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 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 s 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
Brian Smith, 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 in 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. He is also 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 a current member of the NIMH National Mental Health Advisory Committee, chair of the Neuroscience Forum of the U.S. National Academies of Sciences, Engineering, and Medicine; and editor of Biological Psychiatry. He was honored in 2018 by being named a member 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 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
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.
As rewarding as it has been to oversee this transformation with Bob, I believe what we have done is lay an unbelivable 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.

“Meet the Leadership — Harlan Krumholz, MD”
August 8, noon — 1:00 p.m.

“Meet the Leadership — Ann Kurth, PhD MPH”
August 8, noon — 1:00 p.m.

“Good Clinical Practice Refresher”
September 25, 2 p.m. — 3 p.m.

“Faculty Dinner Series”
September 18, 5:00 p.m. — 7:00 p.m.

“Single Subject Modifications”
September 20, noon — 1:00 p.m.

Coffee and Conversation
September 18, 5:00 p.m. — 7:00 p.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 Backenstedt, MD, Harold W. Jacobson Professor of Medicine, Deputy Dean for Faculty Affairs
Michael Craig, 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, Director of Biomedical Engineering, of Medicine (Hematology) and of Pediatrics; Deputy Dean for Scientific Affairs (Clinical Departments); Chair, Department of Laboratory Medicine

YCCI Events Calendar

Coffee and conversation
“Single Subject Modifications”
Linda Coleman, Director, Human Research Protection Program
August 22, 9:00 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 Backenstedt, MD, Harold W. Jacobson Professor of Medicine, Deputy Dean for Faculty Affairs
Michael Craig, 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, Director 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, Director, Human Research Protection Program, Office of Research Administration, Yale University
Alyssa Davidson, MPH, MCID, 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 upcoming events, visit http://ycci.yale.edu/education/stafftraining/
A “lapse of faith” led Christopher Pittenger, MD, PhD, Associate Professor of Psychiatry, to the position director of the Yale OCD Research Clinic immediately after residency. While Pittenger always appreciated 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 covered the mechanism of the glutamate imbalance in the brain—a study which later led to an ROI grant. There was also a parallel treatment study which used an already FDA-approved glutamate modulator. Rituximab, 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 hope will really make a different to patients. The support for me to find my footing in clinical research was essential.”

In 2010, Pittenger was named a YCCI Scholar. “The YCCI award came at a pivotal time in my career. I had received a pilot award from YCCI that supported a program of research in my basic science lab to examine the neuroendocrinology 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 Gruener, MD, 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.”

Christopher Pittenger, MD, PhD, 2009 YCCI Scholar

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

“For 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. “Women with type 1 diabetes 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 of Pediatrics and Chief of Pediatric Endocrinology; Coulter Newkirk, MD, Chief of Pediatric Endocrinology and Endocrinology (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.”

Eda Cengiz, MD, 2010 YCCI Scholar

Lucia Jilaveanu, MD, PhD, 2014 YCCI Scholar
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.

Lucia Jilaveanu, MD, PhD, 2014 YCCI Scholar

Forrest Crawford, PhD
2014 YCCI Scholar
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 advanced 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 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 door to a wide variety of research questions that we have been able to pursue and try to solve.”

Forrest Crawford, PhD, 2014 YCCI Scholar

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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. "I still enjoy teaching, and I 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 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 new drugs," Eid says. "We can help patients, and we can understand what is happening in 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 ROI 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."

Lloyd Cantley, MD
Co-director, Education
Lloyd Cantley, MD, is a noted nephrologist who studies the mechanisms of renal tubule cell proliferation 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 addiction and 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.

Shangqin Guo, PhD
2014 YCCI Scholar
Assistant Professor of Cell Biology
For Shangqin Guo, PhD, a scientist who studies the mechanisms of cell biology, cells are like children. "We can't predict what a child is going to be like," she says. "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 foundations of how to make progenitor cells to try to capture the moment that they, like an unruly child, "go bad," which is a cell mechanism that becomes malignant. Guo hopes that if she can pinpoint that moment and capture it on video, she may be able to determine the mechanism of malignant behavior, 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 cellular mechanism that, when activated, triggers the growth of some kinds of tumors. Guo and her team had developed a way to turn a tumor 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 understand why some blood progenitor cells go bad, will these progenitors become cancerous, or just some of them? If only some of them become cancer, is there anything different about 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 interrupting the rapid cell division, 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 preventative approach to cancer.

The YCCI Scholar Award "was one of my earliest funding sources," Guo says. She is working on expanding the study, which if proven on a larger scale, could eventually lead to a preventative approach to cancer.
YCCI JUNIOR FACULTY SCHOLARS

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

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

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

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

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

Danya Keesee, 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

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

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

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
Statistical Methods for Analyzing Glaucomatous Visual Field Progression

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

Danya Keesee, 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

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

Jason Weinstein
Assistant Professor, Chancellor Scholar, Rutgers New Jersey Medical School
STAT4 Regulation of Pathogenic Follicular Helper T Cells in Autoimmunity
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
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
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.
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 us than Bob Sherwin, and he has guided our Medical Center’s embrace of translational medicine through YCCL since its inception. Thank you, Bob, for blazing this trail for Yale."

Marna Borgstrom, MPH
CEO, Yale New Haven Health System

"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

"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 YCCL. 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 admiring trainees."

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

"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

"It is a special honor and pleasure to follow in Bob’s footsteps at YCCL. 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

"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

"You have been a mentor, a role model for innovative science, generous collaboration, and generative mentorship throughout academic medicine.

Robert Alpern, MD
Dean and Ensign Professor of Medicine

"Yale School of Public Health research has been strengthened by your leadership, including through the YCCL 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
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, Cardiometabolic 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 Honors 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 YCCI IND/IDE support unit and in the management of the multicityte 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

HELP US DISCOVER HEROES

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

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 valuable 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 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.
A 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.

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patients with type 2 diabetes to healthy participants and those who were at increased risk for type 2 diabetes. These findings may help bring 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 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.

John, a firefighter and type 2 diabetic, enrolled in a research study. Helping others has always been a powerful motivator for John, and when he received a call from a Yale School of Medicine 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.

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.

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.

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 84, 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 $50.
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.

HIC #: 1408014461, 1503015469, 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, call the Yale Program for Obesity, Weight, and Eating Research at (203) 795-7330 or fill out an interest form online at powereyclopedia.yale.edu.

HIC #: 000000213

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 1-877-978-8143 or visit helpusdiscover.yale.edu.

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) 785-6161 or email allison.ready@yale.edu.

HIC #: 000005093

Do you 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 at (203) 785-2805 or email her at joan.monin@yale.edu.

HIC #: 000001064

Mood Disorders Study

Do you suffer from Bipolar Disorder or PTSD?

If you are between the ages of 18-64 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 $565 or more.

To learn more or see if you are eligible to participate, please call (203) 737-6404 or take our online survey at www.cbid.yale.edu.

HIC #: 000000297

Primary Biliary Cholangitis Study

Have you been diagnosed with primary biliary cholangitis?

If you are 18-80 years old, have primary biliary cholangitis with moderate to severe fatigue, and are 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) at 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.

HIC #: 000002109

Heart 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 have 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 affect 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 sugars, 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 Laura at (203) 500-9095 or email yaleheartmoms@yale.edu.

HIC #: 000000215

Wart Study

Got Warts?
We are conducting a research study for the painless treatment of warts in patients 7 to 20 years of age.

Patients must have a wart, excluding face and genital, that has not undergone extensive treatments.

We are conducting a research study for the painless treatment of warts in patients 5 to 25 years of age.

Compensation of up to $150 for participation.

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

Yale Dermatology Associates (475) 228-6052.

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.

To find out more about trials at Yale, visit our website, www.yalestudies.org.

Or call 1-877-y-studies for more information.
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:

**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

FOR MORE INFORMATION
Information on all three initiatives can be found at: [https://medicine.yale.edu/ycci/researchers/](https://medicine.yale.edu/ycci/researchers/)