

## Report on Health-Related Research in the State University System of Florida As Part of the Environmental Scan Of the Board of Governors Health Initiatives Committee

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### **CONTENTS**

Executive Summary	3
Part One: System Overview  Background and Purpose Survey Methodology Questions and Responses Implications	8
Part Two: Survey Responses	24
University of Florida	34
Florida State University	41
Florida A&M University	48
University of South Florida	54 50
Florida Atlantic University	59
University of West Florida	64
University of Central Florida	69 75
Florida International University University of North Florida	75 80
Florida Gulf Coast University	85
New College of Florida	87
Appendices	00
A: An Inventory of State University System Health-related Research	89
B: Health-related Research Survey Instrument	95

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#### **EXECUTIVE SUMMARY**

#### The Board of Governors Health Initiatives Committee

In August 2013 the Board of Governors Health Initiatives Committee was established to provide leadership for the development of system-level policy for the twelve State University System institutions regarding health initiatives. The work of the Committee will guide the State University System in both the foreseeable future and the longer-term when Florida is expected to experience even more substantial stress on its health care delivery system.

Two products will result from the initial work of the Committee: an *Environmental Scan* and, subsequently, a *Health Initiatives Strategic Plan*. The environmental scan will identify emerging and evolving program needs and assess the status of existing programs. The strategic plan will advance the quality and coordination of health programs and initiatives across the State University System. The environmental scan and the strategic plan will focus on three major areas of activity: (1) health education, (2) health care delivery and (3) health-related research.

### Roadmap for this Report

The report attempts to answer questions with respect to the health-related research being conducted in the SUS. What are the priority areas of health-related research conducted by Florida's universities? What are the key challenges facing SUS institutions relative to conducting health-related research? Are there critical areas of research that are not being addressed? Can we expand university research opportunities through greater collaboration? What is the contribution of the State University System to translational research?

There are other questions embedded in these fundamental questions. How much research is happening as measured by federal award dollars granted to SUS institutions? What are the challenges associated with research technology transfer? What challenges are associated with health-related research compliance? What is the status of SUS health-related facility and personnel needs? Are SUS animal/veterinary facilities adequate for the health-related research of the future?

Part One of this report identifies, across institutions, recurring strands or themes from responses to the survey. Part Two contains each university's abbreviated response to the survey. Finally, there are two appendices. Appendix A is a list of the health-related research currently taking place. Appendix B contains the health-related research survey instrument that was administered to the institutions.

### A Health-related Research Survey

To answer the above questions, Board staff administered a 15-question *Health-related Research Survey* that was sent to all SUS institutions. (Florida Polytechnic University did not participate in the survey, because it does not currently have any health-related programs or research.) New College of Florida, which chose to participate in the survey, is doing research in biological areas but not health research per se.

The 15-question survey can be broken down into 11 broad topics. The organization of Part One of this report follows the sequence of these topical areas:

- <u>Topic One:</u> Funding magnitude and sources for health related research (survey questions 1 and 2)
- <u>Topic Two:</u> Priority areas of health-related research conducted at SUS institutions (survey questions 11 and 12)
- <u>Topic Three:</u> General health-related research challenges in the SUS (survey question 6)
- <u>Topic Four:</u> Facility challenges/opportunities in the SUS (survey question 10)
- <u>Topic Five:</u> Technology transfer challenges/opportunities in the SUS (survey questions 3 and 4 and 7)
- <u>Topic Six</u>: Research compliance challenges/opportunities in the SUS (survey question 8)
- <u>Topic Seven:</u> Veterinary resources challenges/opportunities in the SUS (survey question 9)
- <u>Topic Eight:</u> Health-related research areas in which SUS institutions are currently collaborating (survey question 14)
- <u>Topic Nine:</u> Health-related research opportunities with other SUS institutions and unaddressed needed research (survey questions 13 and 14)
- <u>Topic Ten:</u> Contributions to translational research (survey question 15)
- <u>Topic Eleven:</u> Listing of health-related research at SUS institutions (survey question 5; Appendix A of this report)

### **Key Results from the Report**

Key results from the report are as follows:

- <u>Federal Funding.</u> The universities reported that approximately \$600M of their federal grant dollars awarded in 2012-13 were associated with health-related research. Over half of UF's and two thirds of USF's federal grant dollars awarded in 2012-13 were associated with health-related research. Taken together, these two institutions were awarded nearly \$500M in federal grant dollars, representing about 80% of the total SUS health-related research funding.
- <u>Personnel Needs.</u> Several institutions reported a challenge associated with recruiting and retaining adequate numbers of research faculty. This involved

salaries, start-up packages, provision of cutting-edge facilities, and adequate stipend support for graduate assistants, postdoctoral fellows, and technicians who are involved in the research agendas of senior faculty.

- <u>Facilities Needs.</u> All institutions indicated facilities needs with regard to health-related research. These needs included entire teaching hospitals, new and renovated laboratories, downtown office space approximate to major hospitals, veterinary facilities, and science annexes. Costs associated with these stated needs ranged from \$600M for a teaching hospital to \$1M for laboratory renovation.
- <u>Priority Research.</u> SUS institutions reported a wide variety of priority research including but not limited to aging research, emerging pathogens, autism, neuroscience, diabetes, cancer therapeutics, cardiovascular diseases, HIV/AIDS, obesity and chronic disease, and Dengue Virus research. Four institutions reported that aging research constituted a priority on their campus. Multiple institutions noted research in HIV/AIDS, neuroscience, and cancer research.
- <u>Collaboration</u>. All SUS institutions excepting NCF reported collaborative research endeavors with other SUS institutions. These included but were not limited to:
  - Concussion/mild traumatic brain injury surveillance and management at UF and FSU,
  - FSU's research in tobacco-related diseases with UF,
  - o FSU's chronic pain study with UF,
  - FAMU's research in biomaterials and nanoparticles for bio-imaging with UF and UCF,
  - o FAMU's research in stem cell therapy with UF and USF,
  - USF health-related research projects with UF and FSU in areas such as substance abuse and stroke,
  - o FAU's work in marine-based cancer therapeutics with UCF,
  - UWF's research in disaster impacts with UF and FAMU,
  - o UCF research in HIV/AIDS with UF,
  - UCF cancer research with USF and FAU,
  - o FIU's collaboration with UF in HIV/AIDS research,
  - o UNF's research in rural health disparities with UCF, and
  - o UNF's research in diet and reproduction on life span with UF.
- Research Compliance. Institutional Review Boards (IRBs) are entities that approve the use of human subjects in research protocols. Each institution has at least one IRB. It was reported that when conducting research across multiple sites, having to secure approvals of multiple IRBs rather than one approval from a central IRB is a cumbersome, time-consuming process that has caused lengthy

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delays in study implementation. The federal government's recent movement toward allowing use of a single IRB review for multi-site studies creates an opportunity for Florida research universities and affiliated health care institutions to collaborate in forming a central IRB for statewide and regional research. Such efforts already are underway between UF and FSU. UF and FSU continue to work toward expanding this IRB cooperative with a goal of including other Florida universities and affiliated public and private healthcare institutions.

- Data Sharing. Information technologies and how to handle complex, big data are common challenges across Florida universities. It was reported that it is critical that the SUS institutions partner around data standardization, since linkage of big data across all Florida universities would present a powerful new paradigm to tackle some of Florida's greatest health-related challenges. It was recommended that a statewide, integrated data repository would allow Florida to compete for major new funding initiatives and would position Florida to be a destination for clinical research, comparative effectiveness research, and implementation science. Such a repository would be a multi-million dollar investment. However, a robust technology infrastructure in both bio- and health-informatics is reported to be needed to better collect, assimilate and analyze data associated with health-related research, particularly patient-centered outcomes. This informatics-focused technology infrastructure would provide the foundation needed to advance clinical translational research across Florida communities.
- <u>Technology Transfer Challenges</u>. The challenge most often articulated with respect to technology transfer was the absence of seed capital and proof-of-concept funds for prototypes and pre-clinical drug development. It was reported that the National Institutes of Health does not traditionally fund critical proof-of-concept studies. Industry partners are reluctant to fund such programs themselves, yet require such studies prior to collaborating on the technology. NIH has almost no funding for medical device research, and very little comes from the National Science Foundation.
- <u>Unaddressed Research/Further Research Needed.</u> The institutions identified over 25 areas in which research was currently either unaddressed or addressed less than it should be. These were also areas in which the SUS institutions expressed a willingness to collaborate with other SUS institutions. Such research areas included disease prevention/healthy lifestyles, environmental health-related issues, health disparities among minorities, under-represented groups in clinical trials, gender-based population health, human trafficking, obesity, geriatrics, chronic diseases of the elderly, successful longevity, early and middle childhood health, health care provision in county schools, college-based mental

and behavioral health, autism, genomic and personalized medicine, biomarker discovery, chronic inflammation, neuroscience, electronic health record systems, health information technology, the handling of health-related big data, and nursing education and workforce issues.

### PART ONE: SYSTEM OVERVIEW

#### **BACKGROUND AND PURPOSE**

In August 2013 the Board of Governors Health Initiatives Committee was established to provide leadership for the development of system-level policy regarding health initiatives. The Committee is charged with being responsible for all issues associated with health education in the State University System. The work of the Committee will guide the State University System in both the foreseeable future as well as in the important longer-term years when Florida is expected to experience even more substantial challenges to its health care delivery system.

The Board of Governors Health Initiatives Committee has undertaken an environmental scan as a major component of its first year's work. The environmental scan focuses on three distinct areas: health education in the State University System (SUS), health-care delivery as it impacts the SUS, and health-related research being conducted in the SUS.

This third component—research—is the subject of this report. The importance of health related research in the SUS cannot be denied. It pervades most institutions, and it represents the work of hundreds of faculty, graduate students, postdoctoral fellows, and even undergraduate students in the SUS. Moreover, it represents a major funding source to the institutions.

The purpose of this report is to better understand what is happening at our universities in the critical area of research. How much and what kinds of research are being conducted? How does the SUS compare nationally with respect to health-related research funding? What are the major challenges associated with conducting health-related research on SUS campuses? Importantly, are there opportunities to better coordinate health-related research among SUS institutions and, if so, in what areas? Are there areas of health-related research that are currently not being addressed? And finally, where can the SUS put its limited resources to produce maximum results in the ongoing research endeavors of our institutions into the foreseeable future?

The results of this environmental scan will assist in producing a health-related strategic plan for the State University System. The strategic plan will make recommendations to close identified gaps in the production of the health care workforce, develop new curricula and mechanisms to address emerging and evolving trends in health care delivery, and address gaps and new opportunities in health-related research. In assisting the creation of the strategic plan, the environmental scan is intended to identify the areas of specialized health-related research, identify areas for greater collaboration, and identify critical areas of health-related research that are not being currently addressed by Florida universities.

#### **SURVEY AND METHODOLOGY**

To attempt to answer the guiding questions, and to better understand the health research landscape at the SUS institutions, Board of Governors staff administered a *Health-related Research Survey*. The survey, the first of its kind with respect to health-related research, was created with the assistance of the State University System Council of Research Vice Presidents. The survey was then administered to the Council in the summer of 2014. All institutions participated in the survey with the exception of Florida Polytechnic University which does not currently engage in health-related research. Results of the survey were compiled into this single report.

The complete survey instrument can be found in Appendix B of this report, and the universities' abbreviated responses to the survey can be found in Part Two of this report. Part One of this report extracts highlights of university responses.

The universities were asked via the survey to respond to a number of questions, including the following:

- What are the types of health-related research being undertaken at the universities?
- What are the top priority areas of health-related research being conducted at the institutions?
- In general, what are the challenges related to health-related research at the institutions?
- What do institutions see as facility challenges now and into the future?
- What are the challenges associated with technology transfer, that is, the path from laboratory bench to commercialization?
- What are the research compliance challenges that the universities are facing?
- As a facility subquestion, are veterinary resources sufficient now and into the future?
- What health-related research opportunities with other SUS institutions and unaddressed needed research do the universities see on the forefront?
- What examples can the universities give of contributions to translational research?

### **QUESTIONS AND RESPONSES**

1. What is the magnitude of State University System health-related research? (Survey questions one and two)

Part One of this report begins with an examination of the magnitude of funding associated with health-related research in the State University System. The data for this section came from three sources. For a summary of grant dollars awarded to SUS institutions by the Department of Health and Human Services, Board staff were able to

rely on the SUS Fact Books. For national comparisons of research expenditures, data from the National Science Foundation were utilized. And for the total award dollars associated with health research at SUS institutions, the Health-related Research Survey served as the data source.

According to the State University System Fact Book, in Fiscal Year 2012-13 the SUS was awarded \$431,310,905 from the United States Department of Health and Human Services (DHHS) and another \$120,565,332 from the National Science Foundation. Prominent funders within DHHS included the National Cancer Institute; the National Institutes of Health; the National Institute on Aging; the National Institute of Allergy and Infectious Diseases; the National Institute of Diabetes, Digestive and Kidney Diseases; and the National Heart, Lung, and Blood Institute. Taken together, award dollars from the Department of Health and Human Services constitute 42% of all award dollars from federal sponsoring agencies in fiscal year 2012-2013 for the State University System. The following table breaks out these award dollars by SUS institution.

Table One: Summary of Grant Dollars Awarded to SUS Institutions by			
the Department of Health and Human Services for Fiscal Year 2012-13			
University of Florida	\$236,594,000		
Florida State University	\$23,772,000		
Florida A&M University	\$7,858,000		
University of South Florida	\$120,687,000		
Florida Atlantic University	\$5,783,000		
University of West Florida	\$330,000		
University of Central Florida	\$14,121,000		
Florida International University	\$20,181,000		
University of North Florida	\$1,543,000		
Florida Gulf Coast University	\$442,000		
New College of Florida	\$0		
Total	\$431,311,000		
Source: State University System 2012-13 Fact Book. Numbers rounded to the nearest			
thousand.			

Prominent were awards in these areas (numbers rounded to the nearest hundred):

•	National Institutes of Health	\$61,069,000
•	National Cancer Institute	\$46,913,400
•	Nation Institute of Diabetes, Digestive & Kidney Diseases	\$36,256,500
•	National Institute of Allergy and Infectious Diseases	\$20,579,500
•	National Institute on Aging	\$20,109,700
•	National Heart, Lung, Blood Institute	\$16,736,000

By further drilling down, it is possible to ascertain which institutions are being awarded dollars in particular areas. For example,

- Of the \$46,913,482 awarded from the National Cancer Institute, \$38,497,109 or 82% was awarded to the University of South Florida.
- Of the \$20,109,724 awarded from the National Institute on Aging, \$16,129,883 or 80% was awarded to the University of Florida.
- Of the \$36,256,542 awarded from the National Institute of Diabetes, Digestive & Kidney Diseases, \$23,479,166 or 65% was awarded to the University of South Florida.

These dollars are indicative of the hundreds of awards made to individual faculty and teams of faculty working in health-related research in the State University System. That the United States Department of Health and Human Services is the key funding source of federal dollars does not, however, provide a complete picture. For example, the United States Department of Defense is providing dollars in brain trauma research, and portions of National Science Foundation dollars may be broadly associated with health-related topics. Health-related research may find its way into the portfolios of colleges of education, departments of psychology, biology, and elsewhere.

In an effort to get a more complete picture, the SUS institutions were asked to provide an indication of the total federal health-related research dollars awarded in 2012-13. Their responses are shown in the following table.

Table Two: Summary of Total Health-related Dollars Awarded By Federal				
Sponsoring Agencies for Fiscal Year 2012-13				
Institution	Health-related Dollars Health-related Dollars as a			
	Awarded	% of Total Dollars		
		Awarded for Each		
		Institution		
UF	\$207,000,000	52%		
FSU	\$40,887,000	21%		
FAMU	\$8,641,000	21%		
USF	\$284,773,000	69%		
FAU	\$5,783,000	26%		
UWF	\$2,167,000	9%		
UCF	\$12,346,000	30%		
FIU	\$30,119,000	30%		
UNF	\$92,000	1%		
FGCU	\$442,000	4%		
NCF	\$0	0%		
Total	\$592,250,000			
Courses Paged of Consumous 2014 Health related Pagengle Courses of CHC tratitutions Dellars and				

Source: Board of Governors 2014 Health-related Research Survey of SUS Institutions. Dollars are rounded to the nearest thousand. Percentages rounded to the nearest whole number.

The two preceding tables demonstrate that, while the 2012-13 Health and Human Services grant funding was at approximately \$431M, total health-related research federal funding approached \$600M. These tables point to conclusive evidence that health-related research in the SUS is a major enterprise that constitutes a core of academic research at several SUS institutions.

How does the State University System compare nationally in terms of its health research enterprise? For national comparisons, R&D expenditure data are the most reliable and comparable data. The table below indicates the top ten states ranked by R&D expenditures in the medical sciences for public four-year institutions for 2011-12. With reported medical sciences expenditures of roughly \$454.5M, Florida ranked sixth in the nation in 2011-12.

Table Three: 2011-12 Top 10 Medical Sciences R&D Expenditures for Public Four-year Institutions			
State 2012 Total R&D Medical Scien			
	Expenditures		
	Dollars in Thousands		
California	\$2,730,721		
Texas	\$1,090,922		
Pennsylvania	\$695,422		
Michigan	\$610,458		
Ohio	\$581,711		
Florida	\$454,425		
Colorado	\$442,576		
Washington	\$429,213		
Wisconsin	\$420,527		
Minnesota	\$392,596		
	State  California Texas Pennsylvania Michigan Ohio Florida Colorado Washington Wisconsin		

Source: Board staff analysis of National Science Foundation research expenditure data available at WebCaspar website (https://nccesdata.nsf.govv/webcaspar/.)

Despite being on the cusp of becoming the 3rd largest state, Florida lags five other states in R&D medical science expenditures. This can be partially attributed to the relative youth of four of the SUS medical schools and their being in the early stages of building research portfolios.

Because federal dollars alone do not represent the totality of funding, the universities were queried as to the sources of their award funding by the categories of federal, state, foundation, industry, and other sources. The following table indicates approximate percentages of award funding for the year 2012-13 by types of funding sources:

Table Four: Approximate Breakdown by Percentage of Health-related Research Funding by Source For Fiscal Year 2012-13					
01110	Federal	State	Foundation Foundation	Industry	Other
UF	74%	6%	7%	10%	4%
FSU	89%	6%	3%	1%	2%
FAMU	89%	1%	0%	7%	3%
USF	43%	10%	8%	5%	36%
FAU	91%	0%	0%	7%	2%
UWF	12%	0%	0%	0%	88%
UCF	85%	3%	1%	4%	6%
FIU	87%	1%	0%	12%	0%
UNF	47%	6%	47%	0%	0%
FGCU	83%	0%	9%	0%	8%
NCF	0%	0%	0%	0%	0%

Source: Board of Governors 2014 Health-related Research Survey of SUS Institutions. Numbers may not add to 100% due to rounding.

This environmental scan would not be complete without mention of the State University System Centers of Excellence. In 2003, the Florida Legislature began an investment into competitively created and funded State University System Centers of Excellence. The Centers are STEM-related and intended to focus on critical problems in Florida and the nation. Since their inception, the State has invested a total of \$84.6M, and the Centers have received \$467M in competitive grants, for a \$5.52 return on investment for every state dollar invested. Several of these Centers of Excellence are directly health-related; others are at least tangentially-related. For example, UCF's Photonics Center of Excellence has a focus on medical and biological applications of lasers, including projects in cellular imaging, optical imaging through tissue, measurement of cell motility and blood coagulation rates, use of laser forces for regenerative medicine, and nanophotonic targeting of metastatic cancer cells. Table five identifies the Centers of Excellence, their initial state funding, external grant awards, licensing income, number of industry collaborations, and number of jobs created.

Table Five: SUS Centers of Excellence					
	State Funds	Grant Awards	Licensing Income	Industry Collaborations	Jobs Created
FAU Center for	\$10.0	\$27.0	\$30.0	11	2
Biomedical and					
Marine					
Biotechnology					
UCF Florida	\$10.0	\$57.9	\$0.18	75	63
Photonics Center					
UF Regenerative	\$10.0	\$41.5	\$0.3	281	290
Health Biotechnology					
FAU Southeast	\$5.0	\$19.0	\$0.0	50	0
National Marine					
Renewable Energy					
Center					
FSU Center of	\$4.0	\$24.9	\$0.0	57	19
Excellence in					
Advanced Materials					
UCF Laser	\$4.5	\$27.2	\$0.0	12	23
Technology Initiative					
UF Center for Nano-	\$4.0	\$22.7	\$0.0	8	71
Bio Sensors					
UF FISE Energy	\$4.5	\$161.4	\$0.06	180	107
Technology					
Incubator					
USF Center for Drug	\$8.0	\$28.4	\$0.16	94	3
Discovery and					
Innovation					
FIU Center for	\$10.0	\$11.1	\$0.0	55	5
Hurricane Damage					
Mitigation and					
Product					
Development					
FSU Center for	\$14.6	\$46.0	n/a	79	285
Advanced Aero-					
Propulsion					
Total	\$84.6	\$467.1	\$30.7	902	868
Source: 2012-13 State University System Accountability Report. Dollars in millions.					

### 2. What are the priority areas of health-related research conducted at SUS institutions? (Survey questions eleven and twelve)

In an effort to understand the priorities and the particular strengths found within the State University System, the universities were asked to indicate their very top priority health-related research areas. Top priority areas were defined by their national/international reputations for excellence, their greatest success in securing funding, and/or their status as most urgently needed. The institutions were limited to a listing of five top priority areas. The following were listed as priority research areas:

UF: Clinical and translational science; aging research; emerging pathogens;

personalized medicine; diabetes.

FSU: Autism; practice-based research; health policy/health care delivery;

biomedical research, neuroscience and molecular basis of human disease;

geriatrics research.

FAMU: Research Centers in Minority Institutions (RCMI) Pharmaceutical

Research Center (PRC); exploratory center of excellence for cancer research, training and community service; the Scholarships for Disadvantaged Students programs; Tallahassee's Healthy Kids for a Healthy Future, Hope thru Childhood Obesity Prevention Education; the role of novel substituted diindolyl methane analogues in the treatment of

triple negative and ERbB2.

USF: Diabetes; neurosciences; infectious diseases and global health;

rehabilitation sciences.

FAU: Child health and human development; aging; cognitive neuroscience;

molecular neuroscience; cancer therapeutics.

UWF: Aging; community health; environmental health; nursing education.

UCF: Cardiovascular diseases; neurodegenerative diseases; infectious diseases;

cancer; simulation.

FIU: HIV/AIDS; alcohol/drug abuse; biomolecular and genetic sciences; child

mental health; health disparities.

UNF: Age- and activity-related muscular and skeletal deterioration; biology and

prevention of insect-borne viruses; maximizing quality and efficiency of health care services; prevention and treatment of obesity; biomedical

devices and instrumentation.

FGCU: Dengue Virus research.

NCF: No response provided.

The list above was limited to five priorities per institution for purposes of focusing on the highest priorities. No doubt the list would have been longer had the limitation been more generous. All priority areas are taken up in detail in Part Two of this report. Here, in abridged form, a description is provided of each institution's first priority listing.

Clinical and Translational Science at UF. The overall mission of the University of Florida Clinical and Translational Science Institute (UF CTSI) is to improve human health by accelerating the translation of scientific discoveries into practical applications and practices for the diagnosis, treatment, prevention and cure of human diseases. It is geared to amplify the capabilities of individual and team investigators, and to help them more effectively and more quickly carry out their clinical and translational research. The UF CTSI's NIH award of nearly \$26 million has been matched by more than \$93 million in UF commitments. The UF CTSI currently offers more than 40 services to UF investigators. Now in its fifth year, the CTSI supports 11 programs delivering CTSI services, 12 affiliated clinical research units, a regional metabolomics center and four core laboratory facilities, and eight educational programs.

Autism at FSU. The FSU Autism Institute was established to coordinate and promote research, education and service related to autism spectrum disorders. The specific aims of the Autism Institute are: to promote interdisciplinary research that advances scientific knowledge of autism spectrum disorders; to bridge the gap between scientific knowledge and clinical/educational practice; to build the capacity of primary care and other service providers, educators, employers, family members, and individuals with autism spectrum disorders to improve outcomes through research and training; and to maximize the use of innovative video and computer information technology in research, education, and service related to autism spectrum disorders. Research areas of focus include: identifying more precise early red flags of autism and studying ways to improve and streamline screening and diagnostic practices to improve early detection of autism in infants and toddlers; and studying ways to coach families and early intervention providers to learn how to implement evidence-based intervention strategies in everyday activities to improve outcomes for toddlers with autism.

Research Centers in Minority Institutions (RCMI) Pharmaceutical Research Center (PRC) program at FAMU. This program has been funded for over 29 years from the National Institutes of Health totaling over \$59 million. The RCMI Program develops and strengthens the research infrastructure of minority institutions by expanding human and physical resources for conducting basic, clinical, and translational research. The overall FAMU RCMI Program goal is to increase the number and skill proficiency of minority scientists engaged in advanced biomedical research. These goals are accomplished through the establishment of synergistic research resource cores that provide services to enable investigative research on specific pathological etiologies associated with health inequity amongst minority groups, especially African-Americans and disadvantaged populations. Drug discovery investigators are developing novel drug candidates to uncover targets for therapy and translational research, and molecular genetics investigators are utilizing new methodologies in genetics, genetic engineering and epigenetic research.

<u>Diabetes Research at USF.</u> USF is home to the number-one funded NIH investigator who specializes in diabetes research. The USF Pediatric Epidemiology Institute coordinates numerous national and international research studies in diabetes and related disorders. The Diabetes Center is currently an affiliate site of the NIH-, ADA-and JDRF Diabetes Exchange group coordinated by the JAEB Center for Health Research in Tampa. The Center focuses on delivering premier clinical care, engaging in cutting-edge research, and advancing diabetes care through patient and professional education and outreach.

Child Health & Human Development at FAU: FAU has a long history of identifying the human abilities and experiences that contribute to purposeful complex behavior and language development. For example, a large body of work is associated with a longitudinal study of English monolingual and Spanish-English bilingual children and the influence their language environment has had on later school performance. The objective of these projects is to provide an empirically-based understanding of preschool oral language and pre-literacy skill development in children from Spanishspeaking families. The language skills that children from Spanish-speaking homes present at school entry are highly variable and poorly understood. The knowledge base regarding the processes and outcomes of dual language development is inadequate either to design maximally effective educational programs or to match children to the programs they need. Another research thrust has investigated how infants manage to integrate the constant onslaught of multisensory information into a perceptually coherent picture of their world. Autism has been growing at an alarming rate of 10-17 percent per year. Because autism and related communication and learning disorders are developmental in nature, the earlier they are diagnosed the more effectively they can be ameliorated and/or prevented.

Aging Research at UWF. The UWF Center on Aging conducts research efforts with the aim of improving the lives of older adults. Faculty researchers work within the community to assess knowledge of aging as well to assess life satisfaction among older adults. The Center on Aging also conducts research into neuronal and biochemical changes in aging. UWF researchers are using animal models to explore the mechanisms by which proteins associated with early onset Alzheimer's disease form, studying cultured neurons to understand the molecular pathways contributing to plaques in the brain, analyzing blood and cerebrospinal fluid to identify potential biomarkers related to development of cognitive disorders, and using electroencephalogram technology to detect early changes in neuronal activity associated with mild cognitive impairment.

<u>Cardiovascular Disease Research at UCF:</u> The cardiovascular team has about seven members who excel in their respective areas of research. Members are well known for their expertise on cholesterol deposition in the artery, stem cell therapy research for heart failure, prevention and treatment of chronic inflammation associated with cardiovascular diseases, defining how the aging process contributes to cardiovascular

diseases, and for studying associated risk factors, such as diabetes, obesity, sedentary life style etc. Investigators also study diet and nutritional prevention of cardiovascular diseases. The research focus also includes studying the effects of left ventricular assist devices (devices that are implanted in patients with heart failure to promote blood pumping). The members have been successful in obtaining research funding from several agencies, including NIH, and have published over 100 articles during the past five years. They represent UCF in several national and international committees and organizations, including NIH review panels, and are well recognized by national and international experts.

HIV/AIDS Research at FIU. FIU has research focused on HIV/AIDS around the globe, including in Latin America, the Caribbean, and China. This research includes federally funded research on the study on migration, tourism, and the HIV/drug syndemic in the Dominican Republic. In Haiti there is a compelling need to integrate new HIV prevention strategies that have recently gained consensus and evidence of efficacy. The purpose of FIU's study in Hunan Province, China is to identify factors associated with disclosure of HIV status to sex partners in a sample of HIV infected individuals. On the treatment front, researchers at FIU have been exploring alternative methods of medication delivery to treat HIV infections such as nanoparticle-based drug delivery systems targeting the brain.

Age- and Activity-Related Muscular and Skeletal Deterioration Research at UNF. Sarcopenia is the gradual deterioration of skeletal muscle that accompanies the aging process and is a serious medical condition facing millions of elderly people. Correlated with this disease condition are the direct and indirect impacts of physical injury on patient skeletal health. Several UNF research projects explore the causes, prevention, and treatment of sarcopenia, osteoporosis, injury, and related diseases. For example, UNF faculty are examining how genes play a pivotal role in regulating important aspects of skeletal muscle physiology, including the processes of sarcopenia and cellular stress or damage. Faculty are particularly interested in understanding the molecular and genetic controls of longevity, and the role that cellular stress may play in aging.

<u>Dengue Virus Research at FGCU.</u> Florida Gulf Coast is currently involved in research to develop a vaccine for the Dengue Virus. Each year the World Health Organization estimates that over 390 million people are infected. The Dengue Virus has reached epidemic levels in Southeast Asia and many Latin American and Caribbean countries. There is currently no specific treatment or cure for the disease. Florida Gulf Coast University is continuing work on developing a vaccine to neutralize all four types of Dengue Virus.

### 3. What are the general health-related research challenges in the SUS? (Survey question six)

The universities were asked to provide, in general terms, what they saw as the greatest challenge or challenges with regard to conducting health-related research. The responses, taken together, indicate the following themes or strands:

- Reduction of federal dollars for health-related research and development has created a challenge to SUS institutions. This challenge was cited by UF, USF, UNF, and FIU specifically, and alluded to by other institutions. FGCU noted the need to increase the number of research grants that it was receiving. Federal funding has become more and more difficult to secure, specifically, National Institutes of Health funding, which supports the majority of research conducted by the various components of the health-related industry.
- Health-related research space and equipment is an issue at the majority of SUS institutions. To varying degrees, institutions reported the need for more and better research laboratory space, more and better veterinary space, the need to renovate research space, the challenge of maintaining adequate core facilities, and the need to secure modern instruments. FGCU, for example, noted the need to improve both laboratory infrastructure as well as the need for an animal research facility. FSU also noted the need to improve research laboratory space. These institutions were not alone, however, and the question of facilities is discretely covered as a separate research question in the next section.
- Having adequate numbers of faculty and other personnel was reported as an issue at several SUS institutions. Start-up packages for new faculty are reported to be insufficient at both senior and junior levels. Retaining the best faculty is reported to be a problem on SUS campuses. Teaching loads are said to be heavy, especially at certain of the smaller institutions (UWF, UNF). Some institutions noted the lack of State matching dollars for donations to establish endowed chairs. Also noted by several campuses was the lack of funding to adequately support graduate research assistantships. FAMU's response was representative. It pointed to lack of sufficient resources to attract and recruit faculty with competitive salaries and start-up packages, as well as decreasing capital dollars as key challenges. FSU also noted start-up costs associated with new faculty as a major challenge
- USF pointed out the shift in pharmaceutical company strategies to use nonacademic institutions to conduct clinical trials.
- USF also pointed out that increasing its research base in order to receive the highest possible Facilities and Administrative rate from the U.S. Department of Health and Human Services is an important factor in meeting its research challenges.
- Among UCF's challenges is the relative youth of its medical school. It should be remembered that the SUS has three very new medical schools, FAU's and FIU's being the other two, and FSU's being relatively new. UCF pointed to the need for maturation of partnerships.

Also noteworthy in UCF's response was the stated need for access to clinical
populations, including the need for a research repository that would allow
investigators to access a research database. Other institutions (UF, FSU) noted
the same challenge.

# **4.** What are the priority facility needs at SUS institutions? (Survey question ten) The institutions were asked to indicate their single highest priority facilities need as it pertains to health-related research, and to estimate the dollar amount necessary to meet that need. Costs ranged from \$1M to \$600M. Responses were as follows:

- UF's response was noteworthy in that it did not list a traditional facility as its highest priority. Rather, UF's greatest priority is to develop data integration tools and standardization that allows electronic medical records to be seamlessly integrated into a statewide network. A statewide, integrated data repository, according to UF, would allow Florida to compete for major new funding initiatives and would position Florida to be a destination for clinical research, comparative effectiveness research, and implementation science. (Cost: \$10M)
- Similarly, FSU responded that it needed a robust technology infrastructure in both bio- and health-informatics to better collect, assimilate and analyze data associated with health-related research, particularly patient-centered outcomes. This would include an electronic medical records system that could be used by FSU's community-based Clinical Research Network. FSU indicated that an informatics-focused technology infrastructure would provide the foundation needed to advance clinical translational research across Florida communities. (Cost: multi-millions)
- FAMU listed as its highest facilities priority a research building for College of Science and Technology scientists. (Cost: \$20M)
- USF listed as its highest facilities priority an immediate need of a new teaching and health research complex, including a modern Morsani College of Medicine and the completion of the USF Health Heart Institute. The total projected cost of the overall project would be approximately \$112M, some of which has already been appropriated by the State. (Cost to complete: \$73M)
- FAU listed as its highest facilities priority the ability to scale up facilities, equipment, and veterinary capabilities to take optimal advantage of having Max Planck Florida and Scripps Florida on its Jupiter campus. (Cost: \$3M)
- UWF indicated its short-term highest facilities need to be a Laboratory Sciences Annex. (Cost: \$18.8M) UWF indicated that this will provide only a short-term solution to its need for appropriate facilities to enable it to meet its health-related academic and research goals.
- UCF listed as its highest facilities priority a research-focused teaching hospital. (Cost: \$500-600M)

- FIU indicated the need for satellite offices located near large hospitals throughout South Florida. These sites would be instrumental in participant recruitment and retention across disciplines. (Cost: \$30-40 per square foot)
- UNF listed as its highest priority new bench and clinical lab space and equipment. (Cost: \$1M)
- FGCU listed as its highest priority an animal research facility. (Cost: \$5M)
- NCF listed as its highest priority a multi-use research/laboratory/collaborative wing added to the current natural science building. (Cost: \$8M)

### 5. What are the technology transfer challenges at SUS institutions? (Survey questions three, four, and seven)

The universities were queried as to their technology transfer and commercialization activities in 2012-2013. The purpose of this was to determine what portion of the totality of that activity was associated with health-related research. Results of the query, in the aggregate, are provided in the table below.

Table Six: SUS Technology Transfer and Commercialization 2012-2013				
Total Health-related				
Invention Disclosures	755	283		
Provisional Patents	545	248		
Patents	317	100		
New Companies	33	17		
Licenses	258	96		
Licensing Income	\$31,854,600	\$3,626,600		

Source: Board of Governors 2014 Health-related Research Survey of SUS Institutions. Dollars rounded to the nearest hundred.

The institutions were further queried as to their biggest challenges and opportunities with regard to health-related technology transfer. The responses, taken together, indicate the following themes and strands:

- The challenge most often articulated was the absence of seed capital and proof-of-concept funds for prototypes and pre-clinical drug development. This challenge was pointed out by UF, USF, FIU, and others. It was reported by USF that the National Institutes of Health does not traditionally fund critical proof-of-concept studies. Industry partners are reluctant to fund such programs themselves, yet require such studies prior to collaborating on the technology. NIH has almost no funding for medical device research, and very little comes from the National Science Foundation. According to USF, a step forward would require a stronger ecosystem of angel and venture capital in Florida.
- FAU noted that patents depict early stage inventions with a high degree of business risk and, therefore, companies are reluctant to license.

- FIU noted opportunities to build stronger relationships with Florida institutes such as Torrey Pines, Sanford Burnham, and health related foundations.
- Among UCF's technology transfer challenges were the education and orientation
  of faculty members towards issues surrounding intellectual property and
  commercialization, and limited funding for translational research, including
  proof-of-principle and pre-clinical studies.
- USF reported that the patent landscape for biomarkers and diagnostics experienced a significant shift due to a recent Supreme Court ruling, resulting in fewer opportunities to secure patents.
- UWF reported that community partners at some universities are focused primarily on providing health-care services, not research. UNF reported that its focus on teaching over research discourages faculty from disclosing their patentable technologies and/or from considering commercializing their inventions.
- FSU indicated that, while the lack of research traditionally performed at medical schools has been a challenge, this is changing significantly as the medical school research base increases. Challenges at FSU also include the decrease in STEM-related faculty over the last few years and the present efforts to replenish the loss. Finally, FSU noted another challenge as the lack of health care industry presence in the Tallahassee area.
- FAMU noted the lack of trained technology staff and the absence of a licensing officer for the institution.
- FGCU pointed out that it simply needed more patentable products.

With respect to industry partnerships, the institutions were asked to provide listings of health-related industry partnerships for the last three fiscal years. The universities provided the following information:

- UF has over 300 partnerships involving clinical trials and translational research.
- Sectors in which FSU has industry partnerships include health education, food health/safety diagnostics, medical research reagents, medical research related to software simulation technology (molecular interactions) health care business organizational management training, and drug development.
- FAMU listed 12 industry partnerships with which it has had relationships.
- USF provided a list of over 750 industry partnerships.
- FAU provided a list of 10 industry partnerships.
- UWF provided a list of 14 industry partnerships.
- UCF provided a list of 30 industry partnerships.
- FIU provided a list of 10 industry partnerships.
- UNF provided a list of 7 industry partnerships.
- FGCU provided a list of 10 industry partnerships.

### 6. What are the major research compliance challenges in the SUS? (Survey question 8)

The universities were asked to indicate their greatest challenges with regard to healthrelated research compliance. The responses, taken together, indicate the following themes and strands:

- UWF reported that it faced very few challenges with respect to health-related research compliance. Similarly, FGCU reported that the health research being conducted at FGCU is not under the auspices of the Food and Drug Administration. UNF reported that it has an unnecessarily conservative approach to research compliance, leading to significant delays and frustration among researchers. This is being addressed by revising standard operating procedures to be more researcher-friendly, and by bringing new faculty onto compliance committees who have experience at other institutions.
- UF, USF, FAU, UCF, FIU and other institutions responded that a more complicated and expansive regulatory environment continues to be a challenge. New unfunded federally mandated rules and regulations require new knowledge and oversight, new ways of doing business, additional reporting requirements, and additional training. Without the proper research administration support structure, faculty can easily become dis-incentivized. Challenges include minimizing the length and complexity of technical medical consent forms, assigning appropriate affiliations for courtesy/volunteer medical research faculty members, and managing the oversight and monitoring of biomedical research studies at external research sites.
- Institutional Review Boards (IRBs) are entities that approve the use of human subjects in research protocols. Each institution has at least one IRB. Having to secure approvals of multiple Institutional Review Boards rather than one approval from a central IRB poses a significant challenge to health-related research compliance. In recent research collaborations with UF, due to multiple study sites and institutions involved, FSU determined that more than a halfdozen IRBs have been involved with the review/approval of its studies. This creates a cumbersome, time-consuming process that has caused lengthy delays in study implementation. The federal government's recent movement toward allowing use of a single IRB review for multi-site studies is promising. It creates an opportunity for Florida research universities and affiliated health care institutions to collaborate in forming a central IRB for statewide and regional research. Such efforts already are underway between UF and FSU. The multiinstitutional agreement is designed to streamline the compliance process, reduce costs by eliminating duplicative regulatory reviews, and ensure consistency in protocols across study sites. UF and FSU continue to work toward expanding this IRB cooperative with a goal of including other Florida universities and affiliated public and private healthcare institutions. According to the institutions, these efforts would be greatly advanced if the Board of Governors

- addressed the cooperative or central IRB concept as a statewide public policy priority to enhance health-related research.
- FAMU also noted challenges with its IRB process. In addition, FAMU noted challenges associated with limitations in dealing with biohazardous materials and a lack of funding for hazardous waste disposal.

# 7. What are the major veterinary challenges in the SUS? (Survey question nine) The universities were asked to indicate their greatest challenges with respect to veterinary resources. The responses, taken together, indicate the following themes and strands:

- UF noted the high cost of animal models traditionally used for translational research such as dogs, cats, rabbits, swine, and non-human primates. FAU reported that federal and state regulations in the proper care of animals have increased with a concurrent rise in the cost of facilities to house and care for these animals.
- FSU reported that relatively minor renovations and modifications in animal
  density of some space will provide sufficient capacity to meet the animal holding
  needs for the next decade. FAMU reported key challenges in the satellite animal
  facilities at the FAMU/FSU College of Engineering. USF reported that the
  biggest challenge is the collection of fees for services and the need for
  modernized facilities located at USF Tampa. UCF, UNF, and FGCU reported the
  need for large animal facilities.
- UWF reported no specific challenges with regard to veterinary resources. With a new vivarium, FIU also reported no challenges at this time.

### 8. In what health-related research areas are SUS institutions currently collaborating? (Survey question fourteen)

The universities were queried as to their current collaboration with other SUS institutions in health-related research. Examples included the following:

- Concussive surveillance and management at UF and FSU
- FSU's research in tobacco-related diseases with UF
- FSU's chronic pain study with UF
- FAMU's research in biomaterials and nanoparticles for bio-imaging with UF and UCF
- FAMU's research in stem cell therapy with UF and USF
- USF' substance abuse and stroke projects with UF and FSU
- FAU's work in marine-based cancer therapeutics with UCF
- UWF's research in disaster impacts with UF and FAMU
- UCF research in HIV/AIDS with UF
- UCF cancer research with USF and FAU
- FIU's collaboration with UF in HIV/AIDS research
- UNF's research in rural health disparities with UCF

UNF's research in diet and reproduction on life span with UF.

### 9. Is there unaddressed needed research that SUS institutions might undertake? (Survey questions thirteen and fourteen)

The universities were queried as to whether there were critical areas of research in the health care field that are not currently addressed by Florida universities and should be supported. The universities cited a number of research areas that either needed to be addressed or needed to be addressed more than is currently the case. These were also cited as potential areas for collaboration among SUS institutions. Such research areas included the following:

- chronic diseases of the elderly, successful longevity, and geriatrics
- population-based community research and associated translational applications
- health care delivery research (including telemedicine, care of rural/disadvantaged populations)
- palliative care
- disease prevention/healthy lifestyles
- nursing education and workforce issues
- the handling of health-related big data
- health disparities among minorities, under-represented groups in clinical trials, and environmental policies designed to protect all populations and for vulnerable groups
- genomic and personalized medicine
- obesity assessment and prevention
- early, adolescent, and middle childhood health; and health care provision in county schools; college-based mental and behavioral health
- biomarker discovery
- chronic inflammation
- neuroscience
- gender-based population health
- health information technology and the use of electronic health record systems
- autism
- human trafficking
- evaluation metrics

With respect to further collaboration opportunities, the institutions specifically indicated the following:

- UF pointed out opportunities to work with FSU's primary care physician based network, data coordinating center capacities with USF, and simulation technologies with UCF.
- FSU indicated that its community-based clinical research through the College of Medicine's Clinical Research Network presents ideal collaborative opportunities for numerous partnerships, including with SUS institutions.

- FAMU pointed out opportunities in the application of newly discovered drugs with UF and FSU; in biomaterials and nanoparticles for bio-imaging with UF and UCF; in stem cell therapy with UF and USF; in high field MRI with UF and USF; in working with health disparities with UF, USF, and FAU; in health related issues involving the medical services to the "baby boomer" population with FSU and UF; and in industrial-scale stem cell expansion and packaging for clinical use issues on the effect of environmental contaminants with UF and USF.
- USF indicated that FAU, FIU, and USF—the only three universities in the SUS located in large metropolitan statistical areas—have the potential to form a strong triad in health-related research areas to address problems specific to urban-suburban communities.
- UCF pointed to working in pharmacy with UF and USF, and to working with the UF Department of Health Services Research, Administration and Policy College of Public Health and Health Professions.
- FIU indicated that its NeighborhoodHealth program in the College of Medicine could collaborate with UF and USF.
- UNF indicated that UCF's Health Administration Program would be a good partner for future health care quality and efficiency research, and that the UF NMR facility and Scripps Institute's screening facility would be useful research partnerships.
- FGCU indicated that any partnerships with UWF, UF, UCF, or FIU would be fruitful.
- NCF indicated that it could partner with other institutions to create 3+2 programs in health-related science degrees.

### 10. What are SUS contributions to translational research? (Survey question fifteen)

Translational research is research that aims to make findings from basic science useful for practical applications that enhance human health and well-being. The universities were queried as to the role and contribution of translational research in health-related areas. Each institution was limited to a description of up to 400 words of its contribution to translational research. Excerpts are as follows:

At <u>UF</u>, research is a core mission of faculty and is integrated into both the education and clinical missions. Greater than 90% of the faculty participate in research, and all colleges/departments have active research programs. UF strives to foster an environment conducive to discovery and innovation in the medical sciences, through supporting strong interdisciplinary teams of basic and clinical researchers. Over the last six years the research mission has undergone a tremendous increase in research activity and, in turn, improvement in the extramural funding of its research programs. The University has seen unprecedented growth in its NIH research-funding portfolio. The research portfolio has also become more diverse. While continuing its traditional

strength in individual investigator-initiated research programs, the research productivity at UF has been further enhanced by a focus on team science. Many UF faculty are creating successful programmatic research awards in areas such as: aging, gene therapy, diabetes, Alzheimer's disease, neurogenetics, infectious disease, reproductive biology, metabolomics, health outcomes and community engagement. Reflective of the national move to enhance the integration of basic research with clinical diagnostic, therapeutic and outcome-based research, the University has significantly augmented its capacity in both quantitative and patient-centered research. The focus on clinical and patient-centered research has the greatest impact on Floridians' lives and can be expanded to help increase statewide research partnerships and funding.

At FSU, The College of Nursing's contributions in the area of translational research are primarily focused within the Tallahassee Memorial Healthcare (TMH) Center for Research and Evidence Based Practice. The Center was established in 2013 with a \$100,000 gift from Tallahassee Memorial Healthcare. In the short time that this program has been enjoined, the collaboration has resulted in increased numbers and quality of projects within TMH. The College has a well-established Doctor of Nursing Practice program, which requires the performance of a clinical research project (essentially translational research). These projects have been highly useful in furthering the faculty's work on translational projects. The College of Medicine formally opened its Translational Science Laboratory in August 2011 as part of an initiative to integrate community-based medical practice with translational science. The state-of-the art laboratory provides genomic, proteomic and metabolomics services for investigators affiliated with FSU and elsewhere across Florida, the nation and even globally. The College of Medicine has more than 2,000 physician faculty members at six regional campuses and multiple rural sites around the state, representing a patient population of approximately 2 million Floridians. The College's developing Clinical Research Network provides access to patient samples from diverse populations typically underrepresented in the search for signatures of disease and targets for treatment. The CRN has completed two pilot studies in the Orlando and Tallahassee regions, funded through a Board of Governors Cluster Award in collaboration with UF. The CRN recently was awarded two grant proposals and has two more pending. Expanding the CRN presence to all regional campuses and rural sites is a goal that could be advanced considerably through additional state-level funding. This would allow FSU to build the needed infrastructure of community research associates who help the local practices implement research studies, interpret results and develop scholarly publications and conference presentations/posters.

<u>FAMU</u> is engaged in translational research through its various programs in the area of biomedical/behavioral sciences. Its faculty have established community outreach and information dissemination activities through translational research that will increase prevention efforts and foster early detection towards reducing breast cancer in African-American women (Leon and Gadsden County, FL). In addition, FAMU has

established partnerships with community engagement/outreach organizations toward addressing and conducting research on minority and other health disparities issues adversely affecting disadvantaged populations. Investigators are seeking to increase multi-disciplinary collaborations in moving research from the "bench to the bed-side." The FAMU-FSU College of Engineering (CoE) biomedical and health-related projects developed by FAMU investigators seek to transform public health by moving the discoveries of basic science into the clinical realm by making them more efficient, practical, safe and widely accessible to the healthcare and patient population. With strengths in chemical analysis, materials research, stem cell modification, genetics and bioimaging, the college is positioned to translate new techniques, discoveries and patents to industrial and clinical partners.

One of <u>USF's</u> successes is the Byrd Alzheimer's Research Center. This facility has bench-to-bedside research, with basic sciences labs in part of the facility for the specific purpose of developing and testing new therapies for Alzheimer's disease and other dementias. The facility also has a clinical research unit that undertakes the testing of new drugs and protocols to reduce the progression of disorders that affect the brain. The facility helps families and the afflicted family member adapt better to their living conditions by modifying the living environment for greater functionality and safety. Many of the psychosocial issues of brain disorders are also addressed by conducting research and providing counseling in the facility. The Morsani College of Medicine also has an extensive Office of Clinical Research that supports faculty interests in investigating new drugs and devices in the medical marketplace. The basic science conducted in the laboratory setting and the pre-clinical research being undertaken by USF faculty lend themselves to eventual approval for early-phase human testing.

<u>FAU</u> has developed a nationally recognized quality system to reduce expensive repeat hospitalizations, with strong funding and support from CMS, NIH, private foundations and industry. The efficacy of this approach has been documented in peer reviewed journals, passionately embraced by healthcare staff in long term care, and the commercial value of this approach is demonstrated by over a dozen licenses with leading software Electronic Healthcare Record companies who are actively incorporating this approach within their software systems. As a final vision FAU proposes a state university/state agency partnership similar to Commonwealth Medicine based in Massachusetts in which a state university partners with state agencies to improve health care outcomes within the state. FAU believes that UF is well positioned to lead this effort, and FAU would welcome the opportunity to contribute to this larger effort through its unique accomplishments which would be complimented by clinical and computational expertise across the SUS specifically to address the healthcare needs of Florida's residents.

<u>UWF</u> has contributed to both aspects of health-related translational research — translation of basic laboratory science to the clinical, applied environment and the

promotion of best practices in health and wellness within the community. The Center for Environmental Diagnostics and Bioremediation has been a campus leader in bringing basic laboratory science to the field. UWF's Center on Aging is actively developing a biochemical cellular-level method for detection of Alzheimer's disease. Other faculty within Biology and Exercise Science are developing vaccination techniques for influenza and studying the effect of endurance exercise on cellular health. Successes in these areas will catalyze other faculty to engage in similar activities. UWF's other major area of translational research focuses on bringing the best practices for health and wellness to the local and regional community. Faculty from Psychology, Exercise Science and Community Health, Social Work, Nursing, and Public Health work closely with local health agencies, non-profit organizations, and industries to identify health-issues, investigate potential solutions, and implement interventions to improve health. In particular, UWF has a strong relationship with a local retirement community for the advancement of research relating to healthy aging and works closely with community partners in providing assessments and interventions relating to infant mortality, obesity, smoking cessation, suicide prevention, and the prevention of chronic disease. This type of translational research will continue to grow as UWF builds more relationships within the community and expands to include other regional partners.

UCF's College of Medicine has initiated pilot clinical studies to determine the efficacy of sesame oil to reduce blood lipid levels and to influence the progression of atherosclerosis. The "cardio group" is also planning to isolate specific stem cells from humans (which will contain a protein that will react with special hormones) to enhance beating heart cells. The neurodegenerative group has an ongoing study to identify molecules that inhibit viability of NF2 (Neurofibromatosis type 2), a rare genetic disease that causes tumors to form in the central and peripheral nervous system. The neuro group plans to develop a bone scaffold to combine with a patient's own stem cells in clinical use. There are ongoing collaborations with Florida hospitals to identify embryonic stem cell gene expression in gluons cancer stem cells. The neuro group is also developing targeted therapies to treat glioblastoma and an eye drop treatment promoting regeneration of the cornea by endogenous stem cells. The group is further testing a combination of drugs, developed in collaboration with NIH as a preclinical study for Alzheimer's disease. The cancer group, in collaboration with physicians of Florida Center for Cellular Therapies and the Oncology group at Florida Hospital Cancer Institute, are developing new clinical treatment methods for acute myeloid leukemia.

A number of <u>FIU</u> research projects have the potential to inform new treatments and cures. In the field of nano-technology, FIU investigators are literally speeding up the process by which drugs are delivered to the brain. Several FIU faculty from the College of Engineering and Computing are working on assistive technology initiatives focused on visual impairments and limb loss, while others are focused on isolation of brain pathways crucial to normal aging, dementias, epilepsy, hypertension, and other

pathological conditions. At FIU's College of Medicine, numerous investigators are conducting laboratory experiments that hold great promise for translational research in the areas of reproductive health, environmental health, infectious diseases, and cancer.

UNF is especially well-known in the region for translational research in various health fields, consistent with the applied undergraduate and graduate programs that it offers. For example, UNF's Pediatric Assistive Technology CBTLO grant allows doctor of physical therapy and engineering students under the direct guidance of their faculty leaders to conjointly design, prototype, and test biomedical engineering solutions for community identified needs. This is being done in partnership with area pediatric physical therapists from several rehabilitation settings, including Wolfson's Children Hospital, Brook's Rehabilitation Hospital System, and the Duval County School District Special Needs Program. As another example, several faculty in the Brooks College of Health, as well as students in the doctor of nursing practice programs, are involved in translational research projects around the pedagogical success of simulation in nursing education, and the value of community involvement with nursing and public health students. UNF is also engaged in technology transfer and commercialization of inventions emerging from health-related research, albeit on a scale consistent with the university's size and mission. This includes an active patenting and licensing program for a series of inventions in chemical and microbial sensors, and the possibility of a faculty-founded spin-off company is currently being explored. An invention for inhibiting mosquito larval development is currently in licensing negotiations with the small Florida business that holds the option on the technology. And a new chemical process that has the potential for revolutionizing the synthesis of widely-used pharmaceutical compounds is in the process of being patented. UNF is very well positioned both institutionally and geographically to expand both kinds of translational research. Jacksonville has a well-established and still-growing healthcare industry, and as the only large public university in the city, UNF is increasingly called upon to assist in a wide variety of translational and applied research projects.

The best example of <u>FGCU</u> contributing to health-related translational research is its efforts to develop a vaccine for the Dengue Virus. The aim of translational research is to make findings from basic science useful for practical applications that enhance human health and well being. The development of a vaccine would alleviate the vast suffering currently being endured by millions of individuals in less developed countries. Regarding the extent to which translational research can be expanded, it would be of great benefit to have an animal facility on sight to conduct animal trials. FGCU currently has to use the facilities of another university.

DRAFT

#### **IMPLICATIONS**

### The Array of University Research

The universities demonstrate in all sections of this report that the array of health-related research being conducted on SUS campuses is pervasive and diverse. Measured by federal research dollars, health-related research constitutes over half of federal funding secured in 2012-2013 for two SUS institutions. Both in the general topical areas they identified and by their discrete examples, the universities have demonstrated a commitment to translational research: research that aims to make findings from basic science useful for practical applications that enhance human health and well-being.

### **Funding**

Funding as a general topic is obviously critical, but it can be viewed in two ways: incoming funding to support health-related research, and expenditure-related funding going toward conducting that health-related research. With respect to the former, this report indicates that the SUS received about \$600M in federal funding associated with health-related research in 2012-2013. Of the top ten states ranked by R&D expenditures in the medical sciences for public four-year institutions in 2011-2012, Florida ranked sixth. Ensuring that this level of funding remains stable and even growing should be a concern for the State University System since health-related research is so central to its core. At the same time, federal funding is reported to be harder and harder to get: grant competition is more intense than ever. Seed capital for proof-of-concept funding is also reported to be a challenge for SUS institutions.

On the expenditure side, the institutions reported challenges in key areas. These included attracting and retaining the best faculty which, in turn, involves substantial start-up packages, and dollars for graduate assistantships, technicians, and post-doctoral fellows. All institutions reported needs in the areas of facilities, including veterinary facilities. Some universities reported deficits in the latest of both laboratory facilities and equipment. These needs have both capital cost and operational cost implications.

#### Collaboration

The results of this report indicate that the institutions are currently collaborating and are eager to collaborate more in at least four ways:

- 1. Seeking federal funding. Experience has demonstrated that federal funding agencies are more likely to provide funding for major federal grants by seeing partnerships among institutions and in pursuing research questions that cross disciplines and institutions.
- 2. Collaborating in research. The universities identified a wide array of health-related research areas that are currently unaddressed or less addressed than they need to be. These were the same areas in which the institutions indicated a willingness to collaborate, provided that they had the expertise and resources to do so.

- 3. *Collaborating in the Institutional Review Board (IRB) process*. The universities note the cumbersome and time-involving process with working with multiple IRBs. The institutions indicated a willingness to explore a central/shared IRB process.
- 4. Collaboration with Big Data. The universities indicated that it was critical to partner around data standardization, since linkage of Big Data across all Florida universities would present a powerful new paradigm to tackle some of Florida's greatest health-related challenges. It was recommended that a statewide, data repository would allow Florida to compete for major new funding initiatives and would position Florida to be a destination for clinical research, comparative effectiveness research, and implementation science.

The State University System's health-related research is a vast enterprise with great strengths. It has the potential to become even stronger. The "Three F's" — Funding, Faculty, and Facilities — present both challenges and opportunities. The universities will have to strive for funding that is becoming more and more competitive to receive.

- The SUS clearly has stellar faculty working in health-related areas, but the key is recruiting more where they are most needed, and in retaining the best faculty that the SUS currently has.
- With respect to facilities, while the SUS has some state-of-the-art facilities, all
  institutions reported needs in important areas.
- Most importantly, the universities are currently collaborating and understand
  the value of even further collaboration. It would behoove the SUS to explore a
  shared/collaborative IRB process that other states have developed.
- The SUS might explore a statewide, integrated data repository that would allow Florida to be a destination for clinical research, comparative effectiveness research, and implementation science.
- The challenges identified with the commercialization of technology span multiple institutions and provide an opportunity for the SUS to enhance training and financial support for technology transfer activities.
- With respect to unaddressed research and potential further collaborative efforts among SUS institutions, the list is long; the challenge will be to focus down to a few key areas.
- The time may be appropriate for the SUS to consider Board of Governors State of Florida Centers to enhance collaboration in critical areas, or in areas where multiple institutions are focused on similar research agendas.

Strategic planning and understanding where to invest limited resources so they will have the maximum return on investment will be essential for the SUS to reach its potential. This will become the work of the Health Initiatives Committee as it crafts a strategic plan for the State University System.

#### PART TWO: INDIVIDUAL UNIVERSITY RESPONSES

### University of Florida Survey Response

### **UF Priority Areas of Health-related Research**

Clinical and Translational Science: The overall mission of the University of Florida Clinical and Translational Science Institute (UF CTSI) is to improve human health by accelerating the translation of scientific discoveries into practical applications and practices for the diagnosis, treatment, prevention and cure of human diseases. It is geared to amplify the capabilities of individual and team investigators, and to help them more effectively and more quickly carry out their clinical and translational research. UF CTSI improvements include awarding support for pilot projects, improving the IRB submission process, creating new informatics resources, and introducing a common reimbursement price list for clinical research charges. The UF CTSI's NIH award of nearly \$26 million has been matched by more than \$93 million in UF commitments. The UF CTSI currently offers more than 40 services to UF investigators. It partners with the other 60 leading biomedical research institutions in the national Clinical and Translational Science Award consortium, Florida State University, Orlando Health, Sanford-Burnham Medical Research Institute, and the North Florida/ South Georgia Veterans Health System. Now in its fifth year, the CTSI supports 11 programs delivering CTSI services; 12 affiliated clinical research units (including the UF Clinical Research Center); a regional metabolomics center and four core laboratory facilities (including a large-scale, CAP-accredited biorepository); and eight educational programs (including the CTSI's TL1 training grants for predoctoral students, KL2 training grants for junior faculty, Academy of Research Excellence, Mentor Academy, and research coordinator programs).

Aging Research (Institute of Aging): The mission of the Institute on Aging is to improve the health, independence and quality of life of older adults by means of interdisciplinary teams in the areas of research, education and health care. The overarching goals of the Institute are to conduct dynamic interdisciplinary research that spans public health, social, health services, behavioral, clinical and basic sciences. Our research focuses on mechanisms, etiology, prevention and rehabilitation of cognitive and physical disability. We strive to accelerate translation, dissemination and implementation of research findings into clinical practice and healthcare policy. At 18.1 percent, Florida has the largest proportion of persons age 60 years or older in the nation, and this age group represents the fastest growing segment of the population in the country. Therefore, it is critical that we address the health concerns of this portion of our population. In this spirit, we are proud to have received funding from the National Institute on Aging to establish the Claude D. Pepper Older Americans Independence Center (OAIC). The mission of the UF-OAIC is to assess the risk factors of physical disability in older adults, develop and test effective prevention therapies, and train new investigators in research on aging and disability, while developing their

leadership qualities. Our center's research theme of "sarcopenia and prevention of disability" is pursued using an interdisciplinary approach that traverses the entire spectrum of biomedical investigation, including molecular biology, animal studies, clinical research, behavioral sciences and epidemiology.

Emerging Pathogens: The Emerging Pathogens Institute was created in 2006 to provide a world-class research environment to facilitate interdisciplinary studies of emergence and control of human, animal and plant pathogens of concern to Florida, to the nation and to the world. The overall goals are 1) To understand the genetic changes (and evolutionary drivers) that lead to the emergence of new pathogens; 2) To appreciate the complex interaction of environmental and host factors that permit these pathogens to spread within plant, animal, and human populations; 3) To use these data to develop and implement interventions to minimize risk of disease transmission; 4) To train the next generation of investigators in emerging diseases, within a unique, interdisciplinary setting; and 5) To disseminate information about emerging pathogens, and their control, to the people of Florida. The major, current areas of research focus include Vector-Borne Diseases (West Nile, Malaria, Dengue Influenza), Tuberculosis/drug-resistant TB/non-TB mycobacterial disease, Enteric and Foodborne Illnesses (Cholera, diarrheal disease Foodborne disease policy and control) and Antibiotic Resistance/hospital infection control (MRSA).

Personalized Medicine: In June 2011, UF created its Personalized Medicine Program to prepare UF Health and the state of Florida to be leaders in this approach to patient care. Led by Julie A. Johnson, Pharm.D., the program's multidisciplinary team developed and launched the clinical infrastructure required to generate electronic medical record alerts that allow UF Health doctors to take a patient's genetic information into account when prescribing certain medications. Three guiding principles shape the program's approach: 1) Ensuring a regulatory body is in place to evaluate the scientific literature and determine when sufficient evidence exists for the health system to consider genetic findings clinically actionable; 2) Providing actionable alerts for healthcare providers through the electronic medical record system and backup support by clinical pharmacists; 3) Developing the capacity to perform a one-time, evidence-based genetic test that screens for hundreds of genetic variations that can be used across a patient's lifespan. To assess and optimize the program's cost-effectiveness and impact on patient care outcomes, researchers are studying implementation metrics and outcome assessments. The program is also creating a large genetics data repository to support future research and expansion of genomic medicine.

<u>Diabetes</u>: Research at the UF Health Diabetes Institute unites a network of clinical care providers, researchers, and lab technicians from around the University of Florida. Since its inception, nearly 3,000 patients have participated in one or more of the UF Health Diabetes Institute's clinical trials or studies. The Institute draws upon the wide range of expertise from over 100 investigators with interests in diabetes, obesity,

inflammation, lipid metabolism, genetics, population health, and disease pathogenesis. Core members of the Institute's faculty conduct both basic research to clarify the mechanisms causing diabetes and their consequences, and translational research to transform their research findings into clinical solutions. The shared technologies available through primary services provided by the University of Florida and private philanthropy allow our investigators to conduct state-of-the-art basic and clinical diabetes research, moving us closer to a cure.

### UF General Health-related Research Challenges

Maintaining growth despite the overall decrease in federal funding. The state of
Florida receives a disproportionate, small amount of overall federal funding
based on its overall population and federal tax revenue. This needs to change by
the combined efforts of improved science in the state as well as increased federal
lobbying.

### **UF Facility Challenges**

• UF'S greatest priority is to develop data integration tools and standardization that allows the electronic medical records to be seamlessly integrated into the research mission. The goal is to develop a comprehensive clinical data research network at UF and then statewide. The estimated dollars to facilitate this statewide effort is approximately \$10M. UF has already invested \$4M to develop an integrated data repository. A statewide, integrated data repository would allow Florida to compete for major new funding initiatives (PCORI, AHRQ, CMS, etc) and would position Florida to be a destination for clinical research, comparative effectiveness research, and implementation science. UF's commitment to the use of "big data" for healthcare purposes can be seen in the recent creation of the Informatics Institute and the hiring of a new director for a biomedical informatics program.

### **UF Technology Transfer Challenges**

 Seed Capital; and Proof of Concept funds (prototypes, pre-clinical drug development, etc.)

### **UF Research Compliance Challenges**

• Responding to a more complicated and expansive regulatory environment continues to be a challenge. An example is the new challenges related to University compliance with ClinicalTrials.gov. reporting requirements, which adds approximately 40-60 hours of staff time per human trial protocol.

### **UF Veterinary Resources Challenges**

• A serious challenge facing the veterinary field, in general, and strongly reflected at UF's College of Veterinary Medicine is the lack of graduates willing to pursue a career in academic medicine. In part, this is based on the fact that (1) the ratio

of debt to future earnings for veterinarians is the highest of any of the healthrelated professions, and (2) this profession is most vulnerable to the nation's economy. The overall impact is a greatly limited pool of veterinarians available as collaborators on health-related research projects involving non-rodent studies. To address this, UF's College of Veterinary Medicine has developed a program in career development that points out the opportunities in academia. A second challenge that impacts the role of veterinary medicine in health-related research is the high cost of animal models traditionally used for translational research, such as dogs, cats, rabbits, swine and non-human primates. Each species has special requirements for housing and care; furthermore, costs are often escalated when special facilities are required by federal and state regulations for proper containment. The third issue that challenges veterinary medical research is funding. Major sources of research in the veterinary field are foundations that provide limited levels of support in comparison to human medicine supported by NIH and major foundations such as American Cancer Society and the JDFR. The lack of (or limited) funding for research is an impediment for veterinarians to actively pursue academic research training and therefore careers. Nevertheless, veterinary medicine is a critical component of health-related research representing the bridge between rodent research and human research. With the generation of, or recognition for, large or small animal models and "patients" seen in clinics exhibiting diseases common to humans, the opportunities exist to create partnerships between veterinarians and physicians to carry out research that is not only translational, but also more likely to be competitive for large extramural funding. Clinical trials in pets provide the preclinical data to transition therapies to human trials. Such partnering has gained great momentum at UF over the past few years and is currently expanding at a rapid pace.

### UF Health-related Research Opportunities with Other SUS Institutions

• The OneFlorida Clinical Research Consortium (CRC) is comprised of four distinct systems and the practices that have referral relationships and/or affiliations with these systems including: (1) the University of Florida (UF) Health System; (2) the Health IMPACTS (Integrating Medical Practice and Community-based Translational Science) practice-based research network in collaboration with Florida State University (FSU); (3) the University of Miami (UM) Health System in partnership with the Health Choices Network; and (4) Florida's Agency for Health Care Administration (AHCA), which is responsible for the Medicaid Program. In addition, the Florida Academy of Family Practice (FAFP) and the Florida Chapter of the American College of Physicians (ACP:Florida) are project partners. The OneFlorida CRC touches all 67 counties and represents over 12 million Floridians. Our coverage area is 43% minority with key metropolitan areas defined as "majority-minority," including Orlando (65% minority), Jacksonville

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(55% minority), and Miami (86% minority). The OneFlorida CRC also includes 30 rural counties with almost 1M Floridians.

The OneFlorida CRC has successfully collaborated on projects including two National Institutes of Health (NIH)-funded implementation studies using health information technology (HIT-enhanced)-interventions in primary care settings to improve provider adherence to: (1) recommended guidelines for adolescent health risk assessments in primary care; and (2) concussion assessment among school-aged children. The OneFlorida Health Network is also the site for an NIH-funded genomic medicine implementation project working with affiliated community-based health systems to introduce pharmacogenetic testing within their patient care processes. Finally, the OneFlorida Health Network also is home to the OneFlorida Cancer Control Network (CCN), which provides an infrastructure for implementation science and pragmatic clinical trials related to preventing tobacco-related cancers and CVD. The Florida DOH James and Esther King Biomedical Research Foundation funds the OneFlorida CCN.

#### **UF Current Collaboration with SUS Institutions**

The Southeast Center for Integrated Metabolomics (SECIM) was created to provide comprehensive and complementary resources for clinical and basic science metabolomics studies. SECIM launched in 2013 with a five-year, \$9 million grant from the NIH Common Fund's Metabolomics Program. SECIM is developing an integrated metabolomics service to provide high-quality data, user-friendly statistical analysis tools, training and pilot funding to help users get the most out of a metabolomics study. SECIM brings together expertise and resources from multiple colleges and units at UF as well as Sanford-Burnham Medical Research Institute, the National High Magnetic Field Laboratory at Florida State University, Ohio State University, the University of Georgia, Imperial College London, the University of Geneva and industry partners IROA Technologies and Thermo Fisher Scientific. SECIM has four closely integrated technical cores: Mass Spectrometry Services for high-throughput global and targeted metabolomics; Nuclear Magnetic Resonance for global metabolomics and biomarker identification; Advanced Mass Spectrometry for biomarker identification, imaging mass spectrometry and isotopic ratio outlier analysis; and Bioinformatics for quality control, data standardization and analytical tools. In addition, SECIM's Promotion & Outreach Core will offer training and pilot funding to help scientists across the state access and use the center's services.

The UF CTSI and its partners are collaborating to develop statewide research infrastructure while advancing specific research and implementation projects that address important health priorities, engage diverse settings and populations, and help test and refine various parts of the infrastructure. Examples of innovative programs include a statewide IRB and Consent2Share program (asks

- patients who are entering healthcare facilities if they are willing to be contacted for research studies).
- Adolescent Health Risk Assessments: This project utilizes the Health IMPACTS
  network to understand which factors might influence a pediatrician to use health
  risk assessments (HRAs), as well as understand what encourages or prevents an
  adolescent patient from fully participating in the assessment. The project aims to
  determine what factors impact counseling related to alcohol use, tobacco use,
  other substance use, sexual activity, depression and weight. Findings are used to
  develop strategies to improve health care provider performance of and
  adolescent participation in HRAs.
- Concussion Surveillance and Management: This project utilizes the Health IMPACTS network for (1) implementing an evidence-based concussion assessment and management program to assess the relationship between health risk factors and injury susceptibility, severity, and recovery for youth participating in organized sports activities in Florida communities; (2) teaching community physicians and medical students to apply evidence-based principles for recognition, assessment and management of concussion and mild traumatic brain injury (mTBI) risk in children and youth; and (3) providing education modules for parents, coaches, physicians/health care professionals and the general public that are designed to reduce long-term consequences of mTBI.
- Genomic Medicine Implementation: As part of a genomic medicine implementation project funded by the National Institutes of Health, the CTSI's UF Health Personalized Medicine Program is working with affiliated community-based health systems to introduce pharmacogenetic testing within their patient care processes. The program also is developing a variety of innovative educational programs for health care providers, students and patients.

#### **UF Unaddressed Needed Research**

- Information technologies and how to handle complex, big data is a common challenge across all Florida universities. It is also critical that we partner around data standardization, since linkage of big data across all Florida Universities would present a powerful new paradigm to tackle some of Florida's greatest health-related challenges.
- Evaluation metrics

#### **UF Contributions to Translational Research**

Research is a core mission of University faculty and is integrated into both the education and clinical missions. Greater than 90% of the faculty participate in research, and all colleges/departments have active research programs. UF strives to foster an environment conducive to discovery and innovation in the medical sciences, through supporting strong interdisciplinary teams of basic and clinical researchers. Over the last six years the research mission of the University has undergone a tremendous

increase in research activity and, in turn, improvement in the extramural funding of its research programs. During a time that has been described the darkest days for NIH-funded research, the University has seen unprecedented growth in our NIH research-funding portfolio. This increase has resulted in a rise of the overall University ranking from 68th to 48th and the medical school ranking from 62nd to 45th in the country. Since 2008, NIH research funding to the UF College of Medicine has been steadily rising, reaching an all-time high of \$85M in 2013. Currently, the UF School of Medicine is ranked #45 (up from #62 in 2008) according to the Blue Ridge Institute for Medical Research and #42 by US News and World Report.

The research portfolio has also become more diverse. While continuing our traditional strength in individual investigator-initiated research programs, the research productivity of the University has been further enhanced by a focus on team science. Many of our faculty are creating successful programmatic research awards in areas such as: aging, gene therapy, diabetes, Alzheimer's disease, neurogenetics, infectious disease, reproductive biology, metabolomics, health outcomes and community engagement. Reflective of the national move to enhance the integration of basic research with clinical diagnostic, therapeutic and outcome-based research, the University has significantly augmented its capacity in both quantitative and patient-centered research. The focus on clinical and patient-centered research has the greatest impact on Floridians lives and can be expanded to help increase statewide research partnerships and funding (see above OneFlorida Clinical Research Consortium)

#### Florida State University Survey Response

## FSU Priority Areas of Health-related Research

<u>Autism:</u> The FSU Autism Institute was established to coordinate and promote research, education and service related to autism spectrum disorders. The specific aims of the Autism Institute are:

- to promote interdisciplinary research that advances scientific knowledge of autism spectrum disorders;
- to bridge the gap between scientific knowledge and clinical/educational practice;
- to build the capacity of primary care and other service providers, educators, employers, family members, and individuals with autism spectrum disorders to improve outcomes through research and training; and
- to maximize the use of innovative video and computer information technology in research, education, and service related to autism spectrum disorders.

#### Research areas of focus include:

- Identify more precise early red flags of autism and study ways to improve and streamline screening and diagnostic practices to improve early detection of autism in infants and toddlers
- Study ways to coach families and early intervention providers to learn how to implement evidence-based intervention strategies in everyday activities to improve outcomes for toddlers with autism
- Study ways to improve active engagement in preschool and elementary students with autism in the classroom
- Study the use of technology-enhanced active learning and wellness to improve social communication, behavior and emotional regulation, language and literacy, and self-determination for high school students with autism and the transition to adulthood.

<u>Practice-based research</u>: The FSU College of Medicine's Clinical Research Network (CRN) was formally launched in the fall of 2010. It is a statewide, collaborative, research network of faculty, community-based healthcare professionals and researchers that supports clinical and translational research. Our College's community-based model of education provides an ideal foundation for the CRN. Clinical, translational and behavioral research opportunities are provided for clinicians, faculty, and students in real world, community-based practice settings. Health outcomes can be measured across the spectrum of health, gender, age, socioeconomic status and geographic location.

The CRN grew out of what has become a global emphasis on more health-related research during the past decade. In 2003, the National Institutes of Health (NIH) launched its Roadmap initiative, which has a fundamental focus on re-engineering the

clinical research enterprise to translate scientific discovery into real health gains for the United States.

Concurrent with the NIH's initiative, the Institute of Medicine has long advocated for academic health science centers to increase their emphasis on research that is clinically-focused, prevention-oriented and community-based. The American Association of Medical Colleges also has recommended that clinical research become part of medical student training, that more resources should be devoted to clinical research, and that medical institutions should form collaborations with community healthcare providers and practice-based research networks.

<u>Health policy/health care delivery:</u> The College of Medicine has several research centers that focus on public health care policy, patient safety and health care delivery, particularly among rural and disadvantaged populations. These include:

- The Center for Medicine and Public Health, is dedicated to improving the shared understanding of the unified nature of "health," as comprised by both disciplines. This vision is achieved through promoting the intersection of medicine and public health at all levels of practice (federal, state, and local), via research, policy change, and service.
- The Center on Patient Safety, which was established to promote and conduct innovative research designed to reduce medical errors and adverse events in all venues of care. The Center is actively engaged in the dissemination of scholarly research on patient safety to medical directors, physicians, policymakers, the media, and other organizations interested in improving patient safety and quality of care both locally and nationally.
- The Florida Blue Center for Rural Health Research and Policy, which is dedicated to the advancement of quality health services and research in Florida's rural communities. The core mission of the center includes researching and addressing the unique challenges and opportunities facing Florida's rural health care system, providers, and consumers. The center's work helps the state better understand what Rural Florida is facing and how to address those needs.

<u>Biomedical research</u>, neuroscience and molecular basis of human diseases: The College of Medicine complex has more than 150,000 sq. ft. of state-of-the-art laboratory space, an extensive inventory of common use equipment and state-of-the art core labs in proteomics, genomics, confocal microscopy, flow cytometry, and cell culture.

The Protein Biology Laboratory provides resources to study biomolecular interactions of proteins, nucleic acids, small molecules, and other cellular components. The studies lend insights into fundamental aspects of molecular mechanisms and help decipher cellular regulatory processes in both healthy and diseased states. As such, they facilitate translation of basic research into clinically relevant applications.

Flow Cytometry is a process in which measurements of physical and/or chemical characteristics of cells or particles are made while the cells pass single file through the measuring apparatus in a fluid stream. The Cell Culture Facility is designed to accommodate the culture of mammalian cell lines and other animal cell lines, such as insect cells.

The College's Center for Brain Repair conducts research on neurodegenerative diseases, developmental disorders, neuro-psychiatric disorders, dystonia and other movement disorders, and traumatic brain injury. The Center's mission is research, discovery, education and community outreach in the areas of prevention, amelioration, treatment, and repair of injuries or damage to the brain and spinal cord resulting from trauma, genetic and degenerative diseases, and cardiovascular anomalies including stroke, drug abuse, environmental toxins, and other causes.

<u>Geriatrics research</u>: Research efforts focus on the multiple domains of health and well-being of older adults and also examine how we can best educate physicians to care for this population. Research is conducted on a wide range of topics related to aging, end-of-life/palliative care, aging policy, health, and healthcare delivery. This research is particularly important to Florida, which has a large elder population that is increasing.

## FSU General Health-related Research Challenges

• Research laboratory space and start-up costs for new faculty

## **FSU Facility Challenges**

- We need a robust technology infrastructure in both bio- and health-informatics to better collect, assimilate and analyze data associated with health-related research, particularly patient-centered outcomes. This includes an electronic medical records system that could be used by our community-based Clinical Research Network. In tandem with our translational science lab's biorepository, and more lab space which is critically needed for our future research growth an informatics-focused technology infrastructure would provide the foundation needed to advance clinical translational research across Florida communities. The cost to develop this technology infrastructure and expand current lab space is yet to be determined but is expected to require a multi-million dollar investment.
- Development of a functional Magnetic Resonance Imaging (fMRI) facility: non-recurring costs: \$3.5M; recurring costs, including staffing: \$400,000.
  - Non-recurring costs- \$3.5M
  - Recurring costs including staffing- \$400,000

## FSU Technology Transfer Challenges

- The initial premise in discussing successful technology transfer is having technology of interest to a specific industry. Florida State University has a significantly diverse approach to technologies that can be used in the health care industry and these technologies are being commercialized. In recent years research at FSU has been emerging with respect to developing a broad base of technologies that are initially thought of when health care is discussed, i.e. drug development and medical devices. This emergence is the result of establishing a medical school at FSU and in recent years beginning a focus on research at the medical school. FSU has traditionally supported strong chemistry research which has been a foundation for FSU's most successful commercialization effort, Taxol. Combining the established expertise in chemistry research and a medical research environment will significantly enhance drug development as well as diagnostic technologies. While the lack of research traditionally preformed at medical schools has been a challenge, which is changing significantly as the medical school research base increases. Technology development as a result of research at the medical school combined with established chemistry research will create significant opportunities. This growing research base will be dependent on developing a tradition of NIH funding, which is an additional challenge that is being addressed at FSU.
- Challenges/opportunities also include the decrease in STEM-related faculty over the last few years and the present efforts to replenish the loss. FSU has lost significant research potential which reflects in the technology quality developed for commercialization. The opportunity is in the present efforts to find outstanding faculty researchers to fill the void. As research projects established by new faculty mature, the resulting technology inventions will become available for commercialization.
- Another significant challenge is the lack of a health care industry presence in the Tallahassee area. This makes technology transfer to the health care industry more difficult but is not an excuse for non-performance. There are significant resources in the state of Florida to aid in the development of technologies produced at FSU including potential industry partners for technology development. Tallahassee also has unique opportunities as the state capital of Florida. Offices for many trade associations for the state of Florida are in Tallahassee. These offices may primarily be involved lobbying activities but may also present an opportunity to make contacts with industry partners in other areas of Florida.
- Every environment has its unique attributes and leveraging those attributes that FSU/Tallahassee possess will be instrumental in increasing the commercialization of technology developed at FSU

## **FSU Research Compliance Challenges**

 Having to secure approvals of multiple IRBs rather than one approval from a Central IRB poses the greatest challenge to the College of Medicine's health-

- related research compliance. In our recent research collaborations with the University of Florida (UF), due to multiple study sites and institutions involved (FSU, UF, various affiliated hospitals, community-based practices and state health clinics) more than a half-dozen IRBs have been involved with the review/approval of our studies. This creates a cumbersome, time-consuming process that has caused lengthy delays in study implementation.
- The federal government's recent movement toward allowing use of a single IRB review for multisite studies is promising. It creates an opportunity for Florida research universities and affiliated health care institutions to collaborate in forming a central IRB for statewide and regional research. Such efforts already are underway between UF and FSU, which have signed an agreement to allow the UF IRB to conduct reviews for new and ongoing studies that are part of the UF/FSU Health IMPACTS research collaboration. This results in only one IRB submission, while allowing the FSU IRB to also have input into the review. The agreement is designed to streamline the compliance process, reduce costs by eliminating duplicative regulatory reviews, and ensure consistency in protocols across study sites.
- UF and FSU continue to work toward expanding this IRB cooperative with a goal
  of including other Florida universities and affiliated public and private
  healthcare institutions. Our efforts would be greatly advanced if the Board of
  Governors addressed the cooperative or central IRB concept as a statewide
  public policy priority to enhance health-related research.

#### **FSU Veterinary Resources Challenges**

 Inefficient use of vivarium space in certain buildings. Relatively minor renovations and modifications in animal density of some space will provide sufficient capacity to meet the animal holding needs for the next decade.

## FSU Health-related Research Opportunities with Other SUS Institutions

 Community-based clinical research through the College of Medicine's Clinical Research Network (CRN) presents ideal collaborative opportunities for numerous partners, including SUS institutions, hospitals, HMOs that provide direct-service health care, county health clinics and federally qualified health centers.

#### **FSU Current Collaboration with SUS Institutions**

- A tobacco-related diseases study with UF and the University of Miami, sponsored through the James and Esther King Biomedical Research Program. (awarded)
- A pediatric oral health project with UF and UM, sponsored through the Florida Medical Schools Quality Network and Agency for Health Care Administration. (awarded; funding is pending).

- A cardiovascular disease study with UF and UM, sponsored through NIH (R-18 pending).
- A chronic pain study with UF, sponsored through the federal Agency for Healthcare Research and Quality (pending).

#### FSU Unaddressed Needed Research

- Population-based community research and associated translational applications
- Health care delivery research (including telemedicine, care of rural/disadvantaged populations)
- Chronic diseases of the elderly
- Palliative care
- Disease prevention/healthy lifestyles
- Successful longevity
- Nursing educational and workforce issues

#### **FSU Contributions to Translational Research**

The College of Nursing's contributions in the area of translational research are primarily focused within the Tallahassee Memorial Healthcare Center for Research and Evidence Based Practice. The Center was established in 2013 with a \$100,000 gift from Tallahassee Memorial Healthcare. As a component of the center, we provide a nurse researcher, Roxanne Pickett-Hauber, PhD, who acts as the nurse scientist for the hospital. In this role, she and center personnel provide direct consultation to TMH nurses and clinical staff in designing and implementing evidence based translational research projects. In the short time that this program has been enjoined, the collaboration has resulted in increased numbers and quality of projects within TMH. As well, the staff at TMH has presented at several national conferences, and have two publications in respected journals. During 2013, we added a biostatistician in order to further these projects. The College has a well-established Doctor of Nursing Practice program, which requires the performance of a clinical research project (essentially translational research). These projects have been highly useful in furthering the faculty's work on translational projects.

The College of Medicine formally opened its Translational Science Laboratory in August 2011 as part of our initiative to integrate community-based medical practice with translational science. Our state-of-the art laboratory provides genomic, proteomic and metabolomics services for investigators affiliated with FSU and elsewhere across Florida, the nation and even globally. The lab provides the infrastructure for novel biomarker studies across the spectrum of health and disease in our diverse patient population. The College of Medicine has more than 2,000 physician faculty members at our six regional campuses and multiple rural sites around the state, representing a patient population of approximately 2 million Floridians. The College's developing Clinical Research Network provides access to patient samples from diverse populations typically underrepresented in the search for signatures of disease and targets for

treatment. The CRN has completed two pilot studies in our Orlando and Tallahassee regions, funded through a Board of Governors Cluster Award in collaboration with UF. The CRN recently was awarded two grant proposals and has two more pending. Expanding our CRN presence to all regional campuses and rural sites is a goal that could be advanced considerably through additional state-level funding. This would allow us to build the needed infrastructure of community research associates who help the local practices implement research studies, interpret results and develop scholarly publications and conference presentations/posters.

#### Florida A&M University Survey Response

#### FAMU Priority Areas of Health-related Research

Research Centers in Minority Institutions (RCMI) Pharmaceutical Research Center (PRC) program have been funded for over 29 years from the National Institutes of Health (NIH) totaling over \$59 million. The Pharmaceutical Research Center at FAMU RCMI program is funded by the National Institutes of Health/National Institute on Minority Health and Health Disparities (NIH/NIMHHD). The RCMI **Program** develops and strengthens the research infrastructure of minority institutions by expanding human and physical resources for conducting basic, clinical, and translational research. The overall FAMU RCMI Program is to develop its infrastructure and increase the number and skill proficiency of minority scientists engaged in advanced biomedical research (breast, lung, and prostate cancers, infectious and neurodegenerative). These goals are accomplished through the establishment of synergistic research resource cores that provide services to enable investigative research on specific pathological etiologies associated with health inequity amongst minority groups, especially African-Americans and disadvantage populations. Biotechnology investigators are involved in highly specialized areas such as proteomics, sequencing, protein identification and post translational modifications, flow cytometry, imaging, high throughput screening and other advanced biomedical technologies to study and develop novel drug therapy in cancer, neurodegenerative diseases and infectious diseases. Drug discovery investigators are developing novel drug candidates to uncover targets for therapy and translational research and molecular genetics investigators are utilizing new methodology in genetics, genetic engineering and epigenetic research with a focus on maladaptive phenotypic changes evoked by environmental factors inherent to disadvantaged population groups.

Exploratory Center of Excellence (COE) for Cancer Research, Training and Community Service (CRTCS) program is funded by NIH/NIMHHD. The COE CRTCS received funding totaling over \$6 million for five years. The overall goal and objective focus on developing innovative cancer research (breast and lung) abnormalities utilizing an interdisciplinary and synergistic approach toward addressing significant health consequences in minority and socioeconomic disadvantaged populations. **The specific aims are to:** develop innovative research plans to address specific cancer (breast and lung) health issues; develop a research team conducting cancer research; train minority PhD graduate students in health disparities (HD)research; increase the number of minority scientists engaged in biomedical/behavioral research; establish and enhance community outreach and information dissemination activities that will increase prevention efforts and foster early detection towards reducing breast cancer in women (Leon and Gadsden County, FL); establish and expand partnerships with community engagement/outreach organizations toward addressing and conducting minority health and other HD

issues; and position FAMU to become more competitive in securing mainstream funding in biomedical and behavioral research support and addressing minority HD in disadvantage and minority populations. This grant promotes minority health and aid in the elimination of health disparities as it relates to breast and lung cancer. HD are closely related to underlying socioeconomic inequalities and have been linked to racial differences among cancer mortality which presents major challenges across the entire spectrum of cancer prevention, early detection, and access to high quality care for disadvantage and underrepresented groups.

The Scholarships for Disadvantaged Students (SDS) Programs at FAMU is funded by the Department of Health and Human Services, Health Resources and Services Administration. FAMU College of Pharmacy and Pharmaceutical Sciences (COPPS) Professional Pharmacy Program; COPPS Institute of Public Health (IPH) and the School of Allied Health occupational therapy programs provide scholarship assistance for health profession students from disadvantaged and/or underrepresented minority backgrounds. Federal funding average \$1.5 million annually. This federal assistance enables FAMU to continue to produce culturally competent public health, pharmacists and occupational therapy practitioners, through professional and graduate education, training, research and service. Scholarships are be provided to students for whom the cost of attendance would constitute a severe financial hardship, and to former scholarship recipients of the Exceptional Financial Need (EFN) Program and the Financial Assistance for Disadvantage Health Professional Students (FADHPS) in accordance with the terms and conditions for receiving HRSA Grant, Scholarships for Disadvantage Students. Scholarships are awarded based on the student's completion of the Free Application for Federal Student Aid (FAFSA) each academic year. These awards promote FAMU initiative to educate, train and graduate health professionals, thereby providing the needed health-related workforce to serve underserved and disadvantaged communities.

Tallahassee's Healthy Kids for a Healthy Future, Hope thru Childhood Obesity Prevention Education (COPE) is funded by the Florida Blue Foundation at \$105,000 annually. The Blue Foundation for a Healthy Florida – Embrace a Healthy Florida objective is to plan, develop, and implement a community-wide coalition focused on reducing childhood obesity in Tallahassee. A coalition of agencies, organizations, institutions, and individuals, in our capital city, serve as a model of best practices in addressing childhood overweight and obesity and to truly illustrate how a formula for success can and will be: Community Engagement (with true partnership in development, implementation, and evaluation) + Community Education (that is culturally appropriate and sensitive to the health literacy needs of its most impacted populations) = Community Empowerment (with achievement of meaningful measures of success and positive long-term outcomes). In general, this "Triple CE" approach can result in a "perfect storm" of achievement in reducing childhood overweight and obesity in Tallahassee, Florida. Specifically, the Hope Thru COPE Coalition (hereafter

referred to as the COPE Coalition) will address the seven priority areas (public health, early care and education, transportation, community planning, parks and recreation, public safety, and medical/health provider (services) through the formation of interdisciplinary COPE Teams (focused on a specific area(s)) within the COPE Coalition. COPE Teams will develop specific goals and measurable objectives for their area of focus (with specific timelines). This is a collaborative initiative between FAMU and Florida State University.

The Role of Novel Substituted Diindolyl Methane Analogues in the Treatment of Triple Negative and ERbB2 - Positive Breast Cancer project is supported by the Department of Defense Institutional Research Award. This grant is supported for four years totaling over \$1.5 million. The objective of this proposal is to develop BCRC at FAMU by strengthening the research capabilities of FAMU investigators in the area of breast cancer. The objectives of this proposal are to provide mentorship and training to FAMU researchers (PI, Co-PIs, postdoctoral fellows and students) in basic chemotherapeutic and preclinical breast cancer research to enhance the research expertise and competitive ability. The goals are to: train FAMU investigators through a well-defined research project investigating the anticancer potential of C-DIM analogs in treatment of breast cancer; develop FAMU investigators grantsmanship skills by submitting extramural grants for independent funding; and create awareness among FAMU researchers and the African-American Community about breast cancer biology and therapy by conducting FAMU research forums, seminars and symposiums. The outcome of this proposal will lead to novel oral therapeutic drugs for treatment of TNBC and EPBC and also result in publications in highly ranked journals. This approach will result in establishment of a successful and independently funded breast cancer research program at the FAMU. The investigators at FAMU will be trained in utilizing the current state-of-the-art technologies such as development of in vivo breast cancer models, molecular imaging, and transgenic mouse models.

## FAMU General Health-related Research Challenges

- Lack of sufficient resources to attract and recruit faculty and experimental support
- Lack of competitive salaries and benefits to young faculty
- Lack of resources to provide adequate research-start-up packages
- Lack of funds to attract, recruit and provide graduate student support (assistantships and scholarships)
- Inability to be competitive to maintain and attract premier faculty and students
- A need to increase private and industry partnerships
- Decreasing capital dollars for funding to construct, renovate, and maintain research buildings and laboratory infrastructure
- Low numbers of investigator-initiated research grants
- Limited access to medical subjects

#### **FAMU Facility Challenges**

- Research Building for COSAT scientists \$20 million
- Dedicated biomedical engineering laboratory space for cell and tissue engineering with adequate technical staffing and instrumentation, including incubators, biosafety hoods, microscopes, cell sorting, fluorescent microscopes, NMR/MRI facilities (Facility = \$15 million, instrumentation/equipment = \$1.5 million; staffing = \$100,000 annually for two technicians) \$20 million
- Establish new facility for Molecular Genetics to serve FAMU needs biomedical research in health disparity (\$35,000,000)
- University Transportation Center Grant to fund the center for accessibility and safety for an aging population. Consortium members are Florida A&M University, Florida State University, and University of North Florida

## FAMU Technology Transfer Challenges

- Lack of trained technology staff and resources (experienced Technology and Licensing Officer)
- Intellectual property regulations
- Patent process
- Transfer of IP/patent licensing to industrial partners
- Connection with appropriate industry

## **FAMU Research Compliance Challenges**

- Animal Care and Use Committee protocol review
- Institution Review Board protocol approval
- Limitations on available stem cell lines
- Limitations in dealing with biohazardous materials
- · Lack of research for the Office of Safety
- Lack of funding for hazardous waste disposal

# FAMU Veterinary Resources Challenges

 Key challenges include satellite animal facilities at the FAMU/FSU College of Engineering, and the review of animal facilities.

# FAMU Health-related Research Opportunities with Other SUS Institutions

- Application of newly discovered drugs: UF and FSU
- Biomaterials and nanoparticles for bio-imaging: University of Florida, and University of Central Florida
- Stem Cell Therapy: University of Florida, University of South Florida, and Mayo Clinic
- High field MRI: University of Florida, USF, and Moffitt Cancer Center
- Health disparities: UF, USF and FAU

- Health related issues involving the medical services to the "baby boomer" population: Florida State and University of Florida
- Industrial-scale stem cell expansion and packaging for clinical use
- Issues on the effect of environmental contaminants: UF and USF

#### FAMU Current Collaboration with SUS Institutions

- Biomaterials and nanoparticles for bio-imaging: University of Florida and University of Central Florida
- High field MRI: University of Florida, USF Moffitt Cancer Center
- Build/NIH Program: Florida Atlantic University
- Stem Cell Therapy: University of Florida, University of South Florida and Florida, Mayo Clinic
- Medication Therapy Management: Florida State University

#### FAMU Unaddressed Needed Research

- Environmental health related issues
- Environmental policies designed to protect all populations and for vulnerable groups
- Enhanced understanding of issues on health disparities among minorities

#### **FAMU Contributions to Translational Research**

FAMU is engaged in translational research through its various programs in the area of biomedical/behavioral and other programs. Its COPPS faculty have establish community outreach and information dissemination activities through translational research that will increase prevention efforts and foster early detection towards reducing breast cancer in African-American women (Leon and Gadsden County, FL); in addition, established partnerships with community engagement/outreach organizations toward addressing and conducting minority health and other health disparities issues adversely affecting disadvantaged populations. Investigators are seeking to expand its effort to increase multi-disciplinary collaborations toward moving its research from the "bench to the bed-side." The FAMU-FSU College of Engineering (Coe) biomedical and health-related projects developed by our investigators seek to transform public health by moving the discoveries of basic science into the clinical realm by making them more efficient, practical, safe and widely accessible to the healthcare and patient population. With strengths in chemical analysis, materials research, stem cell modification, genetics and bioimaging, the college is positioned to translate new techniques, discoveries and patents to both healthcare industrial and clinical partners. To aid in these efforts, the FAMU-FSU CoE, FSU College of Medicine and FAMU COPPS should embark on the creation of a Clinical Engineering and Translational Institute (CETI) to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics, therapeutics and theragnotics across specific range of neurological diseases and conditions. By improving the engineering through which

these techniques, processes and devices are developed and implemented, CETI would make translational science more efficient, less expensive and less risky. Based on existing research and foundational programs, such an institute could target: therapeutic target validation, virtual drug design, preclinical toxicology, tissue chip and other novel analytics, safety and efficacy, pharmaceutical repurposing and advance multimodal imaging. Producing future engineers capable of tackling translational public health research, CETI would need to offer multidisciplinary training from its educational stakeholders and industrial partners. Furthermore, CETI funding would need to come from state, federal (NIH and National Center for Advancing Translation Sciences) and private entities (corporations as well as private foundations). Similar efforts have been undertaken by other educational institutions, including the UF Clinical and Translational Science Institute (CTSI). However, the CETI would be unique in its focus on translating fundamental engineering research to the clinical setting and with strong support from Florida Biotech industrial partnerships.

#### University of South Florida Survey Response

#### **USF Priority Areas of Health-related Research**

<u>Diabetes:</u> USF is home to the number-one funded NIH investigator who specializes in diabetes research. The USF Pediatric Epidemiology Institute coordinates numerous national and international research studies in diabetes and related disorders. The Diabetes Center is currently an affiliate site of the NIH-, ADA- and JDRF Diabetes Exchange group coordinated by the JAEB Center for Health Research in Tampa. The Center focuses on delivering premier clinical care, engaging in cutting-edge research, and advancing diabetes care through patient and professional education and outreach.

<u>Neurosciences:</u> USF specializes in such neurodegenerative diseases as Alzheimer's disease and is home to the USF Health Byrd Alzheimer's Institute, which is dedicated to the prevention, diagnosis, treatment and care of Alzheimer's disease and related disorders. With a state-of-the-art building and a highly qualified team of physicians, memory-care specialists, researchers and educators, the Institute is in the forefront of Alzheimer's research and patient care. The core missions of the Institute include conducting laboratory research to understand the changes in the brain that cause dementia, developing approaches for the prevention and treatment of Alzheimer's disease, and conducting clinical trials to test treatments for individuals with all stages of memory loss. The Institute houses research faculty from multiple colleges and departments, and in fiscal year 2013, the Institute had 35 active research projects, 10 of which were clinical trials. The basic research grants totaled \$3.7 million and the clinical research grants totaled \$600,000. In addition to neurodegenerative diseases, USF Health Research focuses on traumatic brain injury, stroke, and spinal injury. The Center of Excellence for Aging and Brain Repair significantly enhances existing strengths to serve as a fundamental investigational and application unit, integrating basic research, translational research, industrial partnerships, education, and clinical services to address key needs of aging and care of the elderly, as well as to develop unique solutions for repair of degenerative processes.

<u>Infectious Diseases and Global Health:</u> USF has an excellent group of biomedical scientists comprised of faculty from the College of Public Health and Medicine working on better understanding the disease mechanisms of some of the world's most prevalent infectious diseases. This group is also involved in the development of vaccines and new drugs for treatment of these highly prevalent diseases. Faculty members in this group include renowned recruits from the State of Florida's 21st Century World Class Scholars program.

<u>Rehabilitation Sciences:</u> USF has a multidisciplinary group of researchers working on a number of research projects to improve the lives of our returning military personnel. Nursing leads the way with new and improved methods to treat post-traumatic stress

disorder (PTSD). The School of Physical Therapy and Rehabilitation Sciences conducts research in collaboration with faculty in the College of Engineering to improve prosthetics, orthotics, and mobile devices for impaired warriors.

## **USF General Health-related Research Challenges**

- The biggest challenge one faced by all research institutions is the erosion of federal research funding, specifically, National Institutes of Health funding, which supports the majority of research conducted by the various components of the health-related industry. Today, proposals must rank higher than ever before in order to qualify for funding. Raising the funding benchmarks has increased the competition for these very limited funds. Additional challenges include recruiting and retaining research faculty, building and renovating research space, the lack of State matching for donations to establish endowed chairs, unfunded compliance mandates, a lack of funding to support graduate students and medical residents, a shift in pharmaceutical company strategies to use non-academic institutions to conduct clinical trials, and establishing and maintaining adequate research core facilities in order to remain competitive for research funding.
- Increasing the University's research base in order to receive the highest possible Facilities & Administrative (F&A) rate from USF's cognizant agency, the U.S. Department of Health & Human Services (DHHS), is an important factor in meeting these challenges. Equally important is holding fast to the highest allowable F&A rate when negotiating external contracts and grants. The funds recovered from only a few additional percentage points each year would provide new monies that would then elevate health-related research in Florida.

#### **USF Facility Challenges**

- USF Health has immediate need of a new teaching and health research complex, including a modern Morsani College of Medicine and the completion of the USF Health Heart Institute. The total projected cost of the overall project would be approximately \$112 million, some of which has already appropriated by the State. The future estimated dollar amount needed in order to fund this initiative is \$73 million, as delineated below.
  - \$62 million total for a Morsani College of Medicine building, for which USF has already received \$5 million for planning, leaving a balance of \$57 million needed.
  - \$50 million total to complete the USF Health Heart Institute, for which USF has already received approximately \$34 million, leaving a balance of approximately \$16 million needed.

#### **USF Technology Transfer Challenges**

• Two major challenges to transferring health-related technology from the university to industry are (1) obtaining gap funding for proof-of-

concept/prototypes and (2) changes to the patent landscape. The majority of health-related technologies disclosed to the Technology Transfer Office are funded by the National Institutes of Health (NIH). While NIH funds basicscience pursuits, NIH does not traditionally fund critical proof-of-concept studies, such as Investigational New Drug (IND), enabling animal studies or Phase I clinical trials. Industry partners and private funding groups alike are unwilling to fund such programs themselves, yet require such studies prior to collaborating on the technology. In addition, our relationship with USF physicians is a rich source of medical device innovations, but the funding landscape is even starker for device development and prototyping. NIH has almost no funding mechanisms for medical device research and development and very little comes from NSF, but medical device prototypes are essential to any industry partnership. A step forward would require a stronger ecosystem of angel and venture capital in the State of Florida. Separately, the patent landscape for biomarkers and diagnostics experienced a significant shift due to the recent Supreme Court rulings in Prometheus and Myriad, resulting in fewer opportunities to secure patents in this space.

#### **USF Research Compliance Challenges**

• Challenges include issues familiar to all universities: new unfunded federally mandated rules and regulations that require new knowledge and oversight, new ways of doing business, additional reporting requirements, and additional training and oversight. Moreover, contracts (versus grants) are beginning to contain such restrictive sponsor requirements that faculty, without the proper research administration support structure, can easily become dis-incentivized.

### **USF Veterinary Resources Challenges**

- USF researchers are incredibly fortunate to have a premier Comparative Medicine program at their disposal. Comparative Medicine, a department in USF Research & Innovation, serves as the advocate for animals involved in research, provides a fully accredited, centralized service of pathogen-free animal procurement, husbandry, health surveillance, and quality control, and is the Tampa Bay area regional resource for laboratory animal-related services.
- The biggest challenge faced regarding veterinary resources is the collection of fees for services and the need for modernized facilities located at USF Tampa. The Director of Comparative Medicine has been resourceful in obtaining grant funding for equipment and renovations, and the University subsidizes its operation with F&A dollars, which are growing, but still are limited. The unit is currently undergoing a service-cost external audit now that should support an increase in service prices, which would allow the department to recover more direct costs and become more self-sustaining.

#### USF Health-related Research Opportunities with Other SUS Institutions

• Florida Atlantic University, Florida International University, and the University of South Florida – the only three universities in the SUS located in large metropolitan statistical areas (MSAs) – have the potential to form a strong triad in health-related research areas to address problems specific to urban- and suburban-based communities. Thus, we believe that a natural bond exists upon which we would build strong research partnerships in the following areas, among others: Cancer, Diabetes, Drug Discovery, Health Informatics/Health Outcomes, Health Care, HIV/AIDS, Neuroscience and Brain Disorders, and Veterans Health.

#### USF Current Collaboration with SUS Institutions

 USF currently has active health-related research projects with Florida State University and the University of Florida in the following areas: Substance Abuse, Immunity (HIV), Stroke, and Cancer.

#### **USF Unaddressed Needed Research**

- Genomic and Personalized Medicine. Florida universities should undertake research to identify new individualized therapies based on an individual's genetic characteristics and make-up.
- Obesity, Early and Middle Childhood Health, Adolescent Health, Lesbian, Gay, Bisexual and Transgender Health, Health Incident Preparedness.

#### **USF Contributions to Translational Research**

One of USF's successes is the Byrd Alzheimer's Research Center. This facility has bench-to-bedside research, with basic sciences labs in part of the facility for the specific purpose of developing and testing new therapies for Alzheimer's disease and other dementias. The facility also has a clinical research unit that undertakes the testing of new drugs and protocols to reduce the progression of disorders that affect the brain. The facility helps families and the afflicted family member adapt better to their living conditions by modifying the living environment for greater functionality and safety. Many of the psychosocial issues of brain disorders are also addressed by conducting research and providing counseling in the facility.

The Morsani College of Medicine also has an extensive Office of Clinical Research that supports faculty interests in investigating new drugs and devices in the medical marketplace. The basic science conducted in the laboratory setting and the pre-clinical research being undertaken by our faculty lend themselves to eventual approval for early-phase human testing. This translational research may be undertaken in our clinical research program.

With increasing difficulty in securing federal support to undertake translational and clinical research, Florida has an opportunity to fill this gap by expanding its support for medical research through its Biomedical Research Program. The program would need

to be expanded to provide for such research but the return on investment is well documented, making this a very good investment by the State.

## Florida Atlantic University Survey Response

#### FAU Priority Areas of Health-related Research

Child Health & Human Development: Florida Atlantic University has a long history of identifying the human abilities and human experiences that contribute to purposeful complex behavior and language development. For example, a large body of work is associated with a longitudinal study of English monolingual and Spanish-English bilingual children and the influence their language environment has had on later school performance. The objective of these projects is to provide an empirically-based understanding of preschool oral language and pre-literacy skill development in children from Spanish-speaking families. The language skills that children from Spanish-speaking homes present at school entry are highly variable and poorly understood. The knowledge base regarding the processes and outcomes of dual language development is inadequate either to design maximally effective educational programs or to match children to the programs they need which this program seeks to address.

Another research thrust has investigated how infants manage to integrate the constant onslaught of multisensory information into a perceptually coherent picture of their world. Autism, whose hallmark is the inability of children with this developmental disability to respond to the faces and voices of people as sources of social communication, has been growing at an alarming rate of 10-17 percent per year. Because autism and related communication and learning disorders are developmental in nature, the earlier they are diagnosed the more effectively they can be ameliorated and/or prevented. This research thrust investigates the development of these critical perceptual skills that enable infants to respond to people.

Aging: A strong group of researchers have established an international reputation in Geriatrics, as applied to Long Term Care Healthcare Quality Measures. More than 1.6 million Americans live in nursing homes and too many make risky and costly "roundtrips" from the nursing facility to the hospital, only to be readmitted within days or weeks later. To address this national need the INTERACT program has received wide scale recognition as a quality system to reduce the rate of re hospitalizations for nursing home residents. This work has engaged faculty from the Colleges of Medicine, Nursing, and Engineering and has garnered significant funding from CMS, NIH, private foundations and industry. For example, over a dozen industry licenses have been established with premier software companies to build in the INTERACT guidance documents into their Electronic Healthcare Record (EHR) systems.

<u>Cognitive Neuroscience</u>: Concurrently a multidisciplinary group of researchers within FAU's Center for Complex Systems and Brain Sciences have focused on the science of motoric coordination which aims to understand how the very many different elements

of living things - from genes to cells, to neural ensembles, to brains, to societies - are functionally coordinated in space and time. Their current research uses non-invasive imaging methods such as EEG and behavioral measures to investigate brain areas that underlie human learning, the development of multisensory perception and the neuroanatomical correlates of these abilities. The scientific significance of their work has been demonstrated by peer reviewed articles in Science, Nature and PNAS.

One ambitious goal of this multidisciplinary research group is to discover the dynamical principles and mechanisms at play both within and between human brains during real-time social interaction. The research plan employs a three-pronged approach that combines (1) experimental manipulations to test specific hypotheses regarding key issues in the neurophysiology of social neuroscience (2) sophisticated measurement and analysis tools from the theory of dynamical systems, including virtual partner interaction (behavioral dynamic clamp of reciprocally coupled humans and model-partners) and (3) multiscale neurocomputational modeling of both structure and function in order to advance our understanding of how individual behavior and the interaction of individuals drives basic forms of social behavior. Revealing these neuroanatomic correlates of these dynamics will provide insight into a wide assortment of disorders such as Autism and learning disorders.

<u>Molecular Neuroscience</u>: An outstanding group of basic science and clinical researchers explores the neural pathways in the brain that are associated with a wide variety of disorders such as Huntington's disease, Alzheimer's and Parkinson's disease. For example, Huntington's disease (HD) is a fetal inherited neurodegenerative disease and characterized by a selective loss of medium spiny neurons in the striatum. How to prevent the cell loss thus represents one of the most promising therapeutic strategies in treating HD. Their long-term goal is to characterize the molecular basis for mutant huntingtin (mhtt)-induced toxicity, which could lead them to identify potential targets for HD treatment.

Another strong basic science foci of Molecular Neuroscience research at Florida Atlantic University is an examination of mitochondria, often described as powerhouses of the cell. They accumulate in nerve endings where a lot of energy is needed for communicating with other nerve cells and for maintaining the correct concentrations of ions such as Ca2+. These investigations explore the mechanisms that distribute mitochondria according to the energy demands at different synapses of a neuron. A failure in neuronal Ca2+ homeostasis has catastrophic consequences and is a hallmark of many neurodegenerative diseases. Surprisingly, we know very little about the mechanisms that coordinate mitochondrial number and function with presynaptic energy requirements, yet understanding these mechanisms will be critical to understanding the progression of a number of neurodegenerative diseases.

<u>Cancer Therapeutics</u>: FAU has a strong coordinated research effort designed to utilize natural marine compounds as novel cancer therapeutics, especially for solid body tumors. Promising therapeutics derived from marine organisms such as sponges, or from the microorganisms that they host have been identified. Several of these identified compounds induce cell death (apoptosis) which shows potential for blocking tumor metastasis. This work has created a large IP portfolio and has been the source of partnerships with other SUS universities such as the University of Central Florida and the Sanford-Burnham Medical Research Institute.

Other therapeutic research thrusts have explored genetic proteins known to have a role in accelerating tumor growth. Researchers have revealed that a number of molecules show evidence of slowing this growth and reducing the pattern of cancer metastasis. For example, metastasis to the lung is one of the major causes of death in breast cancer patients. Incidence of metastasis is higher in breast cancer patients with chronic pulmonary inflammatory illnesses. Asthma-associated Inflammation plays a key role in the metastasis as well so the impact of success in this basic science research thrust would have substantial impact within the Florida and the US population.

#### FAU General Health-related Research Challenges

FAU has invested heavily in biotechnology-related lab space, equipment and
faculty hires and there is a keen interest concerning this topic on campus.
However, establishing and maintaining these laboratories is very expensive
especially with regard to maintenance costs of specialized equipment and staff
costs supporting biotech cores.

#### **FAU Facility Challenges**

• FAU is fortunate to have Max Planck Florida and Scripps Florida on its Jupiter campus. However, scaling up lab and veterinary capabilities to match these well-funded entities is a strain on available resources. At a minimum, to maximize a strategic benefit to the state, we estimate that we will allocate at least \$3M in new facilities and equipment in the next 2 years to equip FAU faculty to optimally engage these private research partners.

## **FAU Technology Transfer Challenges**

• The pathway from lab-based discovery in the university laboratory to a commercial bio-therapeutic is long and expensive. Patents depict early stage inventions with a high degree of business risk; therefore companies are reluctant to license due to these factors.

#### **FAU Research Compliance Challenges**

 Health-related research compliance regulations continue to expand, and as a result we are staffing in response to these challenges. Relying on constrained indirect cost returns is problematic given other commitments and concurrent responsibilities.

#### **FAU Veterinary Resources Challenges**

The federal and state regulations in the proper care of animals under the scope of
duties of veterinary services have increased with a concurrent rise in the cost of
facilities to house and care for these animals. It is a challenge to balance the valid
needs of faculty's access to these animal models and the Division of Research's
ability to cover these costs.

### FAU Health-related Research Opportunities with Other SUS Institutions

- One suggestion is that the state would benefit from a trans-state Patient-Centered
  Outcomes Research Institute (PRORI) grant which focused on the creation of a
  state wide clinical trial network. In this proposal we believe it would be logical
  and compelling for the University of Florida to serve as the lead in this effort.
  We believe it would be logical to link this university based effort directly with
  the needs of the state through a partnership with Florida state agencies to
  maximize return on investment.
- The strong capacities resident within the state in Informatics and Biomedical Computational resources could be leveraged to address the health care needs across Florida, with lead capabilities established at the University of Florida.

#### **FAU Current Collaboration with SUS Institutions**

• FAU has active partnerships with UCF in the realm of the commercial viability of marine-based cancer therapeutics.

#### **FAU Unaddressed Needed Research**

• There is currently a crucial national need in expanding the utility of Electronic Health Record (EHR) systems utilized within healthcare institutions. Florida with its large population of aging citizens would benefit from advancements in this realm to increase the quality of care while decreasing costs through these EHR systems. Note that expansive federal Meaningful Use Regulations are now in place which operate in conjunction with elements of the Affordable Care Act as part of a larger dynamic in creating a more metric based assessment of healthcare efficacy. We stipulate that the state of Florida would be well served by coordinating a collaborative effort across the state's Universities to address this tractable health challenge combining clinical, engineering, and medical in a translational research thrust.

#### **FAU Contributions to Translational Research**

Florida Atlantic University has developed a nationally recognized quality system to reduce expensive repeat hospitalizations, see <a href="http://interact.fau.edu/">http://interact.fau.edu/</a> with strong funding and support from CMS (\$7M CMS Innovation grant), NIH, private foundations

and industry. The efficacy of this approach has been documented in peer reviewed journals (ex., NEJM, JAMDA), passionately embraced by healthcare staff in long term care, and the commercial value of this approach is demonstrated by over a dozen licenses with leading software Electronic Healthcare Record companies who are actively incorporating this approach within their software systems. As stated above, we suggest a PCORI grant led by the University of Florida and engaging SUS universities across the state to coordinate this initial trans-state effort to build SUS to SUS partnerships, but also to expand existing SUS to industry partnerships with EHR companies. As a final vision we propose a state university/state agency partnership similar to Commonwealth Medicine based in Massachusetts in which a state university partnered with state agencies to improve health care outcomes within the state, see http://commed.umassmed.edu/about-us. We believe that the University of Florida is well positioned to lead this effort and we would welcome the opportunity to contribute to this larger effort through our unique accomplishments which would be complimented by clinical and computational expertise across the SUS to specifically to address the healthcare needs of Florida's residents.

#### University of West Florida Survey Response

#### **UWF Priority Areas of Health-related Research**

Aging: The UWF Center on Aging conducts research efforts with the aim of improving the lives of older adults. Faculty researchers seek work within the community to assess knowledge of aging as well as assessing life satisfaction among older adults. With this knowledge, researchers hope to measure and understand how age stereotypes this affects various behaviors across the lifespan. The Center on Aging also facilitates research into neuronal and biochemical changes in aging. UWF researchers are using animal models to explore the mechanisms by which proteins associated with early onset Alzheimer's disease form, studying cultured neurons to understand the molecular pathways contributing to plaques in the brain, analyzing blood and cerebrospinal fluid to identify potential biomarkers related to development of cognitive disorders, and using electroencephalogram technology to detect early changes in neuronal activity associated with mild cognitive impairment. Additional research conducted at UWF related to aging includes, but is not limited to, psychological studies of cognition in aging, driver safety for the elderly, mobility and gait changes associated with age, caregiver stress, and the prevention of elder abuse.

Community Health: UWF researchers from varied disciplines study health conditions seen in the local community and work with community-groups to establish preventative health initiatives and intervention activities. Researchers conduct studies to assess the impact and severity of pervasive public health issues including obesity, cardiovascular illness, and tobacco use. Epidemiological studies explore factors contributing to the adverse conditions and the relative effects of preventative activities. Specifically, one faculty member works closely with a local healthcare facility to provide data related to cancer clusters while others work to examine the factors related to suicides. UWF researchers are also actively engaged in the design, development, implementation, and evaluation of programs for improving health within the community. Projects include an elementary school garden project aimed to improve child nutrition, a peer educator training program designed to develop community health workers with knowledge of pre-conception health activities, a smoking cessation project for college students, a program to provide mental health services to school-aged children through partnerships with local schools, and more. Additionally, UWF research related to tobacco policies held by employer and health plans across Florida aim to address community health issues on a policy level.

<u>Environmental Health:</u> A great deal of research at UWF has focused upon environmental health—especially in the area of water quality, air quality, and food safety. Researchers from the UWF Center for Environmental Diagnostics and Bioremediation study the prevalence of water-borne pathogens in drinking water and work to develop new methods for detection of these pathogens. Other studies analyze

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the concentrations of toxic chemicals (e.g., mercury, polychlorinated biphenyl, polycyclic aromatic hydrocarbons and dioxins) in fish and shellfish and evaluate fecal loading into local waterways. Other faculty researchers use remote sensing data and geographic information systems (GIS) to analyze the geospatial distribution of air quality.

<u>Nursing Education:</u> The UWF Department of Nursing is dedicated to providing excellence in nursing education. As such, faculty and staff researchers are dedicated to the study of current issues in the field including the use of simulation in nursing education, integration of evidence-based nursing curriculum, and development of a RN-BSN program for veterans.

## **UWF** General Health-related Research Challenges

- As a regional comprehensive university, UWF has the unique ability to conduct applied health-research projects, including prevention and intervention activities, which have a direct impact on our community. Many of our faculty members are actively involved in health-related community groups and much of our research focuses on responses to regionally-identified health issues.
- The biggest challenge that UWF faces in regards to health-related research is the lack of faculty time for research. UWF faculty consistently maintain high teaching loads and are often called to serve administrative functions. These commitments limit the time available to pursue active research projects. For health-related research, another challenge is the lack of resources. Researchers find that they often lack equipment and technical assistance needed for cutting-edge health research. Finally, our University has historically lacked an administratively-coordinated health program. Faculty conducting health-related research are spread among different colleges, and this may have limited collaboration and resource-sharing. The current reorganization of UWF colleges will align health programs in one administrative unit.

## **UWF Facility Challenges**

• UWF has recently completed an administrative reorganization that will bring all health and allied health units within the same college. A new dean for this college will be announced soon. Our intent to enhance health related programs to meet the critical academic, research, and workforce needs of our region will be challenged by the lack of adequate facilities. In 2012, UWF submitted a proposal for a three-phase, \$63.8 million comprehensive health sciences facility. This proposal was withdrawn and a more modest two-phase, \$18.8 million Laboratory Sciences Annex was included in our official facility request. The Annex is desperately needed, but will only provide a short-term solution to our need for appropriate facilities that will enable us to meet our health related academic and research goals. One of the first tasks for the new dean will be to assess UWF health related facility needs and develop plans for a new facility.

## **UWF Technology Transfer Challenges**

• While the opportunities for technology transfer in the health field may seem endless, the community partners with whom UWF faculty might collaborate are focused primarily on providing health-care services, not research. UWF faculty are eager to engage in health-related discoveries, but opportunities are limited.

### **UWF Research Compliance Challenges**

 UWF's current health-related research faces very few challenges in regards to research compliance. The members of UWF's Institutional Review Board for Human Subjects Protection and the Institutional Animal Care and Use Committee are well-versed in the areas of research being performed at UWF and provide researchers with timely responses. UWF is not involved in clinical trials or other complicated health-related projects that would pose challenges related to research compliance.

#### **UWF Veterinary Resources Challenges**

• The animal care and use program at UWF is relatively small and only consists of animals that are considered exempt by the Animal Welfare Act. As such, we have no real challenges in regards to veterinary resources. However, any expansion of our health-related research program, and by extension, our animal care and use program, may present a challenge in regards to limited space for housing of animals, funds for daily animal care, and the stipend for outside veterinary services.

#### **UWF Health-related Research Opportunities with Other SUS Institutions**

 Our faculty report that they are not fully aware of specific health-related research being conducted at other SUS institutions. Therefore, they are not able to accurately identify potential collaborations. However, our researchers would be open to partnerships in the areas of biomarker discovery and obesity prevention, education, and assessment.

#### **UWF Current Collaboration with SUS Institutions**

- In coordination with the University of Florida and Florida A&M University, UWF's Department of Psychology is conducting an examination of the mental, behavioral, and physical health impacts on persons and communities after experiencing a disaster.
- Other collaborations with institutions in our region include a multi-year funded program for mental and behavioral health treatment and longer-term supportive services to people and communities affected by the Deepwater Horizon Oil Spill. For this project, the UWF Department of Social Work is collaborating with Louisiana State University, the University of Southern Mississippi, the University of South Alabama, and Tulane University.

#### **UWF Unaddressed Needed Research**

- Faculty engaged in health-related research at UWF identified four areas of research that could be better addressed by Florida universities. They are:
  - Biomarker Discovery. Biomarker discovery is a necessary field of study as our ability to analyze biofluids for changes in cellular chemistry will aid physicians in individualizing patient care and treatment plans.
  - o Obesity Assessment and Prevention. While individual efforts are being conducted in localized areas throughout the state, a coordinated effort at researching and addressing the obesity epidemic is needed.
  - Interprofessional Collaboration. Although there are pockets of interprofessional collaborations within the SUS, it is the exception rather than the norm. No single discipline can solve some of healthcare's major issues; therefore, strategies to increase collaborations among researchers from different healthcare professions are needed.
  - College-based Mental and Behavioral Health Programs: Universities throughout the state would benefit from an increase in activities aimed to prevent sexual violence, drug abuse and misuse, and other mental and behavioral health issues.

#### **UWF Contributions to Translational Research**

UWF has contributed to both aspects of health-related translational research—translation of basic laboratory science to the clinical, applied environment and the promotion of best practices in health and wellness within the community.

The Center for Environmental Diagnostics and Bioremediation has been a campus leader in bringing basic laboratory science to the field. The CEDB researchers have used their knowledge and expertise in microbial activities to develop, patent, and license a new method for cryptosporidium detection in environmental waters. Other areas of laboratory science are in the formative stages of research that is hoped to have a clinically-relevant outcome. Our Center on Aging is actively developing a biochemical cellular-level method for detection of Alzheimer's disease. Other faculty within Biology and Exercise Science are developing vaccination techniques for influenza and studying the effect of endurance exercise on cellular health. Successes in these areas will catalyze other faculty to engage in similar activities.

UWF's other major area of translational research focuses on bringing the best practices for health and wellness to the local and regional community. This is, perhaps, the greatest strength of UWF's health-related research program. Faculty from Psychology, Exercise Science and Community Health, Social Work, Nursing, and Public Health work closely with local health agencies, non-profit organizations, and industries to identify health-issues, investigate potential solutions, and implement interventions to improve health. In particular, UWF has a strong relationship with a local retirement

community for the advancement of research relating to healthy aging and works closely with community partners in providing assessments and interventions relating to infant mortality, obesity, smoking cessation, suicide prevention, and the prevention of chronic disease. This type of translational research will continue to grow as UWF builds more relationships within the community and expands to include other regional partners.

#### University of Central Florida Survey Response

#### **UCF Priority Areas of Health-related Research**

Cardiovascular diseases: Well-funded, national and international reputation, many areas represented. The cardiovascular team has about seven members who excel in their respective areas of research. Members are well known for their expertise on molecular mechanisms of atherosclerosis (cholesterol deposition in the artery), stem cell therapy research for heart failure, prevention and treatment of chronic inflammation associated with cardiovascular diseases, defining how the aging process contributes to cardiovascular diseases by employing novel animal models of aging, and for studying associated risk factors, such as diabetes, obesity, sedentary life style etc. Investigators also study diet and nutritional prevention of cardiovascular diseases with special emphasis on the potential harmful effects of fried fat as well as the beneficial effects of sesame oil. Research focus also includes studying the effects of left ventricular assist devices (devices that are implanted in patients with heart failure to promote blood pumping). The members have collectively generated several animal models to study heart disease, identified specific stem cell types that might be beneficial, proposed a new model for arterial calcification, and have identified new molecules that might prevent inflammation. The members have been successful in obtaining research funding from several agencies, including NIH, and have published over 100 articles during the past five years. They represent UCF in several national and international committees and organizations, including NIH review panels, and are well recognized by national and international experts. The group would benefit from the availability of a large animal research facility and pre-clinical imaging (MRI, microCT/PET scanner, NIR fluorescence imaging etc).

Neurodegenerative diseases: Well-funded, many areas represented, national reputation. The neurodegeneration team has about seven members who study Alzheimer's disease, Parkinson's disease, Huntington's disease, ALS, multiple sclerosis, and stroke. They are involved in studying the fundamental mechanisms of these diseases, including initiation and progression with a view to diagnose and treat these diseases. Their ultimate goal is to develop new and more effective treatments. The investigators use cutting edge technologies and state-of-the-art approaches to investigate neurodegenerative disease. The members have collectively generated several animal models to study neurological disease, work with stem cells that might be beneficial, and have identified new molecules and mitochondrial pathways that might be involved in the disease process. The members have been successful in obtaining research funding from several agencies, including NIH, and have published over 60 articles during the past five years. They represent UCF in several national and international committees and organizations, including NIH review panels, and are well recognized by national and international experts. The group will benefit from the availability of a large animal research facility and pre-clinical imaging (MRI,

microCT/PET scanner, NIR fluorescence imaging etc). The group also will benefit by the recruit of a neuroimmunologist, neuroendocrinologist, and scientists familiar with neuroimaging. The availability of scientists involved in neuropsychology and cognitive scientists would be a great asset to this group.

Infectious diseases: Infectious disease program is well represented by 11 scientists at UCF. Well studied are Crohn's disease, Cholera and "staph" infection, HIV, chlamydia, Lyme disease, malaria, tuberculosis, and several others. The College of Medicine has recently recruited Dr. Griffith Parks, a well-known virologist and microbiologist. The laboratories studying these diseases are working toward discovering novel drugs and their targets for therapeutic intervention, developing convenient diagnostic tests, and studying the innate ability of humans to resist diseases caused by pathogenic bacteria and viruses. The main objectives include understanding of innate ability of humans to resist bacterial and viral infection, development of new diagnostic methods and identification of targets for developing novel therapeutic agents to treat such infectious diseases. The laboratories use new tools (e.g. novel drug libraries) to screen pathways for potential new drugs. The group has published over 100 publications during the past 5 years and has numerous federally and privately funded programs. The members have national and international reputation and represent UCF in national and international scientific organizations. Many members also have interest in inflammation research which makes this topic a unique unifying theme. The group will benefit immensely by immunologists, both basic and clinical.

<u>Cancer:</u> Over 10 faculty members represent cancer at UCF. Their research covers a wide area of cancer specialization, including Ovarian, breast, prostate, neurological, pancreatic, skin and others. They use numerous animal models and their research covers the study of basic metabolism, including bio-energetics, inhibition of cancer causing pathways by use of novel metabolic drug inhibitors, peptide drug discovery and targeting, diagnostics and treatment. There is a robust and active multidisciplinary collaboration with nano-sciences, Florida hospital, VA, and chemistry. The group has published over 100 publications during the past five years and has numerous federally and privately funded programs. The members have national reputation and represent UCF in national and international scientific organizations. Many members also have interest in inflammation research. The group will benefit immensely by immunologists, both basic and clinical. In addition, tumor imaging is an essential component that is lacking at UCF. Most importantly, this area requires senior investigators and perhaps a group of cancer scientists dedicated to studying one type of cancer.

<u>Simulation:</u> Medically-related simulation research programs range from the development of algorithms for 3-D endoscopic surgery simulation to the use of interactive virtual and mixed reality simulation for rehabilitation of patients with brain injuries. Related research in human factors adds the psychological dimension. Faculty are responsible for identifying, implementing and coordinating the use of simulation

technology for conducting and improving medical education. The team also provides the vision for simulation-based research for medical modeling for both medical education and healthcare improvement. Future areas will include the use of medical simulation in the areas of patient care and community outreach.

## **UCF General Health-related Research Challenges**

#### Faculty

- Insufficient faculty lines
- Need to create additional endowed chairs and lack of endowed professors
- Excessive teaching loads

### Maturation of partnerships

- Research partnerships with community health care providers
- Not enough research generated to establish a "Center" type grant from NIH.
   Need to conduct funded research to get these.
- Finding partners who share the culture of innovation to help move projects forward
- Collaborative grants development strategy
- Need to develop IPEC Interdisciplinary Professional Training: Medicine, Pharmacy, Nursing, Physical Therapy, & Psychology

## Financial resources for research

- Funding for global opportunities
- Federal and State funding limitations
- Competition for large donors
- Funding for graduate students
- Funding for recruiting post-docs and senior scientists and groups
- Funding for high-ticket equipment
- Funding for laboratory space
- Funding for large animal facility
- Funding for GLP chemical synthesis facility/laboratory

## Lack of access to clinical/organizational populations

- Need for a Clinical Research Center Pegasus Health is a logical facility to develop into the Clinical Research Center (while Lake Nona develops)
- Lack of outpatient psychiatric services in East Orlando
- Do not yet have the ability/support for university-initiated research trials or multi-center trials with NIH or industry sponsored protocols
- Enhanced collaborations with local, community hospital health systems
- Need for a research repository that would allow different investigators to access a research database
- Need to build an academic clinical research center at UCF College of Medicine Geography
  - Location of medical school in relation to the rest of the university
  - Relocate Nursing and Allied Health areas to health sciences campus

Increase public transportation to health sciences campus

#### **UCF Facility Challenges**

- Research-focused teaching hospital: Estimated cost: \$500–600 million.
- Large animal facility: Estimated cost: \$5-7 million in building and setup costs and annual \$300K in maintenance cost.
- Preclinical imaging e.g., MRI, MicroCT/PET, Near IR fluorescence: Estimated cost: \$ 2-3 million for initial purchase. \$100-200K in annual tech/service cost.

## **UCF Technology Transfer Challenges**

- Coordination of intellectual property process with respect to publications by investigators for promotion and tenure
- Education and orientation of faculty members towards issues surrounding intellectual property in the evolution of intellectual property to commercialization
- Working with international teams as IP policies differ amongst countries
- Commercialization of early-stage discoveries
- Limited funding for translational research, including proof-of-principle and preclinical studies
- Limited number of seasoned investors with expertise and track record in successful growth of life sciences companies
- Building a critical mass of infrastructure regionally to support all stages of the commercialization process in Life sciences.

## **UCF Research Compliance Challenges**

- Faculty development for new faculty hires
- Uniform standards for compliance with lab safety
- Managing investigators' conflict of interest disclosures, monitoring financial transactions in accordance with HIPAA regulations
- Ensuring the use of students as subjects in research meet FIRPA regulations.
- Managing accurate clinical trial billing compliance standards with sponsors, insurance companies and Medicare.

# **UCF Veterinary Resources Challenges**

Not having a large animal facility

# UCF Health-related Research Opportunities with Other SUS Institutions

- Gender-based and population-health (all State University System institutions)
- Clinical research
- UF Pharmacy
- USF Pharmacy

 UF Department of Health Services Research, Administration and Policy - College of Public Health and Health Professions.

#### **UCF Current Collaboration with SUS Institutions**

- UF: Aids; Advanced Practice Nurses, scope of practice and medically underserved areas; infectious disease antibiotic resistance
- USF: breast and ovarian cancer; cardiovascular disease; longevity and aging; malaria; identify drug leads from marine natural products; prostate cancer
- FAU: infectious disease tuberculosis; pancreatic cancer; malaria; identify drug leads from marine natural products; prostate cancer
- FIU: Agency for Healthcare Research and Quality grant (submission pending)

#### **UCF Unaddressed Needed Research**

- Inflammation: Chronic inflammation has now been recognized as an underlying pathology of many major diseases, such as cardiovascular diseases (including atherosclerosis, diabetes, obesity, congestive heart failure), cancer, arthritis, demyelinating diseases, and infection. It is also the pathological basis of the immune response (deficiency as well as hyper response) and autoimmunity. There is a void of trained scientists to study chronic inflammation and its prevention in children as a means of preventing and understanding major illnesses in adults. There is a need for additional faculty, basic and clinical, as well as preclinical imaging systems to employ suitable animal models to study inflammation.
- Neuroscience: NIH and other agencies have designated neuroscience as a top
  priority area of research. There is an urgent need for translational scientists and
  neuroimmunologists at UCF. Brain imaging and cognitive/brain performance
  science are inadequately represented at UCF. There is also a need for drug
  development, new model development, and functionality testing scientists in
  neurological diseases.
- Other:
  - o Childhood obesity
  - o Gender-based and population health
  - o Health-services research
  - o Minority health

#### **UCF Contributions to Translational Research**

Cardiovascular sciences have several translational components. The UCF College of Medicine has initiated pilot clinical studies to determine the efficacy of Sesame oil to reduce blood lipid levels and to influence the progression of atherosclerosis. The pilot studies conducted by medical students in the research module have demonstrated that even in a short duration of one month, sesame oil supplementation significantly reduced blood fat levels, particularly the cholesterol values associated with low density lipoprotein (which causes clogging of the artery). The "cardio group" is also planning to

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isolate specific stem cells from humans (which will contain a protein that will react with special hormones) to enhance beating heart cells. On a similar note, scientists are also planning to use a specific protein (BMP7, a protein that is already in clinical trials for other applications) to convert cells that promote inflammation to cells that will inhibit inflammation.

The neurodegenerative group has an ongoing study to identify molecules that inhibit viability of NF2 (Neurofibromatosis type 2, is a rare genetic disease) that causes tumors to form in the central and peripheral nervous system. The Neuro group plans to develop a bone scaffold to combine with a patient's own stem cells in clinical use. There are ongoing collaborations with Florida hospital to identify embryonic stem cell gene expression in gluons cancer stem cells. The neuro group is also developing targeted therapies to treat glioblastoma and an eye drop treatment promoting regeneration of the cornea by endogenous stem cells. The group is further testing a combination of drugs, developed in collaboration with NIH as a preclinical study for Alzheimer's disease. This study will increase endogenous brain stem cells and also increase neurogenesis from brain stem cells.

The cancer group in collaboration with physicians of Florida Center for Cellular Therapies and the Oncology group at Florida Hospital Cancer Institute, are developing new clinical treatment methods for AML. Specifically, the translational research is focused on development of a method for expansion of NK cells, both *ex vivo* and *in vivo*, without the use of tumor derived feeder cells. The group is also conducting preclinical evaluation of particle based expansion of NK cells and their efficacy for treatment of AML in NSG murine model, intended for an IND filing to allow initiation of clinical trials.

## Florida International University

#### FIU Priority Areas of Health-related Research

AIDS /HIV: Our AIDS/HIV research spans a broad spectrum of critical and insightful research into various aspects of this disease and its effect on public health as well as possible treatment solutions. We have research that is focused on HIV/AIDS around the globe, including in Latin America, the Caribbean, and China. This research includes federally funded research on the study on migration, tourism, and the HIV/drug syndemic in the Dominican Republic. In Haiti there is a compelling need to integrate new HIV prevention strategies that have recently gained consensus and evidence of efficacy. One such strategy is newborn medical male circumcision (NMMC). Our researchers explore how best to increase uptake among parents of newborn males, particularly in Haiti, in regards to NMMC. In Hunan Province, China, the most common route of HIV infection is through sharing of contaminated injection paraphernalia among injection drug users (IDUs) who then transmit the disease to their sex partners. A major barrier to practicing safer sex is lack of disclosure of HIV status to partners. The purpose of our study is to identify factors associated with disclosure of HIV status to sex partners in a sample of HIV infected individuals in Hunan Province, China. In the treatment front researchers are FIU have been exploring alternative methods of medication delivery to treat HIV infections such as nanoparticle based drug delivery systems targeting the brain. One such funded NIH award proposes to develop a unique magnetically guided nanocarrier bound to CTOP (BBB impenetrable < opioid antagonist), BDNF (Brain Derived Neurotrophic Factor) and 5'-triphosphate-AZT (AZTTP) for drug targeting to the brain.

Alcohol/Drug Abuse: The impacts of alcohol and drug abuse are often felt across all levels of society and know no bounds in terms of age, gender or socio-economic status. Researchers at FIU are involved in studies that examine these impacts at various trajectories. The prevalence of marijuana use is escalating among adolescents, along with declines in perceptions of risk with use. One NIH funded study we have will help to determine if problems with decision-making are one of the reasons that some teens become addicted to marijuana. Another study will help us understand if cannabis use affects the neurocognitive functioning of HIV+ individuals and whether it impairs their ability to conduct important daily activities (e.g., managing medications and finances). The new information provided by this study has the potential to improve the health of individuals living with HIV/AIDS and may help policy makers and healthcare providers in deciding the role of cannabis in HIV/AIDS patient care. Another critical project evaluates the efficacy of a motivational interviewing intervention for reducing drug and alcohol use problems among Native American high school students. Motivational Interviewing (MI) is a behavioral treatment for substance use problems that has already shown efficacy in some populations. Native American adolescents are a public health priority, as they are at greater risk than adolescents from other

ethnic/cultural groups for the development of long-term substance use problems. This significant and innovative study represents an important next step in the development of cross-culturally effective, brief, and school- based interventions for drug use and drinking among teenagers.

Biomolecular and Genetic Sciences: Researchers in our College of Medicine are involved in several critical projects which are at the forefront of biomolecular and genetic sciences. One such federally funded study is the detailed molecular analysis of arsenic transporters and modifying enzymes. Chronic exposure to arsenic has been linked to cardiovascular and peripheral vascular diseases, neurological disorders, diabetes and various cancers. An understanding of both arsenic chemistry and the molecular details of arsenic transport systems is essential for alleviating the problems of arsenic toxicity, as well as for the rational design of drugs to treat drug-resistant microbes and cancer cells. Another funded project studies how hormone signaling suppresses prostate cancer progression. The peptide hormone relaxin (RLN) and its G protein-coupled receptor RXFP1 are expressed in several types of cancer cells, including prostate, endometrial, thyroid and others. It has been shown that the overexpression of relaxin is often associated with advanced metastatic disease. Stimulation of RLN/RXFP1 signaling increases cell proliferation, invasion, migration, adhesion, and decreases cell apoptosis in vitro and in vivo. Our researchers are performing a high throughput screening of a large library of small molecules to isolate chemical compounds that disrupt relaxin signaling which can be potentially used as anti-cancer drugs.

Child Mental Health: Our child mental health research includes studies in ADHD, autism, anxiety and depression and is funded in part through a number of federal agencies, including the National Institute of Mental Health, the National Institute on Alcoholism and Alcohol Abuse, the National Institute of Drug Abuse, the National Institute of Child Health and Human Development, the National Science Foundation, the Institute of Education Sciences, as well as numerous industry and foundation sources. The thrust of this research is conducted at our Center for Children and Families (CCF). In particular, CCF has focused on studying the effectiveness of family, school and medical treatments for ADHD, anxiety and related problems, and disruptive behavior in youth, as well as ways of preventing these problems. They have developed new practices for parent training, classroom interventions, and peer interventions, and have worked with pharmaceutical companies to test and develop new medications. Currently, our research in ADHD focuses on how to combine non-medical treatments and medications to yield the best treatment for each child. Our current research in anxiety disorders, disruptive behavior, and autism examines what type of treatment works best, as well as new, innovative ways in which to provide treatment to families (e.g., via the Internet, intensive programs). Our early intervention and prevention studies highlight the importance of targeting parental involvement, parent-child

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interactions, and parenting skills to promote young children's emotional and behavioral wellbeing as well their school readiness.

<u>Health Disparities:</u> One of the ongoing challenges in the United States is the relevance of disparity in health status amongst racial and ethnic minorities, rural, low-income, and other underserved populations. The National Institute of Minority Health and Health Disparities (NIMHD) funds an Exploratory Center of Excellence at Florida International University. The Center currently explores Substance Use and HIV/AIDS Research on Latinos in the United States, and Intergenerational Transmission Alcohol and Substance Abuse. Other Health Disparities areas with substantial funding from NIH and other federal sources include cancer, neural systems and chronic diseases.

## FIU General Health-related Research Challenges

• The demographics of the State of Florida, from ethnic diversity to the age distribution, place Florida at the vanguard of national trends. This represents opportunities for the SUS to obtain federal funding for translational research, as well as to influence innovation in health care. Two major challenges include the reduction of federal dollars for R&D and the adjusting to the changes brought about by the Affordable Care Act.

## **FIU Facility Challenges**

• FIU is in great need of satellite offices located near large hospitals throughout south Florida. These sites would be instrumental in participant recruitment and retention across disciplines. An estimated cost would be approximately 30-40 dollars per square foot. Initial locations near Jackson Memorial Hospital, Homestead hospital and Hialeah hospital would give FIU access to unique populations that are traditionally underserved and underrepresented. There is also a need for additional biomedical science facilities to support translational research collaboration between basic scientists and clinical researchers. Finally, there is a need to find ways to share core research facilities within the SUS. Not only would this be financially efficient, it would promote collaboration among researchers across the system.

# FIU Technology Transfer Challenges

Opportunities included building stronger relationships with Florida institutes such as Torrey Pines, Sanford Burnham, and health related foundations. FIU is also exploring non-federal sources of funding such as partnering with local health care related companies and encouraging our investigators to explore other types of collaborations and partnerships when conducting research.
 Additionally, we have a very young medical school—as it grows and develops so will research efforts. Challenges in health-related technologies include lack of funding for prototype development and to conduct studies to validate potential therapies and devices. Ultimately, one of the most significant challenges to

technology transfer is the need to further diversify the Florida economy and the need to increase the availability of venture capital in Florida. In these two areas there has been significant progress in recent years.

## FIU Research Compliance Challenges

Opportunities include developing additional strategic collaborations with local hospitals and clinics to streamline the Institutional Review Board (IRB) process for biomedical research projects involving human subjects. FIU will be partnering with the University of Miami, the Baptist Health System of South Florida, the Miami Veterans Affairs and others for an upcoming human subject research conference geared towards best practices to harness greater collaboration, to eliminate redundancies and make the human subject research process as efficient and as effective as possible for all involved. Challenges include minimizing the length and complexity of technical medical consent forms, assigning appropriate affiliations for courtesy/volunteer medical research faculty members, and managing the oversight and monitoring of biomedical research studies at external research sites.

## **FIU Veterinary Resources Challenges**

• Opportunities include the new vivarium—approximately 19,000 square feet, divided as a transgenic facility (3,550 square feet), SPF vivarium (3,000 square feet), auxiliary facility (6,910 square feet) and core facilities / surgical suites (5,540 square feet). The facility is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC Unit #1535), indicating verified compliance with the requirements for the proper care and treatment of all vertebrate laboratory animals, irrespective of species, location, investigator, use, or funding source. The FIU Animal Care and Use Program is therefore positioned to provide adequate support to all our PI's research endeavors involving animal experimentation. Given the above, FIU does not have any challenges as this time.

# FIU Health-related Research Opportunities with Other SUS Institutions

• FIU could partner with other SUS institutions in addressing health disparities research in other health areas by combining FIU's access to populations through its NeighborhoodHealth program in the college of medicine and FIU's history of community-based health disparities research with the clinical and translational capabilities of our more mature partners at UF and USF.

#### FIU Current Collaboration with SUS Institutions

 FIU researchers currently partner with UF faculty in areas pertaining to HIV/AIDS research.

#### FIU Unaddressed Needed Research

It is difficult to ascertain SUS deficiencies in this area. There is one area that we believe is insufficient in South Florida, and believe is the case throughout the State. This is the participation of underrepresented groups in clinical trials. This is a critical national issue, in that underrepresented groups often do not benefit from participating in state-of-the-art potential cures, and equally important, the translational science potentially advances faster by having diverse clinical trial samples.

#### FIU Contributions to Translational Research

A number of FIU research projects have the potential to inform new treatments and cures. In the field of nano-technology, FIU investigators (Nair and Khizroev) are literally speeding up the process by which drugs are delivered to the brain. Several FIU faculty from the College of Engineering and Computing are working on assistive technology initiatives focused on visual impairments (Adjouadi, Ramella) and limb loss (Jung), while others are focused on isolation of brain pathways crucial to normal aging, dementias, epilepsy, hypertension, and other pathological conditions (Riera). At FIU's College of Medicine, numerous investigators are conducting laboratory experiments that hold great promise for translational research in the areas of reproductive health, environmental health, infectious diseases, and cancer.

## University of North Florida Survey Response

## **UNF Priority Areas of Health-related Research**

Age- and Activity-Related Muscular and Skeletal Deterioration: Sarcopenia is the gradual deterioration of skeletal muscle that accompanies the aging process and is a serious medical condition facing millions of elderly people. Correlated with this disease condition are the direct and indirect impacts of physical injury on patient skeletal health. Several UNF research projects explore the causes, prevention, and treatment of sarcopenia, osteoporosis, injury, and related diseases. For example, Dr. David Waddell is examining how genes play a pivotal role in regulating important aspects of skeletal muscle physiology, including the processes of sarcopenia and cellular stress or damage. He is particularly interested in understanding the molecular and genetic controls of longevity, and the role that cellular stress may play in aging. From the perspective of injury impact, Dr. Michelle Boling recently completed a multicenter prospective risk factor study, funded by NIH, investigating biomechanical risk factors for the development of patellofemoral pain (PFP). Patients who develop PFP reduce their physical activity levels, predisposing them to obesity and related diseases such as diabetes, and likely are predisposed to the development of patellofemoral osteoarthritis.

Biology and Prevention of Insect-Borne Viruses: Research in this area includes projects on tick-borne diseases, as well as arthropod-borne viruses (arboviruses) that are transmitted in nature by hematophagous insects, specifically mosquitoes. Viruses transmitted by mosquitoes can and do result in human and/or veterinary infectious diseases. Infection of a mosquito host is prerequisite to biological transmission of such etiologic agents of disease. Currently, such infectious agents have an enormous economic impact worldwide. Dr. Doria Bower's team focuses their efforts on understanding the infection process in the mosquito, a link in the chain of arbovirus transmission. By looking at long-term infection of two similar *Aedine* mosquitoes, they compare host responses to virus. Current studies include evaluation of a patented nontoxic organic mosquito larval growth inhibitor that is in the process of being commercialized.

Maximizing Quality and Efficiency of Healthcare Services: Healthcare Quality and Efficiency research can be used to improve the management of U.S. hospitals as well as address the policy implications for more efficient use of resources across the healthcare industry. Hospital services were the largest category of U.S healthcare expenditures in 2009 and accounted for \$759 billion. This research is important since states like Florida face dramatic increases in Medicaid expenditures. Also, from a federal perspective, the Medicare program faces future insolvency. Research at UNF is assisting in maximizing the quality and efficiency of healthcare services and is providing information on healthcare value, which may support changes in current healthcare policy. Dr. Jeff Harrison, Dr. Mei Zhao, and Dr. Aaron Spaulding are leading public health researchers

who are investigating various aspects of the healthcare system, including existing and prospective payment systems, such as pay-for-performance models, as well as nursing home quality and financial conditions. Much of this research is using a "big data" informatics approach, which is highly popular with UNF's local health-provider partners. The research involves developing techniques to store, protect, and then draw information from large sets of data on hundreds of thousands of patients. The goal is to more efficiently and effectively manage not only individual health care needs (as required by the Affordable Care Act), but also to allow research into possible predictive models that can help develop plans to prevent illness through analysis of thousands of pieces of information on the precursors to illness and disease.

Prevention and Treatment of Obesity: Recent childhood obesity statistics indicate that 24.2% of Jacksonville's school children and 34% of Florida's children are overweight or obese. Minority groups are disproportionately affected by all major chronic diseases, including obesity, diabetes, and cardiovascular diseases. According to the Centers for Disease Control and Prevention, 1 in 3 children born in 2000 in the United States will develop diabetes and nearly 50% of African American and Hispanic children will develop diabetes. The NIH and other governmental organizations recognize that reducing risk factor prevalence rather than treatment is the most desirable strategy for decreasing chronic disease risks, morbidity, and mortality. UNF research on obesity ranges from identification of how obesity develops to treatment and management of obesity and related disease. For example, Dr. Alizera Jahan-Mihan's research is contributing to the growing evidence supporting the role of diet and food components during pregnancy and lactation on development of obesity and chronic diseases in offspring. Dr. John Hatle is looking at the physiological mechanisms that cause calorie restriction to seemingly prolong lifespan, using other organisms as model systems for studying the effects of diet and reproduction on lifespan. From another perspective, Dr. Claudia Sealey-Potts's community-based, participatory-research approach focuses on minority groups for primary prevention of diabetes, obesity, and hypertension, especially focused on projects that address policies, parental engagement, and current lifestyle behaviors of parents, caregivers, and children.

<u>Biomedical Devices and Instrumentation:</u> This research involves the development of new and improved biomedical devices and instruments to assist those that are disabled and/or to improve medical treatment. Ongoing research includes work in high-performing prosthetics, sensors to detect indicators of diabetes in saliva and tears, devices to assist quadriplegics in sensing pressure when using robotic arms, and the development of a computer program that can decipher sign language and provide written translation. Much of this work involves unique collaborations between UNF's health and engineering colleges.

# **UNF General Health-related Research Challenges**

• Difficulty in securing federal and other external funding

- Insufficient graduate research assistantship funding
- Lack of core/shared facilities for supporting major instrumentation
- Need for updated laboratories and modern instruments
- Heavy teaching load limiting time for research

## **UNF Facility Challenges**

- New bench and clinical lab space and equipment (\$4 million)
- Behavioral health animal research facility (\$1 million)
- Next-generation DNA sequencing core facility (\$1 million)
- MALDI mass spectrometer core facility (\$750,000)

## **UNF Technology Transfer Challenges**

UNF's focus on teaching over research discourages faculty from disclosing
patentable technologies and/or from considering commercializing their
inventions. The result is a small UNF patent portfolio and related challenges in
effectively marketing and licensing the technology. To assist with technology
transfer, the SUS might provide centralized marketing and licensing support for
the smaller campuses like UNF.

## **UNF Research Compliance Challenges**

 UNF has an unnecessarily conservative approach to research compliance, leading to significant delays and frustration among researchers. This is being addressed by revising standard operating procedures to be more researcher friendly, and by bringing new faculty onto compliance committees who have experience at other institutions. Both approaches are helping to "recalibrate" UNF's compliance culture to better reflect the kinds of low-risk research that occurs here.

# **UNF Veterinary Resources Challenges**

• UNF has needs for a larger and modernized animal research facility.

# UNF Health-related Research Opportunities with Other SUS Institutions

- UCF's Health Administration Program would be a good partner for future health care quality and efficiency research.
- The UF NMR facility and Scripps Institute's screening facility would be useful research partnerships.
- Much recent biomedical research requires the use of core facilities (no one at UNF has their own next-gen sequencing equipment, for example). However, we currently pay off-campus prices at core facilities at UF (and probably other SUS institutions). To facilitate health-related research throughout the system, it would be helpful to develop less-expensive pricing for analyses done across all SUS campuses.

#### UNF Current Collaboration with SUS Institutions

- Dr. John Hatle is currently collaborating with Daniel Hahn, professor at the
  University of Florida on understanding the molecular basis for the effects of diet
  and reproduction on life span. Dr. Amy Lane has received pilot funding from the
  NIH Southeast Center for Integrated Metabolomics. UNF also partners with UF's
  Center for Health Equity and Quality Research.
- Dr. Terri Ellis is currently collaborating with Kent Seeley, the Director of the Proteomic facility at USF. The ability to get involved in the "big data " projects that need these facilities would be really helpful, since in the medical field these really are the dominant research interests. Dr. Amy Lane was awarded three shiptime grants from the Florida Institute of Oceanography.
- The Southeast Transdisciplinary Collaborative Center on Rural Health Disparities (Southeast TCC) is led by the University of Central Florida in partnership with UNF and other universities.

#### UNF Unaddressed Needed Research

- Health care disparities
- Provision of health supervision in county schools
- Use of health information technology to improve the quality of health care

#### **UNF Contributions to Translational Research**

UNF is especially well-known in the region for translational research in various health fields, consistent with the applied undergraduate and graduate programs that it offers. For example, Dr. Mary Lundy's Pediatric Assistive Technology CBTLO grant allows doctor of physical therapy and engineering students under the direct guidance of their faculty leaders to conjointly design, prototype, and test biomedical engineering solutions for community identified needs. This is being done in partnership with area pediatric physical therapists from several rehabilitation settings, including Wolfson's Children Hospital, Brook's Rehabilitation Hospital System, and the Duval County School District Special Needs Program. As another example, several faculty in the Brooks College of Health, as well as students in the doctor of nursing practice programs, are involved in translational research projects around the pedagogical success of simulation in nursing education, and the value of community involvement with nursing and public health students.

UNF is also engaged in technology transfer and commercialization of inventions emerging from health-related research, albeit on a scale consistent with the university's size and mission. This includes an active patenting and licensing program for a series of inventions in chemical and microbial sensors, and the possibility of a faculty-founded spin-off company is currently being explored. An invention for inhibiting mosquito larval development is currently in licensing negotiations with the small Florida business that holds the option on the technology. And a new chemical process that has the

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potential for revolutionizing the synthesis of widely-used pharmaceutical compounds is in the process of being patented.

UNF is very well positioned both institutionally and geographically to expand both kinds of translational research. Jacksonville has a well-established and still-growing healthcare industry, and as the only large public university in the city, UNF is increasingly called upon to assist in a wide variety of translational and applied research projects. The primary limitations to UNF are faculty workloads, which are dominated by teaching; the amount of graduate student support; and the available facilities and instrumentation available to effectively respond to the many translational research opportunities.

## Florida Gulf Coast University Survey Response

## FGCU Priority Areas of Health-related Research

<u>Dengue Virus Research:</u> Florida Gulf Coast is currently involved in research to develop a vaccine for the Dengue Virus. Symptoms of this disease include fever and joint pain which can be severe. Each year the World Health Organization estimates that over 390 million people are infected. The Dengue Virus has reached epidemic levels in Southeast Asia and many Latin American and Caribbean countries. There is currently no specific treatment or cure for the disease. Trials of the dengue inhibitors are under way in California. Florida Gulf Coast University is continuing work on developing a vaccine to neutralize all four types of Dengue Virus.

## FGCU General Health-related Research Challenges

- The need to improve Lab infrastructure
- Need for an animal research facility
- Need to increase the number of research grants
- Need to develop clinical practices

## **FGCU Facility Challenges**

• Animal Research facility. Estimated Cost: \$5M

## **FGCU Technology Transfer Challenges**

- The need for more patentable products
- New graduate degree programs such as Bioengineering

#### **FGCU Research Compliance Challenges**

• The health research being conducted by FGCU researchers at this time is not under the auspices of the FDA.

## **FGCU Veterinary Resources Challenges**

 Not Applicable to Florida Gulf Coast University. (FGCU does cite the need for an animal research facility.

## FGCU Health-related Research Opportunities with Other SUS Institutions

Potential opportunities exist with USF, UF, UCF, and FIU.

#### **FGCU Current Collaboration with SUS Institutions**

None at the present time.

#### FGCU Unaddressed Needed Research

- Autism
- Human Trafficking

#### Geriatrics

#### **FGCU Contributions to Translational Research**

The best example of Florida Gulf Coast University contributing to health-related translational research is our efforts to develop a vaccine for the Dengue Virus. The aim of translational research is to make findings from basic science useful for practical applications that enhance human health and well being. The development of a vaccine would alleviate the vast suffering currently being endured by millions of individuals in less developed countries. Regarding the extent to which translational research can be expanded, it would be of great benefit to have an animal facility on sight to conduct animal trials. We currently have to use the facilities of another university.

## New College of Florida Survey Response

## NCF Priority Areas of Health-related Research

None

## NCF General Health-related Research Challenges

• No response given.

## NCF Facility Challenges

• With one of New College's top majors being biology, laboratory space is strained and overused. Students need to complete a senior thesis and often times require dedicated lab space for 6 months to a year. Couple this with faculty long-term research and projects, New College faces a space challenge as our enrollment grows over the next several years. A new facility will allow us to develop new research programs designed for students interested in acquiring laboratory skills and workforce training. A multi-use research/laboratory/collaborative wing added to current natural science building would support this need (approximately \$8M).

## NCF Technology Transfer Challenges

None

#### **NCF Research Compliance Challenges**

None

#### NCF Veterinary Resources Challenges

None

#### NCF Health-related Research Opportunities with Other SUS Institutions

• New College of Florida graduates higher percentage of STEM students (per total number of graduates) than most of the other SUS institutions. Many of our Natural Sciences students conduct health-related research. These students usually continue their health-related research projects in graduate or professional schools and build their careers in health-related fields. The 2012-2013 NCF Alumni Survey indicated that 11% of NCF alumni are employed in "Life, Physical, and Science" industry and 10% work in "Health Services". New College can provide other SUS institutions with well-prepared students in the health-sciences and/or New College could partner with other institutions to create 3+2 programs in health-related science degrees.

## NCF Current Collaboration with SUS Institutions

None

# NCF Unaddressed Needed Research

• No opinion

# NCF Contributions to Translational Research

• None

# Appendix A: An Inventory of State University System Health-related Research

(Survey question five)

## University of Florida

Brain/neuroscience

Cancer

Cardiovascular disease

Infectious disease/emerging pathogens

Aging

Implementation science

Personalized medicine

Clinical and translational science

## Florida State University

Healthcare for minorities and underserved or under-represented populations

Aging, geriatrics and successful longevity

Health promotion, prevention and literacy

Obesity, diabetes and cardiovascular health

HIV/AIDS/STD prevention

Autism

Infant and Maternal health

Mental health

Neurodegenerative disease

Community-based clinical research

Health policy and healthcare delivery

Biomedical research

# Florida A&M University

Active Aging

Ameliorative Properties of Synthetic and Natural Products on Xenobiotic Toxicity

Anti-Cancer, Cancer Screening and Prevention

Behavioral and Mental Health

Biotechnology Research Investigations

**Breast Cancer** 

Cardiovascular Disease

Central Nervous System (CNS) Related Diseases

Childhood Obesity Prevention and Education

Clinical Services

Community Health Needs Assessment

Drug Discovery

Educating and Training Future Pharmacists, Public Health and Occupational Therapist Evaluation of Chemotherapeutic Properties of Natural Products

**Environmental Chemistry** 

**Environmental Health** 

**Environmental Monitoring and Restoration** 

**Environmental Restoration and Waste** 

Environmental Toxicology/Risk Assessment

Health Disparities

Health and Wellness

Health Literacy

HIV/AIDS Drugs Assistance and Education

Infectious and Neurodegenerative Diseases

Lung Cancer

Medication Therapy

Mental Health

Molecular Genetics Investigations

MRI and NMR Analysis of Neurodegenerative Diseases (Stroke, Alzheimer's, and

Parkinson's

Nanomedicine and Nanotechnology

Policy and Risk Management

Prevent Underage Drinking

**Prostate Cancer** 

Psychosocial Behavior Associated to Elderly

**Radiation Protection** 

Substances Abuse Workforce Development

Student Wellness Program

Synthesis and Evaluation of Anticancer Drugs

**Tobacco Cessation** 

# **University of South Florida**

Alzheimer's Disease

Cancer

Diabetes

**Drug Discovery** 

Health Informatics/Health Outcomes

Heath Care

HIV/AIDS

Neuroscience and Brain Disorders

Veterans Health

## Florida Atlantic University

Child Health & Human Development

Aging

Cognitive Neuroscience

Molecular Neuroscience

## **Cancer Therapeutics**

# **University of West Florida**

Aging (mobility, quality of life)

Alternative and Complementary Medicine

**Biostatistics** 

**Biomechanics** 

Cardiovascular Health

Cognition

Cognitive Disorders

Community-based Health Improvement

Diabetes Mellitus

Disasters and Mental Health

Domestic violence

Epidemiology of chronic diseases and mental health

End of Life

Environmental Health: Air and Water Quality

Global health

Health care management

Health disparities

Laboratory Technology, Diagnostic Techniques and Procedures

Mental and Behavioral Health

Neurological Disorders

Nursing Education and Practice

Obesity

Pain, including neuropathic pain

Pharmacology

Physical Activity (including motivation, protective effects)

Preconception health, infant health, and infant mortality

Sexual health

Sexual violence

Substance abuse

Suicide prevention

Tobacco use, prevention, and policy research

Vaccine Development

#### **University of Central Florida**

Drug discovery and disease prevention:

Atherosclerosis, obesity, cancer, infectious diseases, chronic inflammatory diseases, including IBS and Crohn's.

Aging:

Neurodegenerative diseases (Alzheimer, Parkinson's etc), musculoskeletal diseases, TBI/PTSD, quality of life, sarcopenia.

## Physiological outcome to interventions:

Critical care, asthma, obesity, airways obstruction, heat stroke and dehydration.

## Patient safety:

Technology to support teamwork, team dynamics, individual and team learning and training.

#### Infectious diseases:

Lyme disease, chlamydia, Tuberculosis, AIDS, Malaria.

## Cardiovascular diseases:

Atherosclerosis, blood lipids, diabetes, heart failure, stem cell therapy, diet and nutrition, exercise, lifestyle modulation, left ventricular assist devices.

## Neurological diseases:

Alzheimer, Parkinson's, Huntington, pain management.

#### Cancer:

Breast, Ovarian, Melanoma, Pancreatic, Prostate, disease management, molecular mechanisms, detection and biomarkers, drug discovery, genetics.

## Population health:

Access to healthcare, public health, health services research, rural healthcare, emergent health emergencies, quantitative research and resource utilization modeling, patient/provider education systems, health communications, health risk assessment, healthcare marketing, blood donations, program evaluation, health care reform, health in non-us populations, ancient cultures, clinical trials design, mathematical epidemiology.

#### Simulation:

Simulation for education and practice, technology mediated health instruction, physical virtual avatars for healthcare training, disease infection specific training, and development of simulation based diagnostic/early warning/disease management systems.

# Bioenergetics and mitochondrial biology:

Cancer and cardiovascular bioenergetics, diabetes and hormonal imbalance, demyelinating diseases.

# Behavioral Health (Mental Health) Research:

Biological underpinnings of severe mental illness, Childhood obesity, mental health and chronic disease, Psychological evaluation and treatment for transplant and bariatric surgery, Treatment of adults and children with anxiety disorders and posttraumatic stress disorders, Primary Care Integration – diabetes, chronic pain, woman's sexual health, Breastfeeding, pregnancy, childbirth.

#### Health Care Policy:

Reproductive health and policies, Fertility tourism, Health communications campaigns, Health risk assessment, health care marketing, Blood donations, program evaluation, health care reform.

#### Other related sciences:

Learning and performance, physiology and behavior, tomography and medical imaging, clinical psychology, human factors, social and behavioral sciences,

medical sociology, exercise physiology and wellness, marriage and family research, nanoparticle technologies and their application in nanomedicine, molecular imaging, and molecular diagnostics, engineered neuronal networks as drug screening platforms, rare earths for nanobiotechnology, nanostructure sensor systems, multi-scale computational bio-fluid dynamics modeling, biomechanics, laser and acoustic devices for medical diagnostics and imaging.

## Florida International University

Engineered tissue model systems

Bio-imaging and bio-signal processing

Cellular and tissue engineering

Aging, geriatrics, and gerontological research

Child mental health - ADHD, autism, anxiety, and depression

Environmental science and toxicology

Reproduction and development

Dietetics and nutrition

Alcohol/drug abuse

Diagnostic imaging and sensor systems

Bio-instrumentation, devices and sensors

**HIV-AIDS** 

Chronic diseases

Cognitive neuroscience

Immunology

Psychiatry

Coronary heart disease

Therapeutic and reparative neurotechnology

Biomaterials, biomolecular sciences and bio-nanotechnology

Maternal child health, family and women's health

Rehabilitation sciences

Cancer biology

Molecular microbiology and infectious diseases

Health disparities

Molecular toxicology

# **University of North Florida**

Aging and Gerontology

- Genetic mechanisms of age-related muscle wasting
- Interactions between signaling proteins in retina
- Walking and balance assessment in stroke patients and older adults
- Strength training and exercise effects on gender and heart disease patients
- Patellofemoral pain causes and risk factors
- Public health and aging services
- Biomedical devices and instrumentation

## Biology and Prevention of Insect-borne Disease

- Mosquito growth inhibitors
- Tick-borne diseases and prevention

#### Nutrition and Dietetics

- Effects of nutrition and reproduction on life span
- Faith- and culture-based health interventions
- Childhood, postpartum, and elderly obesity
- Health professional attitudes towards obesity prevention/treatment

# Cell Biology and Biochemistry

- Study of marine natural products
- Synthesis and study of proteins, enzymes, and enzyme inhibitors
- Imaging flow cytometry of cells
- Surface proteins of pathogenic bacteria
- Bioinformatics

#### Public Health and Health Administration

- Health care quality and efficiency
- Hospital performance and value
- Health care informatics and big-data analytics

# Florida Gulf Coast University

Mental Health
Human Trafficking
Dengue Virus Inhibitors/Vaccines
Therapeutic devices
Biomedical

Drug and Alcohol Intervention and Programming

# New College of Florida

Bioinformatics Epigenetics Metabolism

# Appendix B: Health-related Research Survey



# Board of Governors Health Initiatives Committee Survey on Health-related Research

Please submit this document as a Microsoft Word document.

#### Introduction

On August 20, 2013 Governor Dean Colson established the Board of Governors Health Initiatives Committee to provide leadership for the development of system-level policy regarding health initiatives. The Committee will be responsible for all issues associated with health-related education, especially relating to the development of a strategic plan for advancing the quality and coordination of health initiatives across the System. The purpose of this survey is to assist in conducting an environmental scan that will help to inform the Committee as to the opportunities and challenges associated with health-related research in the State University System.

#### Health-related Research: Definition

A standard definition for health-related research does not exist. Accordingly, it is in the purview of each individual university to consider what constitutes health-related research on its campus. At a minimum, this should include research associated with those academic disciplines in the "51" Classification of Instructional Program category—"Health Professions and Health Programs." Certain programs in engineering (for example, biomedical engineering) and in biomedical sciences might also be included, depending upon the focus of the research. Other examples might include specific areas of health-related research in the disciplines of psychology, education, and so forth.

1. For fiscal year 2012-13, please fill out the table below: "Summary of <u>Approximate</u> Dollars Awarded by Federal Sponsoring Agencies" broken out by non health-related, health-related, and total dollars. (This is an aggregate table: only single dollar figures should be entered in each of columns one, two, and three.)

Summary of <u>Approximate</u> Dollars Awarded By Federal Sponsoring Agencies for Fiscal Year 2012-13								
Non Health-	Health-related	Total	Health-related as					
related		(column 1 +	a % of Total					
		column 2)	(column 2 divided					
			by column 3)					
\$	\$	\$	%					

2. For the year 2012-2013 please provide the approximate breakdown, by percentage of the whole, of health-related research funding dollars by federal, state, foundation, industry, or other sources.

2012-2013 Approximate Breakdown of Health-related Research Funding by Source						
Federal	%					
State	%					
Foundation	%					
Industry	%					
Other	%					
	100%					

- 3. For each of the years 2010-2011, 2011-2012, and 2012-2013 please provide data in the table below for the following categories. In narrative, indicate in what specific health-related areas there were activities.
  - Number of invention disclosures (total and health-related)
  - Number of provisional patents (total and health-related)
  - Number of patents (total and health-related)
  - Number of new companies (total and health-related)
  - Number of licenses (total and health-related)
  - Licensing income (total and health-related)

Technology Transfer and Commercialization									
	2010-2011		2011-2012		2012-2013				
	Total	Health	Total	Health	Total	Health			
Invention	#	#	#	#	#	#			
Disclosures									
Provisional	#	#	#	#	#	#			
Patents									
Patents	#	#	#	#	#	#			
New	#	#	#	#	#	#			
Companies									
Licenses	#	#	#	#	#	#			
Licensing	\$	\$	\$	\$	\$	\$			
Income									

- 4. For the same time frame as above (2010-2011, 2011-2012 and 2012-2013), please list the health-related industry partners with which you have had relationships.
- 5. Please provide a list of general health-related research areas at your institution. (This should be merely a list of general areas, i.e. without narrative.)
- 6. What are your biggest challenges/opportunities with regard to health-related research?
- 7. What are your biggest challenges/opportunities with regard to health-related technology transfer?
- 8. What are your biggest challenges/opportunities with regard to health-related research compliance?
- 9. What are your biggest challenges/opportunities with regard to veterinary resources?
- 10. Please provide your institution's single highest priority facilities need as it pertains to health-related research, and the estimated dollar amount necessary to meet that need.
- 11. In layman's terms, please identify the <u>top</u> areas (up to five) of specialized health care research conducted at your institution. These may be defined by (a) their national/international reputations for excellence, (b) their greatest success in

- securing funding, or (c) their status as most urgently needed. For each area listed, provide a <u>brief</u> (up to 250 words) description.
- 12. With regard to the key areas identified in the preceding question, please give an approximation of their funding as a percentage of all health-related research funding.
- 13. Please describe any critical areas of research in the health care field that are not currently or sufficiently addressed by Florida universities and should be.
- 14. Describe any of your institution's health-related research that you believe could be expanded through greater collaboration with other State University System institutions.
  - a. Specify other institutions by particular strengths of which you are aware and that might be prospects for future research partnerships.
  - b. Describe any health-related research in which your institution is currently partnering with another State University System institution.
- 15. In layman's terms, please briefly (up to 400 words) describe your institution's contribution to health-related translational research and the extent to which it might be expanded.
- 16. Please provide links to any annual reports relative to health-related research that are published electronically by your institution. Alternately, please send a hard-copy to the Board of Governors office, care of Dr. R.E. LeMon, Associate Vice Chancellor, Florida Board of Governors, 325 West Gaines Street, Tallahassee, Florida 32399. Address any questions to Dr. R.E. LeMon at R.E.LeMon@flbog.edu. or (850) 245-0466.