



Photo Harold Shapiro

Implementing a Vision for Clinical and Translational Research

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Almost ten years ago, **Robert J. Alpern, MD**, Dean of the School of Medicine, invited senior faculty members to participate in strategic planning to examine how to make the most of Yale’s strengths in basic research, clinical research and clinical medicine. During this process, it emerged that the success of these investigators was largely attributable to the infrastructure that each of them had built. It became clear that developing a robust infrastructure to support investigators and promote innovative and collaborative research would be critical to expanding Yale’s research program.

About a year later, the **National Institutes of Health (NIH)** launched the **Clinical and Translational Science Awards (CTSA)**, and Yale was among the first 12 institutions in the country to receive an award. The CTSA program is now under the auspices of the **National Center for Advancing Translational Sciences (NCATS)**, and is focused on speeding up the delivery of more effective prevention, diagnosis, and treatment of diseases. Meanwhile, YCCI has evolved into a home for clinical and translational research on the health campus as well as a hub for research taking place across the entire Yale New Haven Health System.

The growth of Yale’s clinical and translational research enterprise during the intervening years – there has been a 300 percent increase in industry-sponsored trials – is a reflection of the tremendous expansion of Yale’s clinical faculty and clinical practice combined with unwavering institutional support. Five years ago, YCCI annually supported about 176 projects involving 140 faculty members; today it annually supports about a thousand projects, mostly sponsored by the NIH, involving more than 500 faculty members. “After approving the strategic plan, I had a vision of what YCCI would encompass and how it would support investigators,” said Dean Alpern. “The progress that’s been made has exceeded my expectations. I couldn’t be more pleased with what YCCI has been able to accomplish on behalf of our faculty.”

In an effort to improve quality and efficiency across the translational research continuum, YCCI has made concerted efforts to eliminate barriers to conducting research and to facilitate an environment that fosters multidisciplinary collaboration. The center has developed a wealth of programs and resources to address every aspect of the research process. YCCI has also helped expand Yale’s state-of-the-art core facilities in imaging, gene sequencing, and other areas and has partnered with other centers to develop such programs as the **Yale Center for Biomedical and Interventional Technology (CBIT)**, an interdisciplinary initiative that brings together expertise from across the institution to develop novel technical approaches to address pressing clinical needs.



Photo Terry DaGradi

Robert J. Alpern, MD, Dean, Yale School of Medicine

Director’s Corner

When I first began my career in research, investigators had to build their own infrastructure. Although there were some resources available, such as the GCRC, there was no single office or body of knowledge to guide researchers. I was excited by the opportunity to serve as director of YCCI and PI for the CTSA because I was convinced that Yale needed to develop an infrastructure that would support cutting-edge research.

I think the progress we’ve made in less than a decade is noteworthy. We have created or expanded an array of resources to aid investigators from the time they conceive an idea to the publication of their results. What’s more, we are constantly evaluating and examining both the research process and our services. Our Executive Board has yearly retreats to strategize how best to realize the task we’ve undertaken in executing the School of Medicine’s strategic plan and our mission under the CTSA. YCCI has gone well beyond the GCRC, which for 40 years was a safe place in which to carry out studies. It has provided a nimble infrastructure that has been reorganized several times in response to our recognition of the changing needs of Yale’s research community.

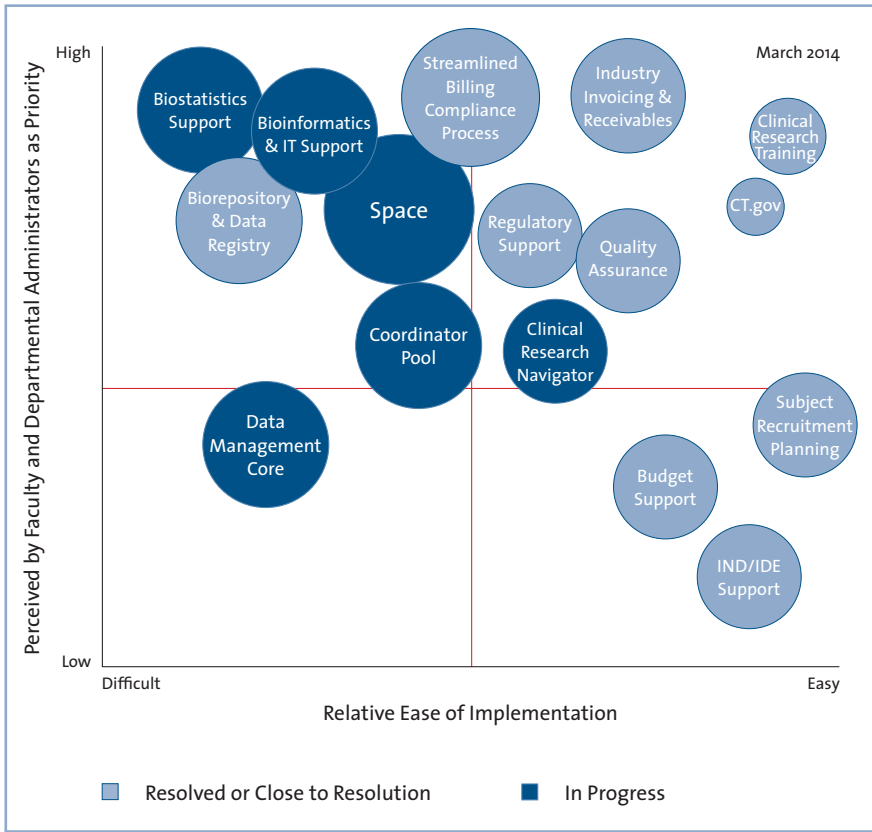
During the last several years we have recruited so many new faculty members that we thought now is an opportune time to publish a guide to YCCI’s resources – an updated version of the one we published in 2008. We hope that you will find it useful as you navigate a research landscape that has become increasingly complex and demanding. I encourage you to peruse this issue to learn what we have to offer and to visit ycci.yale.edu to learn more. I think you’ll agree that YCCI is a valuable resource that you shouldn’t miss out on.

Robert Sherwin, MD
YCCI Director

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New YCCI Pilot RFA Offers Funding for Innovative Research Projects
See page 8 to learn about funding categories.

**SPECIAL EXPANDED
CLINICAL RESEARCH
RESOURCES ISSUE**



Many of these efforts have the potential to benefit not just investigators at Yale but also those at other CTSA sites.

One area in which YCCI is making great strides is promoting research involving special populations. For example, a new program spearheaded by the Department of Pediatrics will conduct genome sequencing of infants who present with unusual illnesses. This initiative has grown from the availability of such new technologies as whole exome sequencing to rapidly identify genetic mutations that may manifest in newborns. The causes of many clinical syndromes are unknown but potentially amenable to treatment if their bases can be identified. One example is a recent study published in *Nature Genetics*, in which high-throughput DNA sequencing was used to diagnose a previously undescribed disease in an infant boy and other members of his family. YCCI is committed to providing study personnel, regulatory expertise, and OnCore support for the project. “This is an exciting collaboration that will maximize Yale’s strengths in basic science and clinical care to bring tremendous benefits to both patients and our research program,” said **George Lister, MD**, chair of the department of pediatrics.

YCCI sought input from faculty and staff to prioritize and reorganize Yale’s clinical research infrastructure.

YCCI was created in order to address faculty needs and is proceeding along this path with continuous efforts focused on such areas as process improvement. For example, in 2012 the center worked with an outside consulting firm to evaluate Yale’s clinical research infrastructure in order to promote economies of scale and help new faculty members develop their programs more rapidly. After seeking input from approximately 85 members of the Yale clinical research community, many of whom conduct NIH-sponsored studies, the center identified a number of areas as critical to the success of Yale’s growing research demands. All of these have been addressed or are in the process of being revamped.

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YCCI: EXPANDED INFRASTRUCTURE TO SUPPORT RESEARCH

When YCCI was created in 2006, it greatly expanded the services offered under the GCRC model. Over the last several years, this growth has continued as YCCI strives to refine Yale’s robust clinical and translational research infrastructure in response to the needs of the research community.

RESOURCE	NUMBER OF FTEs		
	Pre-CTSA	2008	TODAY
Biostatistics and Research Design	1	6	25
IT/Biomedical Informatics	2	4	10.5
Protocol Development/Multicenter Trial Management/Regulatory Support	0	3	6
Financial Management of Research/Budget Development	1	5.5	9.5
Biospecimen Management/Core Laboratory Services	4	6	13.5
Quality Assurance/Research Staff Training	0	1.5	7.5
Patient Recruitment	0	2	5
Study Coordination/Research Nursing	13	16	19
TOTAL	21	44	96

New Recruitment Services

Increase *Help Us Discover* Momentum

Although the majority of patients recognize the benefits of participating in clinical research, recruiting study subjects remains a major roadblock to successful completion of a clinical trial. Recognizing that researchers need help in attracting volunteers, YCCI is launching a series of new services and initiatives that will leverage Yale's electronic medical records (EMRs) to recruit potential research subjects; vastly improve subjects' experience; utilize a unique and novel advertising venue; and provide support for research staff that will increase accrual and allow them to concentrate on carrying out their studies.

The advent of Epic (Yale's electronic medical record system that contains all clinical data for Yale patients) is enabling YCCI to find ways of linking research to patient care in profound new ways. Beginning in January, MyChart will include a *Help Us Discover* tab that will allow patients to set up a user profile for research participation without having to make a separate visit to yalestudies.org, YCCI's clinical trials website for patients. The profile allows patients to sign up for trials; keep track of the kinds of studies that interest them; and edit their preferences. They will also be directed to yalestudies.org, which has lots of useful information about clinical research and will be updated with information for such special populations as children and such hard-to-reach populations as the elderly. For those who aren't patients in the Yale New Haven Health System, there will be a mechanism triggered from yalestudies.org that allows them to set up a MyChart account.

Linking yalestudies.org to Epic will increase its potential to boost recruitment. For example, the site's *Help Us Discover* volunteer database already has about 4,500 names of persons who have expressed interest in participating in clinical trials. YCCI is set to send out monthly e-newsletters that will feature a story and related study ads, with the first issue slated to be sent to these individuals. This concept has already proven successful; an e-mail blast sent to volunteers interested in prostate cancer research was opened by over one-third of its 1,600 recipients and generated approximately 100 referrals.

The monthly newsletters are directed to patients, while the YCCI newsletter is directed to faculty and staff members. Beginning with this issue (see pages 6 and 7), YCCI will run study ads in its newsletters to tap into this potential source of research subjects. The first day it was sent out, the Winter 2014 newsletter was opened by a sizable internal audience of almost 4,000 recipients – again about one-third of recipients – making this medium a viable avenue for reaching a considerable audience.

YCCI is also supporting an initiative by the Epic team to utilize the data contained in Epic, which is linked to Helix, Yale's customized version of Epic's data warehouse. The center will be adding two additional program analysts who will have the capability of using Helix to identify patients in Epic who meet study criteria. For example, 39 subjects were found for a recent study that needed subjects who had already undergone genetic testing. Prior to Epic, finding subjects with such specific criteria might not have been possible or would have taken months.

Identifying potential research subjects is one area in which investigators need help, but another area that can be problematic is responding to potential volunteers. Study coordinators are often occupied with other study-related tasks and have limited availability to field queries. To resolve this dilemma, YCCI will run a pilot program beginning in November for a Recruitment Call Center with a phone line that will be open and staffed from Monday through Friday, 7:00 a.m. to 7:00 p.m.; Saturday, 10:00 a.m. to 5:00 p.m.; and Sunday, noon to 5:00 p.m. The call center will begin with a few selected studies that need healthy volunteers, and YCCI staff will pre-screen callers for eligibility. If successful, the center will be expanded with additional staff and extended hours. This service will be advertised in the monthly e-newsletter, on yalestudies.org, and in individual study ads.

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Events Calendar

Good Clinical Practice & Preparing for FDA Inspection

October 30

9 a.m. to 4 p.m.

Edward S. Harkness Hall Ballroom,
367 Cedar Street

Michael Hamrell, PHD, RAC

Lunch and Learn

October 9

Data Analysis, A Learning Experience

12 p.m.–1:30 p.m.

CSC Cohen Auditorium NIHB Eo2

Torry Cong, PHD, MPH, Biostatistician,
Yale Center for Analytical Sciences

November 13

Through the FDA Looking Glass and What Can Be Found There

12 p.m.–1:30 p.m.

CSC Cohen Auditorium NIHB Eo2

Joe Ross, MD, Assistant Professor of
Medicine and of Public Health

December 11

Holiday Coordinator Appreciation Program

12 p.m.–1:30 p.m.

CSC Cohen Auditorium NIHB Eo2

Susan Anderson, RN, BSN, MFA,
YCCI Director of Training

January 8

TBA

11 a.m.–1 p.m.

CSC Cohen Auditorium NIHB Eo2

Coffee & Conversation

October 15

Reporting Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Protocol Deviations to the Yale IRBs.

7:30 a.m.–9 a.m.

CSC Cohen Auditorium NIHB Eo2

Jeri Barney, JD, Senior Compliance Manager,
Research Quality Assurance and Compliance,
HRPP

November 19

Investigational Drug Service

7:30 a.m.–9 a.m.

CSC Cohen Auditorium NIHB Eo2

Osama Abdelghany, PHARM.D.,
Coordinator, Investigational Drug Service,
Yale-New Haven Hospital

December 17

TBA

7:30 a.m.–9 a.m.

CSC Cohen Auditorium NIHB Eo2

January 21

Beauty is in the Eye of the Auditor:

A Mock Audit Exercise

7:30 a.m.–9 a.m.

CSC Cohen Auditorium NIHB Eo2

Office of Quality Assurance and Training

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YCCI creates a wide range of recruitment brochures, ads, and posters, including culturally sensitive materials for hard-to-reach populations that can also be translated into Spanish.



Other Venues for Recruiting Study Subjects

In addition to assisting investigators with recruitment for individual studies, YCCI has been marketing clinical research at Yale in a number of ways. One such effort is the *Help Us Discover* campaign, originally launched in January 2012, which will have media flights this fall and spring. The message communicated by the campaign's posters, brochures, newspaper ads, radio spots, transit ads, Internet banners, and community health fairs is to encourage participation in clinical trials at Yale. The ads and other materials featuring faculty, patients, and community leaders reach potential volunteers well beyond the Greater New Haven community, as well as Yale students, faculty and staff.

Transit Ads: Utilizing Yale's Bus Fleet

This fall, the ads began running in a new venue that has never been utilized until now. Capitalizing on the ability of transit ads to reach both the Greater New Haven and Yale communities, *Help Us Discover* ads are appearing on Yale's entire shuttle bus fleet that travels around the city, as well as to surrounding towns and the West Campus. This is the first time that advertising has appeared on this mini-transit system, which provides a sustainable and inexpensive advertising forum—the only cost is to produce the ads—that benefits both Yale and the community. A 12-week advertising campaign on a similar number of New Haven buses would cost about \$60,000, highlighting the value of this opportunity, which can potentially run for an unlimited period of time.

YCCI will sponsor a digital campaign this fall and spring featuring banner ads on such websites as NHRegister.com, CTPost.com, wtnh.com, zipo6.com and Yahoo!. Unlike the print campaign, the digital campaign offers the possibility of fine-tuning content while ads are running based on the response.

Photo Robert A. Lisak



YCCI has created *Help Us Discover* ads that appear on the entire Yale shuttle bus fleet that travels around the city, as well as to surrounding towns. Special thanks to Linda Lorimer, Bruce Alexander, Elizabeth Stauderman, Stephanie Spangler, Donald Relihan, Michael Morand, Jeffrey Gworek, Maria McLellan, Edward Van Keuren, Michael Ferguson (pictured above, left) and Greg Tower (right) for their help in bringing this project to fruition.



Photo Robert A. Lisak

Making the Most of the Yale Brand

In order to build upon the Yale brand and ensure that advertising for clinical trials meets Yale's standards, all recruitment advertising must now be approved by YCCI.

Mason, Inc., the firm that created the Closer to Free campaign for Smilow Cancer Hospital, is assisting with the creation of recruitment ads. Mason works closely with the research team to create the ads, ensuring the graphics and logo are consistent with the Yale brand while personalizing each ad to the individual study's requirements.

"The advantage of working with a professional ad agency is that we can help broaden the thinking process and individually tailor materials for specific needs so that there are increased opportunities for recruitment," said **Mason CEO Charlie Mason**.

"The ads created by Mason are much more professional than anything we could do by ourselves," said **Stephanie O'Malley, PHD**, professor of

psychiatry, who worked with Mason on flyers, pamphlets, and a logo for a clinical trial on alcoholism. "I would recommend them as a way to polish your recruitment approach to reflect the scientific caliber of the work you're doing."

Investigators wishing to run ads to recruit subjects should contact YCCI to facilitate the process. All ads must be submitted to and approved by the IRB, following YCCI approval.

Mason's expertise extends beyond creating ads; the firm can also advise on ad placement. A centralized ad creation and approval process also paves the way for a centralized media buy, which would leverage resources to make the most out of advertising budgets.

In the meantime, the turnaround time for creation and approval is short. Mason is often able to respond within a couple of days and YCCI submits the ads to the IRB in an expedited approval process.

Social Media

Last spring, YCCI launched a social media campaign using Facebook and Twitter to keep the public up to date on clinical trials that need volunteers, promote the results of research studies, and share patient stories. The Facebook page is coordinated with a Twitter feed with the shared goal of creating a community of clinical research enthusiasts around the Yale brand. The two platforms can also be used to help recruit volunteers for specific studies. YCCI can supply IRB-approved text to include in research protocols to investigators interested in social media outreach.



Community Engagement: Cultural Ambassadors

Engagement with the New Haven community, which is 36 percent African American and 26 percent Hispanic, has been strengthened through YCCI's Cultural Ambassadors program, a collaboration with JUNTA for Progressive Action and the African Methodist Episcopal Zion Church. Cultural Ambassadors bring community needs and priorities to the attention of Yale investigators in a bidirectional partnership that is mutually beneficial. They aid recruitment efforts by customizing and translating brochures for their communities. Through monthly Community Grand Rounds, they advise Yale researchers on study design and culturally sensitive recruitment materials for hard-to-reach populations. This effort to engage New Haven's minority communities in research that ultimately benefits their health and well-being has resulted in the recruitment of approximately 1,800 volunteers since January 2012.

YCCI is seeking to centralize all advertising and marketing for clinical research (see *Making the Most of the Yale Brand*, above). The enhanced recruitment services and unprecedented access to clinical data are expected to build upon the efforts that are already under way to facilitate study accrual with the goal of accelerating the development of medical advances. 🌐

Cultural Ambassadors met with Marsha Guess, MSC, MD, during Community Grand Rounds to discuss research on women's reproductive health.



Photo: Robert A. Lisak

HELP US DISCOVER | *Be Part of Clinical Research*



Robert J. Alpern, MD
Dean, Yale School of Medicine
Ensign Professor of Medicine
(Nephrology)

www.yalestudies.org
1-877-y-studies

The Yale Center for Clinical Investigation (YCCI) is funded in part by National Center for Advancing Translational Sciences and the Yale Clinical and Translational Science Award.

HIC #0805003779

THANK YOU FOR
CHANGING THE COURSE
OF MEDICAL RESEARCH.

Because of you, each one of us benefits from advances made possible by clinical research. The medicines we take every day are available because people like you choose to participate in research studies. None of them would be possible if you weren't willing to take part. As the Dean of the Yale School of Medicine and a researcher, I know how important you are in bringing new treatments to people who need them. We hope you do too.

Help us discover.

Visit our website, where you can review available trials and build your personal profile. Or call for more information.

Gut Bacteria Study in Clotting Disorders

Do you have Antiphospholipid Syndrome or have you ever had a blood clot?



If you are **18 to 70 years of age** and have been diagnosed with Antiphospholipid Syndrome or have a clotting history, you can play an important role in research by volunteering for this study.

Compensation of \$25 per visit

To learn more or make an appointment, contact: 1-877-978-8343 or helpusdiscover@yale.edu

Supported by the Arthritis Foundation

HIC #1210010962

Alcohol & Smoking Study

ADVANCEStudy ▶ **Is drinking affecting your family?**



... they deserve better.

Participate in a study to help reduce drinking. Treatment is CONFIDENTIAL.

Compensation up to \$525

To learn more or make an appointment, contact: 1-877-978-8343 or helpusdiscover@yale.edu

Supported by National Institute on Alcohol Abuse and Alcoholism

HIC #1106008598

MRI Study

Healthy Pediatric Volunteers Needed for MRI Study



Birth to 18 years old
Healthy volunteers will receive three brain MRIs over a period of 1 year.

Parking reimbursed at Yale.
Gift card for each study visit.

Contact Lauren A. Beslow-Kaye, MD MSCE
lauren.beslow@yale.edu
(203) 785-5708

Supported by National Institute of Neurological Disorders and Stroke

HIC #1211011114

Irritable Bowel Syndrome Study

Do you suffer from Irritable Bowel Syndrome (IBS)?



If you are **18 to 70 years of age** and have been suffering with **active irritable bowel syndrome**, you may be eligible to participate in a four week individualized diet. This study requires follow-up visits at four and eight weeks.

Compensation of \$200 for participation.

For more information or to see if you qualify for the study, please call Theresa Weiss at (203) 737-1391 or email theresa.weiss@yale.edu

Supported by Cell Sciences Systems, Corp.

HIC #1404013784

Stress Hormones & Your Heart Study

Healthy Volunteers Needed
Stress Hormones & Your Heart Study

If you are **30 to 80 years old and healthy** (no heart condition, kidney disease, or other serious illness), you may be eligible to participate. The study involves undergoing scans of the heart with a tracer (dye injected into your vein) similar to those in standard stress tests.

Compensation of \$300 for each day of scanning (maximum of 2), plus parking.

To learn more or make an appointment, contact:
1-877-978-8343 or helpusdiscover@yale.edu

Supported by GE Healthcare

HIC #1405013981

Wart Study

Got Warts?

We are conducting a research study for the painless treatment of warts in patients 5 years of age and older. Patients must have at least 2 warts that have not undergone extensive treatments.

Parking expenses will be reimbursed. (\$50 per visit)

To learn more or make an appointment, call Kristin at Yale Dermatology Associates (203) 785-3852

Supported by Ferndale Laboratories

HIC #1209010850



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

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.

Type 2 Diabetes & Weight Lose Brain Imaging Study

Do you have type 2 diabetes? Do you want to lose weight?

You can play an important role in research by volunteering for a study that will look at the effects of an 8-week weight loss diet on reduced blood sugar and brain responses to food images.

If you are 30 to 58 years of age, have type 2 diabetes, and are above normal weight, you may be eligible to participate. The study involves:

- Screening history, physical exam, and blood work
- Infusions of insulin and glucose and MRI scan
- 8-week weight loss diet, with a once a day free meal replacement
- Free diet consultation

We are also looking for non-diabetic volunteers to participate.

Compensation up to \$750

To learn more or make an appointment, contact: 1-877-978-8343 or helpusdiscover@yale.edu

Supported by the National Institute of Diabetes and Digestive & Kidney Diseases HIC #0108012609



Hypertrophic Cardiomyopathy Study

Do you have hypertrophic cardiomyopathy (HCM)?

If you are 18 to 65 years of age and have been diagnosed with hypertrophic cardiomyopathy, you can play an important role in HCM research by volunteering for this study.

Principal Investigator, Daniel Jacoby, MD

To learn more or make an appointment, call Chris Williams, RN at (203) 737-6407

Supported by the National Heart, Lung and Blood Institute HIC #1402013363



Diabetes Study

GRADE

Glycemic Reduction Approaches in Diabetes: A Comparative Effectiveness Study

Do you have diabetes?

Volunteers must be willing to:

- Come to Yale University 4 times per year for 4 to 7 years
- Take Metformin plus 1 of 4 other diabetes medications that will be randomly assigned
- Take blood and urine tests

You may be eligible if you are:

- At least 30 years old
- Have had diabetes for less than 10 years
- Taking only Metformin
- Willing to take a second diabetes drug

Diabetes care provided by leading experts. Diabetes medications, supplies and lab tests FREE of charge.

To learn more, please contact: Michele Alguard, Recruitment Coordinator (203) 764-6649 • michele.alguard@yale.edu • yalestudies.org/GRADE

Supported by the National Institute of Diabetes and Digestive & Kidney Diseases

HIC #1301011390



Clinical Cancer Trials

Yale Cancer Center, one of only 41 comprehensive Cancer Centers in the country designated by the National Cancer Institute, harnesses the resources of the Yale School of Medicine and Yale-New Haven Hospital in order to advance cancer research and develop effective therapies for cancer treatment. None of these advances would be possible if people like you weren't willing to take part in clinical trials. Our portfolio includes over 100 active trials, providing options beyond the standard care for patients with most cancers.

By participating in a study, you can help Yale continue its tradition of advancing medical knowledge. For more information about cancer trials, visit www.yalecancercenter.org or call (203) 785-5702

Yale CANCER CENTER



SMILOW CANCER HOSPITAL AT YALE-NEW HAVEN

The Cancer Center is partially funded by the National Cancer Institute

Tinnitus Study

Acute Peripheral Tinnitus

Do you suffer from ringing in your ears (tinnitus)?

If you are 18 to 75 years of age and have been suffering with ringing in your ears which began in the last 3 months, you can play an important role in research by volunteering for this study.

Compensation of \$50 per visit, up to \$350

To learn more or make an appointment, contact Sherrie Bitterman, RN at (203) 584-8404 or sherrie.bitterman@yale.edu



Supported by Auris Medical, Inc.

HIC #1403013550

Upcoming Studies

Endometriosis Study - This study will use a novel combination of drugs in a vaginal ring to treat pelvic pain.

M6-C Artificial Cervical Disc IDE Pivotal Study - This is a trial for surgical treatment of adults with cervical radiculopathy. HIC #1408014403

We are also looking for healthy volunteers to participate in clinical studies.

For further information about upcoming trials at Yale, contact us at 1-877-y-studies, helpusdiscover@yale.edu or visit our website at www.yalestudies.org



Tesheia Johnson, Associate Director for Clinical Research for the Yale School of Medicine and YCCI's Chief Operating Officer.

For example, the analysis revealed that billing compliance was a hindrance to initiating studies; as a result, a new centralized billing unit was created to streamline and facilitate the billing process. Faculty members expressed a desire for additional training opportunities for investigators and research staff, which also has been accomplished. YCCI now has a multitude of training activities, including ample opportunities for Good Clinical Practice training, monthly lectures on topics relevant to research staff, and a recently instituted quarterly faculty dinner series. Informatics is another area of concern that has been developed from the ground up. The implementation of OnCore, Yale's clinical research management system, which permits seamless integration of all the components of clinical trial activity, is helping to reduce the administrative burden on investigators, allowing them to spend more time on the research itself. In addition, Yale is at the forefront of integrating OnCore with Epic, Yale New Haven Health System's electronic medical records system. This initiative is a further boon to research, allowing investigators to access clinical data to support their research, and providing automatic transmission of a host of other data to facilitate research administration and regulatory compliance.

"When I arrived at Yale in 2005, the research infrastructure that existed was in siloes and utilized mainly by established investigators," said **Tesheia Johnson, MBA, MHS**, YCCI's chief operating officer, adding that there was a need to develop support so that faculty, including junior investigators, would be able to focus on research, teaching, and clinical care instead of administration of clinical trials. "That's why we set out to create a center staffed by professionals with technical expertise who understand the key elements of research," she said. "I think the progress we've made thanks to the support of the School of Medicine, Yale-New Haven Hospital, Yale's clinical practice, and the CTSA has been remarkable."

YCCI will continue to maximize resources from Yale and the NIH as it evolves to meet the clinical and translational research needs of investigators and research staff across the entire health system. For more information, visit ycci.yale.edu.

NEW PILOT RFA AWARDS FOR PROMISING RESEARCH CONCEPTS

YCCI's pilot program is a funding venue for conducting small-scale research projects to generate data that potentially could lead to further research and funding opportunities. The new RFA containing the categories below is the result of an evaluation process in which YCCI sought to maximize the allocation of resources and identify areas that would represent the highest return on modest investments:

Translational and Interdisciplinary 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 along the road to translation.

Community and Outcomes Research: Ensuring that research is translated into practice is a difficult transition to navigate. This award is for comparative outcomes and community engagement projects that bridge the gap between science and the proven efficacy of treatments in order to translate these findings into practice and into the community to improve health.

Novel Clinical and Translational Methodologies: This award is to advance technologies post discovery with an eye toward preclinical development. The aim is to provide funding for mature new technologies that are clinically viable or for the translational advancement of medical devices or treatments. These projects should be able to generate data that will facilitate industry collaboration in order to move concepts into the healthcare market.

Established Cores: Yale has several world-class cores, but conducting research that utilizes these technologies is costly. This award is for pilot projects using such established cores as flow cytometry, genomics, and imaging for research that will lead to the funding of full-fledged grants.

Emerging Cores: Core technologies change as science progresses. Proposals for projects that utilize Yale's emerging cores will fall into one of these categories:

- **Center for Biomedical and Interventional Technology (CBIT):** Viable prototypes, animal, or pilot clinical data, and a compelling business case enhance the successful commercialization of biomedical technologies. This award provides Stage 1 and Stage 2 awards to promising projects that can benefit from the expertise offered by CBIT, a collaboration among the Schools of Medicine; Management; Engineering and Applied Science; industry; and YCCI.
- **Yale Center for Molecular Discovery (YCMD):** For investigators interested in screening compounds but lacking the resources to carry out this research, YCCI is partnering with YCMD to offer this award for proposals that demonstrate potential.
- **Informatics:** Epic is a powerful new tool in the clinical research arsenal that has yet to be harnessed. This award will involve collaboration with the Epic team and YCCI analysts for projects that utilize the electronic medical record (EMR) to conduct research utilizing the data it contains.

To view the full announcement of the pilot awards, visit www.ycci.yale.edu.



One of the most rewarding parts of my job is guiding junior faculty who are considering research. The resources YCCI offers are invaluable for all investigators, but they're especially helpful to those who are new to the process.

William Tamborlane, MD, Professor of Pediatrics; YCCI Deputy Director for Clinical Research

GUIDE TO YALE CLINICAL RESEARCH RESOURCES

Much of the growth in Yale's ability to support clinical research has been made possible by the infrastructure and services provided by YCCI. YCCI provides resources for novice investigators and senior faculty alike to help turn ideas into fundable research proposals and to carry them out in a timely and efficient manner.

Since 2006, YCCI has sought to continually improve the way in which investigators initiate, conduct, and manage studies by offering new services and centralizing others where appropriate. Following is a summary of the services offered by YCCI for conducting clinical research. Investigators wishing to utilize these services should contact Theresa Katz at 203-785-6335 or visit ycci.yale.edu/researchers/ors/index.aspx to complete an intake form.

Research Expertise and Methods

Biostatistics and Research Design

Developed in collaboration with YCCI and the School of Public Health, the **Yale Center for Analytical Sciences (YCAS)** is a valuable resource for investigators, particularly for those early in the process who need pre-design advice to ensure that their proposals use sound analytical principles. YCAS has more than 30 core faculty and staff members who can help investigators design studies that yield valid data and testable hypotheses. YCAS collaborates with a number of such other centers as the Center for Interdisciplinary Research on AIDS, the Yale Liver Center, and the Diabetes Research Center. It has built cores for the Cancer Center Support Grant and the Yale SPORE in Skin Cancer Grant as well as other large grants.

Recognizing that budget constraints may inhibit investigators – especially those at the beginning of their careers – from turning to statistical scientists, YCAS holds free weekly research and design clinics that are open to the entire Yale community. This service offers access to statisticians with a variety of skills who can collaborate on problems and recognize opportunities in researchers' work that they may not have recognized themselves. "Some investigators think they don't need a statistician because they know how to do design. But there's clinical design and statistical design, and there are different aspects to each," said YCAS director **Peter Peduzzi, PhD**, professor of public health (biostatistics). YCAS can help researchers use their NIH dollars more effectively by helping them plan the study design. "Investigators that do come to us early keep coming back because the results are tangible," said Peduzzi.

In addition to study design, YCAS statisticians are available to assist with data analysis; the center also offers weekly analytics clinics. YCAS's expertise and services include the following areas:

- Data coordinating center capabilities
- Design and analysis of clinical trials and observational studies
- General statistical methods—regression, linear models, categorical analysis
- Statistical genetics
- Genomics and proteomics
- Survival methods
- Longitudinal analysis with missing data
- Structural equation modeling / multivariate analysis (e.g., factor analysis, principal components)
- Spatial analysis
- Cancer statistics
- Survey design
- Exploratory data analysis
- Big data
- Text mining

Photo: Nicholas Licht



Peter Peduzzi, PhD, Director of YCAS (left) and James Dziura, PhD, Deputy Director of YCAS

continued next page

Collaborating with YCAS has given us unprecedented access to a wide variety of biostatistical expertise for research design and analytic plans that would have been impossible to achieve if we had hired one statistician. Their team of multiple experts enables us to develop more sophisticated studies and conduct valuable research.



Earlier this year, YCAS opened its **Yale Data Coordinating Center (YDCC)** to support the unique needs of multicenter clinical research studies. YDCC offers investigators comprehensive coordination including study design; data management (design and implementation of data management systems, data entry, and quality control and security); and data monitoring. Among the current studies that YDCC manages are *Integrated Stepped Care for Unhealthy Alcohol Use in HIV*, a multicenter randomized trial that involves data management services, preparation of **Data and Safety Monitoring Board (DSMB)** reports and data analytic files, and statistical analysis; *Guanfacine for the Treatment of Hyperactivity in Pervasive Developmental Disorder*, a multicenter randomized, double-blind, placebo-controlled trial that involves managing regulatory matters, data management, and biostatistical services, including statistical analysis; and the recently funded **Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE)** Trial, a multicenter cluster randomized trial that involves data management services, preparation of DSMB reports, and data analytic files and statistical analysis. “In this environment of heightened regulatory oversight, it is important to have the right expertise supporting large multimillion dollar studies and the role they carry in translational science,” said YCAS deputy director **James Dziura, MPH, PHD**, associate professor of emergency medicine.

Leveraging the EMR and New Technologies

Yale’s recently implemented research-friendly information technology systems are transforming both clinical care and the conduct of clinical and translational research.

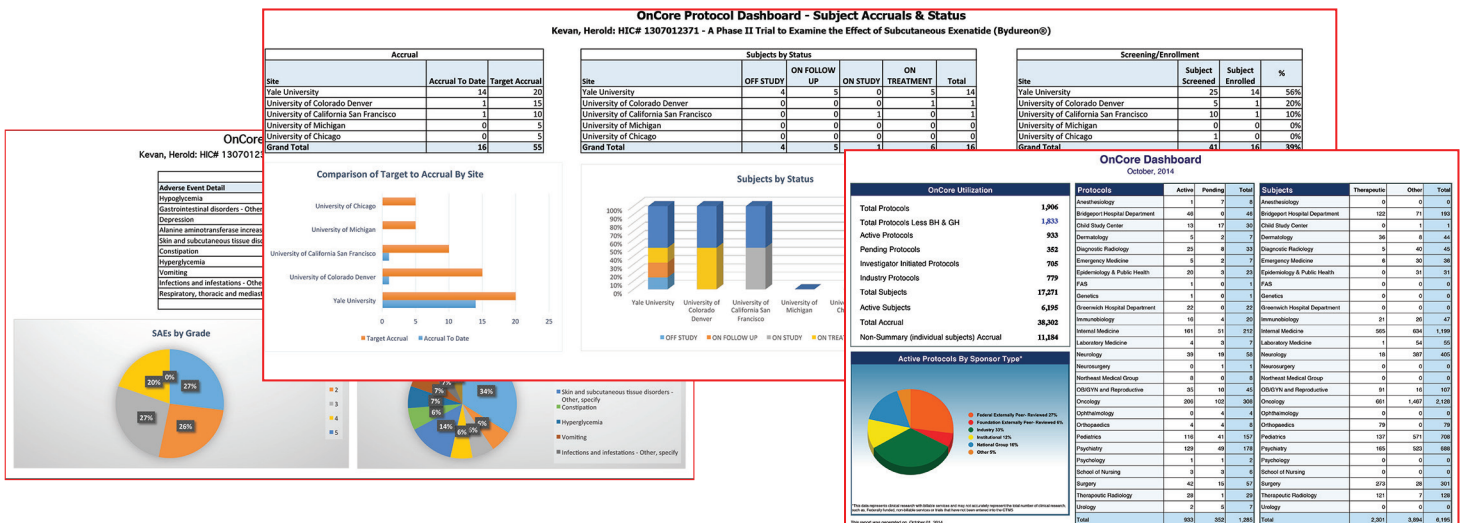
OnCore, Yale’s clinical research management system, provides seamless integration of all components of clinical research, including protocol administration, subject administration, calendar and financials functionality, quality assurance monitoring and auditing, pre-screening of subjects, unified registries, biospecimen management, and case report forms. YCCI has been working with the vendors of OnCore and Epic, Yale’s electronic medical records system, to integrate the two systems to initiate and facilitate clinical research. The Epic OnCore integration allows investigators to access clinical data to support their research; it provides cohort identification, automatic transmission of demographic and laboratory data, study enrollment status, and study billing definitions. Helix, Yale’s version of Epic’s data warehouse allows the combination of clinical data from Epic with data from such separate data repositories as the volunteer database maintained by YCCI via yalestudies.org. This combination enables researchers to identify suitable research subjects quickly.

The IT infrastructure around OnCore and Epic provides oversight and guidance for research data privacy, security and quality control, as well as a secure infrastructure for data collection, integration, storage, retrieval, and backup. This will also be aided by Yale’s pending Opt-Out policy, which would further facilitate the potential availability of blood, tissue samples, and medical records from across the entire health system except in certain limited circumstances, such as when a patient opts out.

Need Help Registering Your Study on clinicaltrials.gov?

Visit ycci.yale.edu/researchers/ors/registerstudy.aspx to find out all you need to know about registering your study, including which studies must be registered and how to request a user account.

Visually appealing management dashboard reports, created by Liat Modiano, YCCI Business Systems Analyst, give new visibility to clinical trial activity.



Informatics associated with YCCI falls into two categories: research/education and informatics that enables the integration of research and clinical care. Training/education and bioinformatics fall under the auspices of **Perry Miller, MD, PHD**, professor and director of the **Yale Center for Medical Informatics (YCFI)**, and **Cynthia Brandt, MD, MPH**, professor of medical informatics and associate director of YCFI. Informatics activities related to Epic, OnCore, and Helix fall under the direction of **Daniel Barchi, MEM**, CIO for the Yale School of Medicine and Yale New Haven Health System, and **Allen Hsiao, MD**, who trained with Miller's group and is associate professor and CMIO for the Yale School of Medicine and Yale New Haven Health System. "It's been extremely helpful to have a faculty member on our team who is focused on research," said Barchi.

YCCI can connect investigators and research staff with resources for database and informatics training. Tools for prospective data collection and storage, as well as retrospective data inquiries, are available. Informatics faculty and staff members develop and support informatics applications and shared resources for investigators across the enterprise. Services provided include:

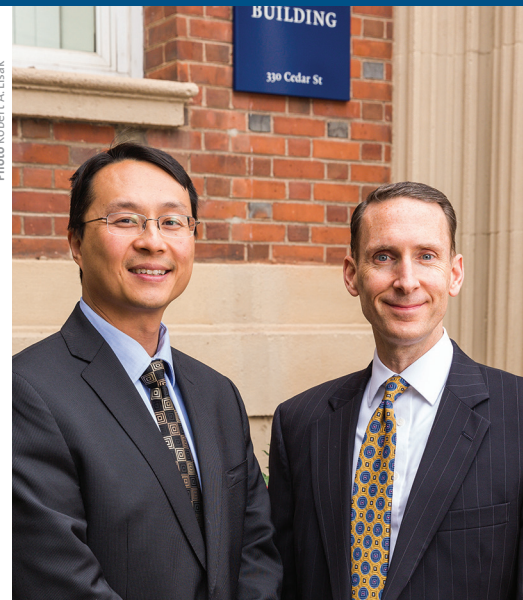
- Biomedical informatics-based metadata management
- Research data management solutions including access to high-performance computing
- New informatics methodology development
- Consultation and analysis for prospective informatics needs
- Selection and design methodology for capturing research data via computerized applications and databases
- Custom data services and consultation support involving specific programming expertise for specialized databases and LIMS
- Domain expertise in biomedical and clinical research informatics to support projects, grants, and the preparation of manuscripts and presentations using study data.
- Development of patient registries that can be used for trial development and for assessing the feasibility of conducting studies.

To learn more about how informatics facilitates research, read the YCCI Winter 2014 newsletter at ycci.yale.edu/news/newsletter/winter2014newsletter/index.aspx.

Protocol Development and Regulatory Support

This unit is available to help investigators navigate the protocol review and approval process, plan ahead for resources required, and develop a timeline for getting studies up and running. YCCI staff can help investigators prepare **Institutional Review Board (IRB)** submissions, develop informed consent forms and data safety monitoring plans, and navigate regulatory mandates. Requests for these services are growing, but YCCI's staff has the expertise to handle them because staff members work on a wide range of studies rather than focusing on a particular area. This versatility is particularly valuable for departments that don't have their own dedicated support, allowing them to achieve economies of scale. One aspect of assistance that is especially helpful is the ability to generate a timeline from the date of receipt of the protocol through the entire scientific and IRB review process. This ability is valuable for industry-sponsored studies, as sponsors typically want to know how long this process takes and expect the information to be readily available.

Photo Robert A. Lisak



Allen Hsiao, MD, Associate Professor of Pediatrics and of Emergency Medicine; Chief Medical Information Officer, Yale New Haven Health System and Yale School of Medicine; and Daniel Barchi, MEM, Chief Information Officer, Yale New Haven Health System and Yale School of Medicine

Photo Robert A. Lisak



Rhoda Arzooonian, RN, MSM, Associate Director YCCI and Yale Cancer Center; and Kelly Anastasio, Associate Director, YCCI Clinical Trial Resources

We are reaping the rewards of the considerable resources and staff support we've devoted to Epic. Every day we're devising innovative ways of utilizing the wealth of data it contains to improve clinical care, recruit subjects for clinical trials, and transform research in ways that weren't possible before.

Peter Herbert, MD, former Senior VP, Medical Affairs, Yale New Haven Health System and Chief of Staff and Senior VP for Medical Affairs, Yale-New Haven Hospital



Research Implementation and Participation

Photo Robert A. Lisak



YCCI COO Tesheia Johnson (center) with YCCI clinical research services leadership team, from left: Alyssa Gateman, Director of QA; Kelly Anastasio, Associate Director, Clinical Trial Resources; Susan Anderson, Director of Training; and Rhoda Arzooonian, Associate Director, YCCI and Yale Cancer Center.

Financial Management of Clinical Trials

YCCI staff members are available to assist investigators with constructing and negotiating budgets as well as with payment terms for recovery of the true cost of studies. Their role includes coordinating the processes between study sponsors and the Office of Grant and Contract Administration, and consulting with junior investigators who are seeking funding sources.

Once the study is funded, YCCI provides extensive support for financial compliance and billing. A YCCI staff member meets with the research coordinator to build the study calendar and contract terms in OnCore, Yale's clinical research management system, allowing invoices to be generated automatically. This process allows for timelier invoicing of industry sponsors; the ability to efficiently collect payment that is specified in the contract, as funds are carefully tracked and accounted for; improved cost recovery; and the ability to identify compliance risks in real time. The financial module is linked to Accounts Payable so that study staff can quickly ascertain where the budget stands. It also helps coordinators keep track of the study's progress so that appropriate reimbursement can take place, eliminating the need for a more cumbersome process in which coordinators would have to contact the Central Business Office. YCCI also prepares **Medicare Coverage Analysis (MCA)** for all research protocols, which is required for all clinical trials incurring charges that are invoiced to third-party payers.



Beginning in January, study subjects will be paid via reloadable and preloaded debit cards and gift cards.

A New Approach to Subject Payments

A survey conducted by YCCI querying research subjects on payment for participation in clinical trials showed that payments often take too long and that subjects are hesitant to cash a check for small amounts; the checks also cost money to generate. To address this issue, the Yale University Controller's Office, working with YCCI, negotiated with Bank of America to develop a program in which reloadable and preloaded debit cards and gift cards are issued to pay study subjects.

Slated to be launched in January, the program will be tracked through the Financials console of OnCore, allowing for easy tracking of subject payments. Once patients have been checked in — whether it's a one-time visit or an ongoing study — a data exchange will be triggered and reimbursement will occur within 24 hours instead of the six to eight weeks now required.

The program, which will be used for research reimbursement across both the medical and central campus, is a collaborative undertaking among YCCI; Bank of America; Yale's treasury department; and Forte, OnCore's vendor. It has been integrated into the existing workflow so that the processing is accomplished with just one click. The program illustrates YCCI's efforts to collaborate with vendors that are commonly used in the clinical research environment to formulate solutions utilizing existing standards so that other institutions can benefit from models developed at Yale. This payment program is just one initiative that highlights Yale's commitment to developing approaches that benefit research institutions across the country.

Both compliance and customer service will be improved with this program. It will simplify subject payments for research staff; moreover, the promise of quick payment is a plus for study volunteers. Keep an eye on YCCI's website for an announcement with further details.



Collaborating on process improvements with YCCI and the Epic team has allowed us to maximize our IT systems and make huge strides in speeding up our ability to launch studies and recruit subjects while upholding our financial commitment to them. This is a major shift from before, when the billing process delayed our ability to get trials up and running.

Paul Taheri, MD, MBA, Deputy Dean for Clinical Affairs and CEO, Yale Medical Group

YCCI recently created a **centralized clinical research coding and billing unit** that was formed as a result of a targeted evaluation process in 2012, in which YCCI sought to identify factors that affect the efficiency of conducting clinical research. Research billing emerged as one of the biggest impediments.

Under the leadership of **Paul Taheri, MD, MBA**, deputy dean for clinical affairs and CEO of Yale's clinical practice, YCCI responded to concerns expressed by investigators and department administrators by spearheading the formation of the new billing unit. There is now a review process in place for research billing; staff members collaborate with Yale New Haven Health system billing units at other sites and handle all professional research-related billing within the health system. This health system includes Yale-New Haven, Bridgeport, and Greenwich Hospitals as well as the Northeast Medical Group, which also utilize OnCore and Epic, Yale's electronic medical records system. Both systems are used to review research charges and allow easy access to records showing how funds are allocated; where money has been spent; and revenue and invoicing history. The billing unit's coding team works in close proximity to the OnCore team, collaborating throughout the life cycle of the project to achieve maximum efficiency. The new billing unit has greatly simplified, streamlined, and where possible, automated research billing. Protocols are automatically forwarded from the IRB to YCCI; and the data built in OnCore are transmitted first to Epic and then to the central billing unit.

The clinical trial budgeting expertise of the budget support team, in combination with the new billing system and the ability to automatically generate invoices, is greatly reducing the administrative burden on study staff, allowing for their increased availability to carry out other study-related tasks.

IND/IDE Support

YCCI provides a comprehensive, centralized resource for FDA submission of **Investigational New Drug (IND)** applications and **Investigational Device Exemptions (IDEs)**, with staff members and consultants with industry experience who provide "soup to nuts" IND/IDE support. This unit provides guidance on whether an IND is required; answers questions about the submission process; and assists researchers in complying with the regulatory requirements associated with IND and IDE applications. The ideal time to contact the IND/IDE service is before a research study is ready to move into human trials; consulting with these experts while still in the preclinical phase will ensure that investigators obtain the appropriate data needed for an IND application. In addition to assisting with collecting and compiling documents and submitting applications to the FDA, YCCI can help reduce the administrative burden on investigators by maintaining, managing, and monitoring INDs and IDEs, including those involving external sites; developing data and safety monitoring plans; assisting with the renewal of applications; and writing and submitting annual progress reports.

Managing my IND for teplizumab is an enormous undertaking involving multiple sites and YCCI's assistance has been invaluable. In fact, I wouldn't even consider this project without YCCI's support.

Kevan Herold, Professor of Immunobiology and of Medicine (endocrinology);
Deputy Director for Translational Science, YCCI



Introduction to Clinical Research

January 30

9 a.m.–4:30 p.m.

CSC Cohen Auditorium, NIHB Eo2

Susan Anderson, YCCI Director of Training

Faculty Education Series

How to Prepare for and Deal with FDA Inspection & GCP Compliance

October 31

Data Analysis, A Learning Experience

9 a.m.–11 a.m.

Cohen Auditorium, Child Study Center, NIHB Eo2,
230 South Frontage

2 p.m.–4 p.m.

N203, The Anlyan Center (TAC), 300 Cedar Street

4:30 p.m.–6:30 p.m.

Cohen Auditorium, Child Study Center, NIHB Eo2,
230 South Frontage

Michael Hamrell, PHD, RAC

For more information:

e-mail **LaToya Howard** at:

latoya.howard@yale.edu or call 203.737.3661

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.)

October 13 and 27

November 10 and 24

December 8 and 22

January 12 and 26

Please visit our website at

ycci.yale.edu/education/lectures/schedule/index.aspx
to find the list of presenters and projects.

Yale Entrepreneurial Institute

November 14

11 a.m.–12 p.m.

Branding 101 YEI,

55 Whitney, 2nd floor

YCAS Research and Design and Analytic Clinics

Held weekly, free of charge.

Visit ycas.yale.edu to schedule an appointment.

To help manage study files, YCCI provides reference guides, checklists and other forms to assist in the record keeping and data management of FDA-regulated and non-FDA-regulated research. Visit ycci.yale.edu/researchers/ors/studyfilesmgnt.aspx to download these documents.

Multicenter Trial Management

YCCI has instituted multiple services to support Yale investigators who wish to design, propose, and execute investigator-initiated multicenter studies. For several years, YCCI has provided assistance upon request for PIS who head investigator-initiated multicenter studies, but this capability is now expanding into a full-service line for Yale investigators who lead multicenter studies. YCCI helps develop management plans and case report forms built in OnCore that can enable electronic data capture from remote sites, so that these complex studies can be carried out in much the same way that pharmaceutical trials are conducted. YCCI provides monitoring through its Quality Assurance office and can set up Data and Safety Monitoring Boards and help conduct those meetings. YCCI can provide the monitoring services or help to screen, interview, and hire contract monitors. Providing these centralized services, which are being launched as a major initiative with the Yale Cancer Center, allows YCCI to retain institutional knowledge and expertise about the conduct of multicenter trials at a central source, providing an economic alternative to hiring ad hoc staff members who may lack experience with this type of research.

Beginning in January, YCCI will also offer project management services. With the ability of YCAS to act as a data coordination center, YCCI now has the capability to support the entire spectrum of multicenter trial management.

Study Recruitment

A variety of resources to aid investigators with recruiting and marketing for research studies are available through YCCI. Staff members can assist researchers with designing and developing such study recruitment materials as flyers, brochures, and newsletters and help develop marketing campaigns that focus on disease- or study-specific patient recruitment. YCCI maintains yalestudies.org, a clinical trials website with a searchable database that allows patients and healthy volunteers to search for trials using a variety of search parameters. Furthermore, those interested in participating in research are included in YCCI's *Help Us Discover* database, which now has about 4,500 names. The website also contains articles about research results and clinical trials that are seeking volunteers. For investigators who would like to post articles about their studies, YCCI provides writing services and will shepherd the article through the IRB approval process – a valuable service for those who need help meeting accrual requirements.

For investigators seeking to reach underserved populations, YCCI provides access to its Cultural Ambassadors Program, a collaboration with JUNTA for Progressive Action, the oldest Latino community-based nonprofit organization in New Haven; and the African Methodist Episcopal Zion Church, one of the nation's oldest African American congregations. Cultural Ambassadors work directly with investigators through monthly Community

Grand Rounds, a bidirectional forum that provides both a training arena for Yale faculty to present their research and an opportunity for Cultural Ambassadors to express the needs of their communities and provide input about the design of clinical studies as well as advice about recruitment. Cultural Ambassadors also work with investigators to create culturally sensitive materials and develop other avenues of accessing hard-to-reach populations. The group is working with Yale faculty to facilitate research in areas that were identified as health priorities through a series of meetings with New Haven community organizations with the goal of bringing faster results to underserved populations.



Photo Robert A. Usiak

Cultural Ambassador
Rev. Timothy Howard,
Presiding Elder, Western
District, AME Zion Church.

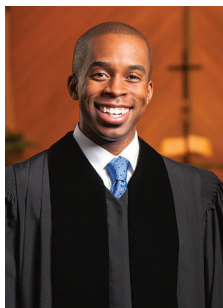


Photo Robert A. Usiak

Cultural Ambassador
Rev. Eldren Morrison,
Pastor, Varick Memorial
AME Zion Church.



Photo Steve Cooper

Cultural Ambassador
Sandra Trevino,
Executive Director of JUNTA
for Progressive Action



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

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

YCCI is also helping investigators access the “graying population” through its collaboration with the **Program on Aging (POA)**. Over several years, the POA had developed a database of over 900 subjects aged 65 and older who expressed interest in participating in clinical research. To reduce duplication of effort, the POA agreed to provide YCCI with access to this valuable resource. After obtaining IRB approval, YCCI merged POA’s database with its *Help Us Discover* database, assuming the responsibility of updating and maintaining this valuable resource that is available to Yale’s research community.

To further aid in recruitment efforts, YCCI offers **translation services** for recruitment materials, informed consent forms, and other study-related materials. Interpreter services are also available upon request. For more information visit ycci.yale.edu/researchers/ors/translation.aspx.

For more information on other recruitment services, visit ycci.yale.edu/researchers/ors/recruitment/index.aspx.



YCCI Recruitment Team, left to right: Theresa Katz, Kristin DeFrancesco, Maurice Williams, Iris Diaz, Lisa Brophy, Yvette Strong, Brittany Harris, LaToya Howard

Research Personnel Resources

YCCI provides two mechanisms for researchers who require study personnel to help carry out their studies. The first is a pool of experienced and qualified research coordinators and nurses, which is slated to expand further. This well-trained group is employed by YCCI, allowing investigators to buy in at the staff level they need, which saves both money and the time it would take to recruit and train part-time staff.

YCCI also helps meet study staffing needs by matching investigators who need research staff members with coordinators seeking employment. These situations may arise when demand for study coordinators exceeds the size of YCCI’s pool or during NIH budget reductions that create funding gaps. Matching allows investigators to hire a temporary study coordinator without a permanent commitment. The next step will be to create a virtual online meeting place via YCCI’s website for investigators to connect with research staff. Together, these initiatives allow YCCI to provide efficient personalized service in assessing each study’s unique needs and the level of staff expertise required.

Biospecimen Management

For investigators who need assistance with acquiring tissue specimens for their biobanks, the **Yale Pathology Tissue Services (YPTS)** is a great resource. Under the direction of **David L. Rimm, MD, PHD**, YPTS is a well-established pathology-based Central Tissue Resource Lab that provides comprehensive tissue-related services and material for investigators. This resource is dedicated to providing the maximum amount and quality of human tissue for research without affecting diagnostic quality, accuracy, and safety related to patients. The four lab groups, **Clinical Trial Tissue Services (CTTS)**, **Developmental Histology (DH)**, **Specialized Translational Services (STS)**, and **Tissue Procurement and Distribution (TPD)** will be able to assist investigators with most tissue-based research requests. For more information on services provided by YPTS, visit medicine.yale.edu/pathology/research/tissueservices/index.aspx#page1.

Under the direction of **Kevan Herold, MD**, YCCI’s deputy director of translational science and professor of immunobiology and of medicine (endocrinology), YCCI’s biospecimen unit can help investigators manage biospecimens electronically. YCCI has staff members to help investigators manage biospecimens electronically and develop case report forms for specimen collection. Staff can help investigators make the most of OnCore’s **Biospecimen Management (BSM)** module, which keeps track of sample inventory, collection, processing, storage, and distribution in a secure environment. BSM is paired with a **Unified Registries Management (URM)** module that uses electronic case report forms for research subject registries and is able to track clinical outcomes. Implemented in 2013, this service provides easy access to data while storing them in a HIPAA-secure environment. Additional security features help investigators manage specimens associated with multicenter trials by allowing collaborating institutions to enter data into a single system through restricted-access portals. Investigators are now able to utilize easy-to-use standard reports to better track key characteristics of their sample collections and inventory; or they can work with YCCI staff for more comprehensive needs.

Investigators with an IRB-approved protocol for biobanking, clinical research involving specimen collection, or a patient registry and data manager who can collaborate with YCCI data analysts to customize their databases are encouraged to utilize the URM and/or BSM systems. Contact **Helen Seow, PHD**, YCCI’s associate director of research administration at helen.seow@yale.edu.



Helen Seow, PHD,
YCCI Associate Director,
Research Administration

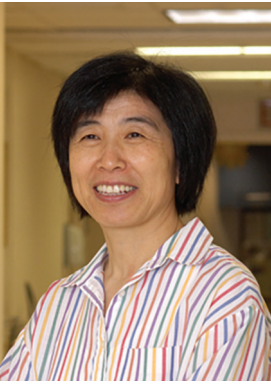


Photo Nicholas Licht

Li Wen, MD, PhD,
Senior Research Scientist in
Medicine; Director, YCCI
Core Laboratory

Core Laboratory Services

YCCI's Core Laboratory services provide investigators with access to analyses and procedures that might otherwise be unavailable or too expensive.

The lab annually provides over 100,000 results, utilizing more than 70 different tests. In addition to offering a variety of point-of-care measurements (including glucose, which is CLIA licensed), the lab features a large facility capable of analyzing a variety of hormones, cytokines and tissue markers utilizing RIA, IRMA, and ELISA techniques, as well as an automated laboratory capable of measuring most routine substrates and clinical enzymes. One of the lab's most utilized resources is the sample processing core. At three sites and servicing over 90 Yale projects, it provides routine centrifugation, aliquoting and long-term freezer storage options, as well as computerized labeling, and assistance with sample packaging for shipping. All the laboratory resources are tied together with a web-based **Laboratory Information Management System (LIMS)**, providing barcoding, storage, and tracking of processing details, POC and analytical results.

Clinical Research Facilities

YCCI manages inpatient and outpatient facilities for conducting innovative research studies, going above and beyond the scope of activities under the previous GCRC model used almost a decade ago. Those unique studies that are stratified as high in risk or those that require overnight procedures are conducted in the **Hospital Research Unit (HRU)**, located on the tenth floor of Yale-New Haven Hospital. The HRU is available to Yale investigators for both adult and pediatric studies, and reaches out to a broad group of investigators, supporting 112 studies across a wide variety of disciplines. Most of these studies would not be possible without this specialized facility.

Following an extensive evaluation to optimize efficiency and yet offer a wide range of innovative potential, the HRU was reorganized several years ago with respect to staffing and operations in order to provide timely availability to researchers and to provide complex and/or round-the-clock care when necessary. The unit's skilled nursing staff places a premium on patient safety and is available to support investigators utilizing YCCI's Magnetic Resonance Research Center and PET Center.

HRU nurses serve as research coordinators and are expert in carrying out sophisticated clinical research in both children and adults. The recent efficiency evaluation suggested that the staff could serve in other non-traditional functions but may require additional training. This novel strategy was considered to be a worthwhile investment, so that on-site oversight functions could be implemented. After appropriate training, nurses serve as auditors for studies in which they are not involved; can administer chemotherapy after appropriate certification; and can be trained to work at the Saint Raphael Campus satellite facility for diabetes technology studies. The implementation of this process has allowed for staff to function in multiple roles requiring wide-ranging skills as necessary, offering an increased flexibility that benefits Yale's entire research enterprise.

The HRU facility includes 10 bed/chair spaces for inpatient or outpatient studies (including two rooms ventilated for smoking studies); a suite with three bed/chair spaces for outpatient studies; direct research pharmacy support; and a bionutrition unit. Its location within Yale-New Haven Hospital ensures the safety of patients should any serious adverse events occur..

The **Church Street Research Unit (CSRU)** provides a patient-friendly environment that is ideal for less invasive, lower-risk studies. It offers accessible parking and is located near the highway as well as the medical school. The CSRU staff includes a full-time nurse to assist investigators in conducting studies or researchers may supply their own staff members for outpatient studies in this facility. The CSRU has become invaluable as Yale's clinical practice has grown dramatically; it is ideal for studies that don't require integration with the clinical practice but benefit from a dedicated research facility.



Photo Harold Shapiro

Thomas O. Carpenter, MD,
Professor of Pediatrics and of
Orthopaedics and Rehabilitation;
Medical Director, Hospital
Research Unit



Photo Robert A. Lisak

Lynda Knaggs, RN, HRU Manager



Quality Assurance, one of the functions that Yale Cancer Center was able to centralize with YCCI, is a perfect example of combining efforts to create efficiencies both financially and in terms of expediting research.

Thomas J. Lynch, MD, Director, Yale Cancer Center; Physician-in-Chief, Smilow Cancer Hospital at Yale-New Haven Hospital

The CSRU is also open to investigators in such disciplines as engineering, that don't have suitable space for conducting clinical research. In addition to examination rooms and a phlebotomy room, the CSRU includes a meeting room appropriate for obtaining patient consent, consultations, interviews, and survey-based research studies; and a blood processing facility.

Quality Assurance

Over the past several years, clinical research at Yale has grown dramatically in an environment of increasing complexity and regulatory exposure. In order to minimize risks while ensuring that investigators are able to conduct innovative clinical research, YCCI provides **Quality Assurance (QA)** support and helps investigators in conducting high-quality compliant clinical research.

In an effort to create a more robust QA system, YCCI has recently expanded its program and has instituted such initiatives as risk-based stratification for large-scale QA audits. Through training and education initiatives, YCCI is identifying institutional trends and working with investigators – who often request audits – so that they understand and are using best practices in conducting research. The goal is to ensure that studies taking place on the medical campus are conducted in an audit-ready environment. Staff members are available to assist investigators in preparing for FDA audits, an increasingly likely occurrence in light of Yale's expanding clinical research portfolio and volume of high-accruing studies.

YCCI also provides monitoring of multicenter studies for which Yale is the lead site and therefore responsible for ensuring that research complies with FDA and other regulations. Furthermore, YCCI has partnered with the Yale Cancer Center to create and provide administrative support for a safety monitoring system consisting of four review committees. In 2012, YCCI engaged the Huron Consulting Group to conduct a detailed assessment of Yale's clinical research infrastructure and design a revised model that would further support investigators. Huron's recommendations – which included expanding YCCI's administrative and research support cores, streamlining billing and financial support, and increasing the size of the staff to address compliance risks – have all been implemented.

YCCI and the **Human Research Protection Program (HRPP)** are collaborating on a strategy to expand quality improvement in clinical research. The two organizations are conducting reviews in collaboration with all the clinical departments in the School of Medicine to ensure that investigators have the resources – both centrally and within their departments – to conduct high-quality research. The project is also intended to reveal any perceived barriers to initiating or conducting research at Yale. Although each department has its own strategic vision for expanding research, this project is helping to identify synergies across the programs as well as provide assistance to operationalize and implement departmental strategies. This information is being used to plan for continued quality improvement across the enterprise and is helping YCCI evaluate existing and new lines of service, as well as formulate guidelines on whether services should be at the departmental level or centralized, and at what volume of clinical trials this centralization should occur.

This initiative is facilitating bidirectional collaboration by bringing faculty concerns to the attention of YCCI and in turn providing direction for YCCI to develop training activities that address these issues. These efforts are helping YCCI develop a strategy and are supplying a vision of quality assurance that is critical to supporting groundbreaking and safe research across the entire enterprise.



Photo Robert A. Usak

YCCI is pleased to announce that Alyssa Gateman, MPH, CCRP (right), has assumed the role of Director of Quality Assurance. Since her arrival in July, she has been instrumental in implementing recent quality initiatives alongside Susan Anderson, RN, BSN, MFA. After almost 30 years of service in clinical research, Anderson is scaling back and has assumed the role of Director of Training, where she will continue to lend her valuable expertise to Yale's research community.



Photo Nicholas Licht

Jan Hewett, JD, BSN
Director of the HRPP

It's really important for us to have dedicated space and staff that can accommodate our complex requirements and ensure the safety of our research subjects. The inpatient and outpatient facilities that YCCI oversees allow us to conduct innovative studies that have the potential to help many patients and that couldn't be done otherwise.



Training to Support Research

Clinical research has grown significantly at Yale over the past decade and is expected to continue expanding in the future. In order to support innovative research that meets the stringent regulations imposed on today's research studies, YCCI offers numerous training activities for investigators and research study staff, and also has the flexibility to provide ad hoc training to address issues that may arise for individual investigators and departments.

Coffee and Conversation and **Lunch and Learn** are two well-attended monthly series that offer presentations from Yale and outside experts covering topics ranging from procedural issues to global trends in clinical trials. These sessions are open to all clinical research staff, including both new employees and those seeking a refresher on fundamental topics. To view the upcoming schedule, visit ycci.yale.edu/education/stafftrain/index.aspx.

For the past several years, YCCI has sponsored intensive face-to-face **Good Clinical Practice (GCP)** training sessions with a leading expert several times each year. Online GCP training is also available and can be accessed by visiting ycci.yale.edu/education/stafftrain/gcptraining.aspx. To date, over 600 investigators and coordinators have participated in face-to-face GCP training and another 200 have participated online. YCCI has continued to provide live training sessions in response to the preference of faculty and staff for this format. Their feedback indicates that the interactive sessions provide the opportunity to ask questions, resulting in a deeper understanding of not only the regulatory requirements, but also how to integrate this knowledge into practice. Last fall, YCCI sponsored a four-part symposium on conducting clinical research, featuring speakers from other academic institutions who shared lessons learned on facilitating compliant clinical research, managing FDA audits, and handling issues that arise related to ethics and privacy. Last spring, Yale offered courses for faculty and staff on preparing for an FDA audit, featuring presentations by an outside expert with more than two decades of experience in regulatory affairs, clinical research and drug development with academic institutions, the FDA, the NIH, and in industry. Additional sessions on GCP training and preparing for FDA audits will be held this fall.

A three-part introduction to clinical research is now being offered to research staff across the School of Medicine. The series was adapted from a course that is mandatory for new employees at Yale Cancer Center. The first session features a broad overview of clinical research; the second session focuses on the important elements of clinical trials that research coordinators need to know; and the third session covers the roles of Yale's institutional review committees that affect clinical trials.

These activities augment the Clinical Skills Training program, which provides nonclinical research staff with the skills needed to perform basic clinical tasks and carry out other aspects of clinical research protocols. The program includes didactic and laboratory sessions in the skills needed to perform hands-on clinical procedures for medical data collection for research protocols, as well as basic emergency care. The sessions are divided into specific classes or modules, so that Research Associates who have already been trained in some clinical procedures can expand their skills by participating in specific modules.

YCCI recently instituted Clinical Research Quarterly Faculty Dinners to discuss the needs and concerns of Yale clinical research faculty. Topics for 2014–2015 include:

- What Constitutes Physician Oversight
- A Research Wish List: Improvement to Yale's Research Environment
- Lessons Learned from FDA Audits
- How to Better Utilize Technology and Current Resources

For more information contact LaToya Howard at latoya.howard@yale.edu.

All of YCCI's training programs are aimed at ensuring that Yale continues to conduct the innovative research that is its hallmark. For more information on YCCI's education and training programs, visit ycci.yale.edu/education/index.aspx.



Photo Robert A. Lisak

LaToya Howard,
Training Coordinator,
Committee Management



The high-quality training provided by YCCI for faculty and research staff has been timely and especially valuable, because it's face to face. I applaud YCCI's efforts for hosting the faculty dinner series; it gives faculty a much-needed venue for discussing our research needs.

Alexandra Lansky, MD, Associate Professor of Medicine (cardiology)

Connections with Other Resources

As an institution, Yale focuses on fostering collaborations among its programs and leveraging resources so that investigators are able to conduct high quality research efficiently and in a compliant manner. Accordingly, YCCI, the **Human Research Protection Program (HRPP)**, and the **Office of Grant and Contract Administration (GCA)** are working together to integrate services where possible to support Yale's growing research enterprise.

"Our relationship with YCCI has grown stronger over the last couple of years in particular because we think there needs to be a synergy between the organizations" said **Andrew Rudczynski, PHD**, associate vice president for research administration, who oversees the HRPP and GCA. YCCI and the HRPP have worked closely on recent departmental assessments to evaluate the quality of the clinical research they conduct, as well as on training activities for research staff. "I anticipate that these activities will continue to evolve so that we can continue to raise the quality with which research is conducted," said Rudczynski.

There is also a drive toward efficiency that has involved a concerted effort to reduce the amount of time needed to initiate research studies. For example, HRPP formed an Institutional Review Board dedicated to oncology trials to ensure more rapid and knowledgeable review of cancer protocols, while GCA has a dedicated staff member for contracts related to oncology trials. GCA staff members work in parallel and in collaboration with the YCCI budgeting unit to ensure that contracts are negotiated and executed in a timely fashion, as well as with HRPP to ensure that the language of consent documents is aligned with the contract.

Yale has invested significantly in its clinical research infrastructure over the past several years and is committed to continuing along this path. "If we want our clinical research portfolio to grow, we have to invest and make sure we have the structure in place and the right people and resources to support it," said Rudczynski.



Andrew Rudczynski, PHD, Associate Vice President for Research Administration

Some of the programs offering resources and support for researchers include:

Grants and Contracts:

The Office of Grant and Contract Administration (GCA) assists investigators in obtaining and managing sponsored research awards and is responsible for reviewing and approving proposals sent to sponsors. GCA staff members provide guidance on writing and preparing proposals (including NIH Institutional Training Grants), approaching foundations, complying with Yale and federal policies and regulations, and processing Material Transfer Agreements. The office also provides a number of reference tools, including proposal checklists and guides, forms, and training materials.

The current and ever-changing regulatory environment makes it challenging for investigators to handle the administrative burden of conducting research. "Having a champion to shepherd a faculty member's

interest is critical to the process," said **Alice Tangredi-Hannon**, interim executive director of GCA. "It allows them to concentrate on their research and have other activities handled by those with the proper expertise." Visit grants.yale.edu/ for more information.



Alice Tangredi-Hannon, Interim Executive Director of GCA

Human Research Protection Program:

In addition to managing Yale's five Institutional Review Boards, the **Human Research Protection Program (HRPP)** facilitates compliance with federal regulations and protection of research participants. The HRPP also develops training and education activities to ensure that studies are conducted in a compliant manner and helps track and monitor research activities. Many of these activities are carried out in collaboration with YCCI. For more information, visit yale.edu/hrpp/.

Office of Cooperative Research and Yale Entrepreneurial Institute:

YCCI collaborates with Yale's **Office of Cooperative Research (OCR)** and the **Yale Entrepreneurial Institute (YEI)** to help faculty members, graduate students, and postdoctoral fellows in their quest to form startups; test the commercial potential of research projects; connect with partners for commercial opportunities; and identify funding opportunities.

In partnership with OCR — whose mission is to facilitate the translation of research from Yale's labs into products and services that benefit society — YCCI offers pilot funding to move translational projects to the next step of commercial development. These strategic investments, which are typically less than \$25,000, have helped a number of projects, such as the development and commercialization of an internal organ retraction device that facilitates minimally

invasive surgery and a new class of synthetic molecules that trigger the body's immune response to HIV and prostate cancer. To find out more about how you can work with OCR, visit ocr.yale.edu/.

YCCI is also providing clinical trial support for design teams at YEI, a multidisciplinary center that supports student entrepreneurs at every stage of the startup process. The first such collaboration was with **Sean Mackay (School of Management '14)**, founder and CEO of IsoPlexis, a startup emerging from the lab of **Rong Fan, PHD**, associate professor of biomedical engineering. The startup is developing a single-cell immunoassay device and software that provides in-depth understanding of immune and cancer cell activity.

Mackay met with YCAS for help with study design and YCCI helped him connect with Yale faculty members who had experience starting their own labs and were willing to mentor him. **Kathryn Miller-Jensen, PHD**, assistant professor of biomedical engineering and molecular, cellular, and developmental biology, who worked with Fan on the device, now regularly uses it to track cell communication. The data that she and other researchers at Yale produce is helping provide IsoPlexis with further proof of concept for the device. IsoPlexis recently closed on a \$1.25 million Series A round with funding from Connecticut Innovations and several investment firms. Visit yei.yale.edu/ for more information.

YCCI CLINICAL RESEARCH RESOURCE DIRECTORY

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