

ADVANCES IN UROLOGY



James M. McKiernan, MD
Urologist-in-Chief
NewYork-Presbyterian/
Columbia University Medical Center
jmm23@cumc.columbia.edu

Peter N. Schlegel, MD
Urologist-in-Chief
NewYork-Presbyterian/
Weill Cornell Medical Center
pnschleg@med.cornell.edu

INSIDE THIS ISSUE

5 A Focus on Faculty
Tanaka J. Dune, MD
Timothy D. McClure, MD

6 SPORE Grant Awarded in Prostate Cancer

AMAZING ADVANCES IN RESEARCH, TECHNOLOGY, AND PATIENT CARE

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NewYork-Presbyterian Urology ranks #8 in the nation.

A Dedicated Team Focuses on Urinary Disorders

Each year, a team of specialists in the Department of Urology at NewYork-Presbyterian/Columbia University Medical Center diagnoses and treats more than 6,000 patients with urinary disorders. Using the latest diagnostic testing and technology available, these urologists – **Matthew P. Rutman, MD, Kimberly L. Cooper, MD, Doreen E. Chung, MD, and Gina M. Badalato, MD** – provide expertise in nonoperative, minimally invasive, and reconstructive procedures. They bring their combined skills and experience in a range of treatment options for urinary disorders, including voiding dysfunction and urinary tract infection. At the same time, they are pursuing clinical research – individually and collectively – in a number of areas critical to improving treatment outcomes.

As Director of the Center for Voiding Dysfunction and Female Urology, **Dr. Matthew Rutman** treats both men and women with voiding disorders. “Many patients can be managed successfully with medical therapy, as well as behavioral and dietary changes,” says Dr. Rutman, who is skilled in reconstructive surgery for vaginal prolapse, urethral diverticulum,

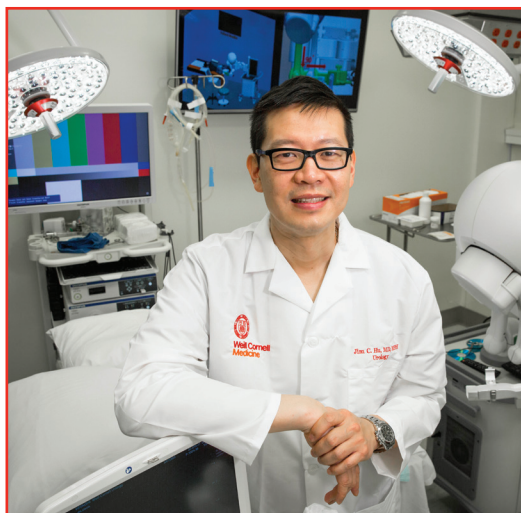


Dr. Matthew P. Rutman

and vesico-vaginal fistulae. “For those who do require surgery, we offer a variety of techniques depending on the complexity of the problem. These include minimally invasive procedures, such as robotic, vaginal, or transurethral surgery, which can be performed on an outpatient basis and can result in quicker recovery times.”

(continued on page 2)

Prostate Cancer: Perspectives on Therapeutic Advances



Dr. Jim C. Hu

“The advent of robotically assisted and minimally invasive surgical practices, along with newer imaging approaches, has dramatically transformed treatment options for patients with prostate cancer,” says **Jim C. Hu, MD, MPH**, Director of The Lefrak Center for Robotic Surgery at NewYork-Presbyterian/Weill Cornell Medical Center. A urologic oncologist and one of the world’s leading experts in robotic surgery, Dr. Hu has performed thousands of robot-assisted surgeries for urologic cancers and benign disease and has developed many technical modifications and refinements to the procedures that effectively safeguard surrounding tissues and nerves during the surgery. Dr. Hu also pursues important work in new technology-enabled approaches that include partial gland or focal prostate cancer treatment and cryotherapy.

(continued on page 3)

A Dedicated Team Focuses on Urinary Disorders *(continued from page 1)*

The Columbia team relies on selective use of ancillary testing that includes urodynamics, cystourethroscopy, and residual urine volume measurements, in combination with a thorough history and physical, to counsel patients and help predict success of surgical outcomes. “In the past, the treatments we had for refractory overactive bladder, for example, left a lot to be desired,” says Dr. Rutman. “They involved significant procedures with hospital stays and difficult convalescence. There were also risks from surgery, as well as significant side effects of medication. But great progress has been made.”

Newer modalities include InterStim®, an option when conventional treatments, such as medications, pelvic exercises, or bladder retraining, have failed to help. InterStim involves implanting a device that delivers electrical impulses to the sacral nerve. “InterStim has been FDA approved for 20 years, but a number of advances have made it even more successful, including its smaller size and lighter weight,” says Dr. Rutman. “Essentially, it is a bladder pacemaker that modulates the bladder voiding reflex arc and can be used for an overactive or an underactive bladder.”

Percutaneous tibial nerve stimulation is the least invasive form of neuromodulation used to treat overactive bladder and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence. “We offer a newer version of percutaneous tibial nerve stimulation that has worked very effectively,” says Dr. Rutman. “We place an acupuncture needle just above the ankle and are able to effect the same response that InterStim elicits. The half-hour procedure, which can be performed in the office, is done once a week for 12 weeks. It is not a cure, but oftentimes we can achieve at least 50 percent improvement in a patient’s symptoms.”

Dr. Doreen Chung specializes in voiding dysfunction, male and female urinary incontinence, neurogenic bladder, and female pelvic medicine and reconstructive surgery for pelvic floor disorders. She performs vaginal, robotic, and open surgery as appropriate. Dr. Chung has a particular interest in complex voiding dysfunction and reconstruction. A significant number of Dr. Chung’s patients with neurogenic bladder have spinal cord injuries or multiple sclerosis.

Recent publications and areas of research have focused on outcomes of different urological reconstructive surgical procedures. Dr. Chung looked at the safety of mesh in vaginal cystocele repair and found that mesh use was associated with an increased risk of complications. “While there is an increased risk of complications with transvaginal mesh repairs in all patients, benefits have to be weighed against risks because in certain patients with limited surgical options a mesh repair may still be the safest and most effective repair for a particular patient,” says Dr. Chung. For another

project Dr. Chung looked at a large contemporary series of patients who underwent vesicovaginal fistula repairs. She found that luckily vesicovaginal fistulas are relatively rare in North America and that fistula repair is very safe and effective with vaginal repairs being associated with fewer complications than abdominal repairs.

A Special Interest in Urinary Tract Infections

Dr. Kimberly Cooper is Co-Director of the Voiding Dysfunction, Incontinence, and Urodynamic Center. Dr. Cooper has a particular interest in urinary tract infections with a specific focus on preventing and minimizing the use of unnecessary antibiotics. “In many cases, patients are prescribed either the wrong antibiotics or too lengthy a course,” notes Dr. Cooper. “Many patients can have symptoms that mimic a UTI, but they may not actually be bacterial related. These patients should not be treated with antibiotics.”



Dr. Kimberly L. Cooper

Dr. Cooper notes that patients often are treated presumptively over the phone and prescribed a course of antibiotics. She requires that her patients submit a urine sample for testing before starting an antibiotic. “We are trying to cut down on unnecessary antibiotic prescriptions because they have sequelae at both the individual patient level, in terms of potential side effects, and at the society level. All of these prescribed antibiotics contribute to increasing antimicrobial resistance.”

A recent study conducted by Drs. Cooper, Rutman, Chung, and Badalato looked at the utility of collecting catheterized specimens in a subset of women with vague urinary symptoms. “The majority of our cohort had false positive voided specimens, and if we had not obtained catheterized samples they would have received unnecessary antibiotics,” says Dr. Cooper. “When female patients present with vague voiding symptoms and positive voided urine cultures, catheterized specimens should be considered, especially when patients have unimpressive urinalyses.”

Seeking to bring awareness to the overuse of antibiotics for UTIs, Dr. Cooper recently surveyed practitioners in the Tri-state region, as well as in Tennessee through her collaboration with colleagues at Vanderbilt University. “Published infectious disease guidelines on managing patients who have bacteria in their urine have been available for years, but are not widely adhered to,” notes Dr. Cooper. “Our survey results demonstrate lack of awareness and observance of these guidelines. We also want to promote that the most narrow-spectrum antibiotics should be used. Broad-spectrum antibiotics tend to contribute more to resistance. In fact, in May 2016 the FDA issued a warning specifically saying that Cipro and Levaquin should not be used for the management of acute UTIs because of the risk of serious side effects. Unfortunately, this information is not widely known among providers.”

(continued on page 4)

Prostate Cancer: Perspectives on Therapeutic Advances (continued from page 1)

As Director of The Lefrak Center, Dr. Hu spearheads clinical and research initiatives in urologic oncology and collaborates with colleagues in Weill Cornell Medicine's Sandra and Edward Meyer Cancer Center. "My goal is to advance treatments with the intention of decreasing morbidity and improving the effectiveness of cancer control," says Dr. Hu. "Our research needs to look critically at why we do the things we do and whether or not it actually makes a difference in outcomes."

Emerging Role of Partial Gland Ablation

"The perception that prostate cancer is overdiagnosed and over-treated remains," notes Dr. Hu. "That is probably why PSA testing continues to be enveloped in controversy, but also why focal therapy is becoming more widely accepted to treat localized prostate cancer. High intensity focused ultrasound (HIFU) and cryotherapy enable us to preserve noncancerous prostate tissue and minimize damage to surrounding healthy tissue or organs, providing the potential for better functional outcomes."

HIFU for the treatment of prostate cancer is in its early stages of use in the U.S. The approach uses an ultrasound-guided transducer to ablate the cancerous tissue. The method is radiation-free and offers significantly lower risk of side effects than radiation therapy.

Prior to November 2015, HIFU was not FDA approved in this country for focal therapy. "American men who wanted to undergo the procedure would need to travel to Mexico, Canada, or Europe, where these devices were readily available," says Dr. Hu.

In 2015, the FDA approved HIFU for the ablation of prostate gland tissue, but not for a prostate cancer indication, citing there was not enough long-term evidence for efficacy or patient benefit. In fact, a review of studies undertaken by Dr. Hu and colleagues in the field supports this concern.

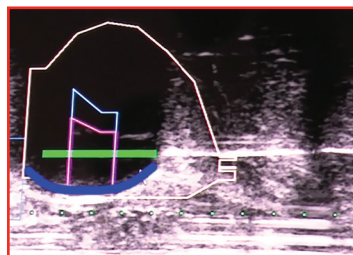
"In the review paper we looked at all of the publications that reference HIFU," notes Dr. Hu. "There were only 12 papers from a handful of international centers that have been using the procedure." The investigators reported that early evidence suggests that partial gland ablation is a safe treatment option for men with localized disease. However, longer-term studies are needed to evaluate its efficacy and functional outcomes, to be able to identify optimal candidates for this therapy, and to provide data that will allow for better comparison between studies and among treatment modalities.

Dr. Hu sees HIFU as a potentially promising therapy and offers the procedure to patients in his practice. "Some men may find value in undergoing HIFU to focally treat areas of prostate cancer and delay surgical or whole-gland irradiation, which have greater risks of erectile dysfunction and urinary incontinence," says Dr. Hu. "Additionally, men diagnosed with slow-growing cancers may find that HIFU is an ideal treatment to alleviate significant distress and anxiety that often accompany a prostate cancer diagnosis. We want to make sure that we are using new technology such as high-intensity focused ultrasound responsibly, and cataloging the outcomes to make sure they are justifiable in the long term."

An alternative to HIFU for focal therapy is cryotherapy, which destroys the cancerous tissue by freezing the cells. Dr. Hu performed the first in-office MRI-ultrasound fusion-guided cryotherapy in New York City and the Northeast.

"Building upon the technology that allows more accurate detection of prostate cancer during biopsy, we use cryotherapy to destroy areas

of biopsy-identified prostate cancer with MRI guidance," says Dr. Hu. "Additionally, we can do this procedure in the office. Patients come in for a 45-minute treatment – no anesthesia is needed – then leave the office and go about their day. This will be a transformative approach for prostate cancer treatment. A benefit compared to HIFU is the real-time monitoring of the area that is being thermally ablated and no limitation in terms of the prostate size. Larger size prostates prohibit the use of HIFU." Dr. Hu is currently leading an effort with the FDA to implement a registry to enable more in-depth study of prostate ablation.



MRI-ultrasound fusion-guided cryotherapy shows the cryotherapy needle (horizontal white line) as it is advanced into the region with cancer. The prostate is outlined in a thin white line; the lesion is outlined in pink. The blue line represents the edge of the ice ball that is monitored under real-time ultrasound.
Courtesy of Dr. Jim C. Hu.

Robotic Approaches in Prostate Cancer: Tried and True

When Dr. Hu began using robotic technology for the treatment of prostate cancer and other urologic cancers more than a decade ago, less than 10 percent of surgeries for all prostate cancer were being done robotically. As one of the highest volume surgeons in the field at the time, it afforded Dr. Hu the opportunity to explore the technology's value and ultimate role in depth. Dr. Hu's work was published in a series of articles, *Surgery in Motion*, in *European Urology*. The articles focus on technique and outcomes in robotic-assisted surgeries, and each article is linked to a video of the procedure that records and corroborates for physicians and patients the development of robotic surgery's efficacy when applied to prostate cancers.

Dr. Hu's published research has consistently furthered the development of robotic surgery, from a study published in 2008 in the *Journal of Endourology* on a technique for sparing the neurovascular bundle and consequently a patient's sexual function, followed by several articles on bladder neck preservation during robotic-assisted laparoscopic radical prostatectomy, and including, most recently, a study published in the *Journal of Urology* in January 2017 that compares cancer control and survival after robot-assisted to open radical prostatectomy. Today 80 to 90 percent of surgeries for prostate cancer involve robotics.

"I want to convey that we need to be experts in all treatments for prostate cancer, and not let our biases or focused expertise with one treatment dictate what patients should receive," says Dr. Hu. "In order to provide personalized care, I believe we need different tools to suit each man's preferences and disease characteristics. These run the gamut from active surveillance and focal therapy to radical prostatectomy."

PSA Testing: Its Relevance is Returning

Dr. Hu also has been at the vanguard of empirically examining and confronting controversies that seem to attend advances in the diagnosis of prostate cancer – most notably PSA testing. "In 2008, our field changed dramatically when the U.S. Preventive Services Task Force put forth their recommendation against PSA testing," notes Dr. Hu. "This reduced the amount of PSA testing, increased

(continued on page 4)

A Dedicated Team Focuses on Urinary Disorders (continued from page 2)

Dr. Gina Badalato, the newest member of the team, specializes in male and female voiding dysfunction, and stone disease. “There are several medical concerns for someone who continues to have urinary tract infections or blood in the urine,” she says. “Is it renal disease or a structural problem? Why is this person

regularly forming kidney stones? What’s going on metabolically? We have focused diagnostic tools to tease out what’s going on and guide our recommendations for intervention. We can get very specific answers to these problems and also have a host of medications and procedures that we can offer our patients.”



Dr. Gina M. Badalato

For More Information

Dr. Gina M. Badalato • gmb2107@cumc.columbia.edu
Dr. Doreen E. Chung • dec2154@cumc.columbia.edu

Dr. Kimberly L. Cooper • klc11@cumc.columbia.edu
Dr. Matthew P. Rutman • mr2423@cumc.columbia.edu

Prostate Cancer: Perspectives on Therapeutic Advances (continued from page 3)

active surveillance, and led to greater uptake and demand for MRI-guided biopsy to make sure we accurately sample the prostate to differentiate men who have low-risk cancers that need active surveillance versus those who had more aggressive cancers needing surgical therapy. With the introduction of fusion technologies, MRI-guided biopsy has really taken off. We now have the ability to fuse MRI images onto an ultrasound, superimposing the areas that are abnormal.”

However, the relevance of screening for PSA remained in question and to assess the effect of the Task Force recommendations, Dr. Hu and his colleagues examined data from the Surveillance, Epidemiology, and End Results Program, a National Cancer Institute database. They found that the decline in PSA screening has significantly altered the way prostate cancer now presents: 12 percent of men over 75 were diagnosed with metastatic prostate cancer in 2013, compared with 7.8 percent in 2011. And the proportion of men diagnosed with aggressive cancer increased from 68.9 percent to 72 percent over the same period. The results were published in the May 2017 issue of *JAMA Oncology*.

“Our study was the first to demonstrate that the incidence of metastatic prostate cancer in older men is rising after reaching an all-time low in 2011,” says Dr. Hu. “The findings suggest a correlation between the increase and the change in prostate cancer screening guidelines recommending against routine PSA testing.”

“It’s what most of us would have predicted, although somewhat sooner,” continues Dr. Hu. “Currently, up to 50 percent of Americans diagnosed with prostate cancer choose active surveillance; however, the implication of our study is that it is important to have the right to choose screening in order to identify whether a patient may have an aggressive or indolent prostate cancer. While in men under 75, there was no change in the rate of prostate cancer metastases, this does not necessarily rule out the value of screening in younger men. The Task Force recommendation came later for younger men. So we might need to watch them over time to see if the data for this population parallels with older men.”

Their study came on the heels of studies published by Dr. Hu and his team in *The New England Journal of Medicine* in 2016 that showed one of the large, randomized trials that stated PSA testing did not decrease the risk of prostate cancer was flawed.

In April 2017, the U.S. Preventive Services Task Force updated its position on PSA screening, issuing a draft of a revised recommendation statement that advises that clinicians discuss with their patients the potential benefits and harms of PSA-based screening for prostate cancer in men ages 55 to 69 years and that the decision whether to be screened should be an individual one. Final recommendations by the Task Force are pending based on their review of public comments to the draft.

Reference Articles

Hu JC, Nguyen P, Mao J, Halpern J, Shoag J, Wright JD, Sedrakyan A. Increase in prostate cancer distant metastases at diagnosis in the United States. *JAMA Oncology*. 2017 May 1;3(5):705-07.

Golan R, Bernstein AN, McClure TD, Sedrakyan A, Patel NA, Parekh DJ, Marks LS, Hu JC. Partial gland treatment of prostate cancer using high-intensity focused ultrasound in the primary and salvage settings: A systematic review. *The Journal of Urology*. 2017 Apr 19. [Epub ahead of print]

McClure TD, Margolis DJ, Hu JC. Partial gland ablation in the management of prostate cancer: A review. *Current Opinion in Urology*. 2017 Mar;27(2):156-60.

Halpern JA, Shoag JE, Artis AS, Ballman KV, Sedrakyan A, Hershman DL, Wright JD, Shih YC, Hu JC. National trends in prostate biopsy and radical prostatectomy volumes following the US Preventive Services Task Force Guidelines Against Prostate-Specific Antigen Screening. *JAMA Surgery*. 2017 Feb 1;152(2):192-98.

Hu JC, O'Malley P, Chughtai B, Isaacs A, Mao J, Wright JD, Hershman D, Sedrakyan A. Comparative effectiveness of cancer control and survival after robot-assisted versus open radical prostatectomy. *The Journal of Urology*. 2017 Jan;197(1):115-21.

Shoag JE, Mittal S, Hu JC. More on reevaluating PSA testing rates in the PLCO Trial. *The New England Journal of Medicine*. 2016 Oct 13;375(15):1500-01.

Hu JC, Laviana A, Sedrakyan A. High-intensity focused ultrasound for prostate cancer: Novelty or innovation? *JAMA*. 2016 Jun 28;315(24):2659-60.

Shoag JE, Mittal S, Hu JC. Reevaluating PSA testing rates in the PLCO Trial. *The New England Journal of Medicine*. 2016 May 5;374(18):1795-96.

For More Information

Dr. Jim C. Hu • jch9011@med.cornell.edu

A Focus on Faculty: Highlighting a Range of Expertise

Tanaka J. Dune, MD

Originally from Zimbabwe, **Tanaka J. Dune, MD**, moved to Canada with her family. As she considered her future, she was certain it would lie in some branch of medicine. “At Queens University in Ontario I received a degree in life sciences and it was there I made the decision to become a physician,” says Dr. Dune, a urogynecologist at the Center for Female Pelvic Health in the Department of Urology at NewYork-Presbyterian/Weill Cornell Medical Center.

Dr. Dune applied to medical schools in the United Kingdom, Canada, and the United States. “All were excellent schools, but I remember thinking there’s something different about the U.S.,” she says. “I can go anywhere and do anything if I do my training there.”

Accepted at Wake Forest University School of Medicine, Dr. Dune then completed an internship at St. Luke’s-Roosevelt Hospital Center, where she learned about the relatively new subspecialty of urogynecology. “I knew this was the field I was meant to pursue. I was already interested in women’s health and have always wanted to be on the cusp of something new and different.”

After competing a residency in Obstetrics and Gynecology at Northwestern University in Chicago, she went on to a fellowship in female pelvic medicine and reconstructive surgery at Loyola University Medical Center. Today Dr. Dune sees patients for the evaluation and treatment of a wide variety of pelvic floor disorders and urogynecologic conditions, including urinary incontinence,



pelvic organ prolapse, frequent urinary tract infections, fistulas, complications of vaginal mesh or slings requiring mesh removal, as well as complex gynecologic conditions.

“One of the biggest advances in the last 20 years has been the advent of the transvaginal tape sling in treating stress urinary incontinence,” says Dr. Dune. “Other new techniques for example, InterStim®, a neuromodulator for urgency incontinence, has also made a big difference in patients’ quality of life.”

According to Dr. Dune, collaboration with other specialties is critical in caring for all of the healthcare needs of her patients. “I believe in treating the whole woman,” she says. “I’m also very interested in holistic approaches, including acupuncture, and working with pelvic floor physical therapists. There are other ways to treat patients without directly going to surgery and I respect those.”

As an obstetrician and gynecologist with additional training in urogynecology, Dr. Dune appreciates the blending of specialties that has allowed her to address many issues affecting women. “I have never been afraid of pushing boundaries and going to that next step, especially if it benefits women.”

For More Information

Dr. Tanaka J. Dune • tjd9004@med.cornell.edu

Timothy D. McClure, MD

A dually trained urologist and interventional radiologist, **Timothy D. McClure, MD**, brings a unique combination of expertise to the Departments of Urology and Radiology at NewYork-Presbyterian/Weill Cornell Medical Center, where he is leading the development of the Urology Department’s Image-Guided Therapy Program. “Our goal is to build a program of clinical studies investigating focal therapies such as high-intensity focused ultrasound and/or cryoblation in the management of prostate and kidney cancer,” says Dr. McClure, a member of The LeFrak Center for Robotic Surgery and the Center for Prostate Cancer Imaging, Diagnosis and Focused Therapy. “I think the future holds a role for focal therapy which may minimize the risk of side effects previously associated with surgery or radiation therapy for urological cancers. This is a promising area of growth within urology and interventional radiology.”

Dr. McClure is currently involved in a number of studies, including a multicenter clinical trial evaluating MR-guided focused ultrasound in the treatment of intermediate risk, localized prostate cancer; a prospective study of focal therapy outcomes in prostate cancer; and the application of ablation to kidney



cancers. In addition, he is working with Weill Cornell colleagues on the application of newer imaging and biopsy techniques to facilitate diagnosis and guide treatment, such as fusion biopsy for prostate cancer and kidney biopsy for the detection of kidney cancer.

Dr. McClure also provides expertise in minimally invasive approaches to kidney cancer, applying similar algorithms as are used in prostate cancer, from active surveillance, biopsy, or ablation. “Oftentimes patients present with a renal mass or a renal mass that is in a position such that if you were to proceed with surgery the patient might lose the kidney,” notes Dr. McClure. “Rather than immediately going to surgery, we will do a biopsy to determine the pathology of the renal mass. This knowledge allows us to make informed treatment plans which frequently change management as there is an ~20 percent chance that the tumor is benign and surgery can be avoided.”

For More Information

Dr. Timothy D. McClure • tim9047@med.cornell.edu

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NewYork-Presbyterian Hospital
525 East 68th Street
New York, NY 10065

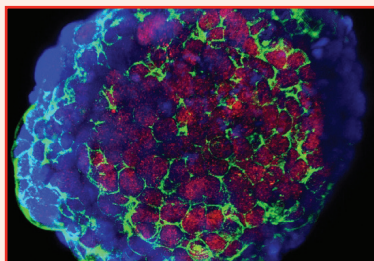
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Weill Cornell Medicine Awarded SPORC Grant in Prostate Cancer

Weill Cornell Medicine has been awarded a five-year, \$11.3 million Specialized Programs of Research Excellence (SPORC) grant from the National Cancer Institute to improve the detection, diagnosis, and treatment of prostate cancer.

Established in 1992, SPORC grants serve as the cornerstone of the NCI's efforts to promote collaborative, interdisciplinary translational cancer research. This SPORC grant is the first ever awarded to Weill Cornell Medicine and will expand an already vibrant prostate cancer basic and translational research program at the institution's Sandra and Edward Meyer Cancer Center and



Neuroendocrine prostate cancer cells from a patient biopsy. Courtesy of Dr. Loredana Puca.

Caryl and Israel Englander Institute for Precision Medicine.

"This prestigious grant will enable us to enhance our innovative, translational research into prostate cancer and inspire new collaborations as we work together to find a cure for this disease," says **Augustine M.K. Choi, MD**, the Stephen and Suzanne Weiss Dean of Weill Cornell Medicine. "The team of SPORC investigators is exceptional and its groundbreaking work will undoubtedly advance our mission of scientific discovery and patient care, reinforcing Weill Cornell Medicine's reputation as a leader in research."