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OFFICE OF RESEARCH SERVICES EXPANDS RESOURCES FOR CLINICAL INVESTIGATORS

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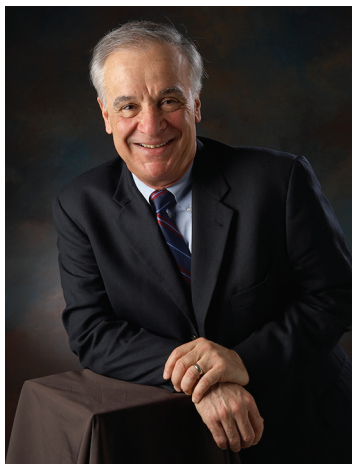
Today's stringent regulatory environment, coupled with ever more sophisticated analytical tools and the need to ensure the safety as well as effectiveness of clinical trials, has helped to create a system that is increasingly difficult to navigate. In fact, according to a recent survey by the Federal Demonstration Partnership, a cooperative of federal agencies and institutions that receive federal funds, 42 percent of the time spent by faculty committed to federal research was devoted to administration – not to active research.

Academic medical centers have responded to this increased administrative burden by allocating increased funds for infrastructure, personnel and IT systems to administer and manage clinical trials, according to the Association of Academic Health Centers. YCCI's answer to the dilemma has been to create the Office of Research Services (ORS) to provide the robust infrastructure required for conducting innovative and collaborative research.

ORS was conceived as a "one-stop shopping service" to house at one convenient site all the support needed for every aspect of cutting-edge studies. "The CTSA has allowed us to really support investigators the way we always hoped to," said William Tamborlane, M.D., professor of pediatrics and deputy director of YCCI. "It used to be that the only service available to researchers was the GCRC, with some nursing support, a lab and one biostatistician. ORS has taken some of that groundwork and expanded it exponentially."

WILLIAM TAMBORLANE, M.D.
*Professor of Pediatrics
 Deputy Director of YCCI
 Director of the
 Office of Research Services*

Tamborlane's experience, expertise, leadership and managerial skills make him uniquely qualified to serve as director of research services for YCCI. He is responsible for administrative oversight of all ORS units; ensuring that services meet researchers' needs; and implementing policy and program changes as those needs evolve.



The ways in which ORS can help researchers go beyond merely guiding them through the maze of regulations surrounding clinical trials. ORS is transforming clinical and translational research at Yale by

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Director's Corner

Clinical research has been in place at Yale for many years. What hasn't been available, however, is an infrastructure that allows researchers to come to one place and find the resources they need to improve the efficiency of conducting clinical trials. With ORS, we've created a comprehensive service that makes it easier and less expensive for investigators to enter a process that can be very daunting.

We have put together another special issue of the newsletter because we feel it is important for you to know that we have the resources and expertise to help you with clinical trials, whatever their stage or size.

Establishing and organizing ORS has been a team effort; we're well aware that it is still a work in progress. In January we had a retreat with YSM leadership to take stock of what we've accomplished and how we can continue to extend the program. We're planning another retreat this summer that will include senior faculty so that we can focus on innovations we can develop to make clinical research accessible to more investigators. In order to improve services, however, we need your support; perhaps more importantly, we need your feedback. Bill Tamborlane and the ORS staff would be happy to meet with you and your department; offer you a tour of our Church Street Research Unit; or help in the transition of new faculty. We're counting on you to let us know what we can do to help you meet your research goals.

Robert Sherwin, M.D.
YCCI Director

SPECIAL EXPANDED ORS ISSUE

Next Issue: YCCI's Research Cores

Learn more about our core resources and how they can be utilized for clinical and translational studies.

BIOSTATISTICS HELPS RESEARCHERS FROM GRANT SUBMISSION THROUGH PUBLICATION

Biostatistical analysis is an important part of any study design; however it is not an area in which every researcher is knowledgeable. YCCI is addressing this need with its biostatistical support unit, which now has seven affiliated biostatisticians available to assist investigators. Their expertise includes:

- General statistical consultation, including optimal study design, sample size/power estimation, and data analysis planning
- Longitudinal, categorical, and survival analysis
- Bayesian methods
- Instrument validation
- SAS programming
- Statistical computing and simulation
- Structural equation modeling
- Statistical genetics

The skills offered by this diverse group are valuable not only when interpreting results but even before the study begins. According to James Dziura, PH.D., M.P.H., the manager of YCCI's biostatistical support unit, most grant review teams now have a biostatistician assigned to them to review study design, examine subject sampling, look at bias control methods, and review how the data will be analyzed. That's why Dziura urges researchers to contact his office early in the development of a protocol. "A lot of clinical investigators understand they need biostatistical input but they don't know where to go," said Dziura. "We'd like to fill in that hole."

Lawrence Scahill, PH.D., M.S.N., M.P.H., professor of nursing and child psychiatry at the School of Nursing and Child Study Center, has worked with the biostatistics unit on two multisite NIMH studies, neither of which was based on an existing model. "They've been instrumental in helping us move these data sets along to get them ready for publication," he said. "We've come to have great faith in the work they produce."

The biostatistics unit is in the process of establishing a new collaboration with the Keck Laboratory. This unit will assist researchers in interpreting the increasingly massive genomics and proteomics datasets generated by the state-of-the-art instrumentation and technologies available at the Keck Laboratory. Researchers should contact James Dziura for more information about this resource.

For those looking for an introduction to statistical topics, a summer course titled "Introduction to Biostatistics," co-sponsored by the Investigative Medicine Program, will provide an overview of common statistical techniques used in clinical lab research and include computer lab sessions to reinforce the lecture material. Medical students, postdoctoral fellows, professors and research assistants are all welcome to attend.

Within the past year, the unit has reviewed 75 protocols and conducted initial consultations with over 100 different clinical investigators. Many of these consultations have led to further collaboration through grant planning, protocol development, data analysis, or manuscript preparation. In response to increasing demands for biostatistical support, a search is currently underway in collaboration with the School of Public Health to recruit a senior faculty member to lead the unit. "It's exciting to see how the biostatistics unit has really developed into an invaluable tool for investigators," said Paul Cleary, PH.D., M.S., C.-E.A. Winslow Professor of Epidemiology and Public Health and Dean of Public Health.

Investigators wishing to consult the biostatistics resource unit should contact James Dziura at 737-4468 or james.dziura@yale.edu; or Theresa Katz at 785-6335 or theresa.katz@yale.edu. 🌐

Events Calendar

Investigative Medicine Program

Joint YCCI/Investigative Medicine Program Scholars Research-in-Progress Meetings

All meetings feature presentations from individual scholars. Topics will be announced at a later date. We encourage all faculty and staff to attend. Lunch will be provided.

TAC N203, 300 Cedar Street

noon to 1:30 p.m.:

September 15

September 29

October 6

October 20

The following course from the IMP is open to investigators. For more information or to register, please contact Pamela Fucci at 785-6842 or pamela.fucci@yale.edu.

Principles of Clinical Research

July 28 - August 8

2:00 to 4:00 p.m.

TAC N203, 300 Cedar Street

Course Director: Eugene Shapiro, M.D.

This course consists of a one-hour didactic presentation followed by an interactive discussion of articles to be read in advance.

North Haven Fair

September 4, 5, 6, 7

Washington Avenue, North Haven

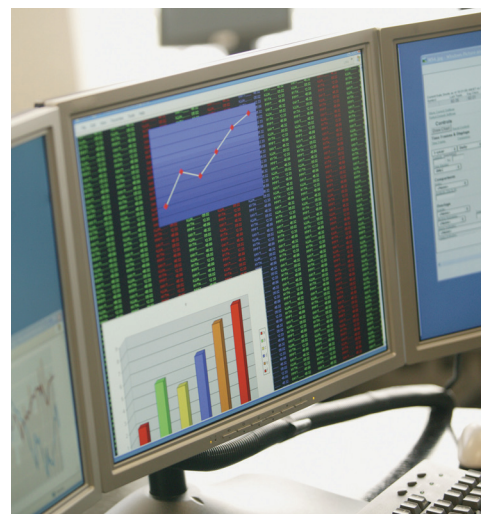
YCCI will host a booth at this event to recruit participants for clinical trials.

JAMES DZIURA, PH.D., M.P.H.

Research Scientist in
Medicine and Pediatrics
Manager of the Biostatistical
Support Unit



Dziura's responsibilities include general statistical consultations with investigators in a variety of disciplines as well as collaborating with investigators to design and analyze their research studies. He also supervises a team of biostatisticians to assist investigators utilizing YCCI's services.



OFFICE OF RESEARCH SERVICES EXPANDS *continued from page 1*

providing the resources investigators need to develop scientifically sound research protocols and competitive grant submissions, as well as assisting them to implement their studies as safely and efficiently as possible. It is here that investigators can find assistance to ease every aspect of completing their trials, whether they are young investigators just beginning their careers or seasoned investigators who need to get studies off the ground quickly. According to Tamborlane, ORS is a key component of YCCI’s vision to enhance the ability of Yale faculty to develop clinical research protocols of the highest quality. He believes that the support the center offers is positioning the university to be more competitive in obtaining extramural funding, including industry investment in translational research for new drugs and devices.

Rather than create an additional system with its own complicated procedures, ORS aims to assist clinical researchers in negotiating the labyrinth of increasingly rigid federal, institutional and grant regulations. Feedback from investigators on the obstacles to setting up and conducting clinical trials – some of which ORS had put in place – has led to the development of streamlined processes to be introduced as early as this fall. The expectation is that investigators will spend less time on the bureaucratic aspects of clinical trials and more time doing the actual research. “One of our goals is to give investigators some of their time back by helping to support them,” said Stacey Scirocco, YCCI associate director and ORS administrator.

In addition to providing expertise in their individual fields, ORS staff members respond to researchers’ needs by collaborating to identify problems and develop workable solutions for today’s complex research environment. By facilitating the process of designing and conducting clinical trials at each step and tailoring activities to meet researchers’ needs as they evolve, ORS is changing the climate of clinical research at Yale.

If you have any questions about services offered by ORS or would like assistance with any aspect of a clinical trial, please contact Theresa Katz at 785-6335 or theresa.katz@yale.edu. ☁



STACEY SCIROCCO
Associate Director of YCCI
Administrator of the
Office of Research Services

Scirocco’s experience includes almost 10 years in clinical research administration. She is responsible for assisting with YCCI development and strategic planning, administration, and the overall operation of the Office of Research Services.



THERESA KATZ
ORS Coordinator

Katz coordinates activities among the various ORS units; sets timelines and keeps them on track; answers questions and directs investigators to the appropriate resource person; and tracks protocols with the IRB. She is the primary contact person for general questions about services offered by the ORS.

YCCI: MOVING BEYOND THE GCRC

	GCRC	YCCI/CTSA
BIOSTATISTICAL SUPPORT	1	6
EDUCATION/QUALITY ASSURANCE	0	1.5
INFORMATICS	2	4
FINANCIAL MANAGEMENT	1	3
PATIENT RECRUITMENT	0	2
BUDGET DEVELOPMENT	0	2.5
PROTOCOL DEVELOPMENT	0	3
RESEARCH NURSING & PCAs	13	16
STUDY COORDINATION	0	14
TOTAL	17	52

Support from the institution and the CTSA has allowed YCCI to move well beyond the capabilities of the GCRC. In fact, YCCI isn’t the GCRC with a new name—it’s a whole new organization. While the GCRC was a valuable resource that provided clinical support to complete research tasks, YCCI provides more comprehensive services and a wider variety of support to investigators.

CLINICAL RESEARCH SUPPORT: A MAJOR MOVE TOWARD FLEXIBILITY

BARBARA GULANSKI, M.D., M.P.H.

Associate Professor of Medicine

Director of Clinical Research Units

Gulanski's experience in hospital-based clinical research administration serves her well in her current role as director of clinical research units. She oversees YCCI's Core Lab and the Church Street and Hospital Research Units, where she is responsible for supervising research support staff and ensuring that study coordination needs are met.



The guiding principle behind Clinical Research Support, the ORS unit that supplies research nursing and study coordination, is partnership with investigators in putting their scientific hypotheses into action.

Clinical Research Support comprises management personnel for inpatient and outpatient facilities; highly skilled research nurses for adult and pediatric studies; clinical research nurse and non-nurse coordinators; research assistants; patient care associates; and experienced bionutritionists. The staff members have a wide range of clinical and research expertise to support a broad range of studies. "The expert nursing support that we have received from YCCI has been an important part of the success of our studies related to schizophrenia, alcoholism and PTSD," said John Krystal, M.D., the Robert L. McNeil, Jr. Professor of Psychiatry, whose work often involves combining highly technical neuroimaging studies with infusion of experimental agents.

The nursing and bionutrition services provided by Clinical Research Support, sometimes referred to as Participant and Clinical Interaction Resources (PCIR), include:

- Complete study coordination from soup to nuts including patient screening and enrollment, completion of case report forms and overall study management.
- Highly skilled research nursing support in the Hospital Research Unit, including such specialized research skills and techniques as insulin-glucose clamps; management of arterial lines; support for a wide range of imaging studies and administration of stable isotopes; chemotherapy; and the use of an array of investigational drugs.

One of the unit's new services is flexibility in meeting investigators' evolving needs. It provides personnel to support all aspects of coordination for research studies wherever investigators need them without being bound to one location. "Our service is unique because instead of investigators having to hire a full-time coordinator for a study, for example, we have the ability to provide support for whatever percentage of that person's time is required to get the job done," said Diane Wall, R.N. Wall is administrator of clinical research support services, a newly created position under the CTSA.



CSRU Waiting Room



CSRU Research Consultation Room

CHURCH STREET RESEARCH UNIT

The GCRC was the only dedicated space available for research studies before YCCI was established. Now the Church Street Research Unit (CSRU), which opened in July 2007, is also available. The CSRU is ideal for less invasive outpatient studies involving simple procedures such as blood draws, physical exams or the administration of oral medications. The unit provides a pleasant environment conducive to clinical research. It offers accessible parking and is located near the highway as well as the medical and nursing schools. The facility includes a phlebotomy room; two fully equipped clinical



CSRU Exam Room

examination rooms; two rooms with reclining exam chairs and televisions where participants can relax during studies of longer duration; and a room equipped with a table and chairs appropriate for obtaining patient consent, consultations, interviews, and survey-based research studies. The CSRU also has a blood processing facility, a storage facility and a limited freezer facility. Researchers currently supply their own staff to utilize this space; they can also bring in personnel trained and supervised by YCCI's clinical research support unit.

"The CSRU allows us to move beyond the walls of the hospital and provide services we couldn't offer before," said Barbara Gulanski, M.D., M.P.H., associate professor of medicine and director of clinical research units and overall study management for YCCI. Gulanski encourages researchers to visit the facility. "It's a major step forward in providing flexibility for a wide variety of research studies."

The CSRU is open from 8:30 a.m. to 5:00 p.m., but arrangements can also be made for access during evening hours. There is currently plenty of availability—there are even same-day appointments—and ORS administrator Stacey Scirocco is available to meet with investigators to discuss use of the facility.

HOSPITAL RESEARCH UNIT

While the CSRU is well equipped for low-risk studies, the Hospital Research Unit (HRU), formerly known as the GCRC, is available for adult and pediatric inpatient studies as well as more complex high risk outpatient studies. “One thing that distinguishes ORS and the HRU nursing staff is that there’s a real depth of expertise,” said Kevan Herold, M.D., professor of immunobiology and medicine, who conducts metabolic studies for his diabetes research. Herold came to Yale last year after 20 years of teaching and research at Columbia University. He said he experienced virtually no downtime in getting protocols set up when he first arrived at Yale, thanks to the assistance of HRU staff and administration.

Well known for its skilled nursing staff that places a premium on patient safety, the HRU is open overnight three nights per week and one weekend per month. Since becoming part of YCCI, the unit has increased its volume of protocols, accommodating over a thousand patients each year. “The HRU collaborates successfully between the university and the hospital because we share a mission of seeking answers and making discoveries,” said Shelley Britt, R.N., patient services manager for the HRU.



HRU Study Rooms

Besides supplying expert nursing care, the HRU has a bionutritional unit to support the nutritional components of the studies conducted there. The unit has a metabolic kitchen for preparing meals for research diets, which can be manipulated for a single nutrient or multiple nutrients. In addition, experienced nutrition staff members are available to prepare controlled research diets and work with adult and pediatric participants on implementing dietary regimens. “The metabolic kitchen has been an essential part of our research over the last decade on the role of dietary protein in skeletal health,” said Karl Insogna, M.D., professor of medicine and director of the Yale Bone Center. Bionutrition staff have designed experimental diets and ensured their palatability for Insogna’s studies. He credits them in large measure for the high rate of compliance the studies have maintained over the years. The HRU also houses a clinical DEXA unit where investigators can request bone densitometry or body composition scans at discounted research prices.

The HRU has a historical association with high-risk intensive studies in such areas as diabetes, but it has also added newly equipped outpatient space and can accommodate a wide variety of studies. YCCI is planning further expansion of the HRU’s clinical space. Investigators are welcome to visit the facility and see what it has to offer.

If you would like to know more about the services offered by Clinical Research Support, please contact Barbara Gulanski at 785-2983 or barbara.gulanski@yale.edu or Theresa Katz at 785-6335 or theresa.katz@yale.edu. Additional information is also available at www.ycci.yale.edu. 🌐



DIANE WALL, R.N.
*Administrator of Clinical
Research Support Services*

Wall has been involved in clinical research trials at Yale since 1999 serving as the project manager for single as well as multi-site investigator-initiated and industry-sponsored studies. She supervises research support personnel for investigators utilizing YCCI’s services.

HRU News

Eight members of the HRU staff have been noted as “YNHH All Stars,” recognized for receiving five or more mentions of service excellence in the Press Ganey survey. The survey is utilized by the hospital to capture satisfaction with service delivery or some other form of recognition.

For more information, visit the YCCI website at www.ycci.yale.edu.



SHELLY BRITT, R.N., M.S.N.
*Patient Services Manager of
the HRU*

Britt has worked at Yale-New Haven Hospital for 26 years, ten of which have been with the HRU, where she currently manages the nursing staff. She is collaborating on the Perception of Care study, a joint venture with The Rockefeller University CTSA, to obtain data on the response of research participants and investigators.

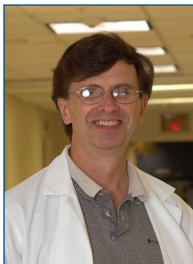
CORE LAB ANALYZES SPECIMENS FOR CLINICAL INVESTIGATORS

LI WEN, M.D., PH.D.
Director of Core
Laboratory Services



Wen is responsible for overseeing the services provided by the Core Lab. She is working on expanding and adapting new technologies to help investigators analyze clinical research samples, as well as developing new systems for laboratory-based analysis in response to investigators' needs.

RALPH JACOB
Manager of Core
Laboratory Services



Jacob has almost 35 years of experience in laboratory services. His responsibilities include managing the system used to track, analyze and process samples collected in research studies.

Most investigators carrying out clinical research need lab work. YCCI's core laboratory provides them with access to analyses and procedures that might otherwise be unavailable or too expensive.

The lab, which was formerly part of the GCRC, provides more than 40 different tests. In addition to offering point-of-care glucose (CLIA license), lactate and ethanol measurements, the lab measures a variety of hormones, substrates and cytokines. The sample analytic unit includes radioactive assays, ELISA, HPLC and substrate analysis.

The demand for lab services has increased by about 30 percent since 2006. In order to meet this demand, the lab is expanding its present services and developing new ones that include:

- A sample repository "freezer farm" with ten -80°C freezers
- A robotics system to carry out serial dilutions of serum/plasma samples more efficiently
- A Bioplex platform capable of analyzing multiple panels of assays simultaneously
- A Laboratory Management Information System (LIMS) to track specimens during processing and storage
- Development of a system for purifying lymphocytes

YCCI understands that the need for a biorepository goes beyond the facilities that currently exist. Future plans include expanding the repository so that samples from all trials, including samples from normal controls, can be stored and shared among researchers. "If you're an investigator and want to do a study, it can be incredibly difficult to start up," said Kevan Herold, M.D., professor of immunobiology and medicine, adding that a comprehensive repository would make samples available that might otherwise be difficult to acquire. The School of Medicine has committed to the biorepository by funding the renovation of space for equipment for systematic storage of samples that investigators collect. Herold has already developed a protocol for the project that is currently under IRB review; meanwhile, a group of investigators is working to define the long-term needs of the project.

"We would like investigators to know that we are here to help them and that in addition to expanding our services, we are developing new ones in response to their needs," said Li Wen, M.D., PH.D., research scientist in medicine and director of core laboratory services. Wen added that she encourages investigators to discuss with YCCI other services or new technologies that would be useful.

The lab operates Monday through Friday from 7:30 a.m. to 5:00 p.m., and is also open two to three evenings a week and one weekend per month. For assistance, please call Ralph Jacob at 785-4422 or ralph.jacob@yale.edu. ☎

IMPROVING THE QUALITY AND SAFETY OF CLINICAL STUDIES AND PROVIDING TRAINING

YCCI has partnered with the Yale Cancer Center to begin a quality assurance and safety monitoring system in order to improve the quality of clinical research at Yale.

Investigators with less experience often call on the quality assurance office in the early stages of their studies to get off to a good start. The unit also assists investigators who have been notified that they will undergo an external audit to correct any deficiencies. The office's expertise is valuable in helping investigators make overall improvements in practices. The quality assurance staff can help investigators make sure they have complied with safety standards for patients participating in clinical trials and ensure that their studies adhere to regulatory compliance and patient safety guidelines. "We're working with the IRB and other regulatory bodies involved in implementing research to see how we can focus on overall quality improvement and streamline clinical research," said Susan Anderson, R.N., administrative director for quality assurance, who oversees a recently expanded staff of four. "We're really another support system for investigators," she said.

Part of that support system involves identifying training needs to augment the education provided institutionally. For example, after noting that an increasing number of drugs are given by mouth—which complicates documentation of compliance—the unit brought in a speaker to address initiating and conducting compliance discussions with patients.

SUSAN ANDERSON, R.N.
Administrative Director for
Quality Assurance



Anderson's background in research nursing as well as building a protocol review and monitoring program has prepared her for her role in developing YCCI's quality assurance program. She currently serves on a subcommittee of the National CTSA Regulatory Work Group.

BIOMEDICAL INFORMATICS HANDLES DATA AND SPECIMEN MANAGEMENT

Due to the widespread implementation of clinical information systems, the need to acquire and integrate data from multiple sources, and the trend toward transmitting large amounts of information to a growing number of users in diverse settings, biomedical informatics technology has become essential to clinical and translational research. "We have teams of people that can work with study teams to help them access, integrate, analyze and manage the mounds of clinical and scientific data involved in clinical research," said Perry Miller, M.D., PH.D., professor of anesthesiology (medical informatics) and molecular, cellular and developmental biology, and YCCI's director of biomedical informatics.

One area of data management in which biomedical informatics can support researchers is implementation of tissue banking and tracking systems. For example, the unit is adopting the NCI's caTISSUE, a tissue banking system used by the Yale Cancer Center, for uses beyond cancer. "Now that YCCI is gearing up, we need informatics to deal with the huge amounts of specimens we're going to accumulate," said Michael Krauthammer, M.D., PH.D., assistant professor of pathology, who is directing YCCI's efforts to expand the system. Some of its features include consent management to ensure proper use of specimens and role-based capabilities so that different users can use the system to complete different tasks. YCCI is also collaborating with three other CTSA sites to share data and specimens with other institutions.

The biomedical informatics staff is available to meet with investigators regarding overall data management; they should be consulted at an early point in a project regarding the best method of collecting and managing data. Staff members can advise on the best way to use the various tools available to researchers, such as Trial/DB, a flexible Web-accessible database that uses electronic case report forms to support clinical trials.

Future plans include collaborating with other Yale centers to explore and utilize tools to manage clinical research data, such as the large database from the Program on Aging. YCCI is also implementing a new service for investigators who are interested in using desktop tools for studies requiring less sophisticated data management. Also under way is a comprehensive laboratory management system (LIMS) that will be used by the core lab to track specimens while they're being processed and stored.

YCCI is forming a new collaboration with the Keck Bioinformatics Resource to manage the large datasets generated by genomics and proteomics research. Staff will be able to provide training for using bioinformatics software; to consult for bioinformatics analyses; or to collaborate on projects requiring long-term commitment of time and effort. Look for the next issue of the YCCI newsletter to learn more about this initiative.

If you would like assistance with biomedical informatics, please contact Theresa Katz at 785-6335 or theresa.katz@yale.edu. 🌐



PERRY MILLER, M.D., PH.D.
*Professor of Anesthesiology
(medical informatics) and
Molecular, Cellular and
Developmental Biology
Director of Biomedical
Informatics*

Miller is responsible for overseeing bioinformatics staff to help researchers analyze and manage research-related data. He can also advise investigators on the most effective tools and methods for collecting and managing data. In addition, Miller serves as the director of the Yale Center for Medical Informatics (YCM1).



**MICHAEL KRAUTHAMMER,
M.D., PH.D.**
*Assistant Professor of
Pathology*

Krauthammer is a co-director of the Yale SPORE in Skin Cancer, the largest translational cancer grant in YSM's history. He has been engaged in developing and expanding caTISSUE for use at the cancer center for the past two years and is now adapting this system for other diseases.

Anderson will also be assuming responsibilities for YCCI's training and education program for clinical research support, taking over from Gina D'Agostino, who started the program (see *Moving On*, page 10). The research assistants/associates training program is the first of its kind at Yale. It consists of a series of instructional and laboratory sessions to train individuals to perform a variety of clinical tasks necessary for biomedical data collection. Classes are open to those assisting researchers in the three health schools. The program has recently expanded with the addition of staff and clinical training in the Hospital Research Unit. The program also sponsors guest speakers, audio conferences and workshops on relevant research topics.

YCCI welcomes suggestions for training opportunities that clinical researchers may find useful; please let us know if you have ideas for specific topics. If you have questions regarding quality assurance and patient safety guidelines or clinical research training, please contact Susan Anderson at 785-2902 or susan.anderson@yale.edu. 🌐



SHELLI EASON, R.N.
Internal Auditor

Eason has many years experience in research nursing, working for both hospitals and pharmaceutical companies. She currently reviews proposed and current research studies to ensure that they meet regulatory, IRB and Yale guidelines.

NEW DATA SYSTEM FOR BUDGETING AND BILLING COMPLIANCE

FREDERIC DE POURCQ
Special Project
Administrator



De Pourcq's background includes eight years overseeing and implementing many aspects of clinical trials, including monitoring data extraction and reporting operations, and supporting numerous databases. He is currently working on developing and implementing the GE/IDX Practice Management System to handle budgeting and billing for research studies.

The cost of conducting clinical trials is rising, in part due to the need for increased staffing for support activities. Keeping track of billing and costs associated with clinical trials, for example, is challenging for investigators. The Yale Medical Group (YMG) has beta-partnered with GE to address this need by developing the GE/IDX Practice Management System to standardize budgeting and billing compliance for research studies and to help investigators track research costs and revenues. "The intent of the system is to help investigators conduct research more efficiently and do appropriate cost recovery," said Frederic De Pourcq, special project administrator for YCCI.

Every clinical department currently has its own billing and tracking system for clinical research; however, the GE/IDX system will homogenize billing and help clarify disbursement patterns of research dollars. GE intends to roll out the system in several phases, the first of which is billing compliance. YCCI as well as Yale investigators and administrators and clinical department heads have worked with GE over the past year and a half to add features to facilitate budgeting and track the finances of clinical studies.

Phase I of the system will enable department chairs and administrative heads to keep tabs on all research within their departments by tracking such data as the total number of patients in each study and projected revenue from enrollment. The system will also assist principal investigators and clinical research coordinators with billing compliance by tagging services that should be billed to the sponsor rather than the patient's insurance.

The new system will interface with YCCI to centralize setting up and activating studies as well as constructing appropriate budgets for conducting them. This feature will allow investigators to see whether they have appropriate funding to complete the study properly and to provide a solid basis for budget negotiations that can be carried out either by the investigator or with help from YCCI. "It will take out some of the guesswork and speed up the process of budget negotiation," said De Pourcq.

YCCI will be working with YMG on rollout and training in the new system, which will be tested in pilot clinical departments beginning in October 2008. Other departments will follow in early 2009. At the same time, YCCI will assist investigators with Medicare qualifying surveys and registration on clinicaltrials.gov.

The second phase of the project, which is expected to undergo pilot testing in early 2009, will involve the capture of electronic data directly into case report forms as study participants progress through trials. This feature will eliminate the need to set up a new database, case report forms and data extraction every time an investigator begins a study. The system will eventually be able to generate invoices to sponsors. "The goal is to eventually have everything on one platform," said De Pourcq.

"Although we recognize that the system won't be able to address every need clinical researchers have identified, it's an important step in the right direction," said David Leffell, M.D., Deputy Dean for Clinical Affairs and CEO of YMG. "We'll be collaborating with clinical research faculty and administrators over the summer on our requirements for future phases of the project, and I believe that will allow us to make substantial progress."

For more information in the GE/IDX system, contact Frederic De Pourcq at 785-4027 or frederic.depourcq@yale.edu. 🌐

BUDGET SUPPORT UNIT ELIMINATES GUESSWORK

LANE CAMPBELL
Manager of Budget
Development



Campbell, a recent arrival, has nearly ten years of experience working in professional, law and compliance-related environments. In his most recent position as Senior Contract & Grant Officer at Northwestern University he managed and oversaw compliance for a broad range of federal, industry and foundation research-related agreements.

YCCI created Budget Support, a new service made possible by the CTSA, to assist investigators in building budgets to manage the costs associated with clinical studies. "Investigators frequently underestimate the time and expense of doing studies," said William Tamborlane, M.D., professor of pediatrics and deputy director of YCCI. "That's why we felt it was important to have an office dedicated to helping them with budgeting."

Budget negotiations were previously carried out by individual departments in which not everyone had the time or skill set to handle this task. The fledgling budget office, while still finding its way in terms of the best ways to assist researchers, is working on managing the costs of clinical trials by coordinating with investigators' departments and expediting collaboration between investigators and sponsors. YCCI is expanding the unit's staff to help address researchers' concerns; it recently recruited Lane Campbell from Northwestern University to manage the unit together with Lynn Mezzanotte. Campbell, who previously practiced law, has nearly a decade of experience in compliance issues, contract negotiations and research-related agreements. YCCI recognizes that the budget office must provide more effective assistance with grant proposals and funding, and is exploring options to provide

RECRUITMENT AND MARKETING UNIT HELPS INVESTIGATORS REACH PARTICIPANTS

Part of YCCI's vision of providing an infrastructure for clinical researchers is helping them recruit participants for trials. In order to do that, the recruitment and marketing department offers tools to help investigators meet accrual goals in a number of ways. Coordinators Kelly Burton and Tracy Yale are available to:

- Develop flyers, brochures and newsletters tailored to specific disease areas or research needs
- Create ads to attract participants and suggest placement
- Help plan and run events to recruit volunteers
- Supply brochures and pamphlets developed by YCCI to explain what's involved in participating in clinical trials
- Facilitate relationships with other departments that can offer assistance

In addition to working directly with investigators, the recruitment and marketing office is undertaking a number of activities aimed at stimulating participation in clinical trials. The unit is responsible for updating and maintaining the new website, www.yalestudies.org, designed to give the public easy access to and information about clinical trials at Yale. The goal is to develop a database of participants willing to volunteer for clinical studies. A protocol is currently under review with the IRB to include studies not registered on clinicaltrials.gov; and to collect the names of individuals interested in volunteering so that they will be accessible once a study has obtained IRB approval. To attract volunteers, the site features a searchable clinical trials database that interfaces with clinicaltrials.gov, where people can look for trials based on disease area or such other parameters as investigator, gender, or age range. There is also a section listing trials open to healthy volunteers.

Recruitment and marketing recently implemented an ad campaign to coincide with National Volunteer Week. A public service-type television campaign on the development of the insulin pump, featuring Robert Sherwin, M.D., the C.N.H. Long professor of medicine, and William Tamborlane, M.D., professor of pediatrics, was aired on Channel 8. Print ads urging people to volunteer for clinical research at Yale also appeared on Metro-North Railroad trains and on billboards. The coordinators of the unit participate in local events that bring them into contact with the public, such as the North Haven Fair that will take place in September. They will have a booth at the fair with information and promotional items for potential volunteers. Looking toward the future, the recruitment and marketing unit is exploring opportunities to attract more industry-sponsored research to Yale.

If you are seeking participants for a clinical trial, need help with recruitment activities, or would like to be listed on yalestudies.org, please contact Kelly Burton at 785-2519 (kelly.burton@yale.edu) or Tracy Yale at 785-7467 (tracy.yale@yale.edu). ☺



KELLY BURTON
Coordinator of Recruitment & Marketing

Burton's clinical background as a surgical coordinator laid the groundwork for her position at YCCI. She has worked with investigators from 15 clinical departments as well as the Community Alliance for Research and Engagement to develop clinical research participant strategies.



TRACY YALE
Coordinator of Recruitment & Marketing

Yale's experience includes working in marketing at GlaxoSmithKline, where she developed grant requests, maintained a web site, and led a team in designing and writing business plans. She is responsible for maintaining YCCI's general and clinical trial volunteer websites as well as identifying and developing resources to enhance subject recruitment.

this service. Meanwhile, the budget office staff has been working closely with Grants & Contracts to facilitate the processing of clinical trial agreements with an eye toward improving efficiencies in industry-based contracts. "YCCI and Grants & Contracts have been working collaboratively to meet the increasing demand and enhance the services needed to effectively budget and negotiate clinical trials," said Penrhyn Cook, director of Grants & Contracts.

Some of the services provided by the budget office include:

- Assistance in developing detailed budgets of the actual costs associated with completing a research study
- Assistance in budget negotiation and payment terms
- Providing consultation services for junior investigators applying for funding

Researchers who would like to consult with the budget office should contact Theresa Katz at 785-6335 or theresa.katz@yale.edu. ☺



LYNN MEZZANOTTE
Manager of Budget Development

Prior to joining YCCI, Mezzanotte was lead contract analyst for HealthNet, where she analyzed hospital charge masters for contracted outpatient facilities in New York, New Jersey, and Connecticut. Her experience also includes developing, negotiating and administering pharmaceutical, clinical trial and managed care contracts for Bayer Pharmaceuticals.

PROTOCOL DEVELOPMENT: NAVIGATING THE APPROVAL PROCESS

MELODY SACATOS, CIP
*Manager of Protocol
Development and
Regulatory Support*



Sacatos's experience includes serving as head of compliance for the biomedical institutional review board. As a member of the IRB, the pediatric protocol review committee and the Yale University Interdisciplinary Bioethics Center, she possesses a wealth of knowledge about current policies and practices that she is eager to share with investigators.

AMY STEFFEN
*Protocol Development
Coordinator*



Steffen works with investigators to initiate studies and develop protocols. She is also available to guide investigators in adapting industry protocols to Yale standards and developing informed consent documents.

YCCI's Protocol Development and Regulatory Support unit was created to assist investigators with developing protocols and guide them through IRB review in order to facilitate patient enrollment. The expert support provided by the protocol unit includes assistance in:

- Translating a research concept into a complete protocol, including schematic diagrams of study design, procedures, and data collection and management
- Development or editing of IRB applications, including consent forms, human subjects protection and ethical provisions and data and safety monitoring plans
- Preparing research authorization forms and waivers of authorization
- Registration on clinicaltrials.gov as required by federal legislation and in accordance with the policy of the International Committee of Medical Journal Editors related to the publication of research findings
- Compliance with federal, state and university regulatory and policy mandates

The protocol unit was formed to assist even experienced clinical investigators in navigating the maze of ever-changing regulatory requirements for IRB approval. "The IRB staff is an excellent source of information, while the protocol staff can do the hands-on work of preparing submissions," said Melody Sacatos, CIP, manager of protocol development.

Sacatos and her staff understand and specialize in all aspects of regulatory requirements. They are available to aid investigators at any stage of a research project's development, including laying the groundwork for a new proposal; helping with the IRB application for a sponsored protocol; or negotiating informed consent. They have worked with 20 different departments during the past year, providing extensive review and guidance through face-to-face meetings and written analyses. For junior investigators struggling with developing concepts into protocols, the unit's expertise can help them hone ideas and work together with such other ORS units as biostatistics. For more senior investigators who are familiar with the process but may need some support, the unit's staff can take over the completion of IRB applications.

While the unit's overall goal is to provide better support for new or junior investigators, its members are available to assist investigators at all levels. The protocol staff welcomes referrals from any department that needs help getting a research proposal off the ground.

To find out how YCCI can provide protocol assistance for your research proposal, please contact Melody Sacatos at 737-4512 or melody.sacatos@yale.edu; or Theresa Katz at 785-6335 or theresa.katz@yale.edu.

MOVING ON

Three of our most accomplished and dedicated staff members are leaving YCCI.

Gina D'Agostino, YCCI's coordinator for training and education, will assume the position of Finance Clinical Coordinator with YNH. She will work with the medical school and YCCI to ensure clinical trial billing compliance for services performed at YNH. D'Agostino had been a Research Nurse Coordinator with the GCRC before joining YCCI in 2006. She was responsible for establishing and implementing the training and education program for clinical research support. Her incredible dedication and limitless energy have been a tremendous asset to investigators, research support staff and YCCI staff.

After 33 years at the School of Medicine, **Rita Kolb** is retiring. She has been a valuable member of the clinical research staff since 1986, starting with her position as Administrative Coordinator of the Children's Clinical Research Center and continuing with the GCRC when the two merged in 2003. Kolb has worked most recently with YCCI as a Special Projects Coordinator. Her professional approach and attention to detail have been the keys to the success of all the programs with which Rita has been involved.

Andrea Belous is also retiring after 35 years of service in the Core Lab, where she is a research associate. She has been instrumental in the lab's development and important to the success of our leading metabolic investigators. Her patience and good humor when confronted by difficulties in the lab have been an inspiration for her coworkers. Her superb skills and her dedication will be missed by all who have worked with her during her long career.

Thank you, Gina, Rita and Andrea for all your hard work!



GINA D'AGOSTINO,
R.N., M.S.N.



RITA KOLB



ANDREA BELOUS

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ADVERTISING EFFORTS BEGINNING TO PAY OFF

YCCI's first advertising campaign to recruit volunteers for clinical trials was launched at the end of April to coincide with National Volunteer Week. Visits to yalestudies.org doubled by the conclusion of the campaign, which included billboards, public service announcements, a print campaign in newspapers, posters on Metro-North trains and platforms, and a direct mail brochure. YCCI is currently working with the IRB to secure approval for additional ads that are expected to run in the early fall.



Clinical Trials landing page within the YCCI web site

Help Develop the Medicine of Tomorrow

Volunteer for Clinical Research at Yale

1.877.Y.STUDIES

www.y-studies.org

 Yale Center for Clinical Investigation



Billboard from the Route 34 connector (each form of media promoted a different URL—all linked to yalestudies.org)

CLINICAL RESEARCH COMPLIANCE



PHONE SCREENING AND HIPAA: YES, IT DOES APPLY! by Tracy Rightmer

Many investigators use telephone screening as a method of identifying eligible subjects for their studies. When done properly, such screening can be a useful and effective recruitment tool. What's important for investigators to remember, however, is that depending on the type of information collected and recorded during this initial conversation, HIPAA regulations may apply even if the potential subject is the one who initiates contact.

The reason for this precaution is that phone screens or pre-screens typically collect HIPAA-protected health information (PHI). PHI includes such individually identified health information as the person's name, date of birth, and/or address linked with medical conditions or other medical information. HIPAA requires that any collection or use of PHI for research be done through written patient authorization or an IRB-approved waiver, be limited to decedents, or qualify as a review preparatory to research. HIPAA does not have a mechanism for verbal authorization other than through a waiver of authorization. Since it is not usually feasible to obtain a signature in the course of a phone screen, most studies using this recruitment tool must do so under an IRB-approved waiver of HIPAA authorization.

Investigators should design phone screening procedures to avoid or minimize the collection and retention of PHI whenever possible (for example, collecting the potential

subject's age rather than birth date). If it is necessary to collect PHI, then the investigator must indicate this in the HIC protocol application and request a waiver of HIPAA-authorization. The waiver can be made effective until the potential subject presents to the research office and signs a Research Authorization Form (RAF) or until the study ends. The waiver request should also address whether information from failed screens will be identifiably maintained until the study ends.

Investigators interested in using a verbal authorization should consider incorporating the following language into telephone scripts used to screen potential subjects: "We will keep the information we just talked about in our files until you come in to screen for the study. If you qualify and choose to be part of the study, this information will become part of your study file. If you don't come in or if you don't qualify for the study, we will keep this information until [the duration can be stated but as a suggestion: the study is over] and then we will destroy it. We are required by law to keep this information confidential and we will not use it for any purpose other than to see whether you qualify for this study."

Investigators who wish to retain information obtained through phone screening to recruit individuals for future studies based on verbal authorization and information provided in the phone screen will also need to indicate this intent in the waiver request. Additionally, a protocol for maintaining a subject recruitment database may be necessary.

For more information on this topic, please see the website <http://info.med.yale.edu/hic/> or call the HIC at 203-785-4688. For a full list of HIPAA identifiers, please visit the website <http://info.med.yale.edu/hic/hipaa/guide/index.html#phi>.