



Photo by Terry Dagradi

YCCI Collaborates with Other Centers to Transform Clinical and Translational Research

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The Yale Center for Clinical Investigation (YCCI) has had a history of collaboration from its inception. This approach began during the planning stages of the Clinical and Translational Science Awards (CTSA) application and has led to the integration and growth of a number of programs and centers. Along the way, many useful synergies have been discovered; resources have been more effectively utilized; and exciting new cross-institutional and interdisciplinary programs have been introduced that are having a major impact on clinical and translational research and training at Yale.

The collaboration between YCCI and the Yale Cancer Center is an example of the benefits of a collaborative approach. Identifying shared goals and seeking joint funding and resources has solidified a partnership that has become beneficial to both centers. "I'm incredibly pleased with our collaboration with YCCI, and I believe that selectively applying this strategy to areas where we have common ground has been very effective," said **Thomas J. Lynch, M.D.**, director of the Cancer Center. "These kinds of partnerships and proposals are critical in managing our institutional and NIH resources."



Photo by Robert A. Lisak

Dean Robert Alpern, Thomas J. Lynch, M.D., and Robert Sherwin, M.D., discuss strategies to meet Yale's clinical and translational needs.

While interaction between cancer centers and CTSA sites was discouraged at one time, that is no longer the case. "We're now expected to work together for mutual benefit," noted **Beverly Ginsburg Cooper, M.B.A.**, senior vice president for research at Dana-Farber Cancer Institute. The joint effort at Yale has allowed both centers to leverage resources and strengths to achieve noteworthy results. For example, recognizing the need to develop a center for biostatistics support, YCCI, the Cancer Center and the School of Public Health together support the Yale Center for Analytical Sciences (YCAS); they collaborated on the search that culminated in the recruitment of **Peter Peduzzi, Ph.D.**, to lead it. YCAS serves as a clearinghouse for a steadily growing number of biostatistics faculty members, providing support for study design and biostatistical analysis to investigators across the medical campus. The Center has both CTSA-supported resources and dedicated cancer resources, due to the high demand from Cancer Center members.

The support of research cores, which requires the investment of millions of dollars to purchase, maintain and repair sophisticated instrumentation, is another

Director's Corner

Facilitating the translation of disease-related discoveries from the bench to the bedside and from the clinic to the community is the heart of YCCI's mission. This issue of our newsletter explores the ways we seek to foster collaboration, both internally at Yale and with the community, in order to create an environment that allows that to happen.

Our collaboration with the Yale Cancer Center, as well as with other centers and departments, illustrates how breaking down silos leads to better utilization of resources as well as opportunities to strengthen the infrastructure that supports clinical and translational research across the entire institution. I'm delighted by the progress of this partnership, and I look forward to building on the groundwork we've already laid.

New leadership and a revamped structure have had a positive impact on our T3 Translational Research Core, and our Cultural Ambassadors program has afforded opportunities for interaction between Yale investigators and members of the New Haven community beyond what we anticipated two years ago when we began working with representatives from JUNTA for Progressive Action and the AME Zion Church. We have also made great strides in involving the community in our research efforts through our recruitment campaign, which has now moved into its electronic phase.

Even our pilot program has reaped the rewards of a collaborative approach with basic science awards to investigators from different disciplines working together, including departments outside the medical campus.

There's no doubt that our philosophy of partnership both within and outside Yale has served us well in supporting and expanding Yale's research enterprise. We look forward to continuing these endeavors in the years ahead.

Robert Sherwin, M.D.
YCCI Director

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Coming Soon: RFA for the next round of YCCI Scholars

Visit <http://ycci.yale.edu/index.aspx> for details.

Working with ocr to Move Discoveries Forward

“These funding opportunities from YCCI allow us to get answers to the questions we will inevitably be asked but don’t otherwise have the resources to get addressed.”

Translating academic research into products and services that benefit patients is a time-consuming and complex undertaking; however, ycci and the Office of Cooperative Research (OCR) are collaborating to speed the translation of research discoveries in order to make them widely available to clinicians and patients around the world.

OCR works with Yale researchers to identify and facilitate the transition of inventions that may ultimately become commercial products. These efforts have been enhanced through the establishment of ycci under the Clinical and Translational Science Award (CTSA) program. OCR is identifying translational projects that can benefit from modest amounts of ycci funding, which are awarded on an ad hoc basis in order to move to the next step of initial commercial development.

“The questions that need to be answered for commercial viability tend to be somewhat prosaic from an academic point of view. From the commerce side, they’re very important because they’re the questions that are critical for assessing commercial viability,” said **David Lewin, PH.D.**, senior associate director of licensing for OCR. “These funding opportunities from ycci allow us to get answers to the questions we will inevitably be asked, but don’t otherwise have the resources to get addressed.”

In some instances, these strategic investments—amounts vary but are typically less than \$25,000—have had a tremendous impact on research discoveries that are currently being developed commercially or have led to other funding or research opportunities. Lewin, who is constantly looking for projects that could benefit from a small investment, noted that a little can go a long way in such cases. The resulting data are free of potential bias, making the information attractive to investors, as is the case for the following projects:



Kurt Roberts, M.D., associate professor of surgery (gastrointestinal), used an award of approximately \$20,000 from ycci to develop an internal organ retraction device that facilitates single-incision laparoscopic surgery (SILS) and natural orifice transluminal endoscopic surgery (NOTES). Roberts has used these techniques to perform pioneering appendectomies and gallbladder surgery using a minimum number of incisions, with lower risk of postoperative complications and much easier and faster recovery periods, including documented reductions in administration of opiate analgesia. OCR spun off a New Haven-based company, NovaTract Surgical, to commercialize the new device. NovaTract has leveraged ycci’s investment over the intervening years with several funding rounds to raise \$4.3 million to support product development. NovaTract expects to launch its first device on the market in 2013.

Barbara Ehrlich, PH.D., professor of pharmacology and of cellular and molecular physiology, used a \$25,000 grant to perform a critical study showing that lithium, a proposed

therapy for preventing chemotherapy-induced peripheral neuropathy, does not interfere with the effects of chemotherapeutic agents. Promising results led to talks with a number of pharmaceutical companies that are interested in Ehrlich’s assay to test whether cancer drugs under development cause peripheral neuropathy. There is also a clinical trial in the planning stages to test the ability of lithium to prevent peripheral neuropathy.

Autotaxin (ATX) is an ecto-enzyme that activates LPA, a signaling molecule that enhances the vascularization of tumors, fosters tumor growth, and enhances cancer’s ability to metastasize.

Demetrios Braddock, M.D., PH.D., associate professor of pathology, and his colleagues at the Yale Center for Molecular Discovery at Yale’s West Campus screened more than 20,000 chemical compounds and found one that inhibits autotaxin’s activity in vitro. Using a \$25,000 award from ycci, Braddock subsequently demonstrated that bithionol, an anthelmintic drug withdrawn for safety reasons in 1992, shrinks tumors in mice. The ycci-supported in vivo studies were subsequently leveraged by Braddock to receive a €50,000 award from Bayer HealthCare’s “Grants4Targets” program.

Photo by Robert A. Lisak

Kurt Roberts, M.D., developed an internal organ retraction device that is expected to be launched on the market in 2013.

David A. Spiegel, M.D., PH.D., associate professor of chemistry and pharmacology, was awarded less than \$10,000 for a project which showed such promising results that he successfully applied for a Basic Science Pilot Award, which provides funding for new research initiatives that combine Yale investigators from different disciplines. Spiegel developed a new class of molecules with a novel bifunctional mechanism of action (antagonist and antibody-recruiting molecules) targeting prostate cancer (ARM-P) and HIV (ARM-H). He had shown in vitro that ARM-P binds to a specific target protein on the surface of prostate cancer cells and then recruits antibodies, tagging them as a threat to be attacked by the body's immune system. He and his laboratory demonstrated the robustness of this approach by showing that ARM-H will cause HIV-infected cells to be killed in a similar antibody-mediated manner. A Basic Science Collaboration pilot award from ycci allowed him to evaluate the efficacy of this novel therapeutic strategy in mice, preparing the way for treatments that have fewer side effects, are inexpensive to produce, and could in theory be administered orally. OCR and the Office of Grant and Contract Administration recently concluded negotiations with Bristol-Myers Squibb for two sponsored research agreements supporting further development and exploration of the ARM technology.

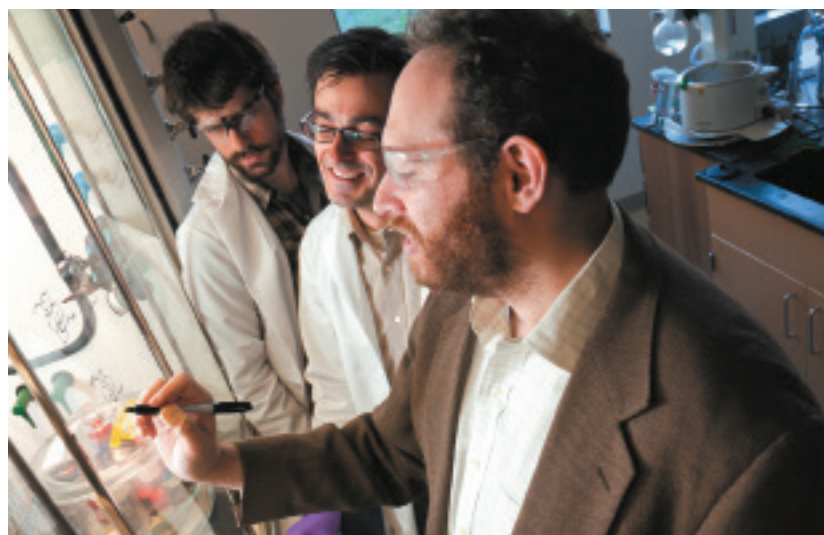


Photo by Robert A. Lisak

ycci supported the research of David A. Spiegel, M.D., PH.D., in the development of a new class of molecules that target prostate cancer and HIV. OCR and Grants and Contracts recently concluded negotiations with Bristol-Myers Squibb for two sponsored research agreements to further develop Spiegel's discovery.

These projects illustrate the innovative ways in which ycci seeks to overcome obstacles that slow the development of therapeutics. "This approach has also allowed us to foster collaborations between investigators from different disciplines that are called upon to evaluate potential research projects and end up working together in unexpected ways," said **Robert Sherwin, M.D.**, director of ycci. "I'm pleased that these efforts align so well with the broader vision of the NIH and its centers that support Yale's research." ❁

Second Annual ycci Scholar Day Retreat

March 1, noon, TAC Auditorium

Open to all students, trainees, scholars and faculty at Yale who are participating or interested in clinical or translational research, this half-day event begins with poster presentations from Scholars in the lobby of The Anlyan Center. This will be followed by presentations by:

• **Ray Dolan, M.D., FRS**, Mary Kinross Professor of Neuropsychiatry at University College London (UCL) and Director of the Wellcome Trust Centre for Neuroimaging at UCL. Dr. Dolan's research concerns a neurobiological characterization of human emotion and how it interacts with other components of cognition, particularly attention, memory, and decision making.

• **Harlan Krumholz, M.D.**, the Harold H. Hines Jr. Professor of Medicine (Cardiology) and professor of investigative medicine, and of public health at Yale School of Medicine; director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE); and director of the Robert Wood Johnson Clinical Scholars Program at Yale. Dr. Krumholz is an international leader in the field of outcomes research, making major contributions to its recent development and growing influence on clinical practice and health policy.

• **John Williams, PH.D.**, Head of Clinical Activities and Head of Neuroscience and Mental Health for the Wellcome Trust. Dr. Williams trained as a neuroscientist before embarking on a career in science administration.



Ray Dolan, M.D., FRS



Harlan Krumholz, M.D.



John Williams, PH.D.

For additional information, visit <http://ycci.yale.edu/news/2ndscholardayretreat/index.aspx>

Events Calendar

Coffee and Conversation

8:00 a.m., Cohen Auditorium
(Coffee at 7:30 a.m.)

• February 20

ROLE OF OFFICE OF RESEARCH
ADMINISTRATION

Presented by Andrew Rudczynski

• March 20

DATA AND TISSUE REPOSITORIES

Presented by Sandra Alfano

• April 17

INTERACTING WITH YOUR BUSINESS
ADMINISTRATOR

Presented by Lisa Wohlert

• May 15

COORDINATING MULTICENTER IITS

Presented by Tesheia Johnson

Lunch and Learn Series

12:00 p.m., Cohen Auditorium unless
otherwise indicated; lunch will be
provided.

• February 14

SCIENTIFIC MISCONDUCT

Presented by Sara Rockwell
300 George Street, 1FR Auditorium

• March 14

CLINICAL RESEARCH AT YALE

Presented by Rick Rohrbach

• April 11

TRENDS IN CLINICAL RESEARCH:
"WHAT ARE THE HOT TOPICS?"

Presented by Dean Robert Alpern

• May 9

ENVIRONMENTAL SAFETY

Presented by Tammy Stemen

T3 Translational Research Core Expands to Support Investigators



Margaret Grey, DR.P.H., RN, FAAN, has been implementing her vision since she took over as director of the T3 Translational Research Core in October 2011.

ycci's T3 Translational Research Core has undergone a transformation over the last year under the leadership of **Margaret Grey, DR.P.H., RN, FAAN**, dean of the Yale School of Nursing. Grey has worked to implement her vision of working with investigators across the institution to improve health in local communities by promoting research that supports rapid dissemination, implementation, and sustained use of effective interventions to prevent and treat such common health problems as asthma, obesity, diabetes, violence-related trauma, and addictions. Her specific aims include:

- Increasing awareness of, interest in, and participation in translational research at Yale
- Enhancing translational research education and training opportunities for patients, students, scientists, clinicians, and community partners
- Attracting and re-training new investigators from multiple fields to conduct translational research
- Providing community partners with the skills and resources to implement high-quality translational research in community settings
- Fostering the interdisciplinary collaborations required to advance translational research

One of Grey's first initiatives was to restructure the core's leadership structure by incorporating representatives from the three health schools: **Patrick O'Connor, M.D., M.P.H.**, professor of medicine, and **Rafael Perez-Escamilla, PH.D.**, professor of epidemiology, joined **Lois Sadler, PH.D., RN, PNP-BC, FAAN**, professor of nursing, as associate directors. Together with Grey and **Nancy Redeker, PH.D., RN, FAHA, FAAN**, director of NetHaven, they have formed a working group that's developing ways to expand and develop Yale's translational research efforts internally at the university and externally in the community.

"Yale excels in basic science and is doing well in academic clinical research," said Grey. "Our group is working on how to get uptake of interventions in the community that can make a difference and how to make that happen in the context of primary or ambulatory care practices in the community. At the same time, we need to and will continue to engage the local community in some of this thinking."

One area of focus is to create education and training opportunities in community based practice research for patients, students, investigators, clinicians, and community partners. The Robert Wood Johnson (RWJ) Clinical Scholars Program and the YCCI/RWJ Community Research Scholars Program offer opportunities for translating health services research into health care practice and applying the principles of community-based research. In addition, 20 percent of the junior faculty members selected for the YCCI Scholars program presently conduct community-based research in areas that include studying falls among the aging HIV-infected population and testing cognitive strategies to regulate cravings in cocaine-dependent individuals.

Because the core is committed to increasing the number of investigators who can preform community-based and translational research in the community, one of its most important goals is to create infrastructure to support that research. The School of Nursing and ycci collaborated to form NetHaven, an interdisciplinary practice-based research network that represents approximately 800 health care providers (see *New Opportunities for NetHaven*, page 5). The core also offers pilot funding for research aimed at enhancing the adoption of best practices in the community, including research focused on the cost-effectiveness of prevention and treatment strategies. In addition, ycci has partnered with the Children's Fund of Connecticut to fund research projects that promote and enhance high-quality health care services for children and families. There are also new grant mechanisms in place, such as funding from the Patient-Centered Outcomes Research Institute (PCORI), that align well with the core's mission and that Grey encourages investigators to utilize.

Increasing awareness and participation in translational research at Yale and speeding up the dissemination and uptake of research findings are the heart of the core's activities. Representatives from the Cultural Ambassadors program in collaboration with JUNTA for Progressive Action and the African Methodist Episcopal (AME) Zion Church (see *Cultural Ambassadors: Collaborating with the Community*, page 6) are involved in engaging the New Haven community in clinical research. They have also helped the T3 Core with several strategic grant applications that are currently under review, providing input and contributing ideas for specific interventions.

"The partnerships with JUNTA and AME Zion are really extraordinary," said Grey.

"I think we've made great progress in our efforts to increase participation in this type of research in the Yale and New Haven communities."

Research-in-Progress Meetings

These meetings feature presentations from ycci Scholars and Investigative Medicine Program students, as well as trainees from the Medical Research Scholars Program (MRSP). We encourage all faculty and staff to attend. All meetings listed below will take place at noon in TACN203; lunch is provided.

February 11
February 25
March 11
March 25
April 8
April 22
May 13
June 10
June 24

Please visit our website at <http://ycci.yale.edu/education/lectures/schedule/index.aspx> to find the list of presenters and projects.

“It’s a great resource that most of Yale doesn’t know anything about but they are an integral part of our objectives to boost this kind of research and translation within the Yale community.”

As part of its efforts to involve the community in research, the core has formed the Yale Affiliated Hospitals Program (YAHP), a partnership between Yale and eight hospitals in southern Connecticut designed to improve the quality of health care in the community. Participating hospitals have access to such YCCI resources as education and training, NetHaven, pilot funding opportunities, and protocol support.

The core’s efforts stem from an awareness of the health challenges facing the community. “Ultimately the collaborative work between the community and ycci changes health parameters in the area,” said Grey. “If we’re successful in what we set out to do, then we should see some prevention and better control of diseases like type 2 diabetes among people in the community in the next five or 10 years.”

The T3 Core is a major focus of ycci; it was one of three topics chosen for the upcoming Strategic Retreat, in which senior leadership from all three health schools will make key decisions on where ycci is headed and how to accomplish its goals. Although it’s been a relatively

short time since Grey became director, she is pleased with the core’s direction. “I believe the new structure we’ve put in place has led to an increased awareness of translational research across the health schools,” she said. “I think we’ve made great progress in our efforts to increase participation in this type of research in the Yale and New Haven communities,” she said. 🌐



Photo by Robert A. Lisak

From left: Patrick O'Connor, Margaret Grey, Rafael Perez-Escamilla, Lois Sadler, Nancy Redeker

New Opportunities for NetHaven

NetHaven, which grew out of the School of Nursing’s Advanced Practice Registered Nurses’ Research Network (APRNet), has become a large interdisciplinary practice-based research network with a membership that includes about 800 health care providers. APRNet was the first practice-based research network for advanced practice nurses to be funded by the federal Agency for Healthcare Research and Quality; it served as a model for engaging community-based health care practitioners in research and facilitating the translation of research findings into clinical practice. NetHaven merges APRNet’s infrastructure and community practices with YCCI resources and expertise in study design, analysis, and regulatory support, paving the way for larger and more sophisticated clinical research studies within the community.

Nancy Redeker, PH.D., RN, the School of Nursing associate dean for scholarly affairs, has recently taken over as director of NetHaven, whose members represent over 200,000 health care consumers in the New Haven area. NetHaven is unique in that only a quarter of its membership is comprised of physicians; nurse practitioners continue to account for a majority of its ranks.

Because NetHaven has an urban focus, Redeker’s vision includes working with the Cultural Ambassadors program in connection with research projects. “NetHaven has always been about primary care in underserved populations, so energizing that group will be a natural partnership,” she said. She also hopes to generate research

data and research questions from Epic, Yale New Haven Health System’s electronic medical record system, which is due to roll out in Yale-New Haven Hospital in February. “It’s an uncharted area in terms of research, especially in primary care settings, looking at how it facilitates providing that kind of care,” said Redeker.

NetHaven research projects have involved such health centers as the Fair Haven Community Health Center and the Yale-New Haven Community Medical Group, but Redeker believes there are a number of centers and opportunities that could be leveraged. NetHaven has already played a role in a number of research studies that are having a positive impact on the health of the community. One example is Bright Bodies, a weight management program that employs a family-based intensive lifestyle intervention specially tailored to the needs of inner-city minority children. Another is a study of tobacco and alcohol addiction by **Stephanie O’Malley, PH.D.**, professor of psychiatry, which used NetHaven to recruit subjects. NetHaven offers the potential for multiple levels of interaction—for example, an infrastructure for providers or investigators generating research ideas; recruitment for existing studies; or dissemination of evidence-based research into practice, notes Redeker.

“It’s a challenging time, given that research budgets are shrinking,” she said, “But there are opportunities around the diverse community we have in New Haven and the various centers we have at Yale.” 🌐

Cultural Ambassadors: Collaborating with the Community



Photo by Robert A. Lisak

Marsha Guess, M.Sc., M.D., met with Cultural Ambassadors to discuss research on women's reproductive health.

“Our collaboration with Yale has been a terrific opportunity to educate people about opportunities that have the potential to greatly benefit all of us.”

Involving the New Haven community in Yale's clinical and translational research is critical to improving health outcomes and was the impetus for YCCI's Cultural Ambassadors program. A joint undertaking with JUNTA for Progressive Action and the African Methodist Episcopal (AME) Zion Church, the program is designed to ensure that clinical trial participation reflects the diversity of New Haven's population. Cultural Ambassadors are committed to increasing awareness within and participation of the Hispanic and African American communities in clinical trials; the ambassadors serve as expert resources to Yale investigators regarding the best ways to engage these populations.

Established in early 2011, the program has been beneficial for both patients and investigators. Initially, representatives from JUNTA and AME Zion underwent intensive education on all aspects of clinical research theory and practice on such topics as patient protections, regulatory requirements, and research in specific disease areas. This training has continued in the form of monthly Community Grand Rounds, a bi-directional forum between Yale faculty and Cultural

Ambassadors in which the faculty members present their research or seek input about the design of clinical studies and advice about recruitment. For example, **Marsha Guess, M.Sc., M.D.**, assistant professor of obstetrics, gynecology, and reproductive services, met with the Cultural Ambassadors to discuss her research on uterine prolapse – a subject some women find distressing to discuss. Guess sought the group's advice on how best to approach this topic in their communities. Similarly, **Rafael Perez-Escamilla, Ph.D.**, professor of epidemiology and associate director of YCCI's T3 Translational Research Core, sought the group's input on a study that involves breastfeeding and obesity, as well as a health disparities center that he is seeking to establish.

Cultural ambassadors have provided valuable input in creating such culturally sensitive recruitment materials as brochures and posters, and have appeared in recruitment advertising with messages aimed at their respective populations. For example, AME Zion and JUNTA representatives provided advice regarding relevant topics to include in YCCI's "Help Us Discover" brochure about clinical trials; and gave testimonials about the importance of volunteering for clinical research. "Our collaboration with Yale has been a terrific opportunity to educate people about opportunities that have the potential to greatly benefit all of us," said **Sandra Trevino**, JUNTA's Executive Director. JUNTA representatives also translated the brochure, as well as standard sections of the informed consent form, into Spanish. They are available to translate study materials and provide interpreter service on an as-needed basis at a reasonable cost (visit <http://ycci.yale.edu/researchers/ors/translation.aspx> for details).

In addition to participation in these activities, there have been further opportunities to collaborate with JUNTA and AME Zion that have been facilitated through the structure created by the program. YCCI representatives have staffed tables at church health fairs and Yale faculty members have made presentations about clinical research at AME Zion conferences and meetings. Cultural Ambassadors have also asked YCCI for assistance in addressing specific health topics that are of concern to their populations, which has led to several faculty presentations at various events. For example, AME Zion pastors expressed concern about high cancer rates in the African



Photo by Robert A. Lisak

Cultural Ambassadors meet monthly with Yale faculty members to discuss clinical research topics during Community Grand Rounds.



Photo by Robert A. Lisak

As a Cultural Ambassador, Rev. Timothy Howard, Presiding Elder, Western District AME Zion Church, helps educate the African American community about clinical research.

American and Hispanic communities, which led to presentations by **Thomas J. Lynch, M.D.**, director of the Yale Cancer Center and **Howard Hochster, M.D.**, associate director for clinical research at the Cancer Center. Both Lynch and Hochster had already met with the group as part of the intensive training in clinical research that took place when the program was established, but welcomed the chance to lead a more focused discussion. “It was a wonderful opportunity for the Cancer Center and YCCI to interact with leaders of the community to address important health issues that directly affect these groups,” said Lynch.

At the same time, Cultural Ambassadors periodically join Yale faculty at community events. On January 26, they were on hand to raise awareness of clinical trials at the Annual Dr. Martin Luther King Jr. Conference at the Wexler-Grant Community School. **Tesheia Johnson**, YCCI’s chief operating officer, conducted several presentations on what clinical trials involve and why it’s important for people to volunteer. **Anees Chagpar, M.D.**, assistant director of diversity and health equity at the Yale Cancer Center and director of The Yale Breast Center at Smilow Cancer Hospital, conducted several sessions on research related to cancer and the latest findings in the field. Also on hand were research coordinators for studies in the fields of diabetes, mental health, and the Yale Child Study Center, as well as studies recruiting healthy volunteers.

“As a 10-year survivor of prostate cancer, I welcome the opportunity to educate our community about clinical research in general and the opportunities to participate in research at Yale,” said the **Rev. Timothy Howard**, Presiding Elder, Western District, AME Zion Church, who participates in the program.

The Cultural Ambassadors program has fostered a level of trust and mutual respect regarding Yale as an institution while at the same time benefiting the population it serves. Facilitating communication involving respected members of New Haven’s minority communities has created an avenue to lower the barriers to research participation in a meaningful way and engage the community in research that has the potential to benefit everyone. ❁

Research Highlight: A New Approach to Advance Care Planning

Traditionally, advance care planning (ACP) involves filling out a form that specifies one’s wishes in the event of catastrophic illness or injury; however **Terri Fried, M.D.**, professor of medicine (geriatrics), has a different idea. Her goal is to develop an intervention that improves communication with loved ones and can be widely disseminated.

During the course of her research to develop such materials to engage older people in ACP, Fried learned that religious convictions are an issue, particularly in the African American community. Knowing she would have to tackle this concern, she met with the Cultural Ambassadors to ask for their help in how to approach the subject.

At their first meeting, the group advised Fried on appropriate language that could be helpful to people while at the same time acknowledging their religious beliefs. During the earliest stages of developing a brochure, she again consulted the group, who suggested changes in wording that could be used to draw in people, since there are cultural/ethnic determinants that affect getting

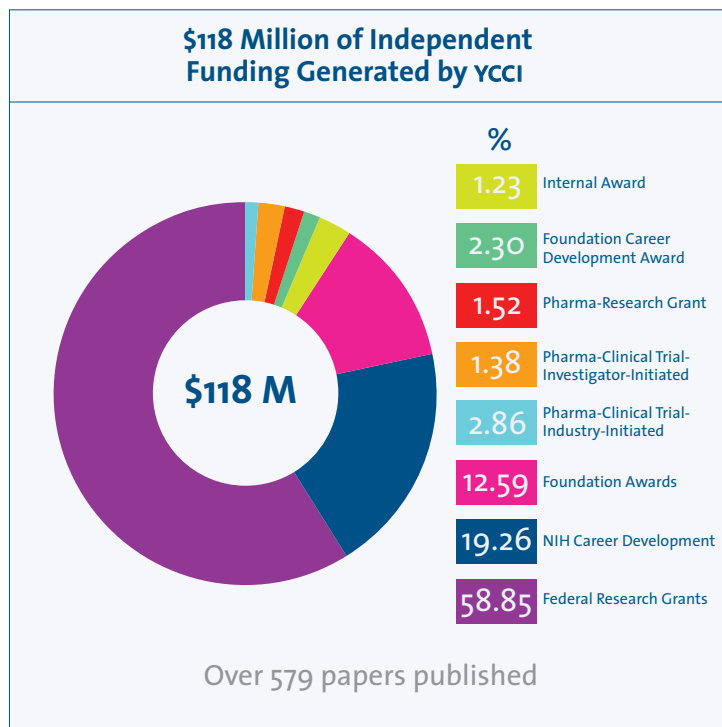
people’s attention when it comes to ACP. Fried ended up changing the title of the brochure based on feedback from the Cultural Ambassadors. The group also convinced her that the brochure should be more concise. “That’s when we went back to the drawing board and came up with a bulleted format,” she said.

Fried is currently pilot-testing the brochure in a series of senior centers. The next step is to use that data to preform a randomized controlled trial with the ultimate goal of getting larger numbers of people to participate in ACP.

“The reason we’re taking this approach is because it would be inexpensive to disseminate widely,” she said. Right now the readiness assessment and materials are given in person but the next step would be to make these available online.

“We went to the Cultural Ambassadors for their thoughts and expertise on this subject and that was incredibly valuable,” she said. “It really was a unique opportunity that melded unbelievably well with what I was trying to do with my research.” ❁

area where the two centers have collaborated. It is much more cost-effective for YCCI and the Cancer Center to jointly shoulder the high costs of these resources, which are available to all investigators, than to maintain separate facilities. For example, the two centers jointly supported the expansion of the Flow Cytometry core, which has multiple applications in cancer research. Originally this resource supported only animal studies, but the collaboration has allowed for expanding it to include human samples. Genomics is another area where it makes sense to leverage resources. The Cancer Center and YCCI collaborated to provide funding for equipment and faculty expertise in bioinformatics and biostatistics for the Yale Center for Genome Analysis, which generates massive amounts of data.



The majority of the \$118 million of independent funding obtained by YCCI Scholars has been sponsored by the NIH.

in the department. The research nurse works at a number of facilities, including the VA Connecticut Healthcare System, the Connecticut Mental Health Center (CMHC), the PET Center, the Clinical Neuroscience Research Unit (CNRU), and the Hospital Research Unit.

“Having a centralized person that can cross institutional boundaries makes it a flexible resource and also offers the unique opportunity of seeing how work is done at different facilities,” said **Robert Malison, M.D.**, professor of psychiatry and director of the CNRU. For example, YCCI-funded nursing support was instrumental in developing a research infrastructure for ketamine infusion studies conducted by **Gerard Sanacora, M.D., Ph.D.**, professor of psychiatry, which are paving the way to developing new treatments for depression.

While senior investigators in psychiatry have benefited from the research nurse position, it has been a tremendous asset to junior investigators, who may lack the resources to run complex studies. “Young investigators bring enormous creativity, intelligence, talent and hard work to the table but all of that would be like seeds in a desert soil without the kind of field created by YCCI,” said Malison.

YCCI has expanded and transformed clinical and translational research training at Yale through its support of existing programs and the creation of new ones. The YCCI Scholars program supports training for the next generation of clinical and translational investigators in departments across all three health schools. Since its inception in 2006, the program has awarded salary and research support to 77 investigators, who in turn have generated \$118 million in independent funding and published over 579 papers. Faculty members from many departments on the medical campus participate in the Scholars mentoring program and are also active in YCCI’s other training programs, serving as mentors to TLI students and on the thesis committees of students in the Investigative Medicine Program.

YCCI has also invested in and collaborated with the NIDDK-funded Yale Diabetes Research Center (DRC), helping to create the Center’s Translational Core; supporting a specialized research nurse to assist with complex metabolic studies; and supporting structured training and credentialing for new investigators and research nursing staff for metabolic research techniques.

“Research today is a complex and costly enterprise due to the nature of the problems we need to tackle,” said Malison. “It’s not possible for one person in one group; it needs to involve multiple individuals with multiple expertise doing multimodality research using a convergence of methodologies.” Collaborating with other centers allows these types of interactions to take place and benefits Yale’s entire research enterprise. ❄

Yale’s IT overhaul, which includes the implementation of Epic and OnCore, a clinical research management system, has also been supported by both centers. Lynch was co-leader of the search for OnCore and was instrumental in ensuring that it would be integrated with Epic and that it would meet the needs of the entire clinical and translational research enterprise. The implementation began with the Cancer Center in preparation for the pending CCSG review and is expected to be complete by mid-February, when the hospital’s Epic-Go Live will take place.

In order to provide the robust infrastructure necessary to conduct clinical and translational research effectively, YCCI and the Cancer Center merged several components of their management structures, including joint financial administration of clinical trials for budgeting; the implementation of systems related to the billing of clinical trials; IND support and development applications; and identifying supplemental staff for data management and support. The two centers also jointly recruited leaders and staff to support these centralized functions and have joined forces to offer staff training on research-related topics. “With both centers committed to working together, I believe the opportunities are endless,” said Lynch.

YCCI has also collaborated with the Department of Psychiatry in several areas. Investigators from the department regularly utilize the Hospital Research Unit, while YCCI funds a research nursing position that provides infrastructure for all research conducted

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