animal studies to provide proof of principle, followed by ex vivo demonstration on human tissues, and then ultimately resulting in clinical trials. As an example, a pathologist may develop a parvovirus-based CRISPR/Cas delivery system that can target immature red blood cells. Such a vector would hold great promise for editing away cross-reactive blood antigens on the surface of red cells, antigens that cause transfusion reactions. This program may evolve from in vitro studies, using banked blood, to animal studies in mice, to human clinical trials on trauma patients who often receive unmatched blood. As a second example, an ophthalmologist may identify a single gene defect that leads to cataract formation. Using existing adeno-associated virus vectors prevalent in gene therapy, a CRISPR/Cas-based gene editing vector might be created which would repair the defect. It would go through a similar bench to bedside translational process. It could then be injected into the cornea, reversing or preventing cataracts. In both examples there is no concern about off-target effects, mutagenesis, or delivery issues that limit other planned corrections.

Current Status of Genetic/Gene Engineering at UTHSC

Currently, several laboratories and the Viral Vector Core (VVC) at UTHSC make routine use of CRISPR-Cas and related technologies to do gene editing as a part of basic science protocols and in pre-clinical discovery science. This is generally accomplished using plasmid or lentiviral vector based CRISPR/Cas9 within each laboratory. The VVC has provided services for lentiviral CRISPR/Cas9 vector based gene editing to several faculty on this campus. So far several genes have been successfully knocked out at the cultured cell level by using the CRISPR/Cas9 system. However, no knockout animals have

been generated yet at this campus. No centralized resource is yet available and there are no human studies currently in process.

Required Growth of Genetic/Gene Engineering at UTHSC

In order to properly support the broad range of research at UTHSC, several initiatives must be undertaken. A centralized Core facility to provide CRISPR/Cas or related technologies as they mature for the purpose of genetic alteration of mice is needed. Eventually this core might also engage in work on human tissues, either ex vivo or in the context of clinical trials of humans. This work needs to take advantage of what we have at UTHSC including a transgenic/knockout facility and viral vector core facility. This new core should be more focused on human tissues or primary cells or coordinate with those two existed core facility in expanding or creating new system for human studies. The Core will require facilities to perform micro-injection to deliver DNA or RNA to embryos. Thought should be given to how this Core will interact with, complement, or grow from the current VVC and the existing transgenic/knockout mouse facility, as some duplication of capabilities would occur.

A working group of interested parties should also be formed to: (a) determine the best areas of focus and synergy for near-term growth; and (b) advise on the restructuring of Core assets to best meet the current and future needs.

Furthermore, we advise that the following initiatives be taken: (a) new recruitment or reorientation of duties for scientists who are experts in viral vector systems (particularly AAV and integration defective lentivirus systems) would be helpful to address delivery to specific tissues / body sites; (b) the Institutional Review Board (IRB) and appropriate ethicists should prospectively engage in discussions of how human studies using this technology will advance at UTHSC in the coming years; (c) the recruitment of research faculty in the T0-T2 spectrum with interests in application of this technology should be undertaken. Genetics and Maternal-Fetal Medicine are particularly important in this context. This may be staged, with basic science recruitment in focus areas followed by clinician scientists to perform clinical trials, or it may involve recruitment of physician scientists who can conceive of and mature a project from start to finish; and (d) the capability to manufacture mRNA/RNPs and cells under GMP conditions is needed; some of this may be contracted out but local capabilities for some applications will be needed. The St. Jude Children's GMP LLC may be a candidate for this.

Synergies and Collaborative Potential

- There is significant synergy with genetic engineering and efforts being undertaken in several areas of disease pathogenesis and with the biorepository and precision medicine initiatives at UTHSC.
- A tremendous collaborative potential exists to partner with St. Jude Children's Research Hospital Gene Therapy and viral vector experts, as gene therapy trials are currently being undertaken with AAV and lentivirus based vectors at that institution, and a conversion in the near future to CRISPR/Cas for some applications is predictable.

6. Faculty Retention and Recruitment

Faculty are our most critical resource at UTHSC. As such, we must actively work to retain faculty. Recommendations at this time include:

1) The research bonus/incentive plan should be maintained. It is one of our best tools for retaining faculty.
2) Faculty mentoring committees should continue in the College of Medicine and be starting in other colleges. These need to be active for junior faculty. This requires initial effort by Chairs to establish committees early-on and oversee throughout multiple years.
3) Team science and working groups in our identified focal areas should be supported with new programs designed to facilitate collaborations. Responsibility for doing this should reside at all levels from the Office of Research to Colleges and Departments.
4) A mechanism and set of criteria by which Clinician – Scientists in all colleges may apply for and be awarded protected time should be established in each college.
5) Workshops and/or a seminar series (live and online) should be established for clinicians wishing to increase research activity. It is recommended the Office of Research take the lead in establishing this, with input from all colleges.
6) We should work to better publicize faculty research activity beyond recognition of grant awards and key publications. For examples, website recognition of a new promising collaboration between two UT faculty or an investigator with a good research story. Recycling of the Alumni Magazine articles onto our webpage should be considered.

7) Benefits are important for both retention and recruitment of faculty. A comprehensive review of benefits and how they relate to benefits at similar institutions is needed. If benefits are not comparable, for example in family college tuition benefits, awareness at the UT system and state level is needed, with an action plan on how to possibly resolve.
8) Added training opportunities for growing our own researchers are needed, especially for our clinicians in all colleges. Additional Master's and certificate programs are needed. The cost of these should be such that faculty will take advantage of the opportunities. In this same vein of growing our own researchers, clear pathways to dual degrees must be established and published. For example for the MD-PhD, PharmD-PhD, or DDS-PhD, etc.

UTHSC should recruit excellent researchers who also fit with our existing research portfolio and, as such, bring added value. Specifically, we recommend:

1) Recruits in research-intensive departments should be in the focal areas as described in this strategic plan. Further, the level of research growth in a given department should match the success of the department in research.
2) Establish Centers or Institutes in focal areas. This will help attract the best recruits in these areas.
3) Establish strong cores and shared equipment at the UTHSC, College, and Department level.
4) Establish an itinerary for possible recruits that have faculty from many departments and colleges in the candidate's area of expertise. The goal is to demonstrate possible collaborators outside the intended department. Further, joint appointments should be encouraged or sought where appropriate.
5) The Office of Research should establish at all colleges:
    A) New recruit information package for the family/home move. This would include items such as: (a) information on moving; (b) the city of Memphis; (c) spouse job possibilities; (d) getting a Tennessee driver's license; (e) cable set up at your home; etc.
    B) Hitchhikers guide to on-boarding as a researcher at UTHSC. This would be a manual of who does what and how we do things such as IRB, HR technician hiring, etc.
6) Establish strategic endowed chairs across departments and colleges, as funding arises, to secure difficult to fill research faculty positions.

7. Research Cores

Effectively and efficiently managing institutional core resources is intimately tied to the overarching goal of the Operational Strategic Plan for Research, namely to accelerate the research enterprise at UTHSC. In this respect, the objective is to ensure the quality of institutional research cores by enabling the necessary infrastructure, accessibility, affordability, accountability, oversight and fiscal responsibility of these institutional investments. Beyond fiscal considerations, there are many unaccounted benefits to warrant the underwriting of cores, which include, but are not limited to, (a) maintaining international recognition of research programs; (b) increasing extramural funding; (c) supporting active research grants that require core services; and (d) retention and recruitment of faculty. Importantly, smaller institutions require the same research infrastructure as larger ones, but have fewer investigators to support the research cores. We also recognize that all research cores at all academic health science centers are subsidized by the institution (i.e., cores don't make money anywhere).

Overview of Existing Cores

Philosophy: Institutional cores are defined as shared resources that are widely used among our faculty, preferably across multiple Colleges and Departments. The institutional cores receive their budget from the institution. The internal service fees are set based upon market evaluation, in which pricing for services is compared among our peer academic institutions, preferably those public institutions located in the South/Mid-South. Using this market-based information, prices for equivalent services will be set to be in the bottom-third to bottom-half of internal prices of our peer institutions. Going forward, institutional cores will be managed with a business-like model using three-year pro forma business plans to develop core budgets and to use data-based metrics to measure core success at least yearly. Each year, core success will be summarized in an annual research cores performance report that will be publicly accessible.

Analysis: During FY16, a new organizational structure for core operations and fiscal management was developed that is consistent with the philosophy stated above. The position of Associate Vice Chancellor for Research- Cores was established and an internal search performed, leading to Tiffany Seagroves being selected for this position. The first step in the process of improving this essential infrastructure was the recommendation of seven institutional cores in February 2016 by the Research Cabinet to the Vice Chancellor for Research; this recommendation was accepted. The seven institutional cores include: (a) the Lab Animal Care Unit

(LACU); (b) the Regional Biocontainment Laboratory (RBL); (c) the Molecular Resource Center (MRC); (d) the Flow Cytometry and Cell Sorting (FCCS) core; (e) the Molecular Bioinformatics Core (MBC); (f) the Proteomics and Metabolomics Core (PMC); and (g) the Research Histology Core (RHC). In addition to these individual cores, an institutional core umbrella budget was established that will provide resources for web-based core management, core marketing and promotion, a small-scale pilot project program and training resources in leadership and lean (constant removal of waste and inefficiencies) management principles.

Notably, none of the seven institutional core facilities is self-sufficient, with sizeable institutional investment in both support staff and other operating expenses. In FY16, the total institutional overhead, including purchase of new equipment, was approximately $2,971,000. In FY17, the projected institutional subsidy of cores, including new equipment, is expected to be approximately $3,116,700. It is expected that improving core operations and core efficiencies through our new core management philosophy, while offering competitive market-based pricing, will over time lead to the ability of institutional cores to purchase new equipment when needed.

Going forward, continuation of each core as an institutionally supported resource will be evaluated with the following perspective as a guide:

1) Relative to a specific core's mission, is the designation as an "institutional core" still appropriate?
2) Does the core pass the multi-departmental, multi-investigator litmus test?
3) Is there sufficient intra- and inter-department use, and if not, why?
4) Can the services of the core be outsourced more economically?
5) Are there returns on core investments beyond fiscal considerations to warrant continued institutional underwriting? (e.g. grants funded through investigator use, publications, etc.)

Suggested outcomes of this evaluation to be considered are:

1) Continued institutional support
2) Transferring financial responsibility to a College, Department, specialized program or Center
3) Eliminating (or "sunsetting") the shared resource

New Institutional Cores

The same guiding principles as outlined above should be applied to any consideration of developing a new institutional core facility or expanding an existing core. First, a detailed analysis of the specific modalities that will best serve the needs of the research community should be developed. Working groups with expertise in relevant technologies and platforms will be developed when a new core is proposed to the Vice Chancellor for Research (VCR) or the VCR Research Cabinet. For each new proposed core entity, detailed business plans will be developed.

Institutional Cores to be Developed that Cross Research Areas: • Advanced microscopy core that includes advanced imaging modalities; • A structural biology core; • A drug discovery, development and design core; • A single cell analysis core; • A gene editing core; • A bio-bank for fluids and fresh or flash frozen tissues. Note: Business plans will be developed for each proposed core

Institutional Cores to be Expanded that Cross Research Areas: • Genomics, transcriptomics and methylomics (MRC); • Proteomics and Metabolomics (PMC); • Flow Cytometry and Flow Sorting (FCCS); • Molecular Bioinformatics (mBIO)

8. Research Space

Laboratory space (as defined in UTHSC's approved Allocation of Research Space policy) is an essential resource that must be of high enough quantity and quality for UTHSC to reach its goal of doubling research over the next ten years. The current status is that the availability of high quality space limits the recruitment of outstanding basic science and clinical research faculty. The coming online of the new Translational Science Research Building (TSRB) and the anticipated renovation of the Nash/Nash Annex will substantially improve this situation.

Campus research space is undergoing a major transition as a result of UTHSC's capital renovation plans. Over the next 3-5 years some research buildings (e.g., Crowe and Mooney) will go off-line, some will be renovated (e.g., Nash/Nash Annex building), and new research space will become available (e.g., Translational Science, Pharmacy, Cancer and Van Fleet buildings). We propose

that these buildings will give UTHSC the ability to develop interdisciplinary, interdepartmental and intercollegiate research themes that will increase collaborations across the entire campus, improve the quantity and quality of both basic and clinical science, and provide the structure for establishing strong and focused translational research unit(s). In short, independent of their college or departmental affiliation, faculty should occupy these buildings based upon specific area(s) of research excellence (as defined by the Operational Strategic Plan for Research), and organized in proximity to each other based on a research focus theme. Additionally, as UTHSC's Allocation of Research Space policy is implemented over time, similar principles of thematic use of space should be applied to other buildings such as Pharmacy and Van Fleet buildings.

To aid in the ongoing transition to the thematic use of research space the standing Research Space Committee should, in addition to its role in the process of research space allocation and solicitation, advise the Vice Chancellor for Research on:

1) The optimal usage of research space throughout UTHSC, including what becomes available as researchers migrate back to the Nash/Nash Annex and other destinations;
2) The design of new thematically driven research space that will come online during the next ten years, and
3) The identification of existing, and further development of, dry laboratory space. In this respect, these considerations should go beyond the typical needs of computer-based research. For example, investigators in physical therapy require dry space for equipment such as treadmills and gate motion analysis, to name a few.

9. Research Mission of Institutes and Centers

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.

Establishment of a Research Institute or Center

A Research Center may be formed by the Dean with the consent of the Chancellor, in consultation with the Research Council, to address needs within a Department or College, to take advantage of opportunities stemming from a key recruitment or new funding stream, or to implement elements of the UTHSC Operational Strategic Plan for Research. Alternatively, a group of faculty with shared research interests may bring a Research Center concept forward and advance it through the hierarchy to the Dean for consideration. The faculty group will need to prepare a proposal that includes a plan encompassing academic, financial, and operational strategies including the sustainability of the funding stream for the Research Center. The initiation of this plan should include short- and long-term objectives and measurable outcomes. The plan will be reviewed by the Research Council after approval by the Dean of that College. With either mechanism, the Research Center Director will be appointed by the responsible Dean.

A Research Institute may be formed by the Chancellor with appropriate vetting with the Research Council, to address needs within the Health Science Center, to take advantage of opportunities stemming from a key set of recruitments or new funding stream, or to implement elements of the UTHSC Operational Strategic Plan for Research. An operational plan and sustainable funding stream for operations and growth, through UTHSC or an outside entity, must be identified prior to the formation of an Institute. The Chancellor, the Vice Chancellor for Research in coordination with the Research Council, and the Development Office will set aside a budget for the purpose of providing seed money and partial initial operational funds for Research Institutes. Additional allocations will be based on an annual performance review. An alternate way a Research Institute may be formed is through a group of faculty, with shared research interests, bringing a Research Institute proposal forward and advancing it to the Vice Chancellor for Research for consideration. This faculty group would need to prepare a proposal much like the one needed for the formation of a Research Center. The plan will be reviewed by the Research Council and requires approval of the Chancellor. As part of this plan, the person who is to act as the Director of the Research Institute may be recommended by the group of faculty. With either mechanism, the Research Institute Director will be appointed by the Chancellor and report to the appropriate Vice Chancellor, Vice Chancellors, or Chancellor designated board. The default reporting position being to the Vice Chancellor for Research.

Operations of Research Institutes and Centers

Research Institutes will report to the Vice Chancellor for Research, except in special circumstances where the Chancellor would designate a different governance or reporting structure. Research Centers will report to the appropriate Dean. Typically, funding for Research Institutes will be provided by the Vice Chancellor for Research/UTHSC or an outside entity. Typically, funding for Research Centers will be provided by the appropriate Dean. Each Research Institute or Center will develop bylaws that must be approved by the executive to which it reports and the Research Council. Membership in a Research Institute or Center will be based on an application to the Director and reviewed based on a process defined in these bylaws to include approval of the relevant executive to which the entity reports. Research Institute or Center performance will be measured by predetermined defined outcomes on a three-year basis. At this time, a recommendation as to whether to continue or discontinue the Research Institute or Center will be made to the Research Council by the executive to which the Research Institute or Center reports.

Research Directors will serve at the pleasure of the administration, and this appointment should be reviewed triennially. All full-time faculty members in a Research Institute or Center must have a primary appointment within a Department. The initial membership and yearly participation in that Research Center or Institute must have the approval of the Chair and Dean. Promotion and tenure packages will be prepared by the Department Chair. Research Institute or Center Directors will be asked to provide a letter which will appear in the applicant's promotion package.

Review of Existing Center and Institutes

Existing Research Centers and Institutes will be reviewed as soon as possible for the scope of contribution and productivity in the various missions. Those deemed no longer active or functional will be recommended for discontinuance, with rationale, to the supervising executive.

10. Research on Educational Effectiveness

Education is a primary mission of UTHSC. Research to improve education and learning outcomes should be a priority focusing on sound pedagogy and effectiveness of instruction and technology integration. As an institution we must be knowledgeable of efficient and effective course design, as well as drive the development of new tools and instructional methods to meet the students' educational needs, and promote 21st century skills through educational research.

To promote and facilitate educational research the following resources and initiatives should be adopted:

1) A culture change must be initiated to value educational research in the same manner as bench to sidewalk research when promotion and tenure decisions are made.
2) Campus resources should be maintained and faculty must be encouraged and educated on their utility. How we educate students is important to the success of our graduates and of our institution.
    A) Teaching and Learning center: A central support entity with instructional design professionals available to support all UTHSC faculty in their efforts to expand and strengthen their use of a wide range of teaching methods and technologies.
    B) The UT Center for Advanced Medical Simulation in Knoxville and the Kaplan Clinical Skills Center in Memphis: These state-of-the-art interdisciplinary facilities in which the use of task and virtual reality trainers as well as standardized patients are used to train our students. Training is carried out in a manner which allows for educational research in a more authentic and controlled environment, involving multiple disciplines and experience levels. Faculty need to be provided with release time to master the use of the simulation facility, as there is a gap between education and implementation.
    C) Inter-professional Education and Clinical Simulation (IPECS) center: Located in the college of Graduate Health Sciences, the IPECS is designed to support and facilitate the integration or expansion of clinical simulation into professional degree programs and residency training programs and to facilitate inter-professional learning opportunities.
    D) Student Academic Support Services and Inclusion (SASSI): A setting to facilitate all students in becoming master learners through quality interactions, theory-driven strategies, and ongoing experiences. This is a resource that should be made available for educational research.

E) Smart Classrooms: Technology for teaching must be easy to implement and faculty must be encouraged to evaluate the effectiveness of the tools used for teaching.
F) Quality Matters Rubric for online education: The subscription must be maintained and the faculty members who engage in online education must be provided release time to learn and incorporate the Quality Matters Rubric into their courses.
G) Library offerings: Librarians should be embedded within each college for easy access and assistance with educational research.

Needs to support educational research:

1) Internal grants to stimulate educational research.
2) Although many resources are identified, an evaluation of what is available must be implemented.
3) Targeted group activities should be nurtured and sustained to inform educators on the scholarship of learning and educational research.
4) Faculty must be exposed early in their career with an established mentoring program to encourage education as their research focus.
5) Establish institutes or centers to promote research on the following:
    A) Diversity
    B) Simulation
    C) Institutional effectiveness of research
    D) Student learning outcomes
6) Identify common data collected in common ways across colleges to determine learning outcomes.
7) Provide on campus support for HRSA writing workshops. Note: UTHSC has received 34 HRSA grants for a total of $24,877,976 for the previous 10-year period. Similarities should be examined to facilitate additional applications.

11. Research Development

The Vice Chancellor for Research has created an Office of Research Development and hired a Director. The Director of the Office of Research Development is responsible for: (a) overseeing the review of Intramural Grants (Bridge Grants, New Grant Support and Memphis CORNET Awards); (b) the review of limited submission Foundation awards; (c) Grant consulting services for faculty; (d) editing services; (e) creating databases to make our faculty aware of intramural research resources and possible collaborations; and (f) providing targeted information on extramural grant opportunities. For the purpose of making our faculty aware of targeted grant opportunities, the Director of the Office of Research Development has analyzed both commercial and non-commercial software platforms. A decision has been made to purchase Elsevier's Pure Funding Discovery Module which will create a fingerprint for all UTHSC Faculty as well as interested students and post-doctoral fellows. This fingerprint, which is based on publications in the Scopus search engine, along with other external sources, can be matched with extramural grant opportunities globally. This will allow our researchers to receive targeted grant opportunities which are specific to their interests.

The Office of Research Development will also be hiring an approved scientific writer to assist faculty in the writing of grants and scientific manuscripts. We expect this service to be helpful to all faculty, but particularly to new faculty and to those where English is not their first language. We anticipate heavy use of this scientific writer. Based on the volume of use, we will bring on additional scientific writers when necessary.

The Office of Research has also hired a Marketing and Communications Coordinator who is responsible for: (a) highlighting the accomplishments of faculty, staff, and students performing research at UTHSC in the Research Rainmaker, a quarterly newsletter publication; (b) preparing all documents and presentations, including the Research Space Allocation Plan, the Research Core Business Plans and Annual Reports, and this Operational Strategic Plan for Research; (c) creating and maintaining a new UTHSC Office of Research Website; (d) marketing our Core Facilities; (e) providing a new social media presence for the UTHSC Office of Research; (f) organizing our monthly research Hot Topics presentations; (g) providing targeted information, developmental, and promotional support for special events hosted by the UTHSC Office of Research; and (h) many other tasks.

12. Stimulating Partnerships and Collaborations

(A) Enhance Mechanisms for Cross-Departmental, College and Campus Collaborations

Developing interdisciplinary research teams that cross our departmental, college, and campus boundaries is a major theme of this Operational Strategic Plan for Research. It is a key to strengthening our research efforts and the funding to support the research enterprise. The Vice Chancellor for Research, Dr. Steve Goodman, has created the Collaborative Research Network to help stimulate the formation of these interdisciplinary teams. He initiated the Collaborative Research NETwork (CORNET) Awards which provide up to $50,000 to successful peer reviewed projects led by faculty investigators from multiple colleges and departments at the UTHSC Memphis campus. The second phase will be the UT CORNET Awards where a key requirement will be that the faculty collaborators span two or more UT campuses.

The Vice Chancellor for Research also created a Federated Model for Clinical Trials, with a UTHSC Clinical Trials Governance Board, which was discussed earlier in this document. This model ties the efforts of the Office of Clinical Research (OCR), the Clinical Research Unit (CRU), and the Preventive Medicine Unit (PMU) into a Federation that will stimulate collaborations in clinical research. Part of the charge of the UTHSC Clinical Trials Governance Board is to bring into this Federation, clinical studies being performed by the Colleges of Dentistry, Nursing, and Health Professions. A long term goal is to build a UTHSC Clinical Trials Network that crosses all four UTHSC campuses.

Our researchers could benefit from a robust research networking system that would allow them to speed up the process of finding researchers with specific areas of expertise. This has recently been put in place by the Office of Research Development and is discussed in the section describing this office.

(B) Academic Institutional Collaborations in Research

The third phase of the Collaborative Research NETwork (CORNET) Awards is the development of focused collaborations with other universities in the southeast United States. Towards this goal, the UTHSC Vice Chancellor for Research has been visiting other universities to begin the development of research collaborations in the Areas of Excellence, and the Focus Areas for each, that are described in this document. The first such collaboration is with the University of Arkansas Medical

Sciences (UAMS). A joint UAMS/UTHSC Mini-Symposium on Substance Abuse Research was held to allow addiction researchers on both campuses the opportunity to meet and identify common interests. At this event the UTHSC and UAMS Vice Chancellors for Research announced the request for applications for the UTHSC/UAMS CORNET Award Collaborative Research Proposals in Substance Abuse thus providing months of time for project development. To meet the criteria, the application must include faculty from both UTHSC and UAMS.

This model will be used to establish meaningful collaborations with other universities in the southeastern United States. To stimulate collaborations in other areas of the US and globally, the Vice Chancellor for Research has hired an Associate Vice Chancellor for Research and Global Partnerships (AVCR). The focus of this AVCR is described below in the National and International Collaborations in Research section.

In addition to the approach described above, we have always encouraged research collaborations with investigators at St. Jude Children's Research Hospital, Oak Ridge National Laboratory, the University of Tennessee Knoxville, the University of Memphis, Vanderbilt University, and even with regional companies. Most of these collaborations have been put together individually (bottom-up) by investigators with shared goals, and often without adequate institutional support. This kind of activity deserves greater administrative support. The Vice Chancellor for Research and Associate Deans of Research encourage our faculty to discuss cross-institutional applications with them at an early stage. At a minimum, the administration can provide letters of support, access to state-of-the-art facilities and resources (basic and clinical), and help with the preparation of grants and contracts. However it may also be possible to help investigators secure CORNET-like funding from other sources to strengthen applications.

(C) Corporate Partners in Research

Business-industry partnerships need to be beneficial in very significant ways to both UTHSC and the industry, as well as support the overall mission of each participant. The current trend is for industry to partner with fewer universities in order to have a more defined and deeper relationship with the academic institution. To that end, we must also identify our strengths and capabilities in the entrepreneurship environment and identify ideal partners. This can be done by utilizing the Areas of Excellence and Focus Areas found in this document, as well as the Cross-cutting Platforms. In addition, critical to effective

partnering, there must be a breakdown of barriers that may delay or hamper the formation of a partnership. Thus, it will be important for leadership to focus on improving the speed and effectiveness of the UTHSC contract process.

Such university-corporate partnerships play an increasing role in grant dollars from public sources. Universities are being encouraged to develop partnerships that include other universities, non-profit organizations and corporations. Economic development programs are being encouraged by the state governments, and by using a combination of state, university and private funds enormous progress can be made at UTHSC.

To stimulate the formation of corporate partners in research, higher education institutions such as UTHSC must collaborate with corporations to strengthen their core curriculum, organization and staffing in order to successfully partner with employers to meet their workforce training and development needs. As the skills gap continues to increase in the marketplace, collaborations between academic institutions and industry are becoming more refined, developing to meet ever-changing economic challenges of both parties. Companies may now even partner with the academic community to assist in curriculum design, enabling students to keep up with technological and IT changes, and providing students with an opportunity to learn how to apply their knowledge and skill set (i.e., experiential learning) to commercial applications. Innovation in higher education and the development of entrepreneurship programs are critical for our workforce to be competitive globally. It is also important for our universities to have an ever-increasing role in their economic well-being and to remain competitive. Memphis is particularly rich in the medical device and translational science industries, even though collaborations are not limited to the local, region or state.

(D) State, County and Community Partners in Research

Strategic partnerships with state, county, and local community partners to conduct research are critical to our mission to improve the health of Tennesseans, and ameliorate disparities in health and healthcare. Through meaningful community engagement, our investigators can understand the needs, priorities, challenges and opportunities facing our city, county and state; leverage the resources, populations, data and connections available through these partners; and ultimately, make significant discoveries and lasting improvements in health and healthcare for the communities we serve.

Strengthening existing collaborations and generating new partnerships with state, county and community partners requires strategic intentionality and commitment. UTHSC investigators cannot be all things to all people; for this reason, we must thoughtfully assess how our inventory of research "assets" can be deployed to meet a prioritized set of community needs. One mechanism we have successfully used for creating and aligning strategic partnerships has been joint appointments of faculty and staff. Additionally, the structure established by iRISE, comprised of a Community Advisory Board (CAB), an Innovations Lab (iLAB) and a Research Synergy Committee (RSC), provides an innovative mechanism for ensuring match between assets and needs. When building partnerships with the community, we must also consider how to maintain relationships even when grant funds wane; while this is challenging, discontinuity is often harmful to community trust, diminishing long-run prospects for collaborations.

(E) Hospital System Partners in Research

UTHSC partners with numerous healthcare systems across Tennessee, such as: Methodist Le Bonheur Healthcare (MLH), Regional One Health, St. Jude Children's Research Hospital, Memphis VAMC, and Baptist Memorial Health Care in the Memphis area, Erlanger Health System (Chattanooga), St. Thomas Health (Nashville) and UT Medical Center (Knoxville). Numerous faculty also have relationships with Church Health Center and Christ Community Health. Our partnerships with these health systems emphasize clinical care and teaching, but their populations and data could provide the foundation for major growth of our research enterprise. Opportunities include: (a) creation of electronic data warehouses (EDWs) and registries using EHRs to conduct a variety of epidemiologic, patient outcomes, health services, and pragmatic clinical trial studies; (b) identification of healthy or condition-specific cohorts that can be combined with EHR data, patient-reported outcomes, and biorepositories for large-scale multi-omics datasets to support high-dimensional analytic modeling that will ultimately lead to more individualized treatments and better health outcomes (the goal of precision medicine); (c) nursing faculty and capacity for nursing research needed for pursuit of hospital MAGNET status; and (d) coordinated recruitments of high profile physicians who can anchor "destination programs" that raise the national reputation of the health systems and UTHSC. Partnering with health systems in this manner provides an additional source of funding through increased clinical revenue, and opportunities to enhance translational research opportunities through structural changes to healthcare delivery which can further support our research needs.

To some extent we have pursued these data- and population-driven opportunities. UTHSC and MLH recently reached an agreement to create an EDW, UT Medical Center (Knoxville) is also developing an EDW, CBMI has constructed a breast cancer registry from various data sources, and Le Bonheur Children's Hospital has created a biorepository from leftover patient blood samples. However, we are years, perhaps even a decade, behind the leading research institutions in this area. Fortunately, the populations we serve are relatively unique, and, because this is a rapidly changing field, we may have the opportunity to leap-frog over "outdated technologies" to more rapidly support fundable research. Another concern is that UTHSC and our partner health systems have not always found a common purpose and goal when pursuing research opportunities, leading to conflicting priorities. Finding and emphasizing mutually beneficial projects/programs offers a strong path forward. We have streamlined IRB processes and approval to facilitate projects across institutions. Additional work needs to occur to streamline credentialing and approval of researchers and research staff within partner institutions. A focus on processes for approval of non-physician researchers to function as principal investigators needs to be explored, so all research scientists may function as principal investigators, not only as research assistants within their programs of research.

(F) The Veterans Administration as a Partner in Research

Strategic partnership between the Veterans Administration (VA) and UTHSC provides an important opportunity for enhancing "team science" across multiple focus areas of investigation at both institutions. It also provides the unique prospect of developing a concentration and diversity of intra-professional research teams (e.g., basic scientists, physicians, physical/occupational/ speech therapists, nurses, psychologists etc.) that can address basic, translational and clinical projects of importance both to the health of our veterans, as well as the general population. The VA Healthcare System is also home to a comprehensive, system-wide data warehouse, housing EHR and administrative data available for a range of epidemiologic, patient outcome, health services, and pragmatic clinical trial studies. This rich phenotypic data is being complemented with genetic data through the ongoing Million Veterans Study. Major VA funding priorities that synergize with our strategic research interests include, but are not limited to, (a) traumatic brain injury; (b) neurodegenerative diseases; (c) rehabilitation (amputees, cognitive, etc.); (d) health disparities; (e) women's health; (f) metabolic syndrome; and (g) cancer. The Memphis VA is also a source of targeted patient populations (e.g., cancer, TBI, and metabolic syndrome), with electronic health records and a long track record of good compliance at the VA, who are also motivated to participate in clinical trials. Because of the VA's unique regulatory environment, the most effective way to incorporate VA patients into clinical trials would be to include VA investigators and fund research coordinators. The VA administration also represents an important

partner in the collaborative recruitment of new scientists (especially clinician-scientists) by providing partial or full salary support, lab space and access to VA intramural (Merit) funding for clinical and basic research. There is no mechanism for start-up funds at the VA, so it depends upon its university partners for this key element of a recruitment package.

(G) National and International Collaborations in Research

To stimulate national and international collaborations in basic, translational and clinical research, existing relationships need to be strengthened and new ones forged. Administrative and strategic coordination, that both fosters and creates operational networks of interdisciplinary researchers, will be provided by the newly appointed Associate Vice Chancellor for Research & Global Partnerships (AVCR). Fundamental to this goal, the AVCR will establish and maintain, on a global scale, recognition of the Faculty in the Areas of Excellence, and the Focus Areas for each, that are described in this document. To accomplish this, the AVCR will identify and promote research links, including multi-disciplinary links, and engagement within the Faculty, across the UTHSC, and with external organizations both nationally and internationally. In the clinical research space, the AVCR will coordinate with the UTHSC Clinical Trials Governance Board to create and foster opportunities for global partnerships in advancing clinical investigation. The AVCR will also evolve strategies to significantly enhance these relationships, by working with the Office of Research Development in both identifying and assisting faculty with multi-institutional and/or large multi-disciplinary grant and contract submissions. To stimulate such interactions at the basic, translational and clinical research levels the AVCR office will provide innovative two-year internship programs for international trainees that will aid in the development of global connections, collaborations, and enhance the UT research environment. Towards this goal, the AVCR will establish cooperative agreements with global academic medical institutions in the Areas of Excellence, and the Focus Areas. The first such collaboration will be with Harbin Medical University. Additionally, the AVCR will work with the relevant Administrative Offices to ensure that systems are in place to maximize opportunities and experiences for global research partnerships, including coordination with Human Resources, the Postdoctoral Office, and the Office of International Affairs, to create seamless interactions across institutions. We will also coordinate with St. Jude's International Outreach Program. In short, we will enhance UTHSC's connectivity within an international network of outstanding researchers.

13. Entrepreneurial Activities at UTHSC

Improving the health of Tennesseans through research is one of the core missions of UTHSC. Our faculty and staff are a powerhouse of ideas that often produce discoveries suitable for intellectual property development. UTHSC and University of Tennessee Research Foundation (UTRF) have an effective partnership to develop and manage intellectual property born in our laboratories. UTRF is the main conduit for commercialization of these nascent technologies. Between 2003 and 2016, 16 startups have been launched by our faculty. These start-ups have developed new therapeutics and diagnostics to improve medical care, facilitated the retention of key faculty and personnel, and have brought new money and jobs into the Memphis economy.

Current Activities and Core Functions

UTRF has several effective programs to promote entrepreneurial activities at UTHSC. These include:

1) Maturation Grants: $15,000 proof-of-concept grants. All our faculty, staff, and students are eligible to apply. This program typically funds four projects per year, and over $400,000 has been invested into our projects since the program started in 2008.
2) Tech Talks: Seminar series focused on commercialization and entrepreneurship. Six to eight events per year. Topics have included: (a) patents and copyright; (b) startup basics; (c) “Ask an entrepreneur”; (d) anatomy of license agreements; (e) FDA, etc.
3) Drug Discovery Funding: Dedicated UTRF support fund to add value to a therapeutics IP by providing financial support to pay for 3rd party drugability studies (ADMET, PK/PD, solubility/stability, etc.). Typically, NIH-funded drug discovery projects are limited to mechanism of action, target identification/validation and pre-clinical efficacy data, but potential pharma/biotech partners also want to see preliminary drugability data on new compounds.
4) Tennessee Venture Challenge: A business plan competition for the UT community. Startups that were founded from any UT intellectual property are eligible to compete for $25,000 in cash prizes, and all competing entrepreneurs receive eight weeks of business mentorship.
5) Technology Transfer Interns: UTRF embeds a paid student/postdoctoral intern in the technology transfer office. The intern, under the supervision of a licensing associate and the Director, learns to evaluate new technologies, conduct patentability searches, and to prepare marketing campaigns on patented technologies. Each internship is for six months at 8-10 hours per week.

6) Collaborations: UTRF partners with a number of groups that also provide entrepreneurial support services, including Memphis Bioworks, LaunchTN, and Life Sciences Tennessee. Through these partner organizations, entrepreneurs can seek business mentorship, access discount purchasing programs, lease space for their startup, and seek seed capital.
7) Memphis Bioworks: The Memphis Bioworks supports entrepreneurial activities through its Bioworks Business Incubator offering more than 34,000 square feet of office space, wet labs, prototype and fabrication facilities, and support equipment for biotech and clean-tech start-up companies. Its ZeroTo510 Medical Device Accelerator has been named as one of the top 25 business accelerators in the country for the second year in a row. The ZeroTo510 program has invested $1 million, creating 20 companies that have generated over $7 million in follow on funding since inception.
8) Startup-friendly licensing: Although UTRF has not adopted a one-size-fits-all express license as some schools have, we offer licensing terms to faculty startups that are designed to support successful fund-raising and early corporate development. This includes: (a) taking equity in lieu of cash for all upfront license fees; (b) not placing special protections on UTRF's shares that would discourage angel or venture investors; and (c) agreeing to deal structures that offer several years post-signing with no additional fees/royalties due to UTRF. UTRF also participates in the Association of University Technology Managers (AUTM) Transactional Academic Comparables Tracking (TransACT) Database, a listing of deals by peer institutions, to ensure that it is offering fair and reasonable terms to its licensees.

Focus Areas for Investment

Some essential areas for investment of this platform include:

1) UTHSC is in the final stages of purchasing, from Bioworks and TriMetis, the land and vivarium on the site of the old Baptist Hospital between Madison and Union Avenues. We support the plans to create a UT Biotechnology Park which should include a Bioincubator building for startup companies, a Research Park building for companies that graduate from the Bioincubator building as well other mature bio-related companies; and a UTHSC Academic Research building. All of these should be connected to the vivarium.
2) While this UT Biotechnology Park is being built, UTHSC should provide appropriate space in an existing building for faculty generated start-up companies with a price structure that allows for initial growth of these businesses. These could become a segment of the early tenants of the Bioincubator.
3) The strategic partnership between UTHSC and UTRF should be strengthened.

4) Our culture should embrace discovery as well as the translation and development of discoveries to improve community health.
5) We should create a Center for Experimental Medicine and Therapeutics (or other appropriate name) that facilitates cross-disciplinary discovery and development. This would spark innovation, grant funding, faculty development and early commercialization.
6) UTHSC and UTRF should foster training for faculty in how to develop their ideas within the university environment using funding available through STTR, SBIR and contract mechanisms.
7) Tech transfer principles should be incorporated in the curriculum of UTHSC colleges, especially the College of Graduate Health Sciences.
8) UTHSC and UTRF should take equity ownership in faculty startups thereby promoting entrepreneurship and also maximizing potential return on investment.
9) Entrepreneurial activities and generation of intellectual property should be included in the annual evaluation process.
10) UTRF should enhance the potential revenue streams for UT mission through technology licensing.
11) UTHSC should extend the university discounts on purchases of supplies and consumables to UTRF-approved startups for an initial period of one to three years thereby stretching the value of startup capital in the newly formed ventures.
12) Our faculty should be encouraged and regularly trained about filing invention disclosures and engaging in entrepreneurial activity.
13) UTHSC and UTRF should create an angel investor group that would seek to make seed investments of up to $500,000 into UTHSC startups with high growth potential.

Synergies and Collaborative Potential

Developing or translating ideas into innovative therapies, diagnostics and devices improves the health and the economy of a community. It is a core mission of health science universities. Generation of intellectual property is an inherent consequence of a vibrant research university. UTHSC should strive to develop a culture where entrepreneurial activities are an integral and recognized part of faculty life.

14. Philanthropy for Research

At the direction of the Chancellor, the Vice Chancellor for Development and Alumni Affairs should organize and lead UTHSC in developing donors interested in supporting our research mission. The Office of Alumni Affairs and Development should work with faculty, Chairs, Deans and the Vice Chancellor for Research to raise funds from both private and corporate donors, and foundations. These efforts will be done in consultation with the Vice Chancellor for Research and the various Deans. Centralizing development efforts and proposals through the Office of Alumni Affairs and Development will avoid conflicting requests or unknowingly competing requests to the same donor.

The following are initial recommendations to the Office of Alumni Affairs and Development:

1) A policy or procedure is needed and must be extensively communicated in terms of how faculty and others solicit philanthropic dollars.
2) An information sheet should be created to help clinicians work with grateful patients and connect grateful patients with the Development office.
3) The Office of Alumni Affairs and Development should actively work to train and assist the various research stakeholders in the art of raising funds.
4) The Office of Alumni Affairs and Development should be mindful that donors are possible in both the high profile diseases typically associated with philanthropic efforts (i.e. cancer) and in the high incidence of disease, but not so high profile with dedicated philanthropic efforts (i.e. asthma).
5) The Office of Alumni Affairs and Development and the Chancellor's Office should communicate with all Deans in terms of what donors are funding or interested in funding. In this way, Deans could be sure the Office of Alumni Affairs and Development and the Chancellor are aware of relevant efforts in the colleges. Furthermore, this will allow Deans to strategically redeploy faculty into efforts that would be of interest to donors.
6) The Office of Research should be mindful when working with donors that support without designated uses by the donor (i.e. flexible) are useful to research units as they try to fill a highly diverse set of needs. For example, creating a pleasant work environment to help retain trained staff or a lunch that recognizes special accomplishments.
7) Strategic planning with action steps should occur around building the number of endowed chairs and professorships.

15. Research Infrastructure

At a time of diminishing grant dollars and increasing competition, it is essential now, more than ever before, that investigators are provided with an outstanding research infrastructure that will enhance their productivity and the research enterprise. Moreover, there is a pressing need to foster an environment in which all investigators - whether working within UTHSC or collaboratively on a local, regional, national, or multi-national scientific initiative - have access to efficient support services and infrastructure, regardless of their physical location.

The research enterprise at UTHSC currently faces a number of systemic challenges that increasingly threaten its productivity. Among these are several prominent issues:

1) Recent estimates suggest that scientists spend in excess of 40% of their time dedicated to administrative and regulatory activities. Unnecessary administrative and regulatory burden significantly diminishes the productivity of researchers and the research enterprise. The Office of Research will maintain an ongoing review of activities and policies related to compliance (e.g., IACUC, IRB, IBC, etc.), grants and research agreements, and safety affairs with the goal of determining whether and where we have self-imposed unwarranted and unnecessary burdens.
2) The Vice Chancellor for Research should expand and strengthen the Office of Grants and Research Agreements (GRA) to provide a centralized administrative support center directed toward facilitating the pace of research. This includes: a) strengthening GRA with appropriate additional hires and workflow management to accommodate the growing portfolio of MTAs, CDAs, sub-awards, clinical trial agreements, and grant submissions, etc.; and b) unifying pre- and post-award under the Office of Research such that there is a seamless integration of the proposal submission process, contract negotiations and acceptance of awards, and the establishment and monitoring of financial accounts. Centralization will also improve efficiencies in conducting regulatory compliance and fulfilling sponsor financial reporting requirements.
3) The Laboratory Animal Care Unit (LACU) represents a critical “Institutional Core” serving the majority of campus investigators. The role of this core is to provide the clinical care and related services for small and large animals used in research, and to train personnel in policies and procedures related to animal care, animal handling, and the use of animals in research protocols. To ensure that investigators receive the highest quality of services, the Office of Research has instituted a change in LACU leadership, and engaged an outside consulting firm to perform a major review and analysis of all aspects of UTHSC’s animal care and use program. Moreover, through the extensive efforts of Dr. Ken Brown, Executive

Vice Chancellor and Chief Operating Officer, UTHSC is finalizing the purchase of the TriMetis vivarium, a state-of-the-art, GLP-compliant, AAALAC accredited animal care facility adjacent to the campus. In conjunction with the CRB and TSRB vivariums, this purchase will enable us to provide our investigators with high-quality facilities well into the future.

16. Metrics and Dashboards

This Operational Strategic Plan provides a 5-year roadmap to grow research at UTHSC. The Chancellor has given us the robust goal of doubling research over a 10-year period which will require 8% compounded growth. In FY15 the growth in research awards was 10%. The metrics and dashboards presented below will allow the UTHSC community to follow our progress towards our common goals, and to measure achievements or shortfalls in reaching short and long-term strategic objectives.

Goal: Increase our UTHSC research grant awards by 8% annually

Metrics:

1) Total Annual Extramural Dollars Funded Based on Award Statements
2) Total Direct and Indirect Dollars Awarded Annually
3) Federal Percentage of Total Award Dollars (Annually)
4) Total Direct and Indirect Award Dollars generated by:
    A) Campuses
    B) Colleges
    C) Departments
    D) Centers and Institutes
    E) Clinical Trials
    F) Students and Postdoctoral Fellows
    G) Industry Sponsored Research
    H) Program Project or Center grants

Goal: Increase UTHSC Entrepreneurial Activity by 8% annually

Metrics:

1) Annual Invention Disclosures
2) Annual Revenue from Licenses
3) Annual US Patents Issued

Goal: Develop research partnerships in the region, state, nation and globally which will lead to $10 million of new research funding over 5 years

Metrics:

1) Total Direct and Indirect Award Dollars/year based on collaborations:
    A) stimulated by the CORNET Awards
    B) with other state, national and international institutions
2) Number of Research Contracts between UTHSC faculty and other academic/non-profit/commercial (e.g. industry) institutions stratified by whether UTHSC faculty were the lead PI or the sub
3) Number of Co-authored Publications with faculty from other Institutions
4) Number of international trainees (students/fellows) who intern at UTHSC

Goal: Hire 50 new UTHSC faculty within the 6 Areas of Excellence, Key Focus Areas, and Cross-cutting Platforms. At least 35% of these new faculty should arrive with extramural funding at the equivalent of a career development award (society or NIH) or R21 (or society/foundation equivalent) or better. Of those who do not, all should be extramurally funded within three years of arrival at the level of a career development award, or R01, or better. For those faculty who come with funding, or receive funding within three years, retention over 5 years should be 90% or greater.

Metrics:

1) Hire 10 new research faculty/year over the next five years.
    A) Number of new research faculty who arrive annually with appropriate extramural funding
    B) For new research faculty who do not arrive with extramural funding, number who are awarded appropriate funding within three years of arrival
    C) Percentage of these new funded research faculty who are retained over rolling 5 and 10 year periods with stratification of those leaving the institution as voluntary or involuntary

2) Number and percentage of faculty hired within each Area of Excellence, Focus Area, or Cross-cutting Platforms
3) Percentage of research faculty that are members of UTHSC Research Centers and Institutes

Goal: Increase the research laboratory and office space to accommodate these new researchers, and the targeted 8% annual increase in research expenditures. As described in the UTHSC Allocation of Research Space Plan, Colleges should maintain 10-30% of their total assignable research space vacant for new initiatives, new hires, expansion of successful researchers and departments, and swing space.

Metrics:

1) Annual percentage of total space renovated for research
2) Annual percentage of growth of research space
3) Annual percentage of research space that remains vacant
4) Annual available research laboratory/office space ratio
5) Federal indirect cost rate as research space expands

Goal: Over five years move 10 spots higher on the ranking of Academic Health Centers based on Total NIH dollars awarded annually. To obtain large increases in institutional extramural grant awards, we will need to recruit and grow our own research stars. These stars would have the needed cache to serve as magnets to draw other research leaders to UTHSC.

Metrics: Institutional and Individual Research Recognition

1) Institutional NIH ranking
2) Number of UTHSC members of the National Academy of Science
3) Number of UTHSC AAAS Fellows

The Office of Research will coordinate with the Office of Institutional Effectiveness to define, track, and interpret parameters of success, as well as establish a culture of mission based management. Together we will develop measurement dashboards and scorecards to monitor and manage progress towards the goals and objectives outlined above.

Mitigation plan

Performance on the metrics described above will be evaluated annually by the VCR's Research Cabinet, who will provide a written report to the VCR. The VCR will in turn share this report with the Research Council for their review, highlighting areas of success and areas where metrics were not met. For those metrics that are not met, the VCR, in conjunction with responsible stake-holders, will develop a set of recommendations to include either a mitigation plan to meet the goal in a defined time-frame, or to revise the metric. A triennial analysis by the VCR's Research Cabinet will include a description of what broader changes need to be made in the Operational Strategic Plan for Research to reach the goals stated in this document. Again this report will be shared by the VCR with the Research Council for review, approval and then implementation.

17. Conclusions

This UTHSC Operational Strategic Plan for Research provides a blue print and framework for creating a more robust research environment for our Institution which includes all campuses and colleges. The Operational Strategic Plan for Research is based upon three underlying principles: a) our Mission, Vision and Metric of doubling UTHSC funding will only be accomplished if we think institutionally when it comes to Research; b) the way to think Institutionally is to eliminate any barriers between departments, colleges and campuses when creating interdisciplinary research teams around focused areas; and c) that we need to provide these interdisciplinary research teams with an infrastructure and the resources that will make them successful.

For this OSPR to provide us with the vision and blueprint to become a leading research institution it will require the support of all components of the UTHSC community: The Chancellery, Deans, Chairs, Faculty, Staff and Students. All Areas of Excellence, Focus Areas, Cross-cutting Platforms and Infrastructure are important and worthy of support, but financial resources are finite and, in part, unpredictable. In such situations, one needs a process to determine how best to utilize funds that are finite and, fortunately, UTHSC has such a process. The UTHSC Research Council, chaired by the Vice Chancellor for Research, has the responsibility to provide the Chancellor with thoughtful advice on such decisions. For this reason, we feel that it would not be fruitful for this document to prioritize Areas of Excellence, Focus Areas and Cross-cutting Platforms when all are mission important. Such recommendations will come from the Deans and VCR via the Research Council to the Chancellor.

The VCR has primary responsibility to make sure that this Operational Strategic Plan for Research is successfully implemented, within the financial constraints described above. The VCR will need the support of the Chancellery, Deans and his Research Cabinet to be successful. Further, many of the strategies presented in the OSPR do not require significant new resources, but change in policy or practice. The VCR is charged with engaging the appropriate stakeholders to encourage them to implement recommended changes. For all elements of the OSPR the VCR's Research Cabinet is to help evaluate the metrics and dashboard data when it becomes available, make suggestions for changes in the OSPR when necessary, and to help advise the VCR on how best to execute the strategic plan.

The OSPR is a five-year plan for the fiscal and academic years 2016-17 through 2020-21. The OSPR committee fully recognizes that biomedical research areas and technologies change rapidly and that this document has to be adaptable enough to incorporate these new opportunities. Yet this document does supply a very strong blue-print, as of today, for the next five years. By 2020-21, we will need to be writing the plan for the next five-year period from 2021-22 through 2025-26. It is our expectation that by 2026 we will be in the top quartile of Academic Health Centers based upon Total NIH dollars awarded annually. It is our expectation that there will be greater meaningful integration between UTHSC and Saint Jude Children's Research Hospital and Oak Ridge National Laboratory that will be essential to reaching these goals. Further, we expect that the Collaborative Research Network (CORNET) awards, and other such efforts towards creating networks and partnerships, will help us reach these lofty goals.

The OSPR Committee has supplied the UTHSC research community with a strong strategic plan. To reach our communal Research Mission, Vision and Metric Goals will require the entire UTHSC research community supporting this Institutional Operational Strategic Plan for Research and working in alignment towards organizational research goals.

Acknowledgements

This Operational Strategic Plan for Research (OSPR) was written by a dedicated OSPR committee, composed of UTHSC research leaders from multiple UTHSC campuses and all colleges. I want to thank all of the members of the OSPR Committee (listed below), with special thanks to our co-Chairs Dr. Wendy Likes and Dr. Robert Williams who provided the excellent leadership required to bring such a detailed and thoughtful document to a successful conclusion. I also wish to point out the important contributions of Tim Fallon who provided insight into the process and excellent summaries of all committee meetings, and Sarah Fenderson who assembled and edited this document.

The document was reviewed by the Faculty Senate and the Research Council who provided important input that helped us polish this document. Ultimately this OSPR belongs to the UTHSC Research Community. As Vice Chancellor for Research, I will lead the implementation of this strategic plan, with full knowledge that success will require help from all of you. I look forward to working with you to execute this very exciting strategic plan over the next five years.

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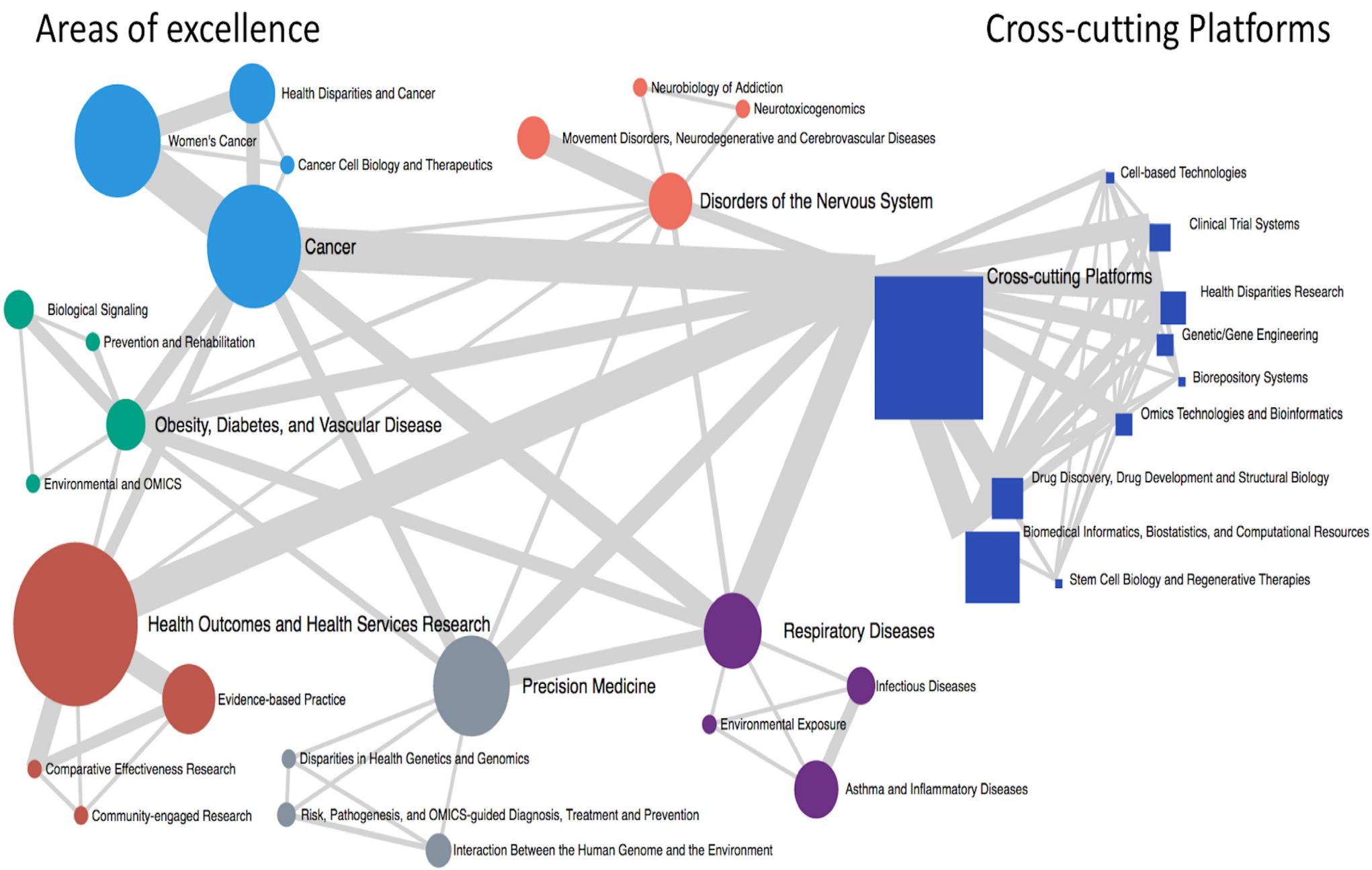

Legend:

Data sources: Grant proposals and Scopus articles from 2010 to present. Node size: represents the number of authors associated with each topic.
Node color: represents topic area. Link width: represent the number of authors in common between topic areas.

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Cross-cutting Platforms