THE UNIVERSITY OF FLORIDA

PROSTATE DISEASE CENTER

An Academic Center for the Prevention, Diagnosis & Treatment of Prostate Disease


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APPROXIMATE VOLUME

THE UNIVERSITY OF FLORIDA PROSTATE DISEASE CENTER
2010 Progress Report

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Virtually every man in the U.S. will suffer from some type of prostate disease – malignant or benign – during his lifetime. Prostate diseases encompass benign prostatic hyperplasia, prostate cancer and prostatitis. Prostate cancer represents a major challenge because it is the most frequent cancer among American men, and every fourth man in Florida will be affected by this debilitating disease. In Florida, many affected by prostate disease have struggled to find an academic center specialized in, and dedicated to, prostate disease—until now. The University of Florida Prostate Disease Center was created to aid in the prevention, diagnosis and treatment of prostate disease by blending its unique strengths in patient care, research and education.

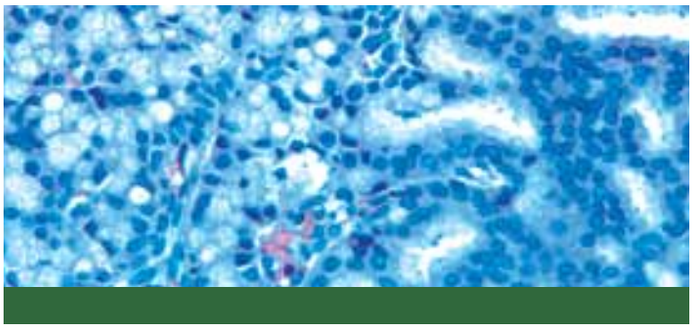
University of Florida leadership has endorsed UF Prostate Disease Center's mission, as it strictly follows the University's strategic plan to become a national leader in urologic healthcare and academic discovery.

UF Prostate Disease Center focuses on four major core missions:

1) Providing outstanding patient care through collaboration of expert physicians
2) Conducting leading-edge research to facilitate new diagnostic tools and treatments for men affected with prostate diseases
3) Performing clinical trials providing the most promising new treatments for prostate disease
4) Educating Florida residents regarding the impact of prostate disease on our communities, providing better guidelines for treatment and raising awareness regarding the availability of clinical trials

Patient Care

Ranked among the top 25 urology programs in the US according to *U.S.News & World Report*, the UF Urologic Cancer Center at Shands at UF offers an integrated, multidisciplinary approach individualized to meet the needs of each patient. A team of UF physicians counsels to all patients and makes expert recommendations regarding the best treatment plan customized to each patient. Together, urologic surgeons, radiation oncologists and medical oncologists provide comprehensive, progressive care, including minimally invasive surgery and a comprehensive range of surgical, radiation and medical treatment options, as well as therapeutic options through collaboration with the pelvic floor center, dietary and rehabilitation programs.



Research

Considering that prostate disease has a debilitating impact on the quality of a man's life, research has never been as critical to improve symptoms, alleviate pain and suffering, and prolong life. The UF Prostate Disease Center is committed to four key areas of research:

1) Studying gene and protein signatures to develop earlier detection strategies and treat prostate disease at earlier stages when it is still curable.
2) Developing new vaccines and drugs for prostate diseases that allow a more precise treatment of the disease without causing serious side effects.
3) Developing new diagnostic tests for prostate cancer to determine who actually needs treatment and who would benefit from delaying therapy at a given point (active surveillance).
4) Developing new diagnostic tools to improve imaging and detection of prostate cancer.

Clinical Trials

Ongoing clinical trials help researchers and clinicians find better methods of preventing, diagnosing or treating prostate disease. Clinical trials represent the ultimate step in clinical research, establishing the safety and efficacy of new treatments and preventive therapies, identifying at-risk populations and standards of active surveillance, and improving the comfort and quality of life of patients with prostate disease. The UF Prostate Disease Center maintains a substantial number of clinical trials, conducted at all phases of the drug discovery process.

Education & Outreach

Education and outreach form a major focus among the UF Prostate Disease Center's core missions to raise awareness about prostate disease and the availability of clinical trials in our Center. UF Prostate Disease Center's outreach extends beyond providing education to rural and underserved communities. Uniquely, the UF Prostate Disease Center aims to provide research, intervention and education at a statewide level to ensure that health disparities and fragmentation of care can be addressed more effectively throughout Florida.

MESSAGE FROM THE EXECUTIVE DIRECTOR

Highlights & Achievements

The UF Prostate Disease Center is committed to continuously broadening and deepening its research portfolio and facilitating an intellectual environment that promotes collaboration among Center investigators and other UF and external centers and programs.

Johannes Vieweg, MD
Professor & Chairman
The Wayne & Marti Huizenga *Chair*
UF Department of Urology
Executive Director
UF Prostate Disease Center
Chair, AUA Foundation Research Council

It is with great pride that we announce that the President of the University of Florida has formally approved establishment of the University of Florida Prostate Disease Center (UF Prostate Disease Center). This Center, the only program of its kind in Florida and adjacent states, conducts leading-edge research for the discovery of advanced treatment methods for patients suffering from prostate diseases. The Center is committed to finding new gene and protein signatures that predict disease course and response to standard therapy before it actually happens.

Among the key focus areas of the Center are cancer vaccines directed against prostate cancer. UF researchers have recently shown therapeutic success in phase III trials, for these vaccines in addition to identification of cancer genes or gene products that can be exploited for molecular diagnosis and therapy. Additionally, many cancer patients travel to UF with advanced disease. Treatment is frustrating for both the patient and physician and represents a major cost burden to our society. Therefore, it is imperative to treat disease in earlier stages.

Another important activity of the Center is examination of statewide patterns of patient care, determination of variations in outcome and recommendation of improvements in quality. In that same vein, unfortunately, there is a lack of critical data for the state regarding how care is provided, and how effective that care is. The Center is committed to analyzing potential gaps in healthcare. We strive to find innovative ways to address unmet medical needs, address healthcare disparities, and identify other obstacles that impede effective and efficient prostate care.

The UF Prostate Disease Center has attracted a multitude of physicians, researchers and patients eager to contribute to excellence in biomedical research and facilitate the conduct of basic, translational and clinical research focused on prostate disease. The UF Prostate Disease Center is committed to continuously broadening and deepening its research portfolio and supporting an intellectual environment that promotes collaboration among Center investigators and other UF and external centers and programs.

With the recruitment of Dr. Yehia Daaka, the UF Prostate Disease Center now houses a world-class effort in cellular signaling and in the development of novel therapeutics to slow prostate cancer growth and dissemination. Innovative clinical trials are underway to test new scientific hypotheses and to produce new drugs and technologies that will eventually improve the lives and health of our citizens. In this area, we are delighted to see the interest from patients throughout the United States enrolling in our trials.

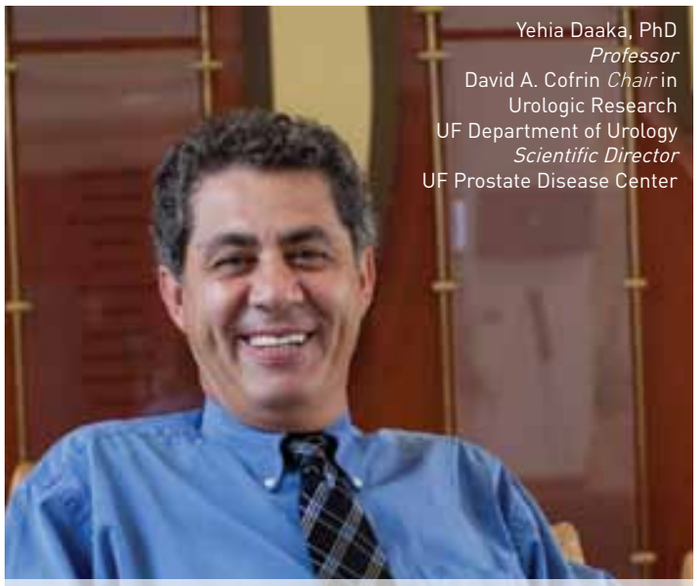
As a result of its ability to secure peer-reviewed research funding, the Center currently ranks 18th in the country in research funding. We expect this ranking only to climb over time. Close interactions and collaborations among clinicians and basic scientists will provide the momentum for continued success in translational medicine and for the development of new tools that will revolutionize care for patients with prostate diseases in Florida and beyond.

The UF Prostate Disease Center was established to drive change that will significantly impact the lives of those affected by prostate disease. The Center's success will be defined by many factors, but of utmost importance is a reduced mortality rate for those diagnosed with the disease. Progress toward that goal will be firmly linked to leading-edge research that translates directly to improved prevention, diagnosis and treatment.

Our basic science portfolio consists of three interconnected and collaborative research domains: molecular oncology, tumor immunology/immunotherapy and developmental therapeutics. The Center's comprehensive research program, composed of highly interactive research teams, provides a stimulating intellectual environment conducive to fostering both training and collaboration.

Molecular Oncology Group. Members investigate signaling networks that regulate cancer cell growth and metastasis. My research focuses on receptors coupled with heterotrimeric G proteins that transduce signals from a wide variety of extracellular factors. We use molecular, cellular and animal models to elucidate the role of G protein-coupled receptors and their associated G proteins and beta-arrestins in the progression of prostate cancer from an androgen-dependent to castration-resistant state. The group led by Zhongzhen Nie, PhD, studies cancer cell migration, invasion and metastasis with special emphasis on regulating vesicle trafficking in focal adhesion remodeling. Sergei Kusmartsev, PhD, is conducting pioneering work on the immunological aspects of the tumor microenvironment and its secreted gene products. He was the first to demonstrate the existence and immunosuppressive activity of myeloid cellular subsets capable of inhibiting T-cell responses and inducing profound immunosuppression. Together, the group uses complementary experimental approaches to further explore the growth and progression of tumors.

Tumor Immunology Research Group. Blending both clinical and laboratory expertise, Johannes Vieweg, MD, and Dr. Kusmartsev were the first to demonstrate the utility of dendritic cell (DC)-based vaccines for the treatment of prostate and renal cancers. They demonstrated that messenger RNA-pulsed DCs are capable of stimulating potent T-cell responses in the cancer patient and pioneered the use of targeted pharmacological interventions to abrogate the immunosuppressive effects of regulatory T-cells or myeloid suppressor cells. Both Drs. Vieweg and Kusmartsev have provided evidence that "universal antigens" such as human telomerase reverse transcriptase (hTERT) can function as highly relevant tumor targets.



Yehia Daaka, PhD
Professor
David A. Cofrin *Chair* in Urologic Research
UF Department of Urology
Scientific Director
UF Prostate Disease Center

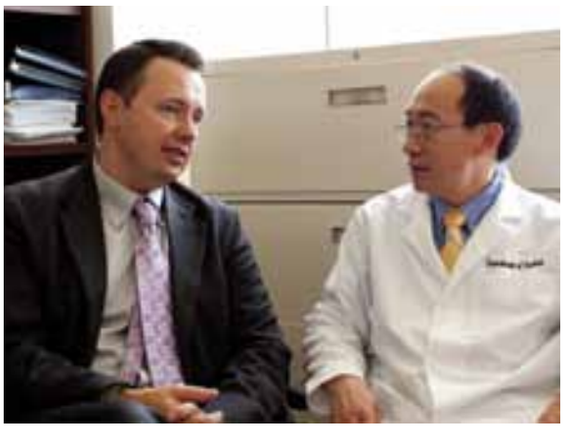
MESSAGE FROM THE SCIENTIFIC DIRECTOR

What Lies Ahead

Translating these concepts into clinical settings, administration of hTERT mRNA-transfected dendritic cells stimulated T-cell responses in prostate cancer patients and reduced circulating tumor cells and PSA velocity in virtually all patients.

Molecular Therapeutics Research Group. Focusing on the tumor microenvironment, this group works to develop and evaluate novel and targeted treatment strategies with direct clinical applications to cancer management. We are exploring the role of the androgen receptor in prostate cancer progression, and have found that AR S-nitrosylation exerts a negative effect on AR function in advanced prostate cancer—a fact that was previously unknown. By administering pharmacologics that modulate the AR S-nitrosylation, we can provide an improved approach to managing patients with advanced, castration-resistant prostate cancer. Dietmar Siemann, PhD, is researching vascular-directed small molecule inhibitors including, antiangiogenic agents that inhibit new tumor blood vessel formation, and vascular-disrupting agents that seek to destroy existing tumor vasculature. He is exploring a variety of therapies that destabilize endothelial shape and attachment, leading to vascular collapse and tumor cell death as a consequence of nutritional deprivation.

The future of prostate disease research is upon us. Our team is working to bring Floridians, and men around the world, tomorrow's medical discoveries today.



Thomas Crawford, MBA, FACHE
Faculty
UF Department of Urology
Chief Operating Officer
UF Prostate Disease Center

MESSAGE FROM THE CHIEF OPERATING OFFICER

Our Priorities

The UF Prostate Disease Center has a unique, multi-faceted mission that distinguishes it from other research and treatment centers within the state. First, we strive to keep Floridians diagnosed with prostate disease in Florida, thus reversing the current trend where a number of patients leave the state to receive their care. Our approach to achieving this objective is to ensure that we offer our patients the latest evidenced-based treatment options through individualized treatment plans. Each individualized treatment plan deploys a vast range of leading-edge technologies that were forged through the latest research discoveries. Second, we're working to translate today's laboratory findings and innovations into tomorrow's leading treatment options. Third, in an effort to decrease the socioeconomic disparities that result in a demographic of men being less likely to seek diagnosis and treatment for prostate diseases, we are currently emphasizing increased awareness and education through focused outreach to Florida's underserved communities. To achieve these goals, the UF Prostate Disease Center is working with members of the Florida Senate and House of Representatives and the Florida Department of Health to assemble a multi-institutional task force of stakeholders. The task force, composed of private practice physicians, academic clinicians, researchers and patient advocates, will work collaboratively to provide statewide outreach; promote awareness of prostate disease and the advantages of early detection; and report the progress in prostate disease research, the availability of clinical trials and best practice principles. Additionally, the geographically disperse task force will create a statewide communications platform for patients, caregivers and their advocates. The collaborative scope of work will establish the UF Prostate Disease Center as a statewide resource and create the systemic synergy required to meet the needs of all Floridians burdened with prostate disease.

The collaborative scope of work will establish the UF Prostate Disease Center as a statewide resource and create the systemic synergy required to meet the needs of all Floridians burdened with prostate disease.

We will deliver high-quality, individualized care to Floridians diagnosed with prostate disease.

We will translate laboratory discoveries into tomorrow's leading-edge cancer treatments.

We will increase awareness and education across the state, especially in underserved communities.

UF PROSTATE DISEASE CENTER CORE FOCUS: PATIENT CARE

A Fully-Integrated, Multidisciplinary Approach to Treating Prostate Disease

For patients with prostate disease, the best treatments involve a comprehensive, multidisciplinary approach, drawing from resources offered by urologic surgeons, medical oncologists and radiation oncologists. This breadth of resources is complemented by the expertise of faculty in a program ranked among the top 25 urology programs nationally by the *U.S.News & World Report* 2010-2011 survey of America's Best Hospitals. Patients meet with all key members of this multidisciplinary team during a single clinic visit. Even after patients have returned home, UF Prostate Disease Center physicians meet weekly to discuss and review individual cases during regularly scheduled tumor board conferences and clinical coordinating meetings. The result: comprehensive assessments and individualized, highly tailored treatment plans that include a team of dedicated physicians assistants, nurse practitioners, nutritionists, social workers and psychologists.

"My diagnosis was very clear when presented to me so that I understood all of my options."

"From the first person I came in contact with to the last, I was treated very well."

"We feel like we could not have been in better hands."

"Outstanding level of care."

"My doctors were compassionate and willing to give me all the time I needed for my peace of mind."

"I have been in the healthcare business for 40 years and was very impressed with the professionalism and knowledge of your staff."

Above: A multidisciplinary team of UF physicians and healthcare providers meet weekly to discuss patient cases at the UF Urologic Cancer Center.

Urologic Oncology

The UF Prostate Disease Center surgeons cover the spectrum of approaches to meet the diverse needs of patients with prostate disease. These approaches range from minimally invasive and ablative techniques to open, laparoscopic, robot-assisted, and image-guided surgical approaches that target everything from early-stage diseases to high-risk cases.

Radiation Oncology

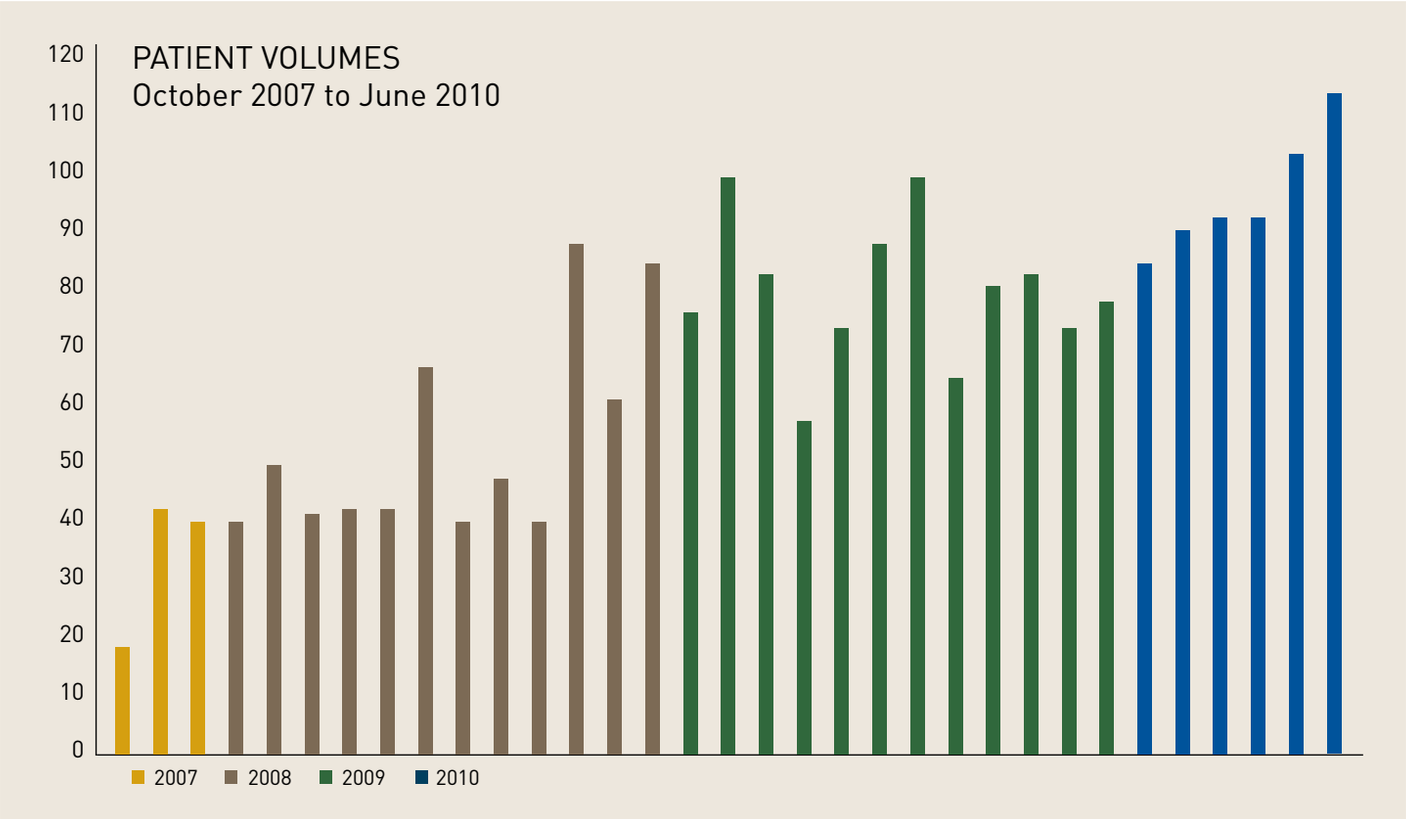
Because the UF Prostate Disease Center provides every patient with a highly individualized treatment plan, patient services include comprehensive radiation therapy, including Intensity-Modulated Radiation Therapy and Image-Guided Radiation Therapy, brachytherapy and systemic radioisotope infusion therapy. The UF Prostate Disease Center also partners with physical therapists in the Pelvic Floor Rehabilitation and Cancer Rehabilitation programs to enhance patient quality of life following treatment.

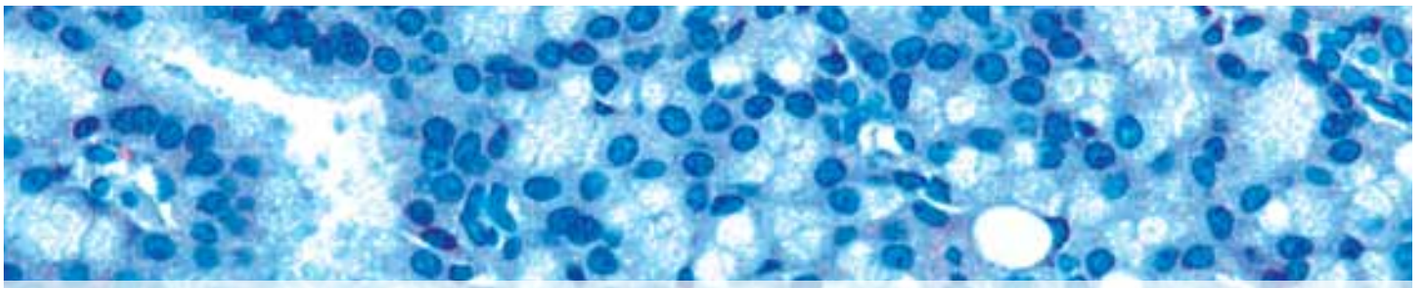
Medical Oncology

A multidisciplinary team of specialists in medical oncology addresses the needs of patients with high-risk or advanced prostate, bladder, kidney or testicular cancers, as well as rarer adrenal, penile and urethral cancers. For outpatient treatment, targeted chemotherapy and systemic treatments are administered in a dedicated infusion center, while inpatient treatments are administered by oncology consultants, nurses and pharmacists.

Clinical Trials

Through the UF Prostate Disease Center, patients may also receive novel clinical treatment through ongoing clinical trials, sponsored by the National Institutes of Health and the pharmaceutical industry. Patients who elect to enroll in clinical trials may be admitted to the Clinical Research Center, an NIH-sponsored unit with its own team of experienced and dedicated nurses, researchers and support staff.





UF PROSTATE DISEASE CENTER CORE FOCUS: RESEARCH

Leading-edge Investigations into Improving Prevention, Diagnosis and Treatment

Given the financial and social costs of prostate disease, the UF Prostate Disease Center focuses on improving treatment and prevention of prostate disease through its research. With collaboration across University of Florida programs, centers and departments, the UF Prostate Disease Center leverages the talents of researchers pursuing basic, translational and clinical investigations.

YEHIA DAAKA, PhD: G Protein Receptors & Cancer Metastasis

Dr. Daaka's research career has been devoted to understanding the biological roles of G protein-coupled receptors that instruct embryonic development and continue to function in adulthood. He has been involved in crucial discoveries that unraveled the contribution of these receptors and their heterotrimeric G protein and β-arrestin effectors to human pathophysiologic processes. For example, in the initiation and progression of cancer, research has contributed to the recognition of these molecules as targets for cancer therapy and resulted in the development of several anti-cancer drugs. Currently, Dr. Daaka's team is examining the contribution of the G protein-coupled receptors and their effectors to the progression of prostate cancer from androgen-dependent to castration-resistant state, and to the metastasis of kidney cancer. Dr. Daaka provided the initial evidence that β-arrestins actively participate in mitogenic signaling by GPCRs; i.e., the expression of a dominant negative form of β-arrestin1 attenuated the β2-adrenergic receptor-mediated activation of ERK MAP kinases. Daaka continues to study novel mitogenic signaling by the β-arrestins and has recently reported that β-arrestin2 functions as a co-repressor of androgen receptor in prostate cancer. Dr. Daaka's lab is also studying mechanisms involved in vesicle trafficking, with emphasis on the G proteins dynamin that support fission of vesicles from the plasma membrane into the cytosol.

JOHANNES VIEWEG, MD: Prostate Cancer Immunology

Dr. Vieweg's scientific efforts have focused on developing cell and gene-based approaches for prostate cancer and renal cell carcinomas, including the discovery and clinical testing of genetically engineered dendritic cells, the discovery of universal tumor antigens, and the modulation of regulatory T cells. He has published more than 100 manuscripts or book articles in high-impact, peer-reviewed journals and has received continuous NIH funding for the past 11 years. His translational work established the foundation for several NIH-funded clinical trials he is conducting under FDA-approved investigator-sponsored new drug applications. Dr. Vieweg's projects also involve the development and clinical testing of targeted therapies, as well as improved prediction models for therapeutic success, an effort to better identify which patients will respond to treatment and which will be unresponsive.

DIETMAR SIEMANN, PhD: Vascular & Immunosuppressive Network of Tumor Microenvironment

The tumor microenvironment has long been identified as a major factor influencing treatment resistance of cancer to conventional anticancer therapies. In addition, it is now well-recognized that the tumor microenvironment

plays a critical role in neoplastic cell initiation, malignant progression and metastatic spread of tumor cells. However, the very characteristics of the tumor microenvironment that lead to therapy resistance also can provide unique treatment opportunities. A major focus of Dr. Siemann's laboratory is the development and assessment of novel anticancer treatment strategies. This research emphasizes approaches targeting two critical aspects of cancer growth: the initiation of a tumor blood vessel network, and the secondary spread of cancer cells.

ZHONGZHEN NIE, PhD: Cancer Cell Migration

Dr. Nie's research has focused on the roles of cancer cell migration and invasion in cancer metastasis. Invasion of cancer cells is a multistep process that requires cell adhesion, remodeling of extracellular matrix and cell migration. As a result, we are studying how mechanisms governing renal cell carcinoma cell migration facilitate effective treatment of RCCs. One current study focuses on the regulation of RCC cell migration by AGAP2, a GTPase-activating protein that selectively hydrolyzes GTP bound to Arf1. Our previous studies demonstrated that AGAP2 forms a complex with the clathrin adaptor protein AP-1. AGAP2 regulates the function of Rab4-positive endosomes and promotes fast recycling through the Rab4 pathway. Significantly, expression of AGAP2 is elevated in different human cancers, including kidney and prostate cancers. Using RCC cells as a model, our ongoing work focuses on the molecular mechanisms by which AGAP2 contributes to the initiation and progression of human cancers to determine if AGAP2 can serve as a target for cancer therapy.

Clockwise from left: Dietmar Siemann, PhD, lab technician Yu Qin(top), Sergei Kusmartsev, PhD (bottom), Yehia Daaka, PhD with Eileen Grigson, Benjamin Canales, MD with a patient (top), Yehia Daaka, PhD, Cleaver, PhD and Zhongzhen Nie, PhD (bottom)

SERGEI KUSMARTSEV, PhD: Pathogenic Inflammation & Tumor-induced Immune Suppression

Dr. Kusmartsev's research aims to redress the shortcomings of existing cancer vaccines by examining the role of tumor-induced immune suppression in patients with advanced cancer or metastatic disease. Advanced cancers overproduce tumor-derived factors, leading to both increased inflammation and an immunosuppressive microenvironment. As a result, our studies aim to identify cancer-specific mechanisms responsible for enhanced pathogenic inflammation and tumor-induced immune suppression in patients with urologic cancers, to counter the immune response.

BENJAMIN CANALES,MD, MPH: Physiology, Molecular Biology, Genomics & Bioinformatics Related to Renal Stone Disease

Dr. Canales' work combines surgical practice in laparoscopy and kidney stone disease with research to compare protein and gene expression in renal papillae. This knowledge will provide histopathological insights into stone disease pathogenesis, particularly in the area of Randall's plaque deposits. He has recently been awarded NIH funding to explore genes important in obesity-related renal disease or nephrolithiasis that can be identified by our microarray analysis. This hypothesis could then be tested by validation of inflammatory markers and protein/gene expression patterns within RYGB stone formers. A primary goal of this research is to develop and validate an animal model that can be used for preclinical research into tissue-specific proteomics and genomics in kidney stone formers. Insights gained from his work will improve our understanding of renal stone disease and assist in the development of new treatments.






In addition to our diverse portfolio of basic and translational research, Center investigators are pursuing innovative topics in the field of clinical research. We are striving to improve the lives of patients diagnosed with prostate disease throughout the continuum of their care, from prevention to diagnosis to treatment and beyond.

LI-MING SU, MD: Improving Imaging Technologies to Yield More Accurate Diagnoses

Over the past two years, Dr. Su has focused on novel medical and optical imaging and biomedical technologies to improve tissue characterization and detection of urologic cancers, collaborating with faculty in the departments of Radiology, Biomedical Engineering, Neuroscience and Computer Science.

Prostate Cancer Imaging Working Group. Prostate cancer screening and detection has increasingly come under scrutiny especially involving overdiagnosis and overtreatment of prostate disease, partly because routine prostate biopsies of understaged cancers limit a urologist's ability to predict the true biological significance of any patient's cancer. Prostate imaging using functional MRI may have the ability to improve detection and staging of prostate cancer and our understanding of the location and true extent of cancer within the prostate gland, determining which patients are at highest risk for cancer progression versus those whose cancer is more likely to remain dormant. This technology also has significant implications with regard to use for intraoperative surgical navigation as well as the delivery of focal therapy for such as cryotherapy for prostate cancer.

Optical Imaging. Optical imaging technologies such as optical coherence tomography, confocal microscopy and optical spectroscopy are new technologies that may provide improved characterization of benign and cancerous tissues through direct contact imaging. Dr. Su, along with a team of bioengineers, is working to develop optical coherence tomography probes that one day may be useful during laparoscopic and robotic surgery to guide surgical management of kidney and prostate cancer.

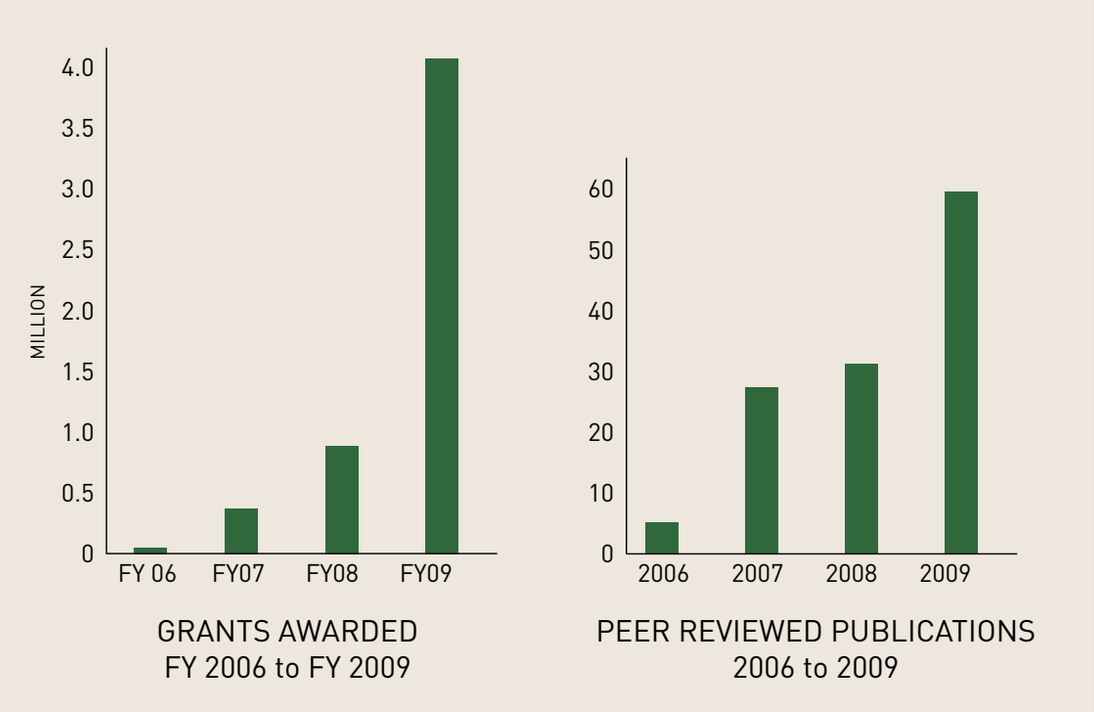
MRI Diffusion Tensor Imaging. Erectile dysfunction remains a significant side effect following radical prostatectomy for prostate cancer as a result of damage to the cavernous nerve fibers surrounding the prostate gland. Dr. Su, along with a team of neuroscientists and radiologists, are investigating the use of MRI Diffusion Tensor Imaging to image these microscopic nerve fibers in hopes of providing a "road map" of their anatomic course. A radiographic depiction of the cavernous nerves has never been performed successfully and if accomplished may prove useful for intraoperative surgical strategies when performing nerve-sparing radical prostatectomy.

SCOTT GILBERT, MD, MS: Health Services and Clinical Outcomes

Dr. Gilbert's research focuses on health services and clinical outcomes associated with urologic cancers. He has worked in health scales development and quality of life assessment following cancer treatment. Collaborating with an interdisciplinary team of health services and health economic researchers, Dr. Gilbert applies advanced analytic methods and observational study designs to measure the effectiveness of cancer-directed healthcare practices. His current research involves clinical and population studies examining variation in cancer and survivorship care among men with prostate cancer. The principal goal of this work is to better understand drivers and consequences of variation and target areas of unwarranted differences in healthcare, such as under use of effective care among men at risk for adverse outcomes.

PHILIPP DAHM, MD, MHSC: Evidence-Based Urology

Dr. Dahm's research focus lies in evidence synthesis, knowledge translation and the development of guidance documents for evidence-based clinical decision-making. He is the founder of The International Evidence Based Urology Working Group, an informal collaboration of individuals with an interest in advancing the evidence-based clinical practice of urology through education and research. Specific aims of the program include: developing, delivering and evaluating education in evidence-based clinical practice for urologists; furthering the methodological quality and transparent reporting of urological research; performing systematic reviews and cost-effectiveness analyses of diagnostics tests and therapeutic interventions in urology; and developing evidence-based resources and knowledge translation services at the point of care to optimize clinical decision-making, improve safety and reduce medical errors.



EXPONENTIAL GROWTH

In the years since the establishment of the UF Prostate Disease Center, the Center's grant portfolio has quadrupled in size and peer reviewed publications have increased more than tenfold.

The UF Prostate Disease Center: Research Facilities to Support a Demanding

In addition to its faculty, the UF Prostate Disease Center has three other key resources: the Good Manufacturing Practice Facility, the UF Prostate Disease Center Tissue Bank and the UF Prostate Disease Center Stone Bank. All three facilities enable Center researchers to engage in leading-edge research by providing resources to produce early-phase clinical trials materials and tissue specimens for research studies.

Good Manufacturing Practice Facility

The UF Cancer & Genetics Research Complex offers an environment uniquely suited to maximize collaboration among researchers across a diverse array of specializations, enabling them to convert scientific ideas into innovative therapeutic, diagnostic and preventive technologies. Among these technologies are medications and vaccines required for early-phase clinical trials. Both interventions and clinical trials require sophisticated facilities for materials production to comply with strict regulations for governing clinical trials. The GMP Facility is conveniently located on-site in the CGRC, offering 1,200 square feet of space, dedicated to biomanufacturing and 11 separate rooms.

UF Prostate Disease Center Tissue Bank

Another exceptional asset, the UF Prostate Disease Center Tissue Bank provides an on-site, dedicated facility that handles the procurement, storage, distribution and study of tissue samples vital to research. The Tissue Bank provides an invaluable centralized and shared resource to researchers by using freshly frozen tissue specimens collected from excess surgical materials and from autopsy. These tissue specimens aid in viable cell studies and provide the source for a database rich in clinical and pathological data. The Tissue Bank enables researchers to perform histological staining and pathological reviews, coordinate patient consent and ensure regulatory compliance.

UF Prostate Disease Center Stone Bank

The UF Prostate Disease Center Stone Bank was established in conjunction with the UF Prostate Disease Center to facilitate biomedical research using stones collected at Shands at UF medical center. The Stone Bank provides services for the procurement, storage, distribution and study of stones, associated blood samples and subject data. Current Stone Bank activities and services include collecting and banking blood components; maintaining a tissue database with links to clinicopathological data; performing histological staining and pathological review; and coordinating patient consent and assuring regulatory compliance. As a centralized shared resource, the Stone Bank adds value through experience, efficiency, standardization, accountability, protection of patient confidentiality and timely completion of research.

UF PROSTATE DISEASE CENTER CORE FOCUS:
RESEARCH AND PATIENT CARE

Clinical Trials of Advances in Prevention & Treatment of Prostate Disease

For some patients with advanced metastatic disease or with complications placing them at high risk, clinical trials hold out singular promise. For the rest of the population, clinical trials represent vital steps toward new therapies for the treatment and even prevention of prostate disease. Since clinical trials are one of the core foci of the UF Prostate Disease Center, Florida patients can, if eligible, enroll in one of the more than 40 investigational studies currently conducted by the UF Prostate Disease Center and its affiliated programs.

Featured Clinical Trials

The Eastern Cooperative Oncology Group sponsored ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer Study. The purpose of this study is to determine whether instituting chemotherapy when starting hormonal therapy can delay the time to progression to a clinically meaningful degree without affecting quality of life in men with extensive disease. This study is currently enrolling new subjects.

CV-9103-002 Study of RNActive®-derived therapeutic vaccine in advanced or metastatic hormone refractory prostate cancer sponsored by CureVac GmbH. CV9103 is an mRNA-based vaccine for the treatment of human prostate cancer that is based on RNActive® technology. CV9103 encodes for four prostate specific antigens (PSA, PSMA, PSCA and STEAP). Because these antigens are present in prostate cancer cells, they are appropriate targets for intervention. These antigens have been shown to correlate frequently with the progression of prostate cancer and are known to be immunogenic in humans, where they induce antigen-specific T-cell or B cell expansion. This study is currently not enrolling any new subjects.

A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients with Metastatic Castration-Resistant Prostate Cancer sponsored by Cougar Biotechnology. The purpose of this trial is to compare the clinical benefit of abiraterone acetate plus prednisone versus placebo plus prednisone in patients with chemotherapy-naïve castration-resistant prostate cancer (CRPC) who are asymptomatic or mildly symptomatic. This study is currently not enrolling any new subjects.

Clinical Trials Under Development

Prostate Disease

Phase 3 Trial in Subjects with Asymptomatic or Minimally Symptomatic Castration Resistant Metastatic Prostate Cancer. The primary objective is to test impact of treatment on progression-free survival.

Phase 3 Trial in Subjects with Metastatic Prostate Cancer on Androgen Deprivation Therapy. The primary objective is to test impact of treatment on bone mineral density.

Built in 2006, the 280,000-square-foot Cancer & Genetics Research Complex (CGRC) houses the UF Prostate Disease Center's many basic science labs. An unconventional research space, the building was designed as a module system with relatively few walls to maximize cross-fertilization of different groups.

Bladder Cancer

Phase 2 Trial in Subjects with Early Muscle Invasive Bladder Cancer. The primary objective is to test impact of treatment on recurrence-free survival.

Urinary Stone Disease

Phase 2 Trial in Subjects with Urinary Stones. The primary objective is to test impact of treatment on urinary stone passage.

Long H. Dang, MD, PhD: Leading Oncology Drug Discovery

Long H. Dang, MD, PhD, is a board-certified medical oncologist with expertise in gastrointestinal and genitourinary oncology. Currently an Associate Professor in the Division of Hematology & Oncology and Co-director of the Oncology Phase I Program, Dr. Dang received his Bachelor of Arts, Doctor of Medicine and Doctor of Philosophy from Harvard University. After Harvard, he finished his residency at the University of Pennsylvania and completed a fellowship in Medical oncology at Johns Hopkins Hospital.

Dr. Dang's research interests are in the translational and clinical development of combination therapy targeting the tumor vasculature and cancer cell survival mechanisms in the tumor microenvironment. His work focuses on the molecular events that facilitate tumor growth and translating this understanding toward the prevention and treatment of gastrointestinal and genitourinary cancers.

Using gene knockout models, he has found that targeted disruption of both the VEGF pathway and the hypoxia-inducible transcription factors (HIF-1 and HIF-2) survival pathway to be synergistic. The hypoxia-induced transcription factor HIF-1 is strongly associated with cancer cell growth and survival. HIF-1 is composed of the HIF-1alpha and HIF-1beta subunits. Whereas HIF-1beta is constitutively expressed, HIF-1alpha protein stability and synthesis are regulated by intratumoral hypoxia and genetic alterations. The HIF-1 complex transactivates hypoxia-responsive genes, including those important for two universal characteristics of solid tumors: angiogenesis and glycolysis. As such, there has been considerable clinical interest in therapeutically targeting HIF-1alpha in cancer. Dr. Dang has discovered novel HIF targets, which may be tested as predictive biomarkers and as targets for therapy. To translate these concepts, he is working with the drug discovery team to develop novel compounds using both high throughput and in silico drug screens.

UF PROSTATE DISEASE CENTER
CORE FOCUS: OUTREACH AND EDUCATION

Addressing Healthcare Disparities in Our Community

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UF Prostate Disease Center

The UF Prostate Disease Center includes a calendar filled with events aimed at improving public awareness of prostate diseases, including prostate cancer. Prostate cancer is not only the most common cancer among men in the US, but Florida ranks second nationally in prostate cancer deaths. While age and a family history of prostate cancer number among the risk factors for developing the disease, race plays perhaps the most important role. In the US, between 2001 and 2005, African-American men experienced incidence rates for prostate cancer that were nearly 60% higher than those for men of European descent. During the same period, African-American men were nearly 2.5 times more likely to die from prostate cancer than their white neighbors. These striking disparities are due less to risk factors than to socio-economic issues, issues that the UF Prostate Disease Center has committed to addressing through an aggressive campaign of education and outreach.

In response, in 2010, a particular focus was cast on reaching out to African-American men who, one UF Prostate Disease Center study revealed, lack knowledge of the signs and symptoms, risk factors and tests needed to detect prostate cancer – including even knowing whether their fathers were ever diagnosed with prostate cancer. Current and recently completed studies include an assessment of risk factors and health needs among African-American men in Florida and the development of a profile of personal factors affecting early detection of prostate cancer in African-American men in Florida, vital in forming the UF Prostate Disease Center's education and outreach efforts.

Dr. Folakemi Odedina, Director of Community Education and Outreach, understands that outreach means not merely distributing educational materials but partnering with state and community leaders, faith-based organizations, and businesses to inform, educate, and empower communities to fight against prostate disease. However, the UF Prostate Disease Center's approach to outreach is also distinguished by its focus on research that seeks to understand the causes and scope of socioeconomic disparities in prostate disease, and to also improve the efficacy of educating, diagnosing and managing the treatment of the disease.

Core Resources Dedicated to Prostate Disease

While the UF Prostate Disease Center is headquartered at the University of Florida, the Center encompasses a network of affiliated hospitals and organizations, serving the needs of Floridians statewide.

University of Florida

Florida's oldest and most comprehensive university, the University of Florida is among the nation's most academically diverse public universities. UF is also one of only 17 public, land-grant universities that belong to the Association of American Universities, an association of the 63 most prestigious universities in North America. Over the decades, UF's research awards have risen steadily to $574 million last year, placing it among the nation's leading institutions. More than $289 million of that total was for health-related research, representing a significant portion of the state's intellectual and economic commitment to biotechnology. Researchers at the Institute on Aging, the McKnight Brain Institute, the UF Genetics Institute, the UF Shands Cancer Center, and the Emerging Pathogens Institute—and throughout the six colleges of the Health Science Center—study everything from adult stem cells to gene therapy.

University of Florida Health Science Center

The UF Health Science Center is the country's only academic health center with six health-related colleges, five major health-related research centers and institutes, and Shands HealthCare, located on a single, contiguous campus. The HSC is also a world leader in interdisciplinary research, generating 52% of UF's total research awards. Five major health-related research centers and institutes are designed to create synergies and collaborative research opportunities. The HSC is closely affiliated with Shands HealthCare, with seven hospitals including the academic hospitals Shands at UF in Gainesville and Shands Jacksonville in Jacksonville, Florida.

Shands at the University of Florida

Shands at UF is the primary teaching hospital for the UF College of Medicine. More than 500 physicians representing 110 medical specialties work with a team of healthcare professionals to provide quality care for patients. The faculty from the UF College of Medicine includes nationally and internationally recognized physicians whose expertise is supported by intensive research activities. Shands' affiliation with the UF Health Science Center allows patients to benefit from the latest medical knowledge and technology as it evolves through research.

Shands Cancer Hospital at the University of Florida

All surgical services for oncology patients, from the preoperative unit to the post-anesthesia care unit, are centrally located on the second floor. Every operating room is equipped with the latest surgical technology including state-of-the-art lighting, endoscopic equipment and high-definition monitors to display X-rays, vital signs and echocardiogram results. In addition, two interventional radiology suites are located in this complex for surgical procedures requiring radiologic guidance and/or catheterization.

Winter Haven Hospital

Established in 1926, Winter Haven Hospital serves as the major medical center for east Polk and Highlands counties and the U.S. Highway 27/ Ridge Corridor. The 527-bed hospital is a locally owned and operated not-for-profit organization. The hospital is fully accredited by the Joint Commission and has more than 300 board-certified physicians on its medical staff representing every major specialty. In January 2010, the hospital was recognized by the American Nurses Credentialing Center with the prestigious designation of Magnet status, a recognition granted to only 5 percent of the nation's hospitals.

Center Leadership

Executive Director, Johannes Vieweg, MD

Johannes W. Vieweg, MD, FACS, is the Chair of the UF Department of Urology. His scientific efforts have focused on developing cell and gene-based approaches for prostate cancer and renal cell carcinomas. He has published more than 100 manuscripts or book articles in high-impact, peer-reviewed journals and has received continuous NIH funding for the past 11 years. His translational work established the foundation for several NIH-funded clinical trials he is conducting under FDA-approved, investigator-sponsored New Drug Applications.

Scientific Director, Yehia Daaka, PhD

Yehia Daaka is Professor and David A. Cofrin Chair in Urologic Oncology Research. His research career has been devoted to understanding the biological roles of G protein-coupled and steroid receptors that instruct embryonic development and continue to function in adulthood. His focus on the function of these receptors has contributed to their recognition as targets for cancer therapy, and over the last decade several anti-cancer drugs have been developed against these molecules.

Chief Operating Officer, Thomas Crawford, MBA

Thomas C. Crawford, MBA, FACHE, is a seasoned senior healthcare executive and former Chief Executive Officer of Springfield Medical Care Systems and Chief Operating Officer of Springfield Hospital. He currently serves as a faculty member in the Department of Urology. Tom has extensive experience working with physician networks, hospitals, medical centers and strategic alliances.

Director of Community Education & Outreach, Folakemi Odedina, PhD

Folakemi Odedina oversees the development of a research program focusing on the socio-behavioral predictors of health disparities and cost-effective, community-based behavioral interventions to improve the health of minorities and all populations. She has directed more than 20 research projects, including the FAMU Center for Minority Prostate Cancer Training and Research, composed of a trans-disciplinary team of clinical, behavioral and basic scientists.

Director of Core Programs, Brian Cleaver, PhD

Brian Cleaver, PhD, joined the University of Florida in 2002. Prior to that, he spent six years as Chief Scientific Officer for a private biotechnology company developing biopharmaceutical products and associated diagnostic assays. In his current role, Dr. Cleaver directs operations of the Phase I/II biopharmaceutical productions and provides Quality/Regulatory oversight and supervision of the Center's clinical trial program.

Clinical Faculty

Chester Algood, MD	Clinical Assistant Professor, Medical Director – Urology Clinic
Michael Binder, MD	Assistant Clinical Professor, Urology Attending – Malcom Randall VA Hospital
Vincent G. Bird, MD	Associate Professor
Benjamin Canales, MD, MPH	Assistant Professor
Marc Cohen, MD	Professor, Director – Urology Residency Program
Philipp Dahm, MD, MHSc	Associate Professor, Director of Clinical Research, Co-Director – Urology Residency Program
Scott Gilbert, MD, MS	Assistant Professor, Medical Director – Urology Quality and Safety Program, Director – Urologic Cancer Center at Shands at UF
Louis Moy, MD	Assistant Professor, Director – Female Urology & Pelvic Reconstructive Surgery
Robert Newman, MD	Professor Emeritus
Sijo Parekattil, MD	Assistant Professor, Director – Male Infertility & Microsurgery, Co-Director – Robotic & Minimally-Invasive Urologic Surgery
Li-Ming Su, MD	Professor, David A. Cofrin Chair of Endourology, Associate Chair of Clinical Affairs, Chief – Division of Robotic & Minimally-Invasive Urologic Surgery
Ahmad Vafa, MD	Clinical Assistant Professor, Urology Attending – Malcom Randall VA Hospital
Johannes Vieweg, MD, FACS	Professor & Chairman, Wayne & Marti Huizenga Eminent Scholar Chair
Zev Wajsman, MD, FACS	Adjunct Professor Emeritus

Research Faculty

Brian Cleaver, PhD	Assistant Professor, Director – Core Programs, Genitourinary Cancer Immunotherapy
Yehia Daaka, PhD, MS	Professor, David A. Cofrin Chair in Urologic Research, Vice Chair – Research
Sergei Kusmartsev, PhD	Assistant Professor
Zhongzhen Nie, PhD	Assistant Professor
Folakemi Odedina, PhD	Professor, UF College of Pharmacy

Affiliated Faculty

Mark Barraza, MD	Pediatric Urologist, Nemours Children's Clinic, Jacksonville, FL
Long Dang, MD, PhD	Associate Professor, UF Department of Medicine, Division of Hematology/Oncology, Co-Director – Oncology Phase I Program
Martin Dineen, MD	Courtesy Professor, UF Department of Urology, Urologist, Atlantic Urology Practice, Daytona Beach, FL
Michael Erhard, MD	Pediatric Urologist, Nemours Children's Clinic, Jacksonville, FL
Mark Gold, MD	Joint Eminent Scholar & Distinguished Professor, UF Department of Urology, Chair – UF Dept of Psychiatry
Saeed Khan, MD	Affiliated Professor, UF Department of Urology, Professor, UF Department of Pathology
Erica Mercer, MD	Pediatric Urologist, Nemours Children's Clinic, Jacksonville, FL
James Mule, MD, PhD	Courtesy Professor, UF Department of Urology, Associate Director – Moffitt Cancer Center & Research Institute, Tampa, FL
David Paulson, MD	Courtesy Professor, UF Department of Urology, Urologist, Duke University Hospital, Durham, NC
Dietmar Siemann, PhD	Professor & Associate Chair for Research, UF Department of Radiation Oncology, Leader – Experimental Therapeutics Program, UF Shands Cancer Center
Bruce Stechmiller, MD	Clinical Associate Professor, UF Department of Medicine, Division of Hematology/Oncology
Tom Stringer, MD	Courtesy Clinical Assistant Professor, UF Department of Urology, Urologist, Citrus Urology Associates, Inverness, FL
Robert Zlotecki, MD	Joint Associate Professor, UF Departments of Urology & Radiation Oncology

Selected Publications

Yehia Daaka, PhD

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Philipp Dahm, MD, MHSc

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Scott Gilbert, MD, MS

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Johannes Vieweg, MD

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PROSTATE DISEASE CENTER

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