



# Yale Center for Clinical Investigation

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Photo: Robert Lisak

## A NEW ERA FOR YCCI AND THE CTSA

*Innovation, Transformation, and Cutting-edge Science to Improve Health*

The retirement of Robert “Bob” S. Sherwin, MD, the inaugural director of YCCI, is truly the end of an era, not only for YCCI but also for the School of Medicine and the wider Yale community. Retiring on December 31, 2018, after 44 years of service, Bob oversaw a period of remarkable growth for clinical and translational research at Yale; first as director of the General Clinical Research Center; then answering the call of the 2004 strategic planning process to lead YCCI; and finally as associate dean for clinical and translational research at the School of Medicine.

“We owe Bob and his family so much. He has given Yale School of Medicine almost a half a century of dedication. He has been an incredible mentor, scientist, clinician, and leader. Although he will be missed, I am so proud of all we have accomplished. Bob and I have worked with the chairs, Yale Medicine, and Yale New Haven Health System to truly transform the face of clinical research at Yale,” said Robert J. Alpern, MD, dean and Ensign Professor of Medicine.

### Sherwin compiled an impressive record of accomplishments:

- Yale became one of the first 12 CTSA in 2006 and then the only funded CTSA in New England (funding was renewed for 5-year periods in 2011 and 2016)
- 137 YCCI Scholars
- OnCore/Epic integration
- Growth of industry work
- Development of the Cultural Ambassador Program

### The Next Chapter...

“The challenge of replacing Bob while preparing YCCI for the future was no small task. Our *continued on next page*”

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## SPECIAL ROBERT S. SHERWIN, MD TRIBUTE ISSUE

Written by: Jill Max and Jeanna Lucci-Canapari

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## A NEW ERA FOR YCCI AND THE CTSA continued from page 1

Executive Committee spent a lot of time speaking to the External Scientific Advisory Board and looking at leadership models around the country,” said Alpern.

Given the massive centralization of institutional responsibilities at YCCI and the broad nature of the CTSA, the YCCI Executive Committee, which includes the deans of the Schools of Medicine, Nursing, and Public Health as well as the executive leadership of both Yale Medicine and Yale New Haven Health, determined that the best strategy was to convert the Yale CTSA to a multi-PI structure. Although this transition came as part of Sherwin’s leave coverage, this change was planned to be introduced in the next Yale CTSA renewal application, as Yale has been reviewing this strategy for some time. It has been successfully implemented at many other CTSA institutions

to enable the operationalization of innovations and transformational visions. After an extensive search, the committee selected Brian Smith, MD, and John Krystal, MD, as the new leaders of the program.

“As rewarding as it has been to oversee this transformation with Bob, I believe what we have done is lay an unbelievable foundation for us to continue to grow and build on. Converting the CTSA to a multi-PI model and recruiting Brian and John to be the next leaders will enable us to continue building for the future,” said Alpern.

### Planning the future

Smith and Krystal were selected on the basis of their achievements and because they have been among the most active clinical chairs and researchers engaged in the CTSA, including assisting Sherwin continued on page 4

## MEET THE NEW LEADERS: BRIAN SMITH, MD, AND JOHN KRystal, MD

*Cutting-edge Scientists and Dedicated Mentors*

### Brian Smith, MD

Brian Smith, MD, deputy dean for scientific affairs (clinical departments) at the Yale School of Medicine, professor and chair of the Department of Laboratory Medicine, with a secondary appointment in the Yale Faculty of Arts and Sciences (Biomedical Engineering), assumed the formal directorship of YCCI on January 1, 2019. Unofficially, however, he took on the leadership after becoming deputy dean. The transition to center director comes after more than 20 years in a number of leadership roles at the School of Medicine and within the health system. He has major administrative responsibility for the school’s research enterprise across the T1–T4 spectrum, as well as educational responsibilities along the scientific pipeline from Laboratory Medicine’s STEM high school student program through undergraduate, graduate, and postgraduate training for MDs, PhDs, and MD/PhDs. He is the initiator and longstanding PI of Laboratory Medicine’s postdoctoral T32 training program in Immunohematology. Continuously funded for over 35 years with nearly 30 years as an NIH R01 PI, Smith has personally mentored over 40 MD, MD/PhD, and PhD trainees who currently hold tenure-track positions at Harvard, Yale, the University of Washington, Rutgers, Duke, Cornell, Dartmouth, St. Jude’s Children’s Research Hospital, MD Anderson Cancer Center, and many other institutions.

Further, Smith’s own research has spanned the basic and clinical fields. He has established in vitro model systems and has also conducted clinical trials. In sum, he has extensive experience in training researchers; in the establishment of core research facilities; and in investigation of the interface between inflammation and coagulation in cardiovascular disease.

Smith completed his BA in chemistry at Princeton University, where he audited a course in biological engineering that inspired him go to medical school. In fact, his first foray into research took place at that time, when he got involved in a community survey on hypertension. He received his medical degree from Harvard Medical School. “During medical school, I was amazed and humbled by the privilege doctors are given by patients in allowing us to enter their lives,” Smith said. “It is an awesome responsibility — and part of that is to make sure that patients are getting the best possible care, which means that where appropriate, they should be given the opportunity to consider research options, as well as standard treatments.”

Smith completed his residency and fellowship training at Brigham and Women’s Hospital, Boston Children’s Hospital, and the Dana Farber Cancer Institute, where he began to focus on bone marrow transplantation. In 1989, Smith arrived at the Yale School of Medicine as assistant professor of laboratory medicine, internal medicine, and pediatrics. He was promoted to associate professor in 1993 and professor in 1996. He was appointed chair of the department in 2006 after serving as vice chair for several years. Smith is board-certified in Pathology/Hematopathology and in Internal Medicine/Hematology-Oncology. Smith practices in the areas of Hematology and Hematopathology consultation. He has received a number of awards for his work, including being named a Stohlman Scholar of the Leukemia & Lymphoma Society and receiving the Evans Award for Outstanding Contributions to Laboratory Medicine from the Academy of Clinical Laboratory Physicians and Scientists (ACLPS).

Smith plays a significant role within Yale Medicine, the school’s clinical practice, and the health system. His department is responsible for the clinical laboratories at all the major facilities as well as several satellite facilities, and has patient service centers located throughout the Greater New Haven area. Performing over eight million tests per year at its various sites, the department provides high-technology reference testing (genomics, proteomics, metabolomics, and cellular assays) to other institutions throughout New England and as far away as Puerto Rico.

*“When I was approached about leading YCCI, I was excited about continuing Bob Sherwin’s wonderful legacy. I am enthusiastic about our future. We will continue to enhance research capabilities within Epic; nurture international collaborations with University College London and the University of Trondheim in Norway; collaborate with the FDA and the Cultural Ambassadors to increase minority participation in clinical trials; and train the next generation of clinician-scientists.”*

Brian Smith, MD

Professor of Laboratory Medicine, of Biomedical Engineering, of Medicine (Hematology) and of Pediatrics; Deputy Dean for Scientific Affairs (Clinical Departments); Chair, Department of Laboratory Medicine

### John Krystal, MD

John Krystal, MD, is the Robert L. McNeil, Jr. Professor of Translational Research; professor of psychiatry, neuroscience, and psychology; chair of the Department of Psychiatry at Yale School of Medicine; and chief of psychiatry and behavioral health at Yale New Haven Hospital. He joins Smith as the co-PI of the Yale CTSA. Krystal, who has been at Yale for approximately 40 years, is the ideal candidate to serve as the permanent co-PI, joining Smith to lead the Yale program. He is a graduate of the University of Chicago, the Yale School of Medicine, and the Yale psychiatry residency training program. He has published extensively on the neurobiology and treatment of schizophrenia, alcoholism, PTSD, and depression, and made the notable discovery of the rapid antidepressant effects of ketamine in humans. He is the director of the NIAAA Center for the Translational Neuroscience of Alcoholism and the Clinical Neuroscience Division of the VA National Center for PTSD. Krystal is also a member of the U.S. National Academy of Medicine. He is also a current member of the NIMH National Mental Health Advisory Council; co-director of the Neuroscience Forum of the U.S. National Academies of Sciences, Engineering, and Medicine; and editor of *Biological Psychiatry* (impact factor=11.982). He is past president of the American College of Neuropsychopharmacology (ACNP) and the International College of Neuropsychopharmacology (CINP).

Like Smith, Krystal plays a significant role within Yale Medicine, the school’s clinical practice, and the health system, as his department is responsible for mental health care and services at all the major facilities as well as several satellite facilities.

“When I arrived at Yale in 1980 as a medical student, I never imagined I would have the opportunity to lead and help shape mental health at the institution, let alone our clinical translational research vision and mission,” Krystal said. “I was honored that Bob asked me to

*“As someone who looked up to Bob Sherwin as a junior faculty member as the model of a translational scientist, I am honored to work with Brian and the leadership to continue Bob’s work. Like Bob, I am passionate about training the next generation of clinician-scientists. I expect that YCCI and the Yale CTSA have a bright future.”*

John Krystal, MD

Robert L. McNeil, Jr. Professor of Translational Research; professor of psychiatry, neuroscience, and psychology; chair of the Department of Psychiatry at Yale School of Medicine; and chief of psychiatry and behavioral health at Yale New Haven Hospital



Photo Robert Lisak

John Krystal, MD

help with our first CTSA applications in 2006. I remember how proud Brian and I, along with all our faculty, were when we heard the news we would be funded as part of the first cohort.” In both his positions as chair of the Department of Psychiatry and chief of psychiatry and behavioral health at Yale New Haven Hospital, Krystal played an active role in the planning of the initial application, as well as the renewals in 2011 and 2016. He has also served as a primary mentor for several KL2 scholars; a member of the Society of Mentors supporting all educational initiatives; a reviewer of many of the CTSA pilots and scholar applications; a user of several resources; and a member of the internal clinical chairs group that assists in YCCI strategic planning on an annual basis.



Photo Anthony DeCarlo

Richard Torres, MD, MS, and Brian Smith, MD.



**Excerpts from the External Scientific Advisory Board October 2018 meeting**

The committee was in unanimous agreement that the progress made by the Yale CTSA was nothing short of spectacular. Three areas that were problematic at the initiation of the grant were informatics (IT), community engagement, and clinical research (including clinical trials). But for the CTSA the extraordinary progress in development of these programs could not have occurred. At the same time, the traditional areas of strength in the Yale program, education and research, have been further expanded and improved by the CTSA. The ESAB was particularly impressed with the progress and potential of several major programs. These include:

- The ESAB was extremely pleased that Dr. Brian Smith has so effectively made the transition to leading YCCI during Dr. Sherwin's medical leave. His total command of all of the strategic and operational aspects of YCCI is both remarkable and commendable given his relatively short tenure as the interim leader. The seamless transition in leadership is also attributable to Tesheia Johnson's outstanding administrative leadership of the program. Her expertise and creativity in designing and then effectively and efficiently introducing exciting new initiatives is a key contributor to YCCI's success and its ability to sustain a leadership position among CTSA institutions.
- **Relationship to the Yale Health System.** The enthusiastic support of YCCI by the Yale Health System is an enormous strength of YCCI and has great potential for identifying opportunities for mutually beneficial collaborations. The continued financial investment from the Yale Health System, Yale Medicine (Yale's faculty practice) and School of Medicine to support of YCCI is not only noteworthy but extremely remarkable. This type of support has allowed the YCCI to develop and maintain a truly robust infrastructure.
- **YCCI Scholar program.** The ESAB was impressed with the commitment to mentor training and the requirement that faculty promoted to Associate Professor participate in formal mentor training. This is a reflection of YCCI's recognition of the importance of mentors to Scholars success and the commitment of YCCI to its core educational mission.
- Particularly impressive has been the advancement of the new Lifespan Research Plan, launched in late 2017 and supported by YCCI. The program involves several medical school departments; although by design its scope goes beyond New Haven's borders, it has the potential to involve multi-generations of the city's residents. The new Lifespan initiative, which creatively integrates the expertise of a multidisciplinary group of clinicians and investigators to focus on a vital issue that has not received the attention it deserves because of the challenges of crossing traditional academic institutional structures. The Lifespan Research program highlights the connector role of the YCCI. By bringing together investigators from pediatrics, aging, child psychology and epidemiology, the program has the opportunity to create new ways of looking at chronic disease and life course research.
- **The integration of Epic and OnCore to support Yale's research mission.** This pioneering and vital achievement will undoubtedly be appreciated by the broader academic community as a major advance; and so the ESAB encourages YCCI to consider how best to share what they have learned with other CTSA institutions and the broader scientific community. Yale is clearly at the forefront of developing informatics capacity and capability for clinical and translational research. It has invested well in expertise and infrastructure that are leveraging the Yale vendor solution EHR (Epic), which has now been implemented across the health system. Yale has a growing list of exemplars that demonstrate how the informatics program is enabling stronger communication with the local population and how it is enabling a deeper understanding of the drivers and motivations of the local population with respect to research.
- In addition to their informatics tools, YCCI should be lauded for its clinical research productivity. Since 2015, a period in which many centers have seen clinical research plateau or even decline, YCCI has grown active protocols by 48%, therapeutic accrual by 46%, and total accrual by an astonishing 219%. However, perhaps most impressive, YCCI's commitment to community outreach and engagement has led to remarkable success in the recruitment of historically underrepresented populations to clinical studies. In FY18, 30% of all accrual at Yale comes from historically underrepresented populations, a rate that unquestionably places the center as one of the most successful in the country in this challenging and critically important area. The successful establishment of the Cultural Ambassadors' program is visionary. The Ambassadors have become important voices for Yale's research in their respective communities.

**Summary**

The ESAB commends the leadership of the clinical enterprise and the medical school for the support of the CTSA. This support, in conjunction with superb leadership of the CTSA, has transformed clinical research at Yale. To say that the progress made under the CTSA, as outlined in this report, is truly remarkable is an understatement.  
Respectfully submitted,

Lewis Landsberg, MD, for The External Advisory Committee



*“As rewarding as it has been to oversee this transformation with Bob, I believe what we have done is lay an unbelievable foundation for us to continue to grow and build on. Converting the CTSA to a multi-PI model and recruiting Brian and John to be the next leaders will enable us to continue building for the future.”*

Robert Alpern, MD  
Dean and Ensign Professor of Medicine

in planning and writing the first Yale application. The executive leadership thought that Smith and Krystal would provide a strong bridge across the clinical practice and the health system, both of which are critical partners in the Yale CTSA. Further, given Smith's secondary appointment in Biomedical Engineering, he will strengthen YCCI's ties to the wider Yale campus. “We are very excited that Brian and John have agreed to accept the new roles. They are the ideal candidates to lead the next phase of clinical research transformation at Yale,” said Marna Borgstrom, CEO of the Yale New Haven Health System. Although the goals of the CTSA have remained essentially unchanged since the 2016 renewal, the YCCI program continues to evolve to address the needs of Yale's clinical and translational research environment and the national CTSA program. Smith and the Yale team, now joined by Krystal, have focused on assessing the program and planning the next renewal application, which is likely to focus on further leveraging the strengths of the program, including training the next generation, leveraging the EHR, and community engagement. “The External Scientific Advisory Board has been continually impressed with the strides YCCI has made over the years. We have gotten to know Brian along the way and are confident that he will help YCCI continue along its solid path of growth,” said Lewis Landsberg, MD '64, dean emeritus of Northwestern University Medical School and chair of YCCI's External Scientific Advisory Board.

*continued on page 26*

*“We are very excited that Brian and John have agreed to accept the new roles. They are the ideal candidates to lead the next phase of clinical research transformation at Yale.”*

Marna Borgstrom, MPH  
CEO, Yale New Haven Health System

**YCCI Events Calendar**

**Coffee and Conversation**

*“Single Subject Modifications”*

Linda Coleman, Director, Human Research Protection Program

Jessica Huening, Asst. Director, Regulatory, Compliance & Quality; Assistant Director, Regulatory, Compliance & Quality

**August 20**  
**9 a.m. – 10:00 a.m.**

CSC Cohen Auditorium NIHB E02

These monthly presentations on topics related to clinical research operations are open to all Yale faculty and research staff.

**Faculty Dinner Series**

*“Create Your Career Path”*

**September 18, 5:00 p.m. — 7:00 p.m.**

CSC Cohen Auditorium NIHB E02

Linda Bockenstedt, MD, Harold W. Jockers Professor of Medicine, Deputy Dean for Faculty Affairs

Michael Crair, PhD, William Ziegler III Professor of Neuroscience and Professor of Ophthalmology and Visual Science; Deputy Dean for Scientific Affairs (Basic Science Departments)

Brian Smith, MD Professor of Laboratory Medicine, of Biomedical Engineering, of Medicine (Hematology) and of Pediatrics; Deputy Dean for Scientific Affairs (Clinical Departments); Chair, Department of Laboratory Medicine

**Good Clinical Practice Refresher**

**September 25, 2 p.m. — 3 p.m.**

CSC Cohen Auditorium NIHB E02

Linda Coleman, JD, Director, Human Research Protection Program, Office of Research Administration, Yale University

Alyssa Gateman, MPH CCRP, Director, Quality Assurance, Office of Quality Assurance and Training, Yale Center for Clinical Investigation

**Lunch and Learn**

*“Meet the Leadership - Ann Kurth, PhD MPH”*

**August 8, noon — 1:00 p.m.**

*“Meet the Leadership - Harlan Krumholz, MD”*

**October 3, noon — 1:00 p.m.**

*“Preparing for an FDA Audit Part I”*

**November 14, noon — 1:00 p.m.**

CSC Cohen Auditorium NIHB E02

These monthly sessions address broader research issues and are open to all Yale faculty and research staff. Lunch is provided. For schedules and registration information for training events, visit <http://ycci.yale.edu/education/stafftrain/>.



# PAST SCHOLARS REFLECT ON BEING A SCHOLAR



Photo Robert Lisak

## Christopher Pittenger, MD, PhD 2009 YCCI Scholar Associate Professor of Psychiatry; Director, Yale OCD Research Clinic

A “leap of faith” led Christopher Pittenger, MD, PhD, Associate Professor of Psychiatry, to the position of Director of the Yale OCD Research Clinic immediately after residency. While Pittenger always anticipated a career in the neurobiology lab, “during residency, I got more and more involved in clinical research—in particular, the Obsessive-Compulsive Disorders

(OCD) Clinic, a long-established research program here at Yale,” he says. “At the end of my residency, the director of that clinic left for a job in industry. I came up with the terrifying, unexpected opportunity to run that clinical research program in parallel with running my own lab.”

The YCCI Scholar Award “came at a fairly pivotal time,” and helped him prepare for the daunting role of directing a clinical research lab early in his career. As director of the Yale OCD Research Clinic, Pittenger investigates a disease in which he was mainly interested on a basic science level prior to his connection with the clinic, and was now

able to translate into clinical research with the potential to help patients. As a YCCI Scholar, Pittenger focused on the imbalance of the neurotransmitter glutamate in people with OCD. He and a team conducted a magnetic resonance spectroscopy study in which they used a version of MRI to measure glutamate and gamma levels in the brain—a study which later led to an R01 grant. There was also a parallel treatment study which used an already FDA-approved glutamate modulator, Riluzole, to try to normalize the hypothesized glutamate imbalance. That study laid the groundwork for an industry-sponsored study on which Pittenger is the lead collaborator. “It’s something I am hopeful will really make a difference to patients. The support for me to find my footing in clinical research was essential.”

Support from YCCI has continued to expand as Pittenger matures in his career. He later received a pilot award from YCCI that supported a program of research in his basic science lab to examine the neurologic underpinnings of Tourette syndrome; that work, he says, has become the foundation of several other grants and ten published papers. Two of Pittenger’s trainees, Benjamin Kelmendi, MD, and Patricia Gruner, PhD, are current YCCI Scholars funded for work they are conducting under his mentorship. Through this next generation, he says, “YCCI has continued to be supportive.”



Photo Robert Lisak

## Eda Cengiz, MD 2010 YCCI Scholar Associate Professor of Pediatrics (Endocrinology)

For Associate Professor of Pediatrics (Endocrinology) Eda Cengiz, MD, the responsibility to help her own community accompanies the knowledge gained through being a clinical scientist. Cengiz is a pediatric endocrinologist focusing on type 1 diabetes in children, but she saw an unmet need among adult women with the disease.

“There is a common approach in diabetes care that is one size fits all,” Cengiz says. “But that is not accurate. What we know is that women actually have more acute and chronic complications of diabetes.” Cengiz is currently investigating changes in insulin action during various phases of the menstrual cycle in women with type 1 diabetes. “Our preliminary results show that there is a 40 percent change in insulin action during different phases of the menstrual cycle,” she says. “It has a major impact on how we will treat diabetes in the future. Now there are so many new diabetes technology tools to customize treatment, we hope our findings will help develop treatments

designed specifically for women that will reduce complications.” Beyond her work improving care for women with type 1 diabetes, Cengiz’s work focuses on clinical research in pharmacokinetics and pharmacodynamics, and her lab is the only one in the world, she says, to conduct research on the action of insulin in pediatric patients. The foundation of that work was laid when she became a YCCI Scholar in 2010, then an assistant professor. With funding, she was able to test methods to accelerate insulin action, including next-generation ultrafast-acting insulins, and was able to show their effects on the efficacy of artificial pancreas systems on diabetes treatment. To do potentially game-changing clinical research, “It takes a village, maybe a city,” she says. “You need a good infrastructure.” This infrastructure drew her to Yale, and then to YCCI. “There are only a few places where you can get structured, systematic clinical research training,” she says. As a YCCI Scholar, she not only received research and educational support, but also the guidance of three exceptional mentors: Robert Sherwin, MD, C.N.H. Long Professor Emeritus of Internal Medicine (Endocrinology) and founding director of the YCCI; Karl Insogna, MD, Ensign Professor of Medicine (Endocrinology); and William Tamborlane, MD, Professor of Pediatrics and Chief of Pediatric Endocrinology. From mentors like these, “You learn from them every minute,” Cengiz says, “and you don’t even realize how much you learn. It’s like osmosis.”



Photo Robert Lisak

## Lucia Jilaveanu, MD, PhD 2014 YCCI Scholar Associate Professor of Medicine (Medical Oncology)

The lab of Lucia Jilaveanu, MD, PhD, Associate Professor of Medicine (Medical Oncology) seeks to uncover the mechanism underlying melanoma that metastasizes to the brain—a potentially deadly outcome that occurs in about half of melanoma patients, she says. Until now, “Research in this area has been limited, and there has been

poor understanding of how brain metastasis really occurs,” Jilaveanu says. “Understanding the biology and how to target brain metastasis continues to be an evolving field that scientists like myself are trying to push forward for the benefit of our patients.”

As a YCCI Scholar, Jilaveanu sought to identify the distinct features of cancer cells that invade the central nervous system and drive the process of metastasis. With that funding, she was able to successfully demonstrate that the melanomas with a tendency to metastasize to the brain have a distinctive molecular structure, and also to uncover several possible mediators of melanomas that metastasize to the brain.

She was also able to expand her study to generate novel preclinical in vitro tests in animal model systems for the disease, which have been limited, she says. “These tools are valuable in the sense that I not only use them for the research I propose, but I continue to integrate them in my current studies for functional analyses and to dissect specific mechanisms in melanoma with brain metastasis,” Jilaveanu says. This work laid the foundation for gathering preliminary data to apply for an R01 grant from the NIH, which Jilaveanu received in 2017. The ultimate goal of her research is to gather enough evidence to justify the development of new drugs that target molecules that she was able to associate with brain metastasis; and down the line, therapies that include already-existing inhibitors of pathways that these molecules regulate.

For Jilaveanu, the YCCI Scholar Award “was an invaluable asset for the start of my career,” she says. “As a junior investigator I came to realize that it is so difficult to obtain research funding. Seed funding is vital for any researcher who is in the process of building her own independent research. This is an especially vicious cycle, as it is hard to acquire preliminary data without having funding, and how do you get funding without preliminary data? It’s a chicken-and-egg paradox. The KL2 mechanism addresses this paradox that we face at the beginning of our careers.”



Photo Robert Lisak

## Forrest Crawford, PhD 2014 YCCI Scholar Associate Professor of Biostatistics, and of Ecology and Evolutionary Biology; Director, Yale Developmental Disabilities Clinic

It was when Forrest Crawford, PhD, Associate Professor of Biostatistics, and of Ecology and Evolutionary Biology; and Director of the Yale Developmental Disabilities Clinic came to Yale that he realized that he could apply his doctoral degree in applied mathematics and statistics to solving some of the most challenging problems in

public health. In New Haven, “I met some epidemiologists who were working on some very hard problems in public health,” he recalls. One of the most influential on the trajectory of his career was Robert Heimer, PhD, Professor of Epidemiology (Microbial Diseases) and Director of the Emerging Diseases Program at the School of Public Health. “Dr. Heimer told me about the research methods that he and his colleagues used to study hidden and hard-to-reach populations at high risk of HIV infection in the US and internationally,” Crawford says. “He articulated several seemingly intractable inferential problems that could benefit from statistical and mathematical insight.” This initial meeting led to a long-term fruitful collaboration between the two researchers. Crawford now seeks new methods for public health research in such infectious diseases as HIV, for such populations as injection drug users, men who have sex with men, sex workers, trafficking victims, and other

people who are difficult to survey using traditional epidemiological methods—with the ultimate hope that these methods will contribute to better public health policy.

“I see my work as helping to provide a framework for making the best decisions possible, learning from the data that we have, and providing evidence that is understandable and persuasive to policy makers so they can make the best possible decisions.” Crawford recently collaborated with Gregg Gonsalves, PhD, Assistant Professor of Epidemiology (Microbial Diseases) on a study published in *The Lancet HIV* that showed that a 2015 HIV outbreak in Indiana could have been drastically reduced if the state government had acted more quickly on warnings. Crawford received the YCCI Scholar Award in 2014. In 2016, he received the prestigious NIH Director’s New Innovator Award on the basis of his work as a YCCI Scholar. This NIH award supports exceptionally creative early-career investigators who propose innovative high-impact projects. The funding and the faith in his work that the funding implies “gave us the freedom to work on a variety of challenges that came up along the way in completing those projects,” Crawford says. “Many of those challenges had to do with estimating the effects of biomedical interventions, when outcomes are contagious. The support of these awards opened the doors to a wide variety of research questions that we have been able to pursue and try to solve.”



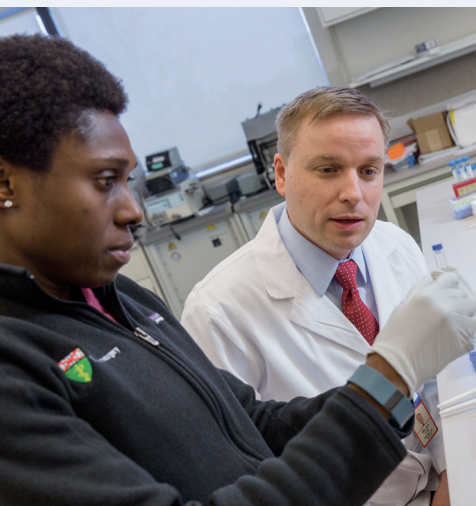


Photo Robert Lisak

**Tore Eid, MD, PhD** 2009 YCCI Scholar  
*Associate Professor of Laboratory Medicine, of Neurosurgery, and of Molecular Physiology*

Despite his call to the laboratory, Tore Eid, MD, PhD, Associate Professor of Laboratory Medicine, of Neurosurgery, and of Molecular Physiology, has always liked to work with patients. “I am a physician and I loved doing that,” Eid says. During his training, he covered health care needs, from childbirth to chronic illness to injury, in the

remote north of Norway where he was only one of two doctors. After his medical training, he arrived at Yale, to conduct research into the mechanisms of epilepsy.

“I thought I would like to combine my clinical knowledge with research,” said Eid. At Yale, he completed a residency in clinical pathology, also known as a laboratory medicine. The field “melds well with research,” he says, as it examines fluids of the body to diagnose and understand disease. It was at this point in his career that he received the YCCI Scholar Award, and employed such techniques of laboratory medicine as mass spectrometry to understand the chemical changes in the brain that occur during epileptic seizures. He used samples of brain fluid collected during work with Dennis Spencer, MD, the Harvey and Kate Cushing Professor of Neurosurgery and Chief of Epilepsy Surgery. The samples were gathered from Yale patients who

underwent electroencephalography, or EEG tests, after seizures to determine the location of the seizures in the brain. Eid found that patients who experience seizures exhibit distinct chemical changes in the brain, some of which occur several hours before seizures begin. “We thought that these chemical changes may be very important for seizure triggering. That is important because there is a big need to develop medications for seizures; four out of 10 people cannot be helped with medications, and really the only option is surgery,” he says. “Our hope now is by understanding the chemistry we can understand why seizures occur, and be able to manipulate the chemistry changes in people as a treatment for seizures.” Using the results generated with his YCCI Award, Eid received an R21 grant to continue his line of investigation, and plans to apply for an R01 with the results.

In addition to his work in epilepsy research, Eid is a practicing pathologist and associate director of Yale New-Haven Hospital’s Clinical Chemistry Laboratory, which analyzes laboratory tests of all kinds ordered by clinicians. “What is great about being a clinician also is that I have available instrumentation that I can use in my research.” The lab is also a place where he can extend his research. With permission he can access the test samples that come through the lab, with the goal of building a biorepository of samples that can be used for biomarker studies, for any disease. Going forward, Eid says, “I would really like to focus on translational projects that are likely to have clinical relevance down the road.”

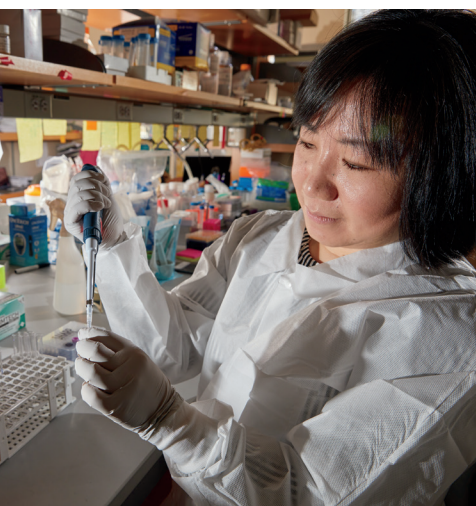


Photo Robert Lisak

**Shangqin Guo, PhD** 2014 YCCI Scholar  
*Assistant Professor of Cell Biology*

For Shangqin Guo, PhD, assistant professor of cell biology, cells are like children. “We can’t predict what a baby is going to be. Some will grow up and do great things; some are going to go bad,” she says. “We can never be certain what caused one child to behave one way and one another.” In her research, Guo is making films of the lives of cells to try to capture the moment that they, like an

unruly child, “go bad,” which in a cell means to become malignant. Guo hopes that if she can pinpoint that moment and capture it on video, she may be able to determine the mechanism of malignancy, and eventually contribute to finding the means to stop it.

Guo was a YCCI Scholar in 2014. At the time of her award, she and a team had found success in visualizing some rare cell biology, namely the moment that a blood cell becomes an induced pluripotent stem cell. “That success gave us inspiration: perhaps we can use similar technology to visualize another rare biology that so far people haven’t been able to really get a handle on,” namely how a normal cell becomes malignant. “Textbooks say, luckily, most of the cells in our body are never going to become cancerous. What is the mechanism that really pushes those few cells to eventually become cancerous? What is the last straw? Our rationale is that if we can understand that, perhaps we can devise

approaches to prevent cancer from occurring.” Guo investigated how normal blood progenitor cells gave rise to leukemia-forming cells, as the tipping point for leukemia requires only one genetic abnormality; it is more easily pinpointed than other cancers that require several. By putting that cancer-causing genetic abnormality into mouse blood progenitor cells, Guo was able to essentially trick cells into expressing the abnormality, and was then able to examine them. “If we can put this same genetic abnormality into all of the blood-forming progenitors, will these progenitors become cancerous, or just some of them? If only some of them become cancer, is there anything different with those few cells?” The challenge was in finding out not whether the cells became cancerous, but why. Guo’s team suspected the reason lies in the speed of division in those cells.

“We are seeing that it is the really rapidly dividing cells that are forming cancer,” Guo says, asking, “If we are able to slow down these rapid proliferation behaviors, are we going to be able to prevent the cancer formation?” Guo conducted animal tests on her hypothesis, and found that in a small sample set, the hypothesis proved correct: without intervention to slow down cell proliferation, all the mice died. This result was enough to elucidate proof of concept, Guo says. She is working on expanding the study, which if proven on a larger scale, could eventually lead to a preventive approach to cancer.

The YCCI Scholar Award “was one of my earliest funding sources,” Guo recalls. The pilot funding from YCCI led to larger awards, including the prestigious NIH Director’s New Innovator Award. At the beginning of her career, “The YCCI Award gave me encouragement and validation for my research, and led me to the NIH Award, which gives me the means to do it.”



Photo Robert Lisak

**Lloyd Cantley, MD**  
*Co-director, Education*

Lloyd Cantley, MD, is a noted nephrologist who studies the mechanisms of renal tubule formation and repair. He has mentored about 40 trainees in his lab, where he studies the mechanisms by which kidney cell regeneration occurs following acute kidney injury in order to develop therapies to enhance this process. His goal is to identify pathways that would be logical targets for drug therapy to either accelerate normal repair in the case of acute kidney injury, or block repair pathways in polycystic kidney disease or chronic kidney disease.

From the beginning of Cantley’s career, he has enthusiastically pursued teaching and mentoring. As a fellow at Harvard University, he taught medical students; today, in addition to his appointment as co-director of education, he teaches physiology case conferences to first-year medical students. He views his role at YCCI as mentoring on a larger scale, in which he has the opportunity to guide young investigators on becoming successful researchers. He is interested in the approach young faculty members take in answering research questions, and relishes the chance to offer a fresh perspective on their work.

**Rajita Sinha, PhD**  
*Co-director, Education*

Rajita Sinha, PhD, is internationally known for her pioneering research on the neural and biobehavioral mechanisms linking stress to addiction. She directs the Yale Stress Center, started with one of the largest interdisciplinary Consortium grants from the National Institutes of Health, to study the effects of stress and self-control on addictive behaviors and chronic disease. The collaborative research conducted at the center by Sinha and other scientists is multidisciplinary. The Stress Center develops and tests interventions to reverse the toxic effects of stress and the loss of self-control that drive addictive behaviors. Sinha is examining the role of long-term stress and repeated stress exposures in alcohol and substance dependence to develop new therapies to reduce compulsive motivation to use alcohol and drugs of abuse.

She brings her interdisciplinary focus to her role as co-director of education, where she seeks to increase the diversity of trainees and mentors, and provides guidance in connecting trainees to colleagues in different disciplines. She enjoys helping young investigators shape their ideas into scientific hypotheses, and watching them get hooked on research.

**Eugene Shapiro, MD**  
*Co-director, Education*

An experienced clinical epidemiologist in pediatric infectious diseases, Eugene Shapiro, MD, is especially interested in vaccines and in Lyme disease. He is currently involved in studies of the effectiveness of the HPV vaccine in clinical practice. This work includes qualitative research to discover why uptake of the vaccine is low in the United States, as well as a case-control study to evaluate the vaccine’s effectiveness by age at the time of vaccination and the number of doses given.

As a researcher who has had continuous NIH funding since 1983 and has mentored hundreds of young researchers, Shapiro is ideally suited to lead YCCI’s educational program. His interest in mentoring extends beyond mentoring younger colleagues. He was an author of a report on the results of a national trial of the effectiveness of a curriculum to train mentors. Despite the significant time commitment involved in mentoring, typically little attention is given to training faculty for this vital role. The response to the training program was so positive that Shapiro and Patrick O’Connor, MD, associate director of YCCI’s community research core, continue to co-teach a yearly course on mentoring for Yale faculty.



# YCCI JUNIOR FACULTY SCHOLARS

2015



**Christopher Benjamin, PhD**  
 Assistant Professor of Neurology;  
 Assistant Professor of Neurosurgery;  
 Assistant Professor of Psychology  
 Mapping Cortical Language  
 Boundaries in Neurosurgical Planning:  
 Validation of a Novel fMRI Protocol



**Rafeed Alkawadri**  
 Associate Professor of Neurology at the  
 University of Pittsburgh (PITT) and the  
 University of Pittsburgh Medical Center  
 (UPMC)  
 Real-Time and Passive Mapping of Brain  
 Functions Based on Electroencephalography:  
 Correlation with Electrical Cortical  
 Stimulation and Surgical Outcomes



**Danya Keene, PhD**  
 Assistant Professor of Public Health  
 (Social & Behavioral Sciences)  
 Affordable Housing Access and  
 Type 2 Diabetes



**Evelyn Hsieh Donroe, MD, PhD**  
 Assistant Professor of Medicine  
 (Rheumatology); Assistant Professor of  
 Epidemiology (Chronic Diseases)  
 Longitudinal Change in Trabecular Bone  
 Score among Individuals with HIV in China



**Dawn W. Foster, PhD, MPH**  
 Assistant Professor of Psychiatry;  
 Assistant Professor, Social & Behavioral  
 Sciences, Yale School of Public Health  
 Characterizing and Understanding  
 Cannabis Vaping in a Representative  
 Sample of Young Adults



**Patricia Gruner, PhD**  
 Assistant Professor; Assistant  
 Director, Yale OCD Research Clinic  
 Characterizing the Contribution of the  
 OFC to Neurocognitive Deficits in OCD



**Eli Lebowitz, PhD**  
 Assistant Professor in the Child Study  
 Center; Associate Director, Anxiety and  
 Mood Disorders Program  
 Biological Moderation of Treatment  
 Response in Childhood Anxiety Disorders



**John D. Murray, PhD**  
 Assistant Professor of Psychiatry,  
 of Neuroscience and of Physics  
 Personalized Computational Modeling of  
 Large-scale Cortical Circuit Dysfunction in  
 Schizophrenia



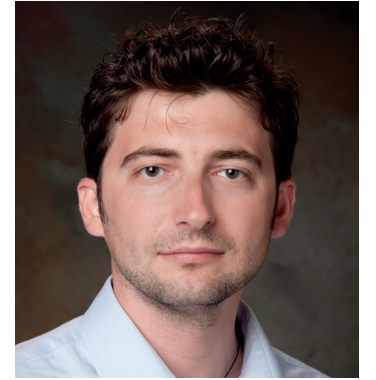
**Sangini Sheth, MD, MPH**  
 Assistant Professor of Obstetrics,  
 Gynecology, and Reproductive Sciences;  
 Associate Medical Director and Director  
 of Colposcopy and Cervical Dysplasia,  
 Women's Center, Yale New Haven Hospital  
 Inpatient Postpartum HPV Vaccination (IP-HPV)  
 As a Targeted Intervention to Increase Vaccine  
 Uptake: A Pilot Study



**Scott Huntington, MD, MPH, MSc**  
 Assistant Professor; Assistant Professor  
 of Medicine  
 Optimizing Imaging During Cancer  
 Management: Barriers to Reducing  
 PET-based Surveillance for Patients with  
 Lymphoma



**Daniel Jane-Wit, MD/PhD**  
 Assistant Professor  
 Enabling Tools to Study Complement-  
 Mediated Microvascular Thrombosis



**Benjamin Kelmendi, MD**  
 Associate Research Scientist  
 Neural Correlates of the Effects of  
 Psilocybin in Obsessive-Compulsive  
 Disorder

2016



**Arjun Venkatesh, MD, MBA, MHS**  
 Assistant Professor of Emergency Medicine;  
 Assistant Professor, Department of Emergency  
 Medicine; Scientist, Center for Outcomes Research  
 and Evaluation; Director, ED Quality and Safety  
 Research and Strategy; Co-Director, Emergency  
 Department Administration Fellowship  
 Hospital Observation Services: Do They Improve  
 Efficiency and Reduce Costs?



**Paul Aronson, MD**  
 Associate Professor of Pediatrics  
 (Emergency Medicine); Deputy Director,  
 Pediatric Residency Program; Director,  
 Pediatric Emergency Medicine Sub-  
 Internship  
 Clinical Prediction Model to Identify Febrile  
 Young Infants with Invasive Bacterial Infection



**Robert Becher, MD, MS**  
 Assistant Professor; Assistant  
 Professor of Surgery  
 Emergency Surgery Outcomes and  
 the Elderly (ESTATE Study)



**Toral Surti, MD/PhD**  
 Assistant Professor of Psychiatry  
 Developing Objective and Ecological  
 Outcome Measures for Cognitive  
 Treatment Trials in Schizophrenia



**Joshua Warren, PhD**  
 Assistant Professor of Biostatistics  
 Spatiotemporal Statistical Methods for  
 Analyzing Glaucomatous Visual Field  
 Progression



**Jason Weinstein**  
 Assistant Professor, Chancellor Scholar,  
 Rutgers New Jersey Medical School  
 STAT4 Regulation of Pathogenic Follicular  
 Helper T Cells in Autoimmunity



# YCCI JUNIOR FACULTY SCHOLARS

2017



**Miraj U. Desai, PhD**  
*Instructor, Program for Recovery and Community Health, Department of Psychiatry*  
 Depression, Culture, and Engagement: Partnering with the Community through Participatory Research



**Julie Gaither, PhD, MPH, RN**  
*Instructor, General Pediatrics*  
 Preventing Opioid Poisonings in Children and Adolescents



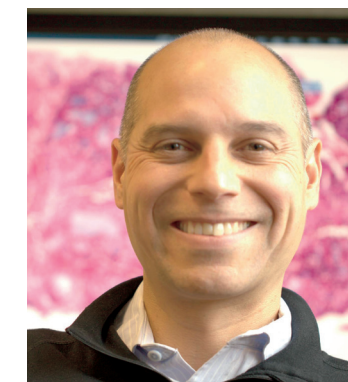
**Ayana Jordan, MD/PhD**  
*Assistant Professor of Psychiatry*  
 A Pilot Feasibility Study of Providing Substance Use Treatment in the Black Church



**Sule Tinaz, MD, PhD**  
*Assistant Professor, Neurology*  
 Effect of Neurofeedback Training on Motor Function in Parkinson's Disease: A Functional MRI Investigation



**Gunjan Tiyyagura, MD**  
*Assistant Professor of Pediatrics (Emergency Medicine) and of Emergency Medicine; Associate Fellowship Director*  
 Piloting a Child Abuse and Neglect (CAN) Advocate Program in General Emergency Departments: Bridging Gaps in Care for Victims of CAN



**Richard Torres, MD, MS**  
*Assistant Professor of Laboratory Medicine and Lecturer in Molecular Biophysics and Biochemistry; Director, Flow Cytometry Laboratory; Director, Immunology Laboratory*  
 High-resolution, Large-volume, Three-dimensional Renal Histology



**Sajid Khan, MD, FACS**  
*Assistant Professor of Surgery (Oncology)*  
 Characterization of Curative Oligometastatic Disease in Liver Metastasis



**Kristen Nwanyanwu, MD, MBA**  
*Assistant Professor of Ophthalmology and Visual Science*  
 Determining the Prevalence and Associated Multi-level Characteristics of Undiagnosed Diabetic Retinopathy



**Ian Odell, MD, PhD**  
*Assistant Professor; Dermatology Director, Adult Primary Care Center*  
 Dendritic Cell Fibroblast Interactions in Scleroderma



**Juan Vasquez, MD**  
*Assistant Professor*  
 Development of a SOX2 Nanoparticle Vaccine with Combined Checkpoint Inhibition for Pediatric Gliomas



**Nils Petersen, MD/PhD, MSc**  
*Assistant Professor of Neurology; Staff Neurointensivist, Neuroscience Intensive Care Unit*  
 Autoregulation-based Blood Pressure Optimization after Large-Vessel Occlusion Ischemic Stroke



**Rajiv Radhakrishnan, MBBS, MD**  
*Instructor*  
 Effect of Antipsychotic Medication on Microglial Activation: An In-vivo Non-human Primate PET Imaging Study



**Ilana Richman, MD**  
*Assistant Professor, General Internal Medicine*  
 Use, Outcomes, and Costs of Digital Breast Tomosynthesis in a Contemporary U.S. Cohort



**Karen Wang, MD**  
*Instructor, General Internal Medicine*  
 Examining the Effect of Utilizing Multiple Health Care Facilities on Health Outcomes

## A Scholar's Thank You



Thank you... I am so grateful for your incredibly generous and wholehearted mentorship over the last decade.

Through sharing your stories of a lifetime of scientific curiosity, unwavering dedication, and resolute passion for your work, you inspired me to become a physician-scientist. Thank you for believing in me. You bring out the best in all of us and help us in surpassing our own expectations.

Our weekly Tuesday afternoon meetings (often 2-3 hours long!) were a benevolent gift to my development as a physician-scientist. This time together, when we deliberated scientific ideas; overcame research dilemmas; and meticulously revised manuscripts, presentations, and grants (getting every sentence, every

word, and every punctuation mark just right) shaped my work in both clinical obesity medicine and clinical-translations research. Thank you for being so incredibly giving of your time, guidance, and support; you will always be an integral part of the work I do.

I owe so much to you, Bob... I will eternally be grateful for your unparalleled mentorship over these last twelve years; and most of all, for exemplifying how to live life through your unconditionally kind, compassionate, and giving nature.

With care and with love, warmly and sincerely,

Ania





## HONORING ROBERT S. SHERWIN, MD

**Robert S. Sherwin, MD, C.N.H. Long Professor of Medicine and associate dean for clinical and translational research, retired on December 31, 2018, after 44 years at the School of Medicine.**

A dedicated mentor, outstanding clinician, and renowned researcher, Sherwin has had a lasting impact on his colleagues, trainees, and patients. He has served as director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded Diabetes Research Center since 1993 and as chief of endocrinology in the Department of Internal Medicine since 2010. Early in his career, he pioneered the glucose clamp technique to measure insulin sensitivity during a fellowship at the NIH. He went on to play a key role in the development of the insulin pump, which was a major step forward in treating diabetes. His research also laid the groundwork for the landmark NIH-funded Diabetes Control and Complications Trial (DCCT), which demonstrated the long-term complications associated with the disease. In addition to clinical research, Sherwin has conducted basic science research leading to discoveries on glucose counterregulation and the immune mechanisms leading to type 1 diabetes. He has also conducted research on type 2 diabetes, showing that the brain processes the simple sugars fructose and glucose differently, suggesting that fructose may promote overeating. He has received over 40 years of continuous NIH R01 support for his research, including two 10-year Merit awards, and has written over 400 peer-reviewed papers.

Sherwin has been passionate about guiding the next generation of clinician-scientists during his long career, mentoring nearly 100 postdoctoral

fellows and students, many of whom are now at the forefront of diabetes research. As founding director of the Yale Center for Clinical Investigation (YCCI), he was instrumental in establishing the YCCI Scholars Program, which has provided support to 137 junior faculty members to date. He is justifiably proud of the success of this program, whose Scholars have gone on to successfully compete for more than 700 grants worth over \$400 million; have published over 4,000 papers; and 99 percent of whom remain engaged in research.

Sherwin has received many accolades: He is a recipient of the Banting Medal for Scientific Achievement from the American Diabetes Association (ADA); the ADA's Albert Renold Award for Mentoring in Diabetes Research; and the Edward H. Ahrens, Jr. Award for Patient Oriented Research. Under his stewardship YCCI, supported by an NIH Clinical and Translational Science Award since 2006, has grown substantially, providing research support and training to an ever-growing number of clinical and translational investigators.

We owe him a tremendous debt of gratitude for his decades of commitment to the School of Medicine and his many contributions to science and to improving patient care. In honor of his outstanding contributions to clinical and translational research, the YCCI All Scholar Day will be renamed the Robert S. Sherwin YCCI All Scholar Day. The inaugural event will be held on March 14, 2019.





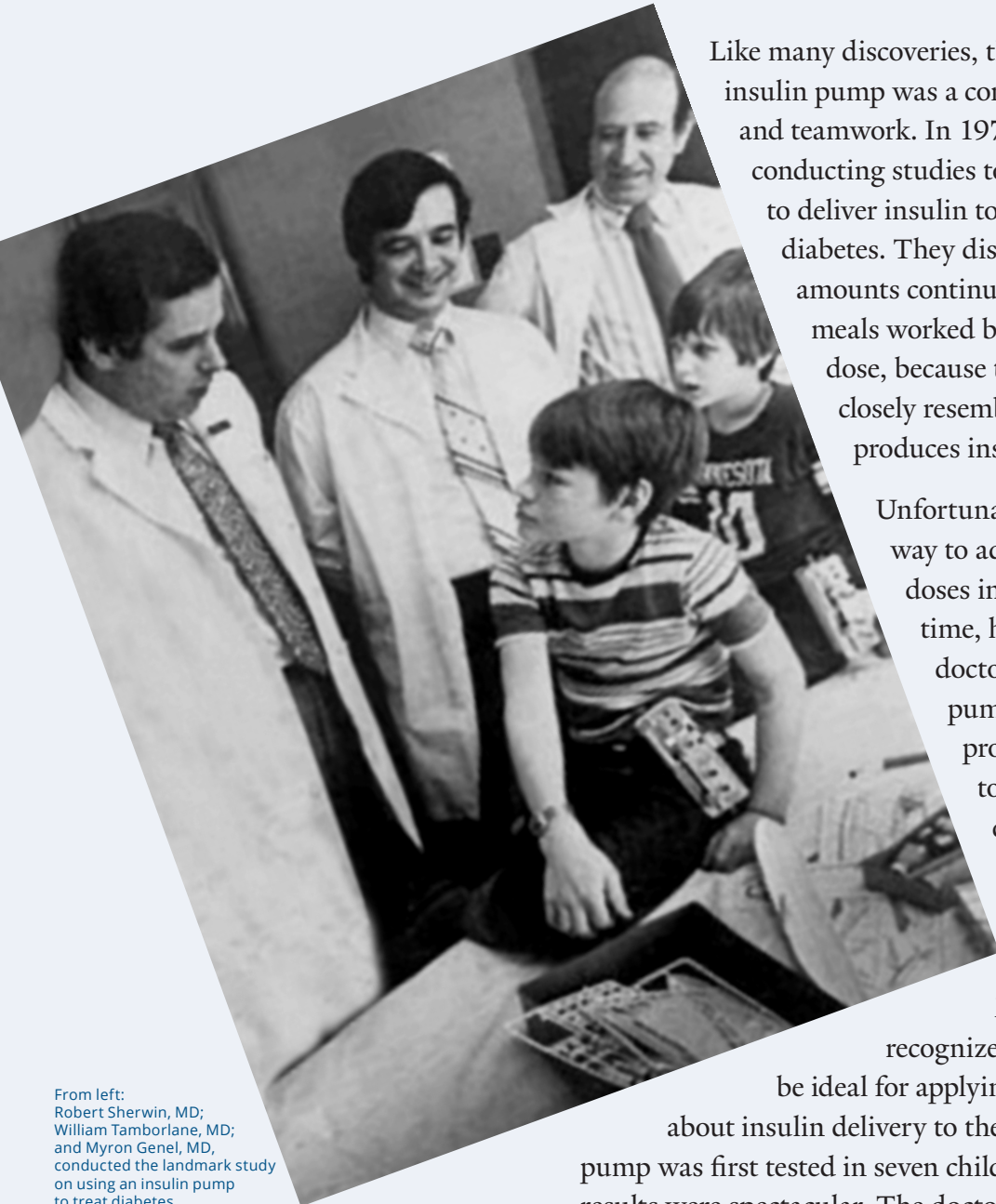
# A LIFETIME OF ACHIEVEMENT

## RECENT HONORS

- Inductee, Worldwide Lifetime Achievement (2017)
- Recipient, Clinical Translational Science Award, Center for Clinical Investigation, Yale School of Medicine (2005-Present)
- Recipient, Edward H. Ahrens, Jr. Distinguished Investigator Award, Association for Clinical and Translational Science (2016)
- Recipient, John K. & Mary E. Davidson Lectureship & Award, Department of Physiology, University of Toronto (2015)
- Recipient, Naomi Berrie Award for Outstanding Achievement in Diabetes Research, Columbia University (2015)
- Recipient, MERIT Award, National Institutes of Health (1995-2003, 2003-2013)
- Recipient, Albert Renold Award for Mentoring in Diabetes Research, American Diabetes Association (2011)
- Recipient, Banting Medal for Service, American Diabetes Association (2007)
- Recipient, Novartis Award for Long-Standing Achievement in Diabetes (2004)
- Recipient, Distinguished Alumnus Award, Albert Einstein College of Medicine (2002)
- Recipient, David Rumbough Award for Scientific Achievement, JDRF (1993)
- Recipient, Research Career Development Award, National Institutes of Health (1977-1982)
- Recipient, Albert Renold Medal, European Association for the Study of Diabetes; Honoree, Denis McGarry Lecturer, National Meeting, JDRF
- Recipient, Jonathan May Award, Connecticut Chapter, American Diabetes Association
- Honoree, Charles Best Lecture, University of Toronto
- Honoree, Harold Rifkin Lecturer, Albert Einstein College of Medicine
- Honoree, Lilly Lecturer, Kings College, London, England
- Honoree, Weinstein Lecturer, Vanderbilt University
- Featured Listee, *Who's Who in Science and Engineering* (2010)
- Featured Listee, *Who's Who in the East* (2009)
- Featured Listee, *Who's Who in America* (2000-2001, 2008)
- Featured Listee, *Who's Who in Medicine and Healthcare* (2006)



# INSULIN PUMP CHANGES DIABETES TREATMENT



From left: Robert Sherwin, MD; William Tamborlane, MD; and Myron Genel, MD, conducted the landmark study on using an insulin pump to treat diabetes.

Like many discoveries, the development of the first insulin pump was a combination of ingenuity and teamwork. In 1979, Yale doctors were conducting studies to figure out the best way to deliver insulin to children who suffer from diabetes. They discovered that giving small amounts continuously with larger doses at meals worked better than giving one large dose, because the smaller doses more closely resemble the way the pancreas produces insulin.

Unfortunately, there was no easy way to administer insulin in small doses in 1979. Around the same time, however, another Yale doctor was using a portable pump to help solve a different problem: delivering medicine to children who had a dangerous buildup of iron due to frequent blood transfusions.

Robert Sherwin, MD, and his colleagues recognized that this pump would be ideal for applying what they had learned about insulin delivery to their patients. The insulin pump was first tested in seven children with diabetes and the results were spectacular. The doctors stayed overnight in the hospital to monitor the results. When they began to see that blood sugar levels remained stable in their young patients, they knew that they had hit upon a novel and effective treatment for diabetes. The insulin pump, which today has evolved into a device the size of a beeper, continues to gain momentum; as of early 2019, 550,000 diabetic patients in the United States are using it, and its popularity continues to grow. Without volunteers like the children and their families who were willing to take a chance on an exciting new treatment, and the work of Sherwin and his colleagues, this groundbreaking discovery would not have been possible.



From left: William Tamborlane, MD, Kevan Herold, MD, Tesheia Johnson, MBA, MHS, and Robert Sherwin, MD.



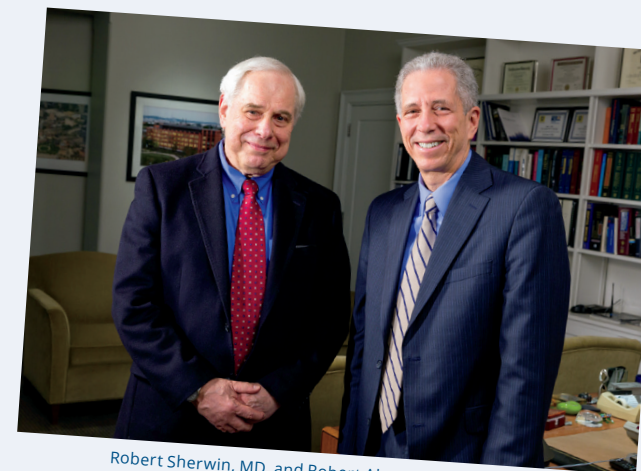
Photo Robert Lisak

Robert Sherwin, MD, and Renata Belfort De Aguiar, MD, PhD Assistant Professor of Medicine (Endocrinology).



Photo Robert Lisak

Christopher Pittenger, MD, PhD, and Robert Sherwin, MD.



Robert Sherwin, MD, and Robert Alpern, MD.

Dear Bob,

Words cannot express how much your mentorship and guidance have meant to me over the years. I could not have asked for a better teacher and guide to show me what it means to be a physician-scientist. I can only hope to live up to the standard you have set as a doctor, teacher, mentor, colleague and scientist.

With love and deepest gratitude,

Janice

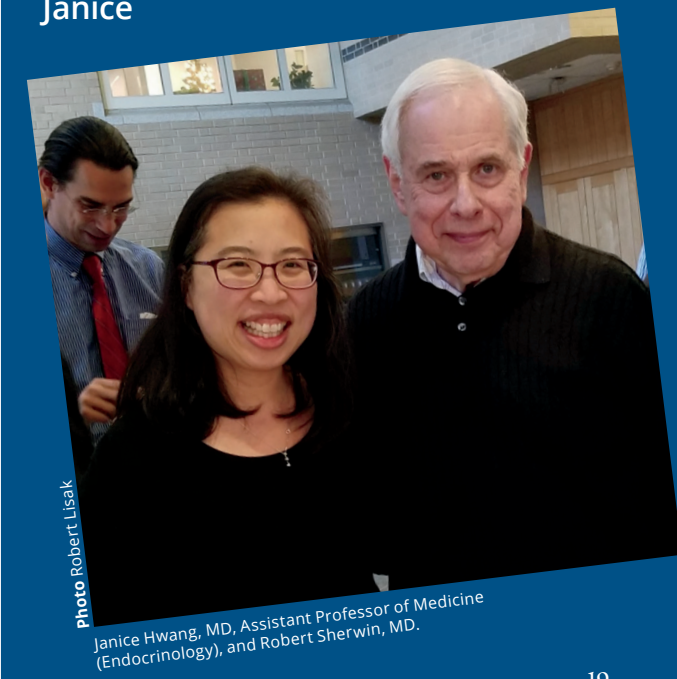


Photo Robert Lisak

Janice Hwang, MD, Assistant Professor of Medicine (Endocrinology), and Robert Sherwin, MD.



# LEADERS THANK ROBERT S. SHERWIN, MD

"Bob Sherwin has been a giant among giants at Yale. He had a long and distinguished career already when our Medical Center decided to compete for the first CTSA award which we viewed as critical to enhancing our research reputation from one earned primarily in the basic sciences to equivalent excellence in translational research. There was no better choice to lead this than Bob Sherwin, and he has guided our Medical Center's embrace of translational medicine through YCCI since its inception. Thank you, Bob, for blazing this trail for Yale."

## Marna Borgstrom, MPH

CEO, Yale New Haven Health System

Photo Robert Lisak



Photo Terry Dagradi

"Bob is among our most distinguished researchers, and we are indebted to him for his decades of mentorship that have shaped the next generation of clinical and translational investigators and his outstanding leadership of YCCI. We will all miss his warm collegiality and insight. It is with deep gratitude that we bid him farewell."

## Robert Alpern, MD

Dean and Ensign Professor of Medicine



Photo Robert Lisak

*"Bob has given us a 44-year legacy of transformational research, compassionate clinical care, and extraordinary mentorship. On behalf of the Yale Medicine and the clinical chairs, Thank You."*

## Paul Taheri, MD, MBA

Deputy Dean for Clinical Affairs, Yale School of Medicine and CEO, Yale Medicine

"I am deeply grateful for Bob's enormous contributions to translational and clinical research at our Medical Center. Bob has displayed a deep commitment to the development of programs and people that have meaningfully enhanced the quality and effectiveness of care for patients locally and across the world. He is a towering example of how collaboration, creativity, and mentorship can result in dramatic changes in science, clinical practice, and organizations."

## Thomas Balcezak, MD

Chief Medical Officer, Senior Vice President, Yale New Haven Health System

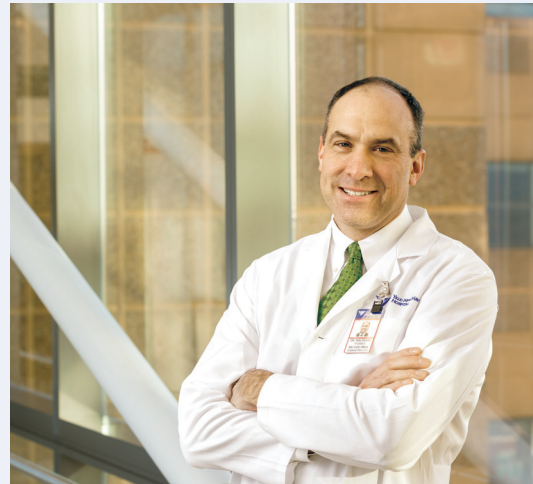


Photo Robert Lisak



Photo Robert Lisak

*"As a colleague and informal mentee for nearly thirty years, it has been wonderful to watch Bob help transform our institution. His dedication to translational biomedical science and to the development of the next generation of clinician-scientists and scientists is legendary, not just at Yale but throughout academic medicine. It is truly a privilege to attempt to carry on his legacy."*

## Brian Smith, MD

Professor of Laboratory Medicine, of Biomedical Engineering, of Medicine (Hematology) and of Pediatrics; Deputy Dean for Scientific Affairs (Clinical Departments); Chair, Department of Laboratory Medicine



"You are an incredible, selfless leader, mentor, and friend to the entire team at YCCI. Your vision for clinical research has truly transformed the institution and the country in so many ways. On a personal note, your mentorship, support and guidance has meant more to me than I can ever express in words. Learning from you these past 14 years is an experience I will always treasure and count myself among the luckiest of your hundreds of admiring trainees."

## Tesheia Johnson, MBA, MHS

Deputy Director for Administration and Chief Operations Officer

"It is a special honor and pleasure to follow in Bob's footsteps at YCCI. He has been a role model for innovative science, generous collaboration, and generative mentorship at Yale for as long as I can remember. His passion for science, kindness, and leadership will never be forgotten by those of us who have had the good fortune of working with him."

## John Krystal, MD

Robert L. McNeil, Jr. Professor of Translational Research; professor of psychiatry, neuroscience, and psychology; chair of the Department of Psychiatry at Yale School of Medicine; and chief of psychiatry and behavioral health at Yale New Haven Hospital



Photo Robert Lisak

Photo Robert Lisak



"Yale School of Public Health research has been strengthened by your leadership, including through the YCCI scholars awards program, pilot funding, and partnership with YCAS. Your commitment to excellence and passion for training and mentorship will be greatly missed. Thank you!"

## Sten H. Vermund, MD, PhD

Dean and Anna M.R. Lauder Professor of Public Health; Professor of Pediatrics, Yale School of Medicine



Photo Mara Lavitt

*"It has been gratifying working with Bob as the School of Nursing contributes to translational research at Yale. He leaves a deep legacy of mentorship to many early career faculty. His dedication is appreciated and will be long remembered."*

## Ann Kurth, PhD, CNM, MPH, FAAN

Dean, and Linda Koch Lorimer Professor, Yale School of Nursing



# A NEW ERA FOR YCCI AND THE CTSA PLANNING THE FUTURE

continued from page 5

## YCCI's Deputy Directors



Margaret Grey, DrPH, RN, FAAN  
Annie Goodrich Professor of Nursing



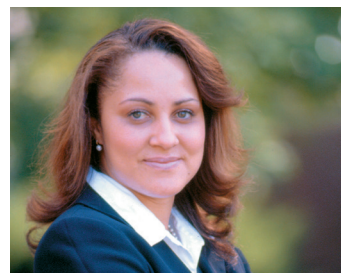
Kevan Herold, MD  
Professor of Immunobiology and of  
Medicine (Endocrinology)



Melinda Irwin, PhD, MPH  
Professor of Epidemiology  
(Chronic Diseases)



Marcella Nuñez-Smith, MD, MHS  
Associate Professor of Medicine  
(General Medicine) and of  
Epidemiology (Chronic Diseases)



Tesheia Johnson, MBA, MHS  
Deputy Director for Administration and  
Chief Operations Officer

To further strengthen, diversify, and expand the expertise of YCCI's leadership team, Eric Jose Velazquez, MD, the Robert W. Berliner Professor of Medicine (Cardiology); chief, Section of Cardiovascular Medicine, Department of Internal Medicine at YSM; chief, Cardiovascular Medicine, Yale New Haven Hospital; physician-in-chief, Heart and Vascular Center, Yale New Haven Health, has agreed to join our team as deputy director for clinical trials innovation. Velazquez, previously professor of medicine in the Division of Cardiology at Duke University, with appointments at the Duke Clinical Research Institute and Duke Global Health Institute, will join the five current Deputy Directors of YCCI.

A first-generation American, Velazquez was born in New York City where he attended Regis High School. He graduated from Williams College with a Bachelor's degree with Honours in Psychology and the Albert Einstein College of Medicine. He completed his internal medicine and cardiology training at Duke University, including Fellowships in clinical research and echocardiography. Named the inaugural Greenfield Scholar of Cardiology in 2001, Velazquez joined Duke University faculty and built a noteworthy career spanning patient care, research, and education. He was named Professor of Medicine with tenure in 2012. He also served as Director of the Duke Cardiac Diagnostic Unit and Echocardiography Laboratories, as the Associate Director of the Duke Heart Center, and Director, Late Phase Clinical Trials at the Duke Clinical Research Institute.

Velazquez is ideally suited for this role as he is a clinician-investigator whose major contributions to science include the design, development, and implementation of landmark randomized clinical trials that have altered international guidelines for the treatment of patients with chronic heart failure, particularly those with concomitant coronary artery disease. Although Velazquez has been at Yale for only a short period of time, joining the institution in June 2018, he has been very actively engaged in YCCI/CTSA activities. In fact, just a month after his arrival, he joined in the YCCI retreat devoted to strategic planning for the future of the informatics and biostatistics resources. The retreat included leaders from Yale and eight other CTSA hubs. In addition, Velazquez has been actively engaged in the restructuring of the YCCI IND/IDE support unit and in the management of the multicenter unit, including embedding his own 50 site NHLBI-funded project within the unit.

"Bob built a wonderful team. With the addition of Eric, who I am sure will be an asset to both the Yale program and the national CTSA consortium, I think John and I are well poised to continue the transformation Bob helped to launch at Yale," said Smith.

*"Prior to making a decision to come to Yale, I met with the YCCI team and was so impressed with their structure and the potential, I embedded my own project with them. It is an honor to join Brian, John, and the YCCI team. Although Yale through the YCCI has achieved much already, there is much more to do and the potential is limitless to innovate and leverage the partnership of the Yale School of Medicine and Yale New Haven Health delivery network to more fully integrate clinical trials in the community and into the fabric of our lives as patients, clinicians, and investigators."*

Eric Jose Velazquez, MD  
YCCI Deputy Director for Clinical Trials Innovation



Eric Jose Velazquez, MD, new Deputy Director for  
Clinical Trials Innovation.

## HELP US DISCOVER HEROES

*Discoveries that help millions of patients are made possible thanks to those who participate in clinical research*



Photo Robert Lisak



Photo Robert Lisak



Photo Edgar Cardenas



Photo Robert Lisak



Photo Robert Lisak

## DO YOU HAVE A VOLUNTEER WHO COULD BE ONE OF OUR HEROES?

Discoveries that help millions of patients are made possible by those who participate in clinical research. These patient volunteers are researchers' most important partners as they work to uncover new treatments for a variety of diseases. Many potential volunteers are unaware of what it means to participate in research and how rewarding it can be. The "Help Us Discover Heroes" series on the YCCI website profiles an array of patient volunteers who tell their stories, and why participating in research has been so meaningful to them.

If you would like to highlight a volunteer who has made a powerful contribution to your research in any area, YCCI can help. YCCI can also help you promote a study that is open for accrual and assist you with recruiting new volunteers.

Once you have confirmed the person's willingness to participate, we will arrange to interview and photograph him or her; write a story describing his or her experience; and have the media consent form signed. You will be interviewed as well, and will have the opportunity to explain why the patient and his or her role in your research have been so valuable. You and the volunteer will have an opportunity to review the story before it is used.

We also publish stories on [yalestudies.org](http://yalestudies.org) to promote clinical trials that are accruing subjects in conjunction with the national health observance month calendar, or upon request.

For more information or to highlight a volunteer, contact Lisa Brophy at [lisa.brophy@yale.edu](mailto:lisa.brophy@yale.edu).



## CULTURAL AMBASSADOR

The Reverend Dr. LeRoy O. Perry, Jr. is the Pastor of St. Stephens AME Zion Church. He earned his BA from Livingstone College, his MDiv from Yale Divinity School, and his STM and doctoral degree from New York Theological Seminary in New York City. He served on Mayor O’Leary’s commission for diversity study for the City of Waterbury, and as chairman of the Clergy Support committee for Waterbury Opportunities Industrialization Center, where he worked to foster Black economic development in the area. He presently serves as the director of the Fatherhood Program at New Opportunities in Waterbury.

Although Perry was aware of health care disparities before becoming a Cultural Ambassador, he was not aware of the clinical research conducted at Yale. Like many African Americans of his generation, he was affected by the historical stigma dating back to the Tuskegee Study (1932-1972) that stymied his interest in clinical research. He was pleased to discover that YCCI wants to establish a partnership with the community built on an informed and clear definition of policies, procedures, and practices regarding clinical research. He is now an ambassador for YCCI and serves as an advocate within the African American community in particular and the larger minority communities in general. He considers the partnership with Yale to be a valuable learning exchange and a necessary in building an effective community relationship to advance clinical research.



*“As an African American, I used to be skeptical about participating in clinical trials. Now we are not only participants but also partners in Yale’s research efforts.”*

Rev. Dr. LeRoy O. Perry, Jr., Pastor, St. Stephens AME Zion Church in Branford, and Cultural Ambassador to the Yale Clinical Research Program



Photo Robert Lisak

## YCCI TEAM MEMBER

*Rhoda Z. Arzoomanian, MSM, BSN, RN, Associate Director of YCCI*

Rhoda Z. Arzoomanian, MSM, BSN, RN, joined Yale in 2014 as Associate Director of YCCI and Yale Cancer Center. A nationally recognized expert in cancer clinical research, clinical trials databases, and the management of an NCI-designated cancer center, Ms. Arzoomanian has over 30 years of clinical research experience. Her position at Yale encompasses clinical research across the medical campus, including Yale Cancer Center. She oversees clinical research regulatory units, developing results-oriented strategies for these areas as well as testing and verifying compliance and good clinical practices. Ms. Arzoomanian was asked to oversee the clinical trials operations of Yale Cancer Center temporarily when she was hired at Yale. She graciously agreed to fill both positions for a limited time. After playing an active role over the past five years in the growth and success of Yale Cancer Center’s clinical research, the Cancer Center is seeking a suitable candidate to work with an experienced team of deputies. Ms. Arzoomanian is excited to finally fill the role for which she was originally hired. At YCCI, she is responsible for the oversight of implementation timelines; the YCCI multicenter unit; the YCCI IND/IDE support unit;

project management resources; and the activities related to eSource and eReg implementation at Yale.

Her background, which included implementation of NCI initiation timeline targets, is a valuable asset to investigators across the spectrum of T1-T4 research.

In addition, Ms. Arzoomanian has long been recognized as a leader in the development and refinement of the NCI’s Clinical Trials Reporting Program and Cancer Informatics for the Cancer Center’s Advisory Board, focusing specifically on NCI data reporting standards. She served as a member of the 2005 NCI Clinical Trials Working Group and of the NCI Clinical Trials Advisory Committee’s Clinical Informatics Working Group. The group’s purpose was the provision of extramural expertise and advice on the implementation of NCI informatics initiatives. These initiatives were intended to improve the value of cancer clinical trial data as well as increase the accessibility of this information to physicians, patients, and the public while minimizing the burden of data management.

## HELP US DISCOVER HERO MITCHELL THEN AND NOW — “PAVING THE WAY” THROUGH A RARE GENETIC DISEASE

Mitchell enjoys recess and math and, at nine years old, has an ordinary on-again off-again relationship with his older sister. In appearance and activity, he’s a typical child—the very picture of health. That picture is a radical reversal from his early months, when it was far from certain he’d survive to his first birthday.

“They basically handed him back to me at 14 days old and said that he might not survive the first year, and probably would not see five years,” said Mitchell’s mother, Amy. “So the fact that he is going to be turning 11 in April is an absolute miracle and blessing.”

While today Mitchell appears healthy, the first three years of his life were riddled with uncertainty and fear as he battled an inherited enzyme deficiency that affects how the body removes the waste made from breaking down protein, leading to toxic levels of ammonia building up in his blood. Mitchell’s condition, argininosuccinic aciduria, one of six urea cycle disorders (UCDs), is chronic. His current stable state is dependent on an exactingly regimented diet of formula and medications delivered to him four times a day through a tube into his stomach. While Mitchell has not had an attack of worryingly high ammonia levels since shortly after his birth, the threat of one developing is a daily specter for Amy.

“When I try to tell people the stress and the worry, and that there is no prognosis, and that he could wake up tomorrow morning and be so ill that he could pass away—not many people can truly understand that, because today he looks like any other child,” Amy said. “It’s very difficult to figure out this condition, because there’s really no rhyme or reason to it. That’s why we have participated in studies; I’m hoping to pave the way for other individuals and parents.”

UCD is a rare, medically mysterious, and largely unknown condition. Its symptoms are widely variable from person to person, and the long-term effects of having it—even barring frequent ammonia attacks—are uncertain. “He could be hyperactive or tired or seem ‘off.’ These could be symptoms of him having an ammonia attack. This could also just be him being a typical nine-year-old, and he’s developing his own personality. The symptoms are unknown,” Amy said. “So, truly, I don’t know if Mitchell is having any symptoms; I don’t know if he’s sitting here at home and he’s having an ammonia attack. That’s very scary to me.”

When Mitchell was 10 months old, Amy enrolled him in a longitudinal study that started at Yale and now continues through Boston, to learn more about urea cycle disorders through observation.

*“That’s why I like to be able to participate in these studies, to be able to pave the way and hope to be able to provide information that will assist other families in making their lives easier.”*

Amy, Mitchell’s mom

Visit <https://medicine.yale.edu/ycci/clinicaltrials/volunteer/>



Photo Robert Lisak

While there is still no cure for his condition, researchers are continually learning more to develop different treatments and medications to manage it. Thanks to his formula and medications, Mitchell has been largely stable since the initial years following his diagnosis.

“Whenever I leave the Children’s Hospital with Mitch, I always think, there are so many families that have it so much harder than we do, and that I’m so fortunate, every single day, that Mitchell is as healthy as he is,” Amy said. “That’s why I like to be able to participate in these studies, to be able to pave the way and hope to be able to provide information that will assist other families in making their lives easier. Because every day that we leave the hospital—Mitchell holding my hand and walking out together—is a wonderful day for me.”



# HELP US DISCOVER | Be Part of Clinical Research at Yale.

## Meet One of Our Help Us Discover Heroes.



**“Give it a try. You have nothing to lose; if anything, you can learn something about your illness.”**

*- John, a firefighter and type 2 diabetic, enrolled in a research study.*

Helping others has always been a powerful motivator for John, who has been a firefighter for 29 years. Intimately familiar with risking life and limb to assist others, John didn't hesitate to take up another kind of heroism when a clinical research ad in his doctor's office caught his eye. The research study was to observe glucose levels in the brain relative to in the blood, comparing patients with type 2 diabetes to healthy participants and those with obesity. Having been diagnosed with type 2 diabetes six years prior, John was an ideal participant.

Janice Hwang, MD, Assistant Professor of Medicine (endocrinology) at the Yale School of Medicine and the primary study doctor on the trial, and her collaborators found that participants with obesity had a reduced rise in brain glucose levels compared to lean participants at equivalent increased blood glucose concentrations. The brain glucose response was even more reduced in participants with type 2 diabetes. These findings may help investigators understand the mechanisms driving eating behaviors and neurocognitive symptoms associated with those diseases.

## GENEX – Lung Disease Study

### Do you have asthma?

If you are **18 years of age or older** and have **asthma or COPD**, you can help us learn more about lung diseases. This will entail a single, 2 to 3 hour study visit that may involve a medical history review, lung function testing, sputum induction, and blood draw.

**Compensation of \$60 for completed visit.**

**Healthy volunteers are also needed.**

To learn more or see if you are eligible to participate, please call or text (203) 500-3808 or email [asthma@yale.edu](mailto:asthma@yale.edu).

HIC #0102012268



## Diabetes and Obesity Research Studies

### We need your help.

You can play an important role in research by volunteering for **free and confidential** Diabetes Research Studies.



If you are **between the ages of 18 to 85**, and have **type 1 or type 2 diabetes, obesity, or struggle with your weight**, you may be eligible to participate in a variety of research studies.

**Compensation up to \$800.**

**Healthy volunteers are also welcomed.**

To learn more or see if you are eligible to participate, call (203) 737-4777 or email [diabetes.research@yale.edu](mailto:diabetes.research@yale.edu).

HIC #'s: 2000022476, 2000022407, 2000021046, 2000020059, 2000020041, 1602017151, 1503015469, 1408014461, 1208010648, 0108012609

## Binge Eating and Exercise Program

### Interested in a free program for binge eating and weight loss?

If you are **concerned about binge eating and weight** and want to take part in an exercise program, and are **18 to 65 years old**, you may be eligible to participate in a **free and confidential** study that will provide behavioral therapy.

**Compensation up to \$50.**

To learn more or see if you are eligible to participate, please call the Yale Program for Obesity, Weight, and Eating Research at (203) 785-7210 or fill out an interest form online at [power.yale.edu](http://power.yale.edu).

HIC #2000023412



## Lupus Studies

### Do you have active Lupus?

If you are **18 years of age or older** and have been **diagnosed with Lupus**, you may be eligible to participate in a treatment study. There are very few treatment options available to patients with Lupus. Dr. Koumpouras at Yale University is currently conducting several clinical research studies that examine investigational new treatments for Lupus symptoms.

**Compensation is offered, but varies by study.**

To learn more about our clinical trials program and see if you are eligible, please contact Allison Ready, Study Coordinator at (203) 785-6631 or email [allison.ready@yale.edu](mailto:allison.ready@yale.edu).



Yale has hundreds of clinical studies under way for a wide variety of conditions. None of them would be possible without volunteers who were willing to take part in clinical studies. Volunteers like you are the only way for medical breakthroughs to reach the public. Please consider participating in a clinical study and helping Yale continue its tradition of advancing medical knowledge.

## Mood Disorders Study

### Do you suffer from Bipolar Disorder or PTSD?

If you are **between the ages of 18 to 65 years old** and suffer from **major depression, bipolar disorder, or PTSD**, you may be eligible to participate in a **free and confidential** study that will help us better understand the neurological causes of mood disorders. The study will entail a screening session that includes a physical and blood work, and a PET scan and MRI.

**Compensation of \$365 or more.**

To learn more or see if you are eligible to participate, please call (203) 737-6484 or take our online survey at [www.tbip.yale.edu](http://www.tbip.yale.edu).

HIC #1101007933



## Cardiovascular and Lupus Research

### We need your help.

**Healthy volunteers needed.**

If you are a **healthy adult with no history of cardiovascular disease** and **do not take cardiovascular medication**, you may be eligible to participate in studies that further cardiovascular and lupus research. All that is required is a blood draw and urine sample.

**Participants will receive a \$20 gift card. Parking is free.**

To learn more or see if you are eligible to participate, call 1-877-978-8343 or visit [helpusdiscover@yale.edu](mailto:helpusdiscover@yale.edu).



## Stress Reduction Study for Partners with Early Dementia

### Does your partner have early stage dementia?

If you are **married or in a committed relationship**, are **at least 60 years old**, and **you live with a partner who has early stage dementia**, you may be eligible to participate in a study geared towards lowering daily stress and supporting you in your relationship. Participation involves three short home visits. During the visits, we will teach you a stress reduction technique and ask you and your partner to complete a brief survey.

**Compensation up to \$200 per couple.**

To learn more or see if you are eligible to participate, please contact Joan Monin (203) 785-2895 or email her at [joan.monin@yale.edu](mailto:joan.monin@yale.edu).

HSC #2000021852



## Yale ♥ Moms Study

### Healthy Women Needed for a Research Study at Yale New Haven Children's Hospital.

We are recruiting women between the ages of **18-45** who had a baby within the past 12 months to play an important role in research by volunteering for this study.

Your participation in this research study involves drawing blood in order to better understand how some pregnancy complications can effect long-term health. The research will involve two 40-60 minute visits and blood pressure monitoring.

**Compensation of up to \$50 for participation** and you will also receive a personal evaluation of your blood sugar, blood pressure, and cholesterol and learn skills on how to get (and/or stay) healthy after having a baby.

To learn more or see if you are eligible to participate, contact Lauren at (203) 500-3995 or email [yaleheartsmoms@yale.edu](mailto:yaleheartsmoms@yale.edu).

HIC #2000021647



## Primary Biliary Cholangitis Study

### Have you been diagnosed with primary biliary cholangitis?

If you are **18 to 75 years old**, have **primary biliary cholangitis with moderate to severe fatigue**, and **on stable therapy for at least 6 months**, you may be eligible to participate in a **free and confidential** study. This will entail completing an 8-week mindfulness-based intervention program (2.5 hours once weekly; and one weekend day retreat) in a group setting at the Yale Stress Center, as well as blood tests, symptom questionnaires, and wearing an activity monitor as needed.

To learn more or see if you are eligible to participate, please contact Laura Cusack at (203) 737-6839 or email [autoimmuneliver@yale.edu](mailto:autoimmuneliver@yale.edu).

HIC #2000022299



## Wart Study

### Got Warts?

We are conducting a research study for the painless treatment of warts in **patients 5 to 25 years of age**. Patients must have a wart, excluding face and genital, that has not undergone extensive treatments.

**Compensation up to \$50 per office visit (screening visits excluded).**

To learn more or make an appointment, call Carmen at Yale Dermatology Associates (475) 228-6052.

HIC #1209010850



To find out more about trials at Yale, visit our website, [www.yalestudies.org](http://www.yalestudies.org). Or call 1-877-y-studies for more information.

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# Yale



# YALE REGULATORY UPDATE

Clinical trial activity at Yale has grown significantly in recent years and is expected to continue growing. In FY2015, Yale had over 700 open clinical trials; in FY2016, this number increased to 1,327; and as of March 1, 2019, this number is 1,947.

Conducting clinical trials is a critical and exciting component of medical research but obligates Yale to ensure compliance with numerous important regulations. Yale has made tremendous progress in recent years, with considerable investments in the people, processes, and technology that comprise our current compliance capabilities.

YCCI was established to support clinical and translational research at Yale. YCCI has developed and continues to enhance, a robust enterprise-wide infrastructure designed to provide integrated operational and compliance support to Yale's faculty, whose innovative research leads to new discoveries and medical advances. YCCI is a national leader in many respects, including the integration of Epic and OnCore to support billing compliance; moreover, Yale's overall compliance practices in relation to clinical trials are strong. However, as we strive to improve our robust clinical and translational research supporting pioneering science and ground-breaking therapy development, our top priorities must continue to be the safety of our participants while building a structure allowing for continuous quality improvement.

With both safety and quality in mind, we have identified opportunities to further enhance the university's compliance practices and will be introducing new policies, practices, and training to support each of the following initiatives:

## FOR MORE INFORMATION

Information on all three initiatives can be found at: <https://medicine.yale.edu/ycci/researchers/>

### Clinical Research Billing

Clinical trials often but not always involve the provision of billable medical services. When subjects participate in such a trial, the medical services they receive fall into one of three categories:

- (1) research-specific services related to the study, which should be billed to the clinical trial's sponsor, and should not be billed to the patient or their insurer;
- (2) standard-of-care services related to the study, which should not be billed to the research sponsor, but should be billed to the patient and/or their insurer, although an insurer may require special coding and other information (such as the national clinical trial number) to indicate the service is study-related; and
- (3) non-study-related services, which are billable to the patient and/or their insurer.

To achieve our goal in this area, a special billing compliance task force led by Alice Tangredi-Hannon, University Research Compliance Officer, and Kelly Santamauro, YCCI Associate Director for Clinical Research Billing Compliance, was convened which included clinical research coordinators, HRPP leadership and departmental business office representative to recommend further enhancements to our current practice. Based on the work of this group, a new policy has established which will centralize Medicare Coverage Analysis management.

### ClinicalTrials.gov

ClinicalTrials.gov is a government registry that provides the public with access to information regarding a wide range of federally and privately funded clinical trials. The website is maintained by the U.S. National Library of Medicine (NLM) at the NIH. Federal law requires that sponsors or investigators affiliated with applicable clinical trials register trial and report results through ClinicalTrials.gov. Penalties for non-compliance may include fines of over \$11,000 per day per incidence after notification of noncompliance until resolved. For federally funded grants, penalties may include the withholding or recovery of grant funds. To further enhance our efforts, the work flows supporting HRPP policy #1000 PR.1 Clinical Trial Registration and Reporting Results has been enhanced.

### Investigational New Drug or Device Application (IND or IDE) management

An Investigational New Drug or Device Application (IND or IDE) is applied for to seek authorization from the FDA to administer an investigational drug or biological product to humans. A faculty-sponsored IND/IDE authorization is significant because it makes the faculty member holding the authorization the trial "sponsor," possibly in addition to the role of site principal investigator. Although YCCI has introduced services to help support IND/IDE and multi-site studies, we have determined that enhanced YCCI support would further enable innovative clinical studies requiring an IND/IDE.

*Written by Linda Coleman, Kelly Santamauro, Helen Seow, Rhoda Arzoomanian, Alyssa Gateman, and Kelly Anastasio*