



Yale Center for Clinical Investigation

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Photo Harold Shapiro

YCCI Beginning a Second Decade of Support

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Although it is hard to believe, the Yale Center for Clinical Investigation (YCCI) is now in its second decade providing training resources and support for Yale's clinical and translational investigators. With the second renewal of the Clinical and Translational Science Award (CTSA), YCCI is well poised to continue supporting innovative science to improve the health of patients everywhere.

In July 2016, the National Center for Advancing Translational Sciences (NCATS) awarded Yale \$53.6 million to renew its five-year CTSA. Yale was among the first 12 institutions to receive CTSA funding when the National Institutes of Health established the program in 2006. Today there are more than 60 CTSA-funded hubs across the country. YCCI also receives substantial funding from the School of Medicine to provide investigators with research support and education, as well as support from Yale Medicine (the School of Medicine's clinical practice) and Yale New Haven Hospital.

"We've made incredible strides under the CTSA in establishing a robust infrastructure and resources for investigators," said **Robert J. Alpern, MD**, Dean of the School of Medicine. "I'm delighted that CTSA support will allow us to continue to expand our research enterprise to support the acceleration of treatments from the bench to the bedside."

Reflecting on the First Decade

YCCI was established in 2005 to provide robust infrastructure to support research and educate the next generation of clinician-scientists. It was formed as a result of a strategic planning process that took place in 2004 and identified a need to significantly bolster and support the School of Medicine's research enterprise. In its first decade, YCCI developed 36 new programs and strategic initiatives that had not existed prior to the CTSA, and made major investments that have expanded or enhanced the resources of 23 additional programs that span the institution. These initiatives have transformed the research landscape at Yale and across Yale New Haven Health. Highlights include:

- The Junior Faculty Scholars Program, which provides protected time for Scholars to focus on research projects as well as mentoring from senior faculty. Since 2006, there have been 123 past or current Scholars who have successfully applied for more than \$314 million in independent grant funding and have published more than 2,400 papers. Yale is among the ten top-performing CTSA institutions for NIH career development (K) awards.
- Last year YCCI provided support to approximately 700 faculty members for nearly 4,000 projects.
- Implementation of OnCore, a clinical research management system integrated with Epic, Yale's health record for laboratory and demographic data, study enrollment and consent, serious adverse events reporting, and financial and billing data.

As we begin the second year of our third round of funding under the CTSA grant, our focus has been unwavering: we continue our full commitment to training the next generation of clinician-scientists. Going forward, we are eager to build upon our exceptional educational programs, which have already ushered in a new generation of more than a hundred junior faculty investigators as well as scores of PhD physicians and medical students who have been able to gain meaningful research experience.

We have made substantial progress in expanding Yale's research enterprise in the past eleven years. We will continue to build upon the infrastructure we have established to bolster collaborations within and across departments at Yale as well as with community providers, community partners, industry, and other CTSA institutions. Our focus will be on streamlining the research process; leveraging information technology to conduct research; and implementing initiatives to promote team science.

In many ways, the renewal process itself mirrored the spirit of the CTSA grant. It required the collaboration, cooperation, and hard work of senior leadership, faculty, and staff across the medical campus, the university, the practice, and the entire health system. I am happy to report that all of us came together to build and devise strategies to implement our vision under the new requirements of the CTSA. The YCCI team could not have undertaken this enormous task without the widespread collaboration of our entire research and clinical communities.

We look forward to continuing this work in the coming year so that we can more quickly bring improved therapeutics to our patients in New Haven and around the world.

Robert Sherwin, MD
Director, YCCI



Photo Robert Usiak

Robert Sherwin, MD, and Robert J. Alpern, MD.

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For information on new CTSA pilot grants, please see page 20 — the back cover of this newsletter.

CTSA ISSUE

YCCI RECEIVES CTSA RENEWAL, BEGINNING A SECOND DECADE OF SUPPORT

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YCCI's Five Deputy Directors



Photo Robert Usiak

Margaret Grey, DrPH, RN, FAAN
Annie Goodrich Professor and former Dean,
Yale School of Nursing



Photo Robert Usiak

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



Photo Robert Usiak

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



Photo Robert Usiak

Marcella Nunez-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

- Creation of the Help Us Discover database, which now has more than 9,000 patients who have expressed interest in participating in clinical research.
- In March 2015, implementation of the Help Us Discover research tab in MyChart, which allows patients to view open trials and create a research profile. To date, more than 1,753 new volunteers have signed up through MyChart; 1,170 who were referred and screened for specific studies, and 409 who have already participated in studies (including 145 who are underrepresented minorities). To date, only 300 patients have opted out of research.
- Creation of study recruitment services, including a Recruitment Call Center staffed seven days a week; preparation of recruitment materials in English and Spanish; and advertising campaigns featuring ads on the Yale Shuttle Bus system, a location that had never before been utilized for advertising.
- Establishment of the Cultural Ambassadors program, a partnership with Junta for Progressive Action and the African Methodist Episcopal (AME) Zion Church to promote clinical research education and awareness in New Haven's Hispanic and African American communities. Over the past two years, in studies where Cultural Ambassadors have been engaged, minority participation has not been lower than 12 percent, with an average minority participation ranging between 20 and 65 percent.
- Supported 101 pilot awards for promising research projects that resulted in more than \$50 million in grants.
- Achievement of more than 580 percent growth in industry-sponsored trials.
- Establishment of a centralized multicenter trial unit to support investigator-initiated multicenter studies — an economic and efficient alternative to hiring ad hoc staff members who may not have appropriate expertise.

All in all, the CTSA awards have brought more than \$156 million in research support to the School of Medicine since 2006; Yale now has over 1,600 open clinical trials. Beyond that, YCCI has created and implemented initiatives that have increased Yale's capacity to conduct high-quality clinical and translational research, and decreased the administrative burden on investigators so that they can more readily focus on the research itself.

Looking Ahead

Under the renewal of the CTSA, YCCI and other CTSA hubs are charged with accelerating the discovery, development, and delivery of interventions to improve health outcomes across the lifespan. This task involves:

- Streamlining the study initiation process.
- Collaborating with other CTSA sites as well as with community providers, patients, and industry.
- Promoting teamwork in science.
- Developing effective ways to improve recruitment and retention of clinical trial participants.

YCCI's application included plans to strengthen the infrastructure connecting investigators with community health providers and stakeholders throughout Connecticut, and expand collaborations with other CTSA sites. Yale's IT infrastructure will support the creation of a research hub that includes the Schools of Medicine, Nursing, Public Health, and Engineering; Yale Medicine; Yale New Haven Health, and the VA Connecticut Healthcare System. YCCI will also continue to centralize resources to streamline the research process and ease the administrative burdens of conducting clinical trials.

“Our focus has been unwavering: we continue our full commitment to training the next generation of clinician-scientists.”

Robert Sherwin, MD, YCCI Director

Providing the next generation of clinical and translational researchers with the skills needed to conduct multidisciplinary team science remains a top priority. “I'm very proud of the success of our educational programs to train medical students, physicians, post-doctoral fellows, and junior faculty,” said YCCI Director **Robert S. Sherwin, MD**, who is PI of the CTSA and the C.N.H. Long Professor of Medicine (Endocrinology). “Continuing these efforts under the CTSA is a critical part of our mission that will have a far-reaching impact going forward.”

During this grant cycle, the number of slots in the TL-1 Multidisciplinary Pre-Doctoral Training Program in Translational Research is expanding from 10 to 20, the maximum number allowable. The KL-2 Mentored Clinical Scholars Program is also expanding from seven partially funded Scholars to nine.

We will be able to track our progress via our system-wide evaluation tracking system. This powerful evaluation tool allows us to track grants; publications; core use; institutional support and investments; pilot awards; community projects; such data related to trainees as educational outcomes, awards, and collaborations; patents; and survey data. These capabilities can be used for reporting to funding agencies — including for the CTSA and Yale's 22 NIH-funded centers — and institutional reporting. This administrative innovation has the potential to change the way investigators and research staff work, allowing them to track their progress and determine which measures are successful.

Moving forward, YCCI's focus will be on collaboration — not just across departments, disciplines, and the university, but with patients, community partners, and institutions across the country and around the world. We plan to pursue partnerships with the School of Engineering & Applied Science and the School of Management to develop and market therapeutics that address unmet clinical needs. We will also build upon our strong relationships with community partners and leverage Yale New Haven Health's more than four million electronic health records to provide investigators with access to a large and diverse patient population for outcomes and clinical research. CTSA support will help transform Yale into a “learning health system” that generates innovative strategies to benefit tomorrow's patients. 🌟



Photo Robert Usiak

Robert J. Alpern, MD

When I was appointed dean in 2004, more than a year before the original CTSA program was announced, I initiated a strategic planning process aimed at strengthening and expanding clinical and translational research at YSM. YCCI was launched as a result of that process, with support from the highest levels of Yale University and Yale New Haven Hospital. Two major goals that emerged were (1) to establish a “home” for the training of the next generation of clinical and translational scientists; and (2) to provide a robust infrastructure that would promote innovative and collaborative research directed at improving patient care. Today, the fruits of our strategic planning and subsequent investments by both Yale and the NIH are remarkable. This is evident in the outstanding faculty members who have been recruited, and in the excellence of YCCI's education, training, and research support.

I firmly believe that supporting an integrative environment for clinical and translational research is fundamental to the success of the medical school. I view YCCI as critical to achieving our broader strategic goals. YCCI has gone above and beyond what we thought we could accomplish, exceeding our expectations by far.

Robert J. Alpern, MD
Dean and Ensign Professor of Medicine

LIFESPAN RESEARCH: IMPACT OF CHILDHOOD DISEASE ON ADULT HEALTH

YCCI's renewed CTSA grant award allows Yale to continue its leadership in cutting-edge areas of research. One such novel initiative under the grant renewal is Diseases Across the Lifespan, which will explore the rising field of lifespan research — a new approach to examining the ways in which diseases that commonly strike adults have their roots in infancy and early childhood.

A trio of physician-researchers who are experts on both ends of the lifespan leads the new initiative:

- **Clifford W. Bogue, MD**, Professor and Chair of the Department of Pediatrics
- **Thomas M. Gill, MD**, the Humana Foundation Professor of Medicine (Geriatrics) and Professor of Epidemiology (Chronic Diseases) and of Investigative Medicine, and Director of the Yale Program on Aging and of the Claude D. Pepper Older Americans Independence Center
- **Linda C. Mayes, MD**, the Arnold Gesell Professor of Child Psychiatry, Pediatrics, and Psychology; and Chair of the Yale Child Study Center.

biological, social, environmental, and clinical issues that are of great importance, and there are a lot of unanswered questions.”

While the leaders of this new initiative have yet to determine particular diseases of interest for lifespan research at Yale, one obvious candidate is obesity. “We know that our society is becoming increasingly obese, and there are some startling statistics about the high rates of obesity in childhood as well as the increase in metabolic conditions such as diabetes,” says Gill. Obesity is also a strong candidate for lifespan research because of its link to diabetes and such other conditions as heart disease.

Addressing these conditions more deliberately and earlier in life may not only improve a patient's health, but also has the potential to reduce the high health care costs related to treatment of chronic disease in the long term. “By making the right intervention earlier and diagnosing it properly, we can have a huge impact on our national health picture,” says Bogue.

The diseases that will ultimately be chosen will harness Yale's current strengths in a variety of areas. “Historically, Yale has been one of the leading institutions studying diabetes and metabolism, with considerable expertise in childhood diabetes, and increasingly, old age,” says Gill.

Lifespan research may also broaden understanding of how stress in childhood may be linked to adult disease. “In child mental health, one of the most compelling questions is how early stress and adversity, defined not just as child abuse or neglect, but family alcoholism, or profound family stress, break up, or exposure to war, can regulate a child's stress system,” says Mayes. “We are just beginning to learn that those individuals that appear in our internists' offices at age 40 with serious heart disease are often the individuals that are more likely to have had these early kinds of stressors in childhood.”

Yale has a reputation for robust collaboration between a variety of departments, and the new initiative also has the capacity to spawn ever more collaborative efforts between

disparate departments. “In many places where departments are siloed, we have people who are willing to work collaboratively because they want to find answers,” says Bogue.

“Lifespan research provides a much broader perspective, and opens up many new avenues for scientific inquiry and opportunities to collaborate,” says Gill. “I think that that is one of the important objectives of this new initiative—to foster and promote collaborations between investigators who have been focusing their research on a specific segment of the lifespan.”

Collaborations between pediatricians and internists, however, are less common, and lifespan research aims to change that. “When we do get together, we realize we have more in common than not,” says Gill. “There are a lot of issues involving caregivers, for example, which are common between the populations. There are also issues relating to cognitive capacity. Judgment doesn't often become fully developed until someone is 25, and we often start losing our cognitive and physical capacity as we get older.”

Lifespan research seeks not only to examine the impact of disease within the life of an individual, but also to examine how factors that influence health can be transmitted from one generation to the next. The field aims to understand how adults can affect children's development, and how children's development affects adults in turn through the parenting relationship. “In the act of being a caregiver, we know that caring has potential psychological as well as health benefits,” says Mayes. “Is the role of being a primary grandparent health-promoting? For me, being able to take this lifespan perspective, not just on disease but on health, on how things are transmitted generation to generation, is incredibly exciting.”

In the United States, lifespan research is still an emerging field. To date, most of the work in the field has come from the United Kingdom, where the discipline is known as life course research. University College London, a partner institution of Yale with strong connections to the Yale Child Study Center and the Program on Aging, has many resources in the field that Yale can look to, says Gill. In some ways, the United Kingdom is ideally positioned to conduct research across the life of an individual because of the existence of a national health service; the infrastructure is already in place to enroll an entire generation into a birth cohort study. Part of the challenge of building a lifespan research initiative at Yale would be to determine how to proceed without built-in birth cohorts. This goal can be achieved, says Mayes. “Lifespan studies require investment and some creativity,” says Mayes.

Although the initiative is in its very early stages, its leaders have begun to investigate the best direction to take. “At this point, we are brainstorming about the best opportunities in which Yale is positioned to take a leading role,” says Gill. These initial meetings have already led to a new pilot RFA (see announcement in this newsletter) and the development of the new Gesell Lifespan lecture series launched in April 2017 with its inaugural visiting scholar, **Steve Suomi, PhD**, currently Chief of the Laboratory of Comparative Ethology at the Eunice Kennedy Shriver National Institute of Child Health and Human Development. During the visit, Suomi met with the lifespan team and gave several lectures to students, trainees, and faculty focused on multi-generation studies among rhesus monkeys reared under a range of different conditions.

Plans are also underway to develop a registry service to support lifespan research with linked biologic samples. “There's an amazing depth of expertise both in basic science and in clinical translational areas that will provide a very strong foundation for our initiatives,” says Bogue.

“Yale has been a leader in child/adolescent research with the world-renowned Yale Child Study Center; at the other end of the aging spectrum, the Yale Program on Aging/ Claude D. Pepper Older Americans Independence Center is focused on research directed at enhancing the independence of older persons,” says YCCI Deputy Director **Melinda L. Irwin, PhD, MPH**. “YCCI can and should coordinate research and training efforts between these centers and other Yale centers/programs, with a focus on translational research that can ultimately shape policies that impact the entire lifespan.”

“I think YCCI is the logical vehicle to bring investigators together to advance this type of initiative,” says Gill. “YCCI can help provide the infrastructure that others who are working in this area can leverage, and ideally provide incentives so investigators in different disciplines will come together.”



From left to right: Clifford W. Bogue, MD; Linda C. Mayes, MD; and Thomas M. Gill, MD.

Lifespan research seeks to recognize risk factors in early childhood that can cause problems later. “We are looking at a lifespan perspective on how diseases emerge,” says Mayes. Doing so opens the door for earlier diagnosis and intervention, and the capacity to lessen the impact of disease as people age. “We talk about how biology is adapted to a given period or context, but then becomes a disease later in life.”

“Sometimes, the die is already cast when someone enters old age from events that occur earlier in life,” says Gill. “The aging process operates from the beginning of life. There are many

YCCI Events Calendar

Research-in-Progress Meetings

TACN203 at Noon Lunch is provided.

These meetings feature presentations from YCCI Scholars and Investigative Medicine Program students as well as trainees from the Medical Research Scholars Program. We encourage all faculty and staff to attend.

December 12, 2017 March 12 and 26, 2018
January 8 and 22, 2018 April 9 and 23, 2018
February 12 and 26, 2018

Coffee and Conversation

Cohen Auditorium, 9 am – 10 am
Breakfast is provided.

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

January 16, 2018 July 25, 2018
February 20, 2018 August 21, 2018
March 20, 2018 September 18, 2018
April 17, 2018 October 16, 2018
May 15, 2018 November 20, 2018
June 19, 2018 December 18, 2018

Lunch and Learn

Cohen Auditorium, Noon – 1 pm
Lunch is provided.

These monthly sessions address broader research issues and are open to all Yale faculty and research staff.

January 10, 2018 July 12, 2018
February 14, 2018 August 9, 2018
March 7, 2018 September 6, 2018
April 11, 2018 October 11, 2018
May 10, 2018 November 8, 2018
June 14, 2018 December 13, 2018

Introduction to Conducting Clinical Research at Yale Onboarding Course

January 25, 2018 July 31, 2018
April 24, 2018 November 15, 2018

Society of Clinical Research Associates (SOCRA) Prep Course and Certification Exam

April 4, 2018: Clinical Research Professional Certification Preparation & GCP Review Course
April 5, 2018: CCRP Certification Exam

For a list of presenters and topics, and for schedules and registration information for training events, visit <http://medicine.yale.edu/ycci/education/clinrestraining/index.aspx>.

CREATING A BLUEPRINT FOR DIVERSITY IN CLINICAL RESEARCH



Photo: Michael Wiersland

Yale President Peter Salovey and New Haven Board of Alders President Tyisha Walker-Myers presented six individuals and two groups with Yale University Seton Elm-Ivy Awards at a ceremony on campus on April 19, 2017. The Elm-Ivy Awards honor people whose efforts support collaboration between the university and its hometown. Elm Awards are given to members of the broader New Haven community, and Ivy Awards are given to Yale faculty, staff, and students. The awards were established at Yale in 1979 by Fenmore R. Seton '38 and his wife Phyllis.

Engaging a diverse community in clinical research trials has long been a challenge for investigators: while African Americans represent 12 percent of the U.S. population, they make up only five percent of clinical trial participants. At the same time, Latinos comprise 16 percent of the population, but only one percent of clinical trial participants.

Researchers continually seek to recruit and retain members of minority groups for trials so that their results can reflect the experiences and needs of those groups, and ultimately aid in developing interventions and treatments that will benefit the specific needs of these communities. It has also been noted that developing trust within minority communities can advance the health of these populations.

Seeking to address the need for increased minority participation in clinical research, YCCI created the Cultural Ambassadors program in 2011. The program is a collaborative partnership with the African Methodist Episcopal Zion (AME Zion) Church and Junta for Progressive Action. The Cultural Ambassadors program educates and engages leaders of New Haven's African American and Latino populations by involving them in study design; the creation and translation of culturally sensitive recruitment materials; direct subject recruitment; and dissemination of results.

The program has gone from strength to strength in the past seven years. Over the past two years, minority participation

in studies in which Cultural Ambassadors have been engaged, has not been lower than 12 percent, with an average minority participation ranging between 20 and 65 percent. Minority participation in research has been particularly important at Yale, as the City of New Haven's population is 27 percent Latino and 33 percent African American.

“Our partnership has shown me that Latino needs matter and our voices are heard.”

Sandra Trevino, LCSW,
Former Executive Director of Junta

The program has been such a success at Yale that YCCI has begun work to expand the Cultural Ambassadors program to the Duke University CTSA hub. In this new initiative, YCCI builds upon the lessons learned from the implementation of Yale's Cultural Ambassadors program with the goal of creating a blueprint for easy transfer of the program to other sites. Leaders from the Yale program are helping to train AME representatives in North Carolina to play a similar role at Duke, where they will help minority communities to better understand clinical trials and the benefits of participating in them.

AME Zion, based in Charlotte, North Carolina, is a large religious denomination and one of the oldest African American congregations in the United States. Nationally, the church has congregations in all but four of the states with CTSA. Duke, located in Durham, North Carolina, is a natural choice for the first setting to transfer the Yale program model to another CTSA, with the potential of other sites to follow in other areas with AME Zion participation. Following implementation of the program at Duke going forward, any site, regardless of prevalent diseases in the area or the types of studies local researchers would be interested in pursuing, would already have a blueprint for successfully implementing the program, and would be able to build upon relationships and sustain them for future studies.

The AME Zion Church in North Carolina is also considering a collaboration with Yale that would incorporate teaching the benefits of clinical research in its curriculum. “AME Zion is a ministry with a special focus on health,” says the Reverend Dr. Daran Mitchell of the North Carolina AME Zion Church. “The African American community is plagued by myths and misconceptions about clinical research that impede participation in clinical trials. I am anxious to pare down those barriers so that research more accurately reflects those who may benefit from its findings. There is an opportunity here to embed knowledge and attitudinal shifts within the educational process that has the potential for far-reaching effects.”

Junta for Progressive Action is the oldest Latino community-based nonprofit in New Haven, and provides services and advocacy to improve the lives of Latino people in the area. As Cultural Ambassadors, Junta representatives translate the

“The African American community is plagued by myths and misconceptions about clinical research that impede participation in clinical trials. ... There is an opportunity here to embed knowledge and attitudinal shifts within the educational process that has the potential for far-reaching effects.”

Reverend Daran Mitchell,
Adjunct Professor of Pastoral Theology,
Hood Theological Seminary

program's brochures, forms, and study materials into Spanish, and are also available as interpreters for researchers.

While Junta works only locally, its Cultural Ambassadors could provide leadership gained from its extensive experience working with Yale since the program's inception as the program expands to other areas. “Junta representatives have benefitted tremendously from learning directly from researchers about developments in research and clinical trials,” says Sandra Trevino, LCSW, former Executive Director of Junta, and a Cultural Ambassador. “Our partnership has shown me that our needs matter and our voices are heard.”

YCCI continues to build on the strength of the Cultural Ambassadors program at Yale and beyond with the long-term goal of building a national framework for recruiting and retaining members of minority communities in clinical research that will ultimately benefit both the research and the people who participate in clinical trials. ☺

Representatives from the Yale Cultural Ambassadors Program, the AME Zion Church in North Carolina, as well as Duke and Yale Universities, met in New Haven with Roy Herbst, MD, PhD, the Ensign Professor of Medicine (Medical Oncology) and Chief of Medical Oncology at the Yale Cancer Center to talk about diversity in cancer clinical trials.

Photo: Anthony DeCarlo



REMEMBERING REVEREND HOWARD



This spring, the Yale Cultural Ambassadors program received a Seton Elm-Ivy Award, presented annually by Yale University to individuals and groups from Yale and New Haven who have strengthened partnerships between the university and its home city. The award was not only a particular honor for the Cultural Ambassadors program, but also a meaningful tribute to one of its key team members: AME Zion Church Presiding Elder **Reverend Timothy Howard**, who passed away on February 6. Reverend Howard was presented with the Elm Award posthumously.

Reverend Howard played a crucial role in initiating and sustaining the Cultural Ambassadors program. “He was so committed to the program and its growth that even as his own health deteriorated, he traveled with YCCI team members to North Carolina to attend early meetings with local AME Zion leaders and Duke CTSA representatives,” said YCCI Chief Operations Officer **Tesheia Johnson, MBA, MHS**. “His spirit and dedication will be deeply missed among us at YCCI, but his spirit continues to inspire us.”

“Our work is seemingly just begun,” Reverend Howard said in a September 14, 2015, letter of support for the Yale CTSA renewal. “We look forward to continuing the work we have started with Yale to increase awareness of clinical research that will reach those most in need.”

Reverend Howard’s voice was crucial in carrying forward the program’s mission of breaking down barriers between Yale researchers and the communities they seek to help with their discoveries. With his guidance and support, the Cultural Ambassadors program has gone from strength to strength. Its recent honor doubly recognized the program’s ability to reach out to Yale’s surrounding community. While Elm Awards are given to representatives from New Haven and Ivy Awards to those from the university, the Cultural Ambassador program received both because its members hail from both the university and the city, and have done much to unite the two in a common purpose.

Yale President **Peter Salovey** and New Haven Board of Alders President **Tyisha Walker-Myers** presented the awards at a luncheon at Yale’s Schwarzman Center on April 19. The program was nominated for the award by **Robert Alpern, MD**, the Ensign Professor of Medicine and Dean of the Yale School of Medicine. “The Cultural Ambassadors Program exemplifies the positive change that occurs when the university and the community unite to share knowledge and spread opportunity,” Alpern said. “We are forever indebted to Reverend Howard and his pioneering efforts to launch this partnership. As the program continues to grow and flourish, it does so keeping in mind the Reverend’s spirit of inclusion and service to a diverse community, not only in New Haven but in other communities that share this vision.”

Photo: Robert Usiak

A Passion and a Commitment to Change

“Presiding Elder Howard was an incredible individual. We were always energized by his passion and excitement for our research partnership. We are very grateful for all he did for Yale, the community here, and our colleagues at Duke. We will miss him.”

Robert Sherwin, MD, YCCI Director

I met Reverend Timothy Howard in LaGuardia Airport in 2007. We were both flying in from the Carolinas; he was coming back home to Waterbury, Connecticut, and I was coming to New Haven as the newly appointed pastor of the Varick Memorial Church. From that day until the day he passed, I have always been impressed with the energy he brought to every endeavor; his will to live and find a cure for cancer; and his commitment toward the church and those he loved. Reverend Howard had an unusual passion for helping to make life better for people around him. I was privileged to travel to his home town in South Carolina, and I saw where his passion for people was nurtured in him from a loving family. That love for helping to improve the lives of others was seen in many ways; one profound way was in YCCI. What Timothy Howard helped to establish between Yale and the religious community is something that has helped countless persons across Connecticut and has inspired this kind of collaboration between other universities and communities across the country. He has left an impression in the religious community of Connecticut as well with those in YCCI that can’t be easily forgotten. Those who knew Elder Howard knew how he would close any conversation with you—with a hearty, “I love you, man!”

Reverend Eldren D. Morrison
Pastor of Shaw Temple AME Zion Church, Atlanta
Former Pastor of Varick Memorial AME Zion Church, New Haven

“Presiding Elder Howard’s passion and dedication to serve others was inspiring. He was instrumental in ensuring our partnership would flourish while focusing on getting the work done. We certainly miss him.”

Sandra Trevino, LCSW
Former Executive Director, Junta for Progressive Action



Photo: Robert Usiak

In 2011 at the Mount Olive AME Zion Church in Waterbury, CT, YCCI held a groundbreaking meeting with local religious leaders. Presiding Elder Howard spoke to church leaders about the importance of research participation, and the possible partnership with Yale. Without this alliance, he said, it would not be possible to address the diseases that plagued their community.

Historically, minorities have not participated in clinical research in the same proportion as Caucasian Americans, and therapy approvals are based on the results of trials. Race and ethnicity sometimes play a part in treatment efficacy and yield different results. Reverend Howard realized that if working with Yale were to be an effective partnership, the churches would need to be active ambassadors delivering this education more broadly to the community and encouraging members’ participation for their own benefit.

“Reverend Howard was my Presiding Elder, my brother and friend. He was enthusiastic about life and ministry. Whether he was preaching or teaching, advocating for our youth and children, or as a pioneer for clinical research, or just sharing one of his great culinary dishes, he believed God and often quoted this text in faith —

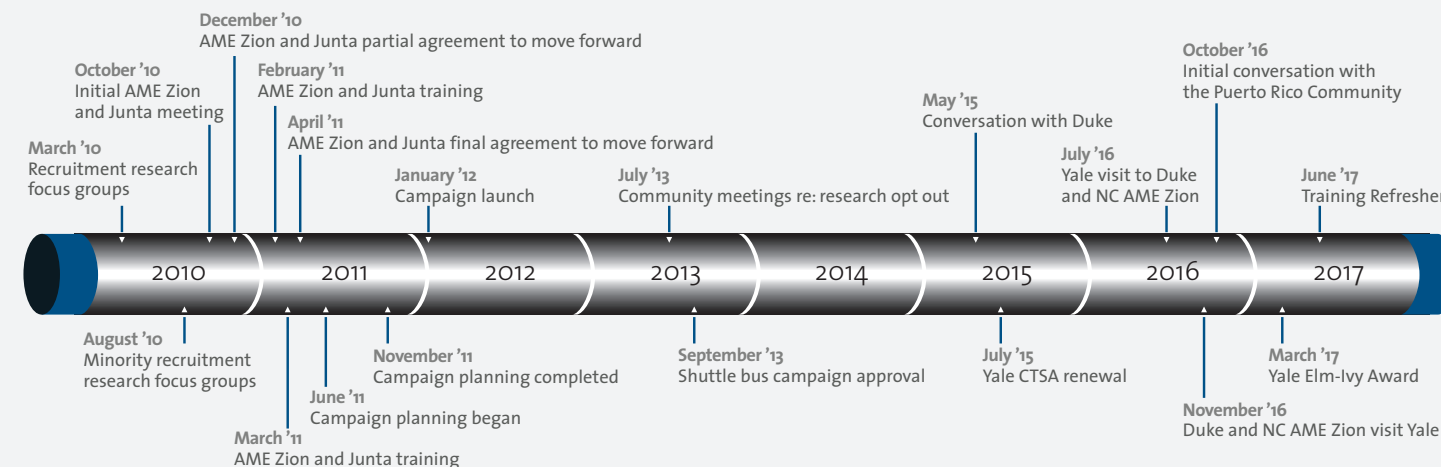
As I was with Moses, so I will be with you; I will never leave you nor forsake you.” (Joshua 1:5)

Reverend Elvin Clayton
Pastor of Walters Memorial AME Zion Church, Bridgeport

“In his book *The Wounded Healer*, Henri Nouwen describes a wounded healer as an individual who ‘must look after his own wounds while at the same time be willing to heal the wounds of others.’ I believe that the Reverend Timothy Howard, while binding his own wounds, unselfishly sought to bind the wounds of others. Pastor Howard gave immeasurable service to others regardless of his own wounds. It was his dedication to the service of those in need that led to the dialogue and eventually the formation of the Ambassador program within YCCI. His spirit continues to guide us as we seek to bring the Gospel of healing to a world ensconced in pain and suffering. His message was one of hope that he lived every day of his life, and it serves as an inspiration to us all.”

Reverend Dr. Leroy O. Perry
Pastor of St. Stephens AME Zion Church, Branford

THE LEGACY CONTINUES: YALE COMMUNITY PARTNERSHIPS, SEVEN YEARS IN THE MAKING



WITH THE RENEWAL OF THE YALE CTSA COMES NEW FUNDING OPPORTUNITIES

Yale's status as a funded CTSA site opens several additional opportunities for external funding through National Center for Advancing Translational Sciences (NCATS). Through the NCATS's Division of Innovation, the NIH institute and division that oversee all CTSA funding, Yale investigators can now apply for new research opportunities available only to universities with funded CTSA hubs. As part of this program, **Robert Sherwin** and the Yale CTSA have already been awarded three of these grants; in addition, new opportunities will continue to become available.

The first supplement is a multicenter project in collaboration with Washington University and Rockefeller University. The project focuses on sharing Yale's lessons learned leveraging Epic, the electronic health record, and OnCore, the clinical trial management system, to



Photo: Anthony DeCarlo

Allen Hsiao, MD, FAAP, and Lisa Stump, MS, RPh, FASHP

support clinical and translational research. The project is led by **Allen Hsiao, MD**, Associate Professor of Pediatrics and Chief Medical Information Officer at the Yale School of Medicine and Yale New Haven Health. "I am eager to lead this project, and collaborate with others to think about how the electronic health record, which has already done so much to improve patient care around the country, can also be used to support research and ultimately create new therapies that will benefit future generations of patients," said Hsiao. Yale project collaborators include: **Lisa Stump, MS, RPh, FASHP**, Senior Vice President, Information Systems and Chief Information Officer, Yale School of Medicine and Yale New Haven, Health System; **Kevan Herold, MD**, Professor of Immunobiology and Internal Medicine, YCCI Deputy Director; **Tesheia Johnson, MBA, MHS**, YCCI Deputy Director and Chief Operating Officer of YCCI and Associate Director for Clinical Research for YSM; and **Rhoda Arzooonian, MSM, BSN, RN**, Associate Director of YCCI and Yale Cancer Center.

"I am so excited to be a part of leveraging our EHR to support innovative science."

Lisa Stump, MS, RPh, FASHP



Photo: Anthony DeCarlo

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

Assistant Professor of Laboratory Medicine **Richard Torres, MD, MS**, has received the second grant, a diversity supplement that will foster his research in much the same way as the CTSA program's Junior Faculty Scholar Awards. Torres will receive a two-year funding supplement that will support 75 percent of his work dedicated to launching his research career. He conducts research at the intersection of engineering and medicine, and in his laboratory he seeks to apply new innovative new techniques to important clinical laboratory problems. His research interests include translating technological developments in optics and machine learning into practical approaches to problems in diagnostic pathology. Dr. Torres's mentor, Chair of the Department of Laboratory Medicine **Brian Smith, MD**, proposed Torres for this supplemental award. "It was clear from the extraordinary work Rick has done up until

now that he was a very strong candidate for this award," Smith says. "We are proud of his accomplishment, and anxiously await the new, innovative work this award will likely spur as his career continues to develop."

"It was clear from the extraordinary work Rick has done up until now that he was a very strong candidate for this award." Brian Smith, MD

The third supplemental grant focuses on innovative approaches to facilitate a single IRB review for multi-site research across the range of research funders and IRB models. The project is led by **Tesheia Johnson, MBA, MHS**, YCCI Deputy Director and Chief Operating Officer of YCCI and Associate Director for Clinical Research for YSM; **Rhoda Arzooonian, MSM, BSN, RN**, Associate Director of YCCI and Yale Cancer Center; and **Linda Coleman, JD**, Director of Yale Human Subjects Research Program. Yale project collaborators include: **Lisa Stump, MS, RPh, FASHP**, Senior Vice President, Information Systems and Chief Information Officer, Yale School of Medicine and Yale New Haven Health System; **Allen Hsiao, MD**, Associate Professor of Pediatrics and Chief Medical Information Officer at the Yale School of Medicine and Yale New Haven Health; **Kevan Herold, MD**, Professor of Immunobiology and Internal Medicine, YCCI Deputy Director; **Pamela Caudill**, Senior Associate Provost for Research Administration; **Howard S. Hochster, MD**, Professor of Medicine (Medical Oncology); Associate Director for Clinical Sciences, Yale Cancer Center; Clinical Program Leader, Gastrointestinal Cancers Program, Smilow Cancer Hospital; Disease Aligned Research Team Leader, Gastrointestinal Cancers Program, Yale Cancer Center; and **Thomas Carpenter MD**, Professor of Pediatrics (Endocrinology) and of Orthopaedics and Rehabilitation and Clinical Professor of Nursing; Director, Yale Center for X-Linked Hypophosphatemia; Medical Director, Hospital Research Unit. The project managers include **Helen Seow, PhD**, YCCI and **Monika Lau, MEd, HRPP**. The project also includes several external partners from the technology and commercial IRBs space.

Current open opportunities

YCCI is pleased to pass on details of several open grant opportunities and CTSA administrative supplements. Some of the RFAs require multiple CTSA centers. If you do not already have collaborators for your projects at other institutions, this is an area in which YCCI can help. In addition to these awards, there are other resources available through the CTSA, such as the clinical trials innovation network, that are intended to facilitate multicenter studies.

If you are interested in applying for these awards or would like additional information on the CTSA local or national resources, please contact YCCI.

Collaborative Innovation Award, Clinical and Translational Science Award

- U01—\$500K–\$1M directs / year for 5 years (Requires 3 CTSA partnerships)
- Total award max: \$5M plus indirects
- Upcoming deadlines: March 8, 2018; July 11, 2018
- PAR-15-172 <https://grants.nih.gov/grants/guide/pa-files/PA-15-172.html>

Administrative Supplements to Enhance Network Capacity for the CTSA Program

- Admin Supplement—\$300K directs / year for 2 years (Requires 2 CTSA partnerships)
- Total award max: \$600K plus indirects
- Upcoming deadline: March 1, 2019
- PA-16-328 <https://grants.nih.gov/grants/guide/pa-files/PA-16-328.html>

Limited Competition: Exploratory CTSA Collaborative Innovation Awards (R21)

- R21—\$300K directs for up to years (Requires 2 CTSA partnerships)
- Total award max: \$300K plus indirects
- Upcoming deadlines: November 29, 2017, March 29, 2018, July 30, 2018
- PAR-16-343 <https://grants.nih.gov/grants/guide/pa-files/PA-16-343.html>

The Yale CTSA can nominate two candidates in each of the categories below. To ensure that we identify the best candidates, we welcome all nominations. Each nomination should include a summary of why the nominee would be a suitable candidate, along with NIH bio-sketches of the nominee and their primary mentor. We ask that all nominations be submitted to us by December 15. Once selections are made, YCCI will assist the selected candidates in preparing the applications, which are due by February 1, 2018.

Promote diversity in health-related research

Research supplements to promote diversity in health-related research (<https://grants.nih.gov/grants/guide/pa-files/PA-16-288.html>).

The diversity supplement is designed for individuals from groups underrepresented in the biomedical sciences, including racial and ethnic minorities; persons with disabilities; and individuals from economically and educationally disadvantaged backgrounds.

Funding: The supplement will provide up to \$100,000/year for salary plus fringe. Additional funds of up to \$10,000 may be requested. Costs may not exceed \$150,000 in direct costs.

Promote re-entry

Research supplements to promote re-entry into biomedical and behavioral research careers (<https://grants.nih.gov/grants/guide/pa-files/PA-16-289.html>).

In general, the duration of the career interruption should be between one and 8 years. Examples of qualifying interruptions include a complete or partial hiatus from research activities for child rearing; an incapacitating illness or injury of the candidate, spouse, partner or a member of the immediate family; relocation to accommodate a spouse, partner or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service. **Candidates who are managing a clinical workload full time and are not conducting research activities are eligible to apply. The aim of these supplements is to encourage such individuals to re-enter research careers within the missions of all the program areas of NIH.**

Funding: The requested salary and fringe benefits for a re-entry candidate must be in accordance with the salary structure of the institution, consistent with the level of effort. An additional amount up to \$10,000 may be requested. A proposed budget should include only funds requested for the additional supplement activities.

FOR MORE INFORMATION, PLEASE CONTACT THE YCCI GRANTS TEAM

Helen A. Seow, PhD
helen.seow@yale.edu or 203-737-4512

Nicholas Licht, MBA
nicholas.licht@yale.edu or 203-785-7467

MULTICENTER TRIAL MANAGEMENT UNIT EXPANDS THE SCOPE OF RESEARCH AT YALE

In the past, Yale investigators who led multicenter trials had to put together ad hoc study teams, relying on unconnected siloed services to carry out their research. At the end of these trials, these teams, which had compiled so much experience and knowledge, disbanded and their knowledge was lost. This system was inefficient and put Yale at a disadvantage when competing with other institutions for grants for multicenter studies.

To harness this capacity, and to allow Yale to lead multicenter trials more efficiently, YCCI formed a Multicenter Trial Management Unit in 2014 in collaboration with the Yale Cancer Center. “The multicenter unit is a wonderful example of Yale’s ability to leverage the resources of CTSA and NCI-funded Cancer Center Support Grant to aid our faculty in translating innovative science into the clinic,” said **Charles S. Fuchs, MD, MPH**, Richard Sackler and Jonathan Sackler Professor of Medicine (Medical Oncology); Director, Yale Cancer Center and Physician-in-Chief, Smilow Cancer Hospital. This unit offers full-scale clinical trial management services, allowing Yale to operate much like a sponsor of a multicenter study with all the necessary services, just as a pharmaceutical company is able to do.

Led by YCCI Associate Director **Rhoda Arzooanian, RN, MSN**, the unit:

- Assists with selection and oversight of external sites and provides site activation and training.
- Oversees project managers for individual trials.
- Manages central or multiple IRBs.
- Develops management and communication plans, SOPs, and milestones.
- Provides remote or on-site monitoring.
- Sets up Data and Safety Monitoring Boards and helps conduct those meetings.
- Tracks progress.



Rhoda Arzooanian, RN, MSN

Photo Robert Usak

The Yale Data Coordinating Center (YDCC), part of the Yale Center for Analytical Sciences (YCAS), offers investigators comprehensive data management (including design and implementation of data management systems, data entry, quality control and security), and data monitoring. As part of the YDCC, faculty from the Schools of Medicine and Public Health offer their expertise in biostatistics, epidemiology, clinical trials, and informatics along with a highly trained technical staff skilled in systems programming, data management, data analysis, and statistical programming.

Providing centralized multicenter trial management allows YCCI to retain and leverage institutional knowledge and expertise, which is more efficient and cost-effective for investigators.

The unit now manages approximately 30 investigator-initiated studies in a variety of disciplines, and is planning to add several more. In some cases, the unit works with investigators from the time of grant submission; in others, investigators turn to the unit in the middle of a project for additional help. The following projects have utilized the services of the Multicenter Trial Management Unit:

- The Autism Biomarkers Consortium for Clinical Trials (ABC-CT). Led by **James McPartland, PhD**, Director of the Yale Developmental Disabilities Clinic, this multicenter study includes Yale, Boston Children’s Hospital, Duke University, UCLA, and the University of Washington/Seattle Children’s Hospital. The goal is to develop a set of reliable and objective measures of social function and communication in children with autism. These measures can then be used to determine which children are more likely to respond to treatment and to demonstrate that treatments are influencing targeted brain systems.
- The STRIDE Trial (Strategies to Reduce Injuries and Develop confidence in Elders), a collaboration between investigators, patients, and other stakeholders from 14 aging programs and 10 health care systems that is evaluating the effectiveness of an evidence-based intervention to reduce the risk of serious fall injuries among older adults. STRIDE involves data management services; preparation of DSMB reports and data analytic files; and statistical analysis. YDCC serves as the Data Coordinating Center.

James McPartland, PhD.



Photo Robert Usak

Another service YCCI provides to multicenter trials is Quality Assurance (QA) evaluation to ensure patient safety and the appropriate use of resources; to assess the ability of the study to achieve realistic accrual targets; and to monitor timelines. The YCCI Quality

Assurance unit is led by **Alyssa Gateman, MPH, CCRP** (former Director of Quality Assurance for the Dana-Farber Cancer Center). The Quality Assurance program reflects an institutional culture focused on carrying out research of the highest quality; ensuring its safe and ethical conduct; and reducing administrative burdens on faculty and staff in order to speed the translation of scientific discoveries.

The multicenter unit is a wonderful example of Yale’s ability to leverage the resources of CTSA and NCI-funded Cancer Center to aid our faculty in translating innovative science into the clinic.

Charles S. Fuchs, MD, MPH

YCCI’s QA efforts focus on working with Yale’s Human Research Protection Program (HRPP) to manage research, including QA reviews of all Yale studies and monitoring multicenter studies at other sites. Milestones, timelines, and other metrics are continuously tracked in OnCore and CTMS to identify issues that may require QA intervention or a targeted component review. By tracking audit trends, the QA team identifies areas for targeted retraining and introduction of new study workflow.



Alyssa Gateman, MPH, CCRP

The QA team conducts study audits that enable YCCI to recognize trends within a team, across teams, or across the entire institution, and put in place additional training. Taken together, these steps provide continuous monitoring of enterprise-wide trends and afford Yale an agility that helps to ensure the

quality and efficiency of clinical research. The goal of the program is not only to promote regulatory compliance, but also to improve patient safety and educate researchers about best practices in clinical trials.

With these comprehensive services aimed at improving the quality of research at Yale in place, it is even more likely that the scope of research at Yale will increase as well. With the support offered, Yale investigators increasingly lead multicenter trials, with the ultimate end result of speeding the development of novel therapies that will help patients everywhere. ☺

LINDA COLEMAN: INNOVATING YALE’S REGULATORY STRUCTURE TO BETTER SUPPORT RESEARCH



Linda Coleman, JD, CIP, CHC, CHRC, CCEP-I

Having a single IRB of record is an important component of conducting multicenter trials. YCCI is working with Yale’s Human Research Protection Program (HRPP) to ensure this capability. “The IRB is the gatekeeper for ensuring the ethical protection of human research participants in clinical trials,” said **Linda Coleman, JD**, Director of Yale’s HRPP, who joined Yale in April 2016. YCCI works closely with Yale’s HRPP, which is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and provides regulatory and administrative support to the institution’s five institutional review boards.

As the director of the HRPP, Coleman brings to Yale the experience she gained in the areas of legal and regulatory compliance, strategic planning, quality improvement, and operations management while at Quorum Review and its division, Kinetiq. Quorum is an organization that provides commercial IRB and regulatory and technology consulting services to industry-sponsors, institutions, and other organizations conducting research in the United States, Canada, and other countries.

The initiatives Coleman implemented or is considering at Yale include: using external IRBs more extensively for industry-sponsored trials that meet certain Yale guidelines and studies that require the use of a single IRB; revamping the internal IRB convened meeting schedule to move studies more efficiently through the review process; adding videoconferencing capabilities so that members can participate remotely; and adding special IRB meetings to address workload demands of the various IRB panels. The HRPP also fully implemented a new electronic IRB system earlier this year to simplify the IRB submission and review process.

Changing Yale’s policies to allow use of commercial IRBs and to improve the efficiency of Yale’s internal submission and review process is part of positioning Yale as a better partner for industry participation, supporting continued growth and expansion of clinical trials.

Linda Coleman, JD, CIP, CHC, CHRC, CCEP-I

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

Treating And Preventing Diabetes



"I really want to see a cure in my lifetime, so I'm helping to find one. That's the coolest thing ever."

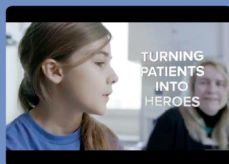
- Jacob Conte

The five teenagers who went rock climbing at City Climb in New Haven, Connecticut were typical high school students who lead busy, active lives. What sets them apart is that they were taking part in a pioneering clinical trial to test a system for treating their type 1 diabetes.

Yale doctors have worked with industry partners to develop what many refer to as an "artificial pancreas," an insulin pump that works with a continuous glucose sensor to automatically adjust insulin delivery in response to the body's demand. This closed-loop system would be a major advance for patients with diabetes.

During the clinical trial, the teens spent four days round-the-clock with a team of Yale doctors and nurses who monitored their blood sugar levels while they took part in activities that included hiking, playing laser tag, and climbing a rock wall.

For the teens who participated in the study, it was an opportunity to learn more about the disease and play a part in finding ways to more easily manage their diabetes.



Please watch and like our new video on Yale School of Medicine and Yale University YouTube Channels.

Moving Science Forward – Yale Center for Clinical Investigation

Diabetes Study

Do you have Type 1 or Type 2 diabetes?

If you are between 18 to 60 years old and have Type 1 or Type 2 diabetes, Yale has several trials that you may qualify for.

Compensation varies according to study.

For more information, please contact Nadia Freire at (203) 785-6222 or email glucose.studies@yale.edu

Sponsored by National Institute of Diabetes and Digestive & Kidney Diseases, HIC #1503015469, #0108012609, #1408014461



Pregnancy Study



Are you pregnant for the first time?

If you are 18 years or older, pregnant for the first time, and African-American, you may be eligible to participate in this study. This study examines women's experiences of discrimination and the things that women do to have a healthy pregnancy. The interview will last 45-60 minutes.

Compensation is \$40

To learn more or see if you are eligible to participate, please contact Renee Mehra at (203) 737-6393.

The aim of this research study is to better understand the effects of institutional or structural discrimination on pregnancy and birth outcomes among African-American women.

Sponsored by Yale University, HIC #1611018675

Veteran Heart Disease Study

Are you a veteran who was deployed post-9/11?

If you are a veteran who is 21 to 50 years of age and were deployed post 9/11, you can play an important role in research by volunteering for a free and confidential study that is looking at an early risk marker for heart disease.

Compensation up to \$200

To learn more or see if you are eligible to participate, please call (475) 224-1193

This study is being conducted by researchers at VA Connecticut Healthcare System. VA HIC #MB0014



Mindfulness-Based Stress Reduction Study

Have you or your spouse been told by a doctor that you are overweight, have high cholesterol, high blood pressure, or high blood sugar?



If you are married or in a committed relationship and living together, are both at least 60 years old, and one partner is overweight, has high cholesterol, high blood pressure, or high blood sugar, you may be eligible to participate in a study that looks at a stress reduction program. Participation includes an orientation class, 8 weekly classes, and a half-day retreat with other couples learning to reduce stress through mindfulness meditation techniques. The study will also require a blood draw and completing 3 brief surveys.

Free parking and compensation up to \$300 per couple

To learn more or to see if you are eligible, please contact Kathleen Williams (475) 331-1501 or email kathleen.williams@yale.edu

Sponsored by Yale Claude D. Pepper Older Americans Independence Center, HIC #2000020175

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.

Irritable Bowel Syndrome & Fibromyalgia Study

Do you have Irritable Bowel Syndrome (IBS) and/or Fibromyalgia (FM)?



If you have IBS and/or FM, are 18 to 70 years old, and are otherwise healthy you may be able to participate in this free and confidential study. The study involves 2 visits to the Yale School of Medicine, collecting a stool sample, answering a dietary questionnaire, and a small blood draw. No medications or treatments are provided.

Compensation is \$100

To learn more, please contact Maxine Fields at (203) 785-5691 or email maxine.fields@yale.edu

Sponsored by the Wallace Research Foundation and Yale University School of Medicine, HIC #1604017522

Sudden Onset Hearing Loss Study

Do you have sudden hearing loss?

New drug for sudden onset hearing loss.

Yale School of Medicine, Section of Otolaryngology is working with Auris Medical to investigate a new drug for sudden onset hearing loss. You must have severe, one-sided hearing loss that began within the past 3 days. There should be no explanation for the hearing loss and no history of hearing loss within the past 2 years. Study participation will last about 3 months and include 5 scheduled clinic visits.

Compensation up to \$500

Please contact the Clinical Research Team at (203) 584-8404 or email sherric.bitterman@yale.edu

Sponsored by Auris Medical, Inc., HIC#1608018207



Cluster Headaches Study

Do you suffer from Cluster Headaches?

If you suffer from cluster headaches and are between 18 to 70 years old, you may be eligible to participate in a new clinical trial. This 12-week study (plus additional screening period) involves monthly visits to the clinic with monthly injections to potentially control the number of cluster attacks. Participants will also be asked to complete daily eDiary entries to monitor the number of cluster attacks between visits. Those who participate may be eligible for a long-term treatment study after completion. Study medication and study-related procedures will be at no cost to the participant.

Compensation up to \$370

For more information, please contact Lindsey Fraczkiwicz at (203) 785-3490 or email lindsey.fraczkiwicz@yale.edu

Sponsored by Teva Branded Pharmaceutical Products, R&D, Inc., HIC #2000020131, #2000020133

Healthy Children Needed

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

We are recruiting children between the ages of 1 and 17 years old who can play an important role in research by volunteering for this study. Your child's participation in this research study involves a blood draw, which may help us better understand the different causes of liver problems in children with liver transplants. The research will involve 3 quick blood draw visits, that can be coordinated with other visits held here at the hospital, if need be.

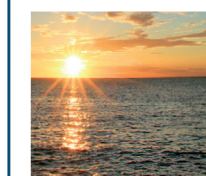


Compensation of \$40 per visit and free parking

For more information, please contact Danielle Paquette at (203) 785-7526 or email danielle.paquette@yale.edu

Sponsored by Yale University School of Medicine, HIC #1302011561

Heart Sleep Study



Insomnia Self-Management in Heart Failure

Do you have heart failure? Do you have problems sleeping?

If you are 18 years or older, have heart failure or congestive heart failure, and have difficulty falling asleep, staying asleep, waking too early, or feeling unrefreshed, you can play an important role in research by volunteering for this study.

Compensation up to \$300

To learn more or to make an appointment, contact Sarah Linsky at (203) 240-0122 or heart.sleep@yale.edu

Sponsored by the National Institutes of Health, HIC #0904005041 VA HSS# 0001, NIH Grant #R01NR 016191

Binge Eating and Obesity Study

Are you overweight and have problems with binge eating?

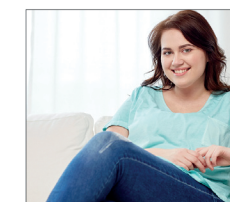
Behavioral and Pharmacologic Treatment of Binge Eating and Obesity

If you are 18 to 70 years old with binge-eating disorder and obesity, and are not taking antidepressant medications, you may be eligible to participate in a free and confidential study. The study will provide well-established, no cost treatment (FDA-approved medication, behavioral, or both) and may help with long-lasting weight loss.

Compensation up to \$400

To learn more or to see if you are eligible to participate, call the Yale Program for Obesity, Weight, and Eating Research at (203) 785-7210 or visit our website at <https://tinyurl.com/YaleBinge>

Sponsored by the National Institutes of Health, HIC #1506016065



To find out more about trials at Yale, visit our website, www.yalestudies.org. Or call 1-877-y-studies for more information.

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Yale

YALE STUDENTS OFFER NEW PERSPECTIVES ON RESEARCH CHALLENGES

Photo Robert Lisak



From left to right: Doug Streat, MPH; Cassandra Lincoln, MPH; and Paul Taheri, MD, MBA.

When in need of a solution to a challenging problem, Yale turned to its best resource: its own students.

As the administrative home of the university's CTSA grant, YCCI is constantly looking for new ways to better support clinical trials. YCCI's typical strategy for tackling large-scale institutional challenges is through targeted component reviews. In this process, YCCI hires industry consultants to come to Yale for a limited period to gather and analyze data, and offer solutions.

When YCCI's question turned to the merits and demerits of centralizing research support services, **Paul Taheri, MD, MBA**, the CEO of Yale Medicine (the university's 1,200 physician-strong clinical practice group) and Deputy Dean for Clinical Affairs at the Yale School of Medicine, had a novel idea: why not turn to students in the Yale School of Public Health?

“YCCI would benefit from unbiased well-informed analysis from people who as students are truly invested in the success of the institution of which they are an integral part.”

Paul Taheri, MD, MBA
Deputy Dean and Chief Executive Officer, Yale Medicine

Students in the school's Health Care Management Program, Taheri figured, would “jump at the chance to have in-depth hands-on experience taking on a major issue in research medicine.” Not only would the students benefit from the

experience, “YCCI would benefit from unbiased well-informed analysis from people who as students are truly invested in the success of the institution of which they are an integral part,” he says.

Taheri reached out to **Howard Forman, MD**, who directs the Health Care Management Program in the Yale School of Public Health. “Working with YCCI provides our students with a real-world opportunity to apply classroom learning from the spheres of Healthcare Operations and Healthcare Finance,” says Forman.

Forman put out a call to students; two, **Cassandra Lincoln** and **Doug Streat**, both students in Yale's joint BS/MPH program, responded immediately. They graduated from Yale College with Bachelor of Science degrees in 2016, and from the School of Public Health with a Health Care Management Program in May 2017. The Health Care Management Program is operated in conjunction with the Yale School of Management, and course work is split between the two schools.

Lincoln and Streat were ready to delve into the challenge. “This was a really exciting opportunity to make a significant difference in the management space at the Yale Medicine practice, which is such an influential clinical practice in Connecticut and in this region of the country,” says Streat. Their project also fulfills an MPH degree requirement in which students must complete a substantial practicum in a degree-related subject.

The interns were tasked with compiling stakeholder views on centralization (or potential decentralization) of services, and whether centralization would help streamline YCCI operations. They sent a survey to all principal investigators, and conducted in-person interviews with leadership at YCCI, the Yale School of Medicine, and Yale Medicine's eight clinical chairs.

They also looked at research support services at peer institutions and examined data from YCCI's clinical trial management system, OnCore, as well as its research evaluation system. Through the spring, they met weekly with Taheri, their project mentor, and also met with YCCI Deputy Director and Chief Operating Officer **Tesheia Johnson, MBA, MHS**. They also sat in on meetings with senior administrators on a variety of issues, and were able to gain an understanding of the wide range of work YCCI does beyond the scope of their individual projects.

“Many students in health care management come to the program focused on two popular post-school career goals: consulting and health care administration,” says Forman. “One of the greatest benefits of the program was that it opened the students' eyes to other career options. There are many important and substantive opportunities in research and research administration.”

“It was a win-win,” says Taheri. “Not only was it a really great educational experience for them, it also was phenomenal for us.” Last summer, Lincoln and Streat presented YCCI and Yale Medicine's clinical chairs with an extensive report on their findings, and recommendations on how centralization might improve the delivery of their services.

As a result of their research, Lincoln and Streat recommended four areas that could benefit from centralization: research navigation, research finances, study coordination, and recruitment. “The next step for us is turning these recommendations into reality,” says Lincoln. Both students were asked to extend their relationship with YCCI through this past school year to work on implementing their suggested solutions. Their most recent focus is the development of a coordinator workload tool that is being piloted at YCCI.

“Working with YCCI provides our students with a real-world opportunity to apply classroom learning from the spheres of Healthcare Operations and Healthcare Finance.”

Howard Forman, MD
Professor of Public Health (Health Policy) and
Director of the Health Care Management Program

“As a new Dean of Public Health attending my first YCCI External Scientific Advisory Board, I was immensely gratified that our student work was featured in presentations to the board,” said **Sten Vermund, MD, PhD**, Dean of the School of Public Health, and the Anna M.R. Lauder Professor of Public Health. “It's a testament not only to the potential of our students to become future leaders in their fields, but of YCCI's commitment to collaboration across the entire institution.”

The success of this project was the beginning of a valuable continuing partnership between YCCI and the School of Public Health. MPH candidate in Health Care Management **Josh Tan** worked with his mentor, Chief Medical Information Officer **Allen Hsiao, MD**, to conduct a review of the effectiveness of clinical trials recruitment methods. Tan compared the new Epic-directed recruitment system to traditional measures, and found that the Epic-enabled recruitment produced a significantly higher number of leads compared to such methods as newspaper advertising.

Asia Brown (left) and Igla Muskaj (right)



Photo Lisa Brophy

YCCI has two current interns from the MPH program completing evaluation projects.

Asia Brown, YC '16, is an MPH candidate in Health Care Management, and is an MDiv candidate as well. In line with her interest in community-engaged research, Brown is working with the Chief of General Internal Medicine, **Patrick O'Connor, MD**, on a needs assessment of YCCI's services to investigators in this area, and presented her findings and recommendations to YCCI and other stakeholders this fall. As YCCI continually seeks to reevaluate and improve its services related to cultural engagement, Brown surveyed several faculty members, investigators, Cultural Ambassadors, and community members to understand what was important to them in the program as YCCI considers its next steps.

Igla Muskaj, an MPH candidate in Health Care Management, is working with the Chair of the Department of Laboratory Medicine, **Brian Smith, MD**, and YCCI Deputy Director **Kevan Herold, MD**, to conduct a review of YCCI's laboratory services to determine how YCCI can improve efficiencies within its Core Lab and reduce any duplication of services with Yale New Haven Hospital's clinical laboratory service. Through the project Muskaj was able to bridge her prior experience in basic science with her career goals in health care management, she says.

“...I was immensely gratified that our student work was featured in presentations to the board. It's a testament not only to the potential of our students to become future leaders in their fields, but of YCCI's commitment to collaboration across the entire institution.”

Sten Vermund, MD, PhD
Dean and the Anna M.R. Lauder Professor of Public Health

Both Brown and Muskaj have been asked to continue their work with YCCI in the coming year. “I love YCCI's dedication to developing the next generation of leaders,” says Muskaj. “It's not only a welcoming environment, but one in which you can grow and learn.”

“It pushes you to be self-directed,” says Brown. “You need to know the questions and ask them. You are not going to have someone holding your hand in the real world. It gives us a sense of independence.”

“It's a mutually beneficial relationship,” says Taheri. “We are getting a great, thoughtful work, and the students are getting irreplaceable experience that will help them contribute in the future to their chosen field. This is an investment in Yale's most valuable asset, its people.”

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 WOULD LIKE TO BE PART OF OUR "HERO" CAMPAIGN?

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 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.

NEW CTSA PILOT GRANTS NOW AVAILABLE

Grants bring additional funding opportunities to Yale researchers

YCCI's pilot grants provide funding for researchers to conduct small-scale research projects to generate data that may lead to further research and funding opportunities. YCCI is offering the following upcoming opportunities:

Clinical Junior Faculty Pilot Award: This award is intended to address the challenges many faculty face balancing clinical practice commitments with launching independent research programs. The primary aim of these awards is to prepare the applicant for successful independent research careers; emphasis will be placed on career development and mentoring plans.

Lifespan Research: This award is aimed at fostering interdisciplinary teams to work collaboratively on key experiments that may lead to the next phase of discovery. These projects should be strategically targeted to conduct research that will lead to the next step to translation.

Community-engaged Research: The purpose of this funding opportunity is to provide pilot awards to support community engagement projects. The specific community engaged can take many forms, and the partners can include organized groups, agencies, institutions, clinical practices, or individuals, as the NCATS definition of "community" is broad. It may include church groups, civic leaders and civic organizations, hospitals, companies, schools, and other academic medical centers, among others.

Application Deadlines:

Due date for full applications: December 18, 2017

Earliest anticipated start date: January – February, 2018

Applications must be submitted using the templates that will be available on the YCCI website.

Questions? Please contact:

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SCHOOL OF MEDICINE VOICEMAIL UPGRADE SCHEDULED FOR DECEMBER 6

As part of plans to renovate the historic University Commons and Memorial Hall into the state-of-the-art Schwarzman Center, a project to modernize Yale's telephone infrastructure is under way. The project includes an upgrade to the School of Medicine's voicemail system. Beginning Wednesday, December 6, all voicemail users will use a new number to access voicemail messages.

Key Details:

- You will be switched to a new number (436-4477) to access your messages (note: your actual phone number won't change).
- In preparation, you will need to set up a new voicemail outgoing message beginning Monday, November 27 (instructions will be forthcoming).
- Yale's legacy voicemail (2-8000 or 5-7777) will be shut off 10 days after the upgrade. Please be sure to retrieve any old messages.

You will receive an e-mail communication from Yale ITS on Monday, November 27, with instructions for setting up your new voicemail box message prior to the December 6 upgrade.



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