PROFILE 2010

NIH CLINICAL CENTER
DIRECTOR’S ANNUAL REPORT

There’s No Other Hospital Like It
THE ART OF HEALING

Tiles from the Clinical Center’s Art of Healing project are displayed on the cover of Profile 2010. CC patients and their family members created individual, hand-painted tiles for the project, an art therapy initiative of the Rehabilitation Medicine Department’s Recreation Therapy Section. The project’s goal was to offer a way to depict personal perspectives about participating in clinical research at the Clinical Center. What emerged is a collection of nearly 150 tiles that reflect hope, fear, faith, care, isolation, and personal fulfillment. A group of the tiles are displayed in an exhibit on the Clinical Center’s 7th floor. The display is entitled “Hope Flows from One to Another.” (Above) Dr. John I. Gallin, Clinical Center director, talks with Benjamin Lopez during the exhibit’s unveiling in March 2009. Benjamin’s mother was a contributor to the project and spoke at the ceremony.
RENEWED COMMITMENT

More new patients, along with increases in admissions, inpatient days, and outpatient visits, set a busy pace for the Clinical Center in 2009. One result has been a substantial increase in patient census. That increase, which we hope will continue, is great news for clinical research. As patient activity expands, so do opportunities for stimulating and sustaining promising research.

Devising organizational efficiencies allowed the Clinical Center to successfully meet the demand for more services, even in light of a flat budget. Improved planning with our Institute partners will be a key component in future efforts to manage costs while fostering excellent and productive clinical research.

In 2010 there will be unprecedented opportunities thanks to Clinical Center initiatives. The Biomedical Translational Research Information System provides an invaluable new tool for clinical researchers. Innovative imaging capabilities enhance disease diagnosis and treatment. Our barcoding project strengthens patient safeguards. The new GMP (good manufacturing practices) facility for making candidate drugs provides a unique resource for our clinical investigators. Training programs in clinical research continue to expand globally.

In 2010, we face changes in funding models and in governance, changes that hold promise for even greater efficiencies and progress. Continued success depends on our shared commitment to future possibilities, a commitment that our extraordinary Clinical Center team demonstrates daily.

John I. Gallin, MD
Director, NIH Clinical Center
OUR VISION  As America’s research hospital, we will lead the global effort in training today’s investigators and discovering tomorrow’s cures.

MISSION  To provide a versatile clinical research environment enabling the NIH mission to improve human health by:

• Investigating the pathogenesis and natural history of disease
• Developing state-of-the-art diagnostic, preventive, and therapeutic interventions
• Training the next generation of clinical researchers
• Ensuring that clinical research is safe, efficient, and ethical

There’s No Other Hospital Like It
RECENT CLINICAL CENTER ACHIEVEMENTS

IN 2009 WE:

• Increased patient census.

• Received an outstanding score from The Joint Commission following its annual visit to evaluate our commitment to quality.

• Began the Traumatic Brain Injury project, a collaboration involving the Rehabilitation Medicine Department, Radiology and Imaging Sciences, and the Department of Defense.

• Implemented a barcoding initiative to enhance patient safety and improve collection of research specimens.

• Activated BTRIS, the Biomedical Translational Research Information System.

• Attracted record enrollment in clinical research training programs expanded program reach globally.

• Improved the environment and services for patients and families.

• Opened two new trans-NIH imaging resources, the Center for Interventional Oncology and the Center for Infectious Diseases Imaging.
Patients come to NIH from every corner of America seeking answers to their scientific and medical questions. Finding these answers through leading-edge clinical research is the sole mission of the NIH Clinical Center, guiding all of its activity.

The Clinical Center has a staff of approximately 2,000.

Nursing & patient care/support services 42%
Administrative & operations 17%
Clinical departments & imaging sciences departments 41%

Salaries and benefits 55%
NIH assessments 7%
Drugs 10%
Contracts (labor) 7%
Contracts (non-labor) 10%
Equipment 3%
Supplies 6%
All other 2%

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PATIENT ACTIVITY 2007–2009

Admissions
- 2007: 5,825 (4.4% decrease)
- 2008: 6,105 (4.8% increase)
- 2009: 6,426 (5.3% increase)

New patients
- 2007: 9,435 (2% increase)
- 2008: 9,460 (0.3% increase)
- 2009: 10,315 (9% increase)

Inpatient days
- 2007: 51,189 (0.7% decrease)
- 2008: 51,311 (0.2% increase)
- 2009: 55,664 (8.5% increase)

Average length of stay (days)
- 2007: 8.6 (3.7% increase)
- 2008: 8.5 (1.5% decrease)
- 2009: 8.7 (2.6% increase)

Outpatient visits
- 2007: 90,889 (4.5% decrease)
- 2008: 90,254 (0.7% decrease)
- 2009: 96,372 (6.8% increase)

ONSITE CLINICAL ACTIVITY FOR 2005–2009

Active Protocols
- 2005: 1,357
- 2006: 1,372
- 2007: 1,390
- 2008: 1,449
- 2009: 1,451

New Protocols
- 2005: 180
- 2006: 205
- 2007: 166
- 2008: 155
- 2009: 162

Principal Investigators
- 2005: 487
- 2006: 505
- 2007: 484
- 2008: 478
- 2009: 481
RAISING THE BAR ON PATIENT SAFETY

A new strategy to enhance patient care, barcode technology was introduced to the Clinical Center’s clinical care and research work this year.

This initiative allows a patient’s care team to link the patient to medical orders, ensuring that clinical and research specimens are accurately obtained and that blood and medications are given safely. Use of the patient-specific barcode helps minimize human error in medicine and blood administration and in specimen collection by requiring staff to scan the patient’s barcode at various points while drawing blood or giving medication, for example.

The updated barcodes are printed on inpatient wristbands and on outpatient extended visitor badges. Current outpatients are being asked to visit the new barcode station near the P1 level Hospitality Desk to have a label with their barcode affixed to their extended visitor badge. Outpatients without an extended visitor badge will be issued a barcode card to bring with them to appointments.

In fall 2009 the barcode technology was implemented into outpatient specimen collection in phlebotomy. Phase III—now in progress—introduces barcode technology in the inpatient, outpatient, and day hospital settings. Phase IV will add the barcode process to blood and blood component transfusions.

MORE THAN FUN AND GAMES

The Clinical Center has a Wii in the main playroom, one in the Rehabilitation Medicine Department, and a portable Wii system for bedside treatment, serving both child and adult patients. The CC’s Recreation Therapy Section has used the game system with patients in a variety of protocols to address identified treatment goals, said recreation therapist Robin Greenfield. All patients are invited to use the Wii, with a medical clearance form, to help achieve therapy goals as part of their treatment plans.

“I use the Wii with patients from the National Institute of Neurological Disorders and Stroke to address problems with memory, balance, and range of motion, and to increase the overall activity level of patients,” Greenfield said. “The game controls can be easily adapted based on one’s strengths and abilities, so even those with limited abilities can use it.”
NEW DIAGNOSTIC IMAGING DEVICES AUTOMATICALLY RECORD RADIATION EXPOSURE

Radiology and Imaging Sciences at the Clinical Center has taken a significant step to further safeguard clinical research patients who are exposed to radiation during certain imaging tests. Computed tomography (CT) and positron emission tomography (PET)/CT equipment purchased by the Clinical Center is now be required to routinely record radiation dose exposure in a patient's hospital-based electronic medical record.

“When a hospital or clinic patient receives a medication or a treatment, it is routinely recorded in the patient's medical record,” said Dr. John I. Gallin, CC director. “The Clinical Center’s approach is an important first step in making it possible to more easily document and track information about a patient's exposure to radiation.”

Today, electronic radiology information systems in hospitals generally do not collect or report radiation exposures. “CT and PET/CT scanners do not currently forward data on radiation dose to our radiology information systems,” said Dr. David A. Bluemke, CC director of Radiology and Imaging Sciences.

The risk of exposure to low doses of medical radiation from diagnostic medical-imaging tests isn’t known, but very high radiation doses have the potential to cause cancer. The ability to keep track of an individual’s exposure to radiation through routine imaging tests is needed so that researchers can begin to determine if these exposures pose a health risk.

“The National Council on Radiation Protection and Measurements reported recently that Americans received seven times more radiation exposure from medical tests in 2006 than was the case in the 1980s,” said Dr. Ronald Neumann, CC chief of nuclear medicine and deputy associate director for imaging sciences. “CT and cardiac nuclear medicine studies accounted for much of this increased medical radiation exposure.”

Ultimately, radiation dosage could become a standard element of a universal electronic medical record used to assess radiation risk from life-long medical testing, the radiologists said. “Recording radiation dose is technically possible and an ethical imperative,” Neumann said.

“We also will require that newly purchased equipment allows patients to record their radiation dose exposure in their own personal health record,” Bluemke added. Online resources to help individuals organize their health information as a personal medical record are becoming more prevalent. Currently, patients can easily receive their diagnostic imaging studies records on CD-ROM, Bluemke said. The imaging program will work with vendors who supply CC imaging equipment to develop software tools to extract the examination type, date, and radiation dose exposure from the CD-ROM, for uploading to a personal health record. As both the American College of Radiology and the Radiological Society of North America have recommended, patients should keep a record of their X-ray history.

About 25,000 CT and 1,250 PET/CT scans are performed here each year as part of NIH research protocols. The clinical research hospital currently houses five CT scanners and two PET/CT scanners.

SEND IN THE CLOWNS

Thanks to the NIH Recreation and Welfare Association, Clinical Center patients have for many years attended the Ringling Bros. and Barnum & Bailey Circus. Before the 2009 performance, the Children’s Inn hosted a pizza party, with many of the circus artists in attendance. The clowns brought smiles out from two Inn residents: Samantha and Kegan Druckenmiller.
Dedication
The Steinway grand piano in the Hatfield Building’s atrium was formally dedicated April 17, 2009, during a concert by Dr. Tracy Rouault of the National Institute for Child Health and Human Development (fourth from left) and her instructor Grace McFarlane (second from left). Also present at the event were (from left): donors Michael Batza and Earl Linehan; Dr. W. Marston Linehan of the National Cancer Institute; CC Director Dr. John I. Gallin; and donors Pattie Batza and Darielle Linehan.

Series begins
The inaugural performance of the NIH Clinical Center piano concert series was given Friday, March 13, 2009, in the Clinical Center’s atrium. In his opening remarks, CC Director Dr. John I. Gallin (top right) thanked Dr. W. Marston Linehan, and his wife, Dr. Tracy Rouault, for finding the piano and helping to launch the series. Performing was Grace McFarlane, (right) a Jamaican-born pianist who has played Carnegie Recital Hall and the Kennedy Center. “This center focuses on healing and researching ways to heal people, not just physically, but also healing the soul. I hope today this music can heal the soul,” McFarlane said before the concert.

HOLIDAY TRADITION
It’s a tradition for Marvin Hamlisch (right) to conduct the National Symphony Orchestra’s Happy Holidays POPS concert every December. It’s also a tradition for Hamlisch to visit the Edmond J. Safra Family Lodge to present a special concert—one for the designed to bring cheer to lodge guests. This was Hamlisch’s fifth visit to NIH. Joining him were (from left) flutist Emma Resmini, tenor Jonathan Ansell, and soprano Michele Ragusa.
Members of the Baltimore Symphony Orchestra serenaded Clinical Center staff, patients, and visitors with a July concert in the atrium. Joseph Young, Baltimore Symphony Orchestra/Peabody conducting fellow, directed the wind ensemble and pointed out that though the ensemble’s summer residence is “just one red line stop away” at The Music Center at Strathmore, it was the first time the group had been to the NIH. “The piece that we are playing today originated from a place just like this one, from an open forum,” said Young, gesturing towards the open, light-filled atrium.

**WORLD-CLASS PERFORMANCE**

A world concert tour hits the major spots—New York City, Budapest, Paris, and Bethesda, Md. In the midst of a three-month trip playing his music around the globe, international piano sensation Adam György of Hungary stopped at the Clinical Center in October.

**DUET**

Sister and brother prodigies, Olivia and Jeffrey Ly, 13 and 14 respectfully, played Strauss, Gershwin, and Brahms in August. They were accompanied by their long-time instructor, Dr. Bella E. Oster, professor of piano performance at the European Academy of Music and Art.
The Research Participant Education Committee meets quarterly to review submitted programs. Co-chairs Nonniekaye Shelburne (left) and Wendy Schubert (second from left) lead the team.

The Research Participant Education Committee, new in 2009, is leading a more formal process to deliver quality research participant education. The policy that established the committee gives staff a systematic way to develop and access education tools for research participants. Tapping the expertise of more than 10 Clinical Center departments and disciplines, the committee will bring new education efforts to life and be the main conduit through which CC staff have their education materials approved.

The Research Participant Education Committee’s multidisciplinary representatives will funnel research participant education programs through the committee at quarterly meetings. Once vetted and approved, the programs appear on an intranet Web site, which links to Medline and NIH resources and can be customized for unit-specific information so staff have ready access to what they need. The committee’s multidisciplinary focus helps make research participant education programs meet the educational needs of the CC diverse patient population.

“CC staff, historically, have done a world class job of providing our research participants with accurate and timely information about the protocols in which they are enrolled and the care they receive. The committee enhances these activities by providing the CC with a central forum where educational materials can be vetted and coordinated,” said Laura Lee, special assistant to the deputy director for clinical care.

Members of Cyclists Combating Cancer, a small slice of Lance Armstrong’s LIVESTRONG army, stopped at NIH and toured the Clinical Center in September as part of their nationwide bicycle tour to raise awareness about the need for cancer research funding. “We are [cancer] survivors, but we do not think of this as an appropriate term for us,” said Cindy Hart, director of the group. “We would much rather be referred to as cancer warriors.” Emblazoned on their bright yellow jerseys: unity is strength, knowledge is power, attitude is everything.
The Second Annual Sibling Day, a collaboration among the National Cancer Institute, the Clinical Center, and The Children’s Inn, on July 14 led 11 siblings of NIH patients to different CC departments and through therapeutic exercises to better understand and express what they are going through. The children visited the CC’s Department of Laboratory Medicine and got to take a ride in a mock scanner in the National Institute of Mental Health Behavioral Health Clinic. At left, clinic manager Frances Myers demonstrated to Ane Roesvik (right) and Anna Torres (left), how the simulator works; Samantha Druckenmiller played patient. The mock scanner is used to introduce the MRI procedure to children to test if they could manage the high-cost/high-demand imaging test, Myers said. With the CC’s Rehabilitation Medicine Department’s Recreation Therapy Section, the children shared tips on coping with a sibling’s illness and made worry boxes with art therapist Megan Robb. Sibling Day ended with an awards ceremony at The Children’s Inn. The event’s director, Dr. Lori Wiener, coordinator of NCI’s Pediatric Psychosocial Support Program, presented each participant with a super sibling certificate. “They have shown us strength, courage, insight, and compassion. They are truly our teachers,” Wiener told the families and staff gathered at the ceremony.
One recent addition to the Clinical Center’s permanent art collection—a program to enhance the patient experience—comes from one of the target audience. *River Cells* is an oil painting by former patient Paula Crawford, an associate professor of painting at George Mason University who has exhibited nationally and internationally.

“I’ve been an artist most of my adult life,” Crawford said. “That is what I’ve gotten up in the morning to do every day.” Some of those days were spent in the CC to participate in a protocol under Dr. Yaron Rotman from the Liver Diseases Branch of the National Institute of Diabetes and Digestive and Kidney Diseases for treatment of chronic Hepatitis C. Crawford cited a contaminated gamma globulin shot received before a trip to Mexico as the probable source of her infection.

Despite the taxing treatment regime, Crawford said, “I had the best medical care that I have ever experienced in my life … Everywhere at the Clinical Center I encountered a rare and unparalleled combination of organization, competence, and kindness.”

While around the building, her artist’s eye noticed the aesthetics. “The care to the physical building coupled with that of the doctors and staff become critical to a kind of total experience the patient receives.”

Of *River Cells* she said, “I was trying to make a painting that both felt like watching river stones beneath rushing water (outside landscape), but also somewhat like looking through a microscope (interior landscape),” she said. The piece hangs in the Hatfield Building’s seventh floor breezeway. “I hope that the art work inspires patients and co-workers the way Paula’s courage and determination inspired me,” Rotman said.

Twenty-two other art pieces were donated to the CC collection in 2009 and eight works were purchased. The new pieces comprise 24 paintings by artists Pat Goslee, Angela Hennessy, Chris Stephens, Jean Meisal, and John Hughes; three mixed media works by Janet Graham; two watercolors by Sean Callahan; and a mosaic by Annette Abrams.

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**Area Improvements**

Phlebotomy moved into a newly renovated space in mid-2009. More specimen-draw booths and a more open and cheerful patient waiting area allow the busy department to accommodate visits more efficiently and comfortably. Radiology and Imaging Sciences sports a new, more open look thanks to renovations in the patient reception area aimed at making the space more welcoming and comfortable.
THE CLINICAL CENTER’S SCHOOL

Teachers in the NIH Children’s School, located across from the main playroom on the Hatfield Building’s first floor, tutor patients in grades kindergarten through 12 and patients studying for the General Educational Development Test. Teachers include Anne Wasson, going over a math assignment with Erik Santa, 14.

RECREATION THERAPY PILOTS NEW PATIENT ACTIVITIES CALENDAR FORMAT

The Recreation Therapy Section in the Clinical Center’s Rehabilitation Medicine Department is developing new ways to share information about events here. One uses calendars that are easier to read and update. A permanent poster depicts descriptions of programs, a map, and a weekly set schedule of events, and the same information is printed on a flyer, currently available in both English and Spanish, for visitors to take with them and reference. The current week’s events—a trip to the movies, a visit from the therapy dogs, and a chili festival, for example—are listed on a separate flyer.

The schedule of events is also audiocast each month on CC Radio, accessible through the CC Web site, and posted on the patient portal. “A lot of collaborative energy has gone into this patient-centered initiative,” said Recreation Therapy Section Chief Donna Gregory. “We have received positive feedback from patients and families in the first few weeks of piloting the project. The most frequent response from patients so far is, ‘it is so much easier to read.’ Several families have commented on the value of having the new activity schedule format in Spanish and on the patient portal Web site.”
Who you gonna call? At the Clinical Center, we don’t need ghostbusters, but we sure do need Messenger and Patient Escort Services.

The more than 40 escort employees field upwards of 10,000 calls per month for patient transport (about 23 percent of the requests) and movement of research specimens, blood products, and medications. The department, recently brought under Hospitality Services, has integrated customer service standards and training to elevate their interactions with patients and other staff. The escorts have seen their morale elevate with the change.

“I love patient escort; I love my job,” said Shelia Genrette, training coordinator.

Signs in the escort office—behind the South Elevators on the P1 level—remind staff to introduce themselves and confirm patient identity and their location when taking a patient to or from an appointment, and outline the standards for front-line patient-care service.

Denise Ford, chief of Hospitality Services, emphasizes professional attitude and appearance.

“Patient escorts feel good about what they do, and that shows in how they deliver service,” she said.

With the increased patient census, Messenger and Patient Escort Services has seen a surge in orders. As Genrette and intake coordinators Chris Strickland and Nicholas Clarke explain their process, the phone rings off the hook. Each call and computer order is entered into their system that records what they do and how much time it takes them to do it. “We measure the workload and how we perform, so we can adjust and improve,” Strickland said.

High-volume requests, like stat orders and those from the Pharmacy Department, get dedicated escorts. The pharmacy’s tube system is used as much as it can be, but many research medications cannot be agitated and must be moved by hand. Messengers check the outpatient clinics, phlebotomy, and inpatient units on rounds every hour. Putting orders in the system correctly and placing specimens in the proper pick-up locations helps the escorts expedite the process of translational research.
Advancing Clinical Research

PROTOCOLS BY RESEARCH TYPE
(ONSITE INTRAMURAL PROTOCOLS, FISCAL YEAR 2009)

Total active protocols: 1,451

Clinical trials: 635 (44%)
Training: 25 (2%)
Sample data analysis: 84 (5%)
Screening: 69 (5%)
Natural history (disease pathogenesis): 623 (43%)

(15 protocols are pharmaco-dynamics/kinetics studies.)

Clinical studies are medical research studies (or protocols) in which human volunteers participate. Clinical trials are studies developing or investigating new treatments and medications for diseases and conditions. Natural history studies investigate normal human biology and the development of a particular disease. Screening studies determine if individuals may be suitable candidates for inclusion in a particular study. Training studies provide an opportunity for staff physicians and other health-care professionals to follow particular types of patients.

Clinical trials phases

Phase 0: An initial first-in-human study (20–30 participants) under an exploratory IND (investigational new drug) for early identification of biologic and molecular markers in new clinical agents. There is very little agent exposure with no therapeutic or diagnostic intent.

Phase I: Researchers test a new drug or treatment for the first time in a small group of people (20–80) to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II: The study drug or treatment is given to a larger group of people (100–300) to see if it is effective and to further evaluate its safety.

Phase III: The study drug or treatment is given to large groups of people (3,000 or more) to confirm its effectiveness, monitor side effects, compare it with commonly used treatments, and collect information that will ensure safe usage.

Phase IV: These studies are done after the drug or treatment has been marketed. Researchers continue to collect information about the effect of the drug or treatment in various populations and to determine any side effects from long-term use.
Precision is the goal of a new collaboration involving the Clinical Center, the National Cancer Institute, and the National Heart, Lung, and Blood Institute. The Center for Interventional Oncology will pull on the strengths of each to investigate how imaging technology can diagnose and treat localized cancers in ways that are precisely targeted and minimally or non-invasive.

“The Center for Interventional Oncology will help bridge the gap between emerging technology and the everyday practice of medicine,” said chief of the new center, CC Radiology and Imaging Science’s Dr. Bradford Wood. “Advanced imaging methods have ushered in an era of early detection of cancers that are frequently localized to a single organ.” The new center will use the CC’s advanced imaging technologies, including cutting-edge magnetic resonance imaging (MRI), positron emission tomography (PET), and computed tomography (CT)—as well as the capability to use all three technologies simultaneously—to navigate a therapeutic device through the body.

The localized therapies use a thin needle or sound waves to ablate (or cook) tumors and to enhance drug delivery. Energy sources include high-intensity focused ultrasound, freezing, microwaves, and radiofrequency, Wood said. Researchers will also expand investigations into electroporation—the use of electricity to make cells more ‘open’ to targeted drug delivery.

The new program provides an interdisciplinary environment combining training, patient treatment, and translational research and development in interventional oncology. Wood said. Goals include image-guided “dose-painting”—tailoring drug delivery based on disease location; use of ‘medical GPS’ for tumor biopsy and treatment; and first-in-human investigations involving new drugs, devices, molecular probes, nanoparticles, and targeted therapies.

Dr. David A. Bluemke, director of CC Radiology and Imaging Sciences, will head the Center for Interventional Oncology steering committee that comprises two NCI appointees and one each from NHLBI and the CC.
Looking at common illnesses like influenza and rare conditions such as hemorrhagic fevers, Clinical Center imaging specialists have begun a partnership to learn more about the presentation and characteristics of various infectious diseases.

The CC Radiology and Imaging Sciences group has teamed with the National Institute of Allergy and Infectious Diseases to establish the new Center for Infectious Disease Imaging, which will use state-of-the-art imaging methods to understand, diagnose, and aid the medical management of public health threats such as influenza, severe acute respiratory syndrome (SARS), poxviruses, and other emerging pathogens.

“The radiology and NIAID partnership will form an image-based strategy to understand infectious diseases and translate that understanding into applications for diagnosis and staging and for monitoring response to therapy,” said Dr. Daniel Mollura, a staff radiologist. Research will take place at the newly constructed NIAID Integrated Research Facility at Fort Detrick in Frederick, Md. The facility is a state-of-the-art research laboratory designed to conduct research in biological safety laboratory level 4 conditions—the highest possible rating.

The center will have the tools available to allow discoveries in infectious disease imaging to be translated to the care and treatment of patients,” noted Dr. David A. Bluemke, director of Radiology and Imaging Sciences and acting director of the Center for Infectious Disease Imaging.

Advanced imaging will help clinician-scientists learn more about how infections present, allowing for quicker disease detection. Imaging pathogen movement throughout the body at systemic and cellular levels will also help scientists determine optimal therapies and tracking strategies, said Mollura.

“This effort will be critical for understanding the pathophysiology of infectious diseases that are potential threats to public health.”

**Recovery Act funds support CC projects**

Funding from the American Recovery and Reinvestment Act (ARRA) is enabling major equipment purchases in support of initiatives that will help stimulate advances in science and technology. The projects are:

- Expansion and upgrades to Electronic Picture Archiving Communications Systems that support filmless radiology operations, including integration with the electronic Clinical Research Information System.
- New PET/CT scanner to strengthen and expand support for clinical research and patient care.
- Replacement and installation of a CT scanner to strengthen and expand support for clinical research and patient care.
- A pharmacy information/dispensing system, including a dispensing robot, to automate and track prescriptions for outpatients and discharged patients in clinical research studies.
- Support for the implementation of clinical research data repository to allow NIH researchers access to and use of National Cancer Institute intramural clinical research data to accelerate research.
What are the top five ways to use BTRIS?

2. Search across one protocol or multiple protocols for demographic data.
3. Tell an investigator all the patients on his/her protocol receiving a particular drug.
4. Find all an investigator’s patients with a lab value over a certain amount.
5. Create subsets of protocol subjects for retrieving detailed data sets.

BTRIS, the Biomedical Translational Research System, was implemented in two phases in 2009. The July launch of the NIH-wide intramural research data repository allowed principal investigators to view identified data from their active protocols. In December, intramural researchers were able to access de-identified data from clinical and research systems across the intramural program.

“The idea is to take all the NIH-generated data and put them into a single database, provide standards for accessing those data, and provide mechanisms for getting out the data and various kinds of reports,” said Dr. Jim Cimino, BTRIS project director and chief of the CC Laboratory for Informatics Development. “BTRIS sits in the middle of the research process helping with things like hypothesis generation, identifying patients for recruitment, data gathering, and analysis.”

He noted that use of the data for research requires oversight by the Office of Human Subjects Research and that BTRIS provides an automated process to meet the standards.

When introduced, BTRIS contained data from the Clinical Center’s Clinical Research Information System and its predecessor the Medical Information System; the National Institute of Allergy and Infectious Diseases; and the National Institute on Alcohol Abuse and Alcoholism. Plans for 2010 include further incorporation of historical data, the addition of clinical images, and addition of subject data from other NIH systems, beginning with the National Cancer Institute.

“It is so great that we can expand horizons with new data sets and at the same time protect the privacy of our human subjects,” said Dr. Michael Gottesman, NIH deputy director of intramural research, at the BTRIS go-live event on July 30. At a BTRIS Town Hall meeting on Sept. 15, he said of the project, “It’s a new informatics tool designed to help clinical researchers achieve efficiency in doing clinical research ….it’s probably a tool that will transform the way we do clinical research both at NIH and eventually, as this kind of tool is established throughout the country, clinical research will change dramatically.”

By the end of 2009, BTRIS contained 120 million rows of data from 7,160 active and terminated protocols.
The Uniformed Services University of the Health Sciences and the Clinical Center are collaborating on an initiative to improve treatment of traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). This program will pool the resources of local research and clinical entities to develop more accurate diagnostic tools and novel approaches to treatment.

The research subject population will include civilians, as well as members of the military seen at Walter Reed Army Medical Center and the National Naval Medical Center. “When Congress approved funds for this project, it was stipulated that the partnership include the neuroimaging capabilities at the NIH Clinical Center,” noted Dr. John I. Gallin, Clinical Center director.

The six proposed areas of research are improved diagnostics, neuroregeneration, neuroplasticity, rehabilitation and evaluation, biomarkers, and neuroprotection and modeling. The imaging technology and rehabilitation therapy of the CC lend themselves to the project’s dual mission—characterization and treatment of brain injury.

Modern warfare has resulted in different brain injuries than seen in previous combat, and improved body armor and medical attention in the field have increased survivorship. The Center for Disease Control and Prevention reports that 1.4 million people sustain a TBI each year. Falls and motor vehicle accidents account for almost half of those injuries. Not much is known about the pathology and recovery options for TBI and PTSD.

The Clinical Center’s state-of-the-art capabilities in magnetic resonance imaging and positron emission tomography will be major assets to investigations. Advanced imaging technology will be used to explore neuroplasticity, a promising rehabilitation technique in which a part of the brain takes over function from another damaged part. The outcomes of the research could lead to clinical trials to address brain plasticity in general, benefiting a range of patients including stroke victims.

The CC Rehabilitation Medicine Department will contribute its phenotyping capabilities to all of the center’s programs. Phenotyping is the observation of a patient’s clinical characteristics, both from gene expression and the influence of environmental factors. Dr. Leighton Chan, chief of the Rehabilitation Medicine Department, is careful to describe the work as foundational. “There is not a lot known about brain injury, especially blast injury,” Chan said. “An important part of the phenotyping core may be following patients over time and seeing how they change.”
CC PHARMACY’S PHARMACEUTICAL DEVELOPMENT SECTION UPGRADES

The unique and groundbreaking work of the Clinical Center calls for clinical trial drugs not always available from a study sponsor, so the CC makes its own. The Pharmacy Department’s Pharmaceutical Development Section (PDS) has operated in several hospital locations since it was established in 1956. Evolving “good manufacturing practices,” guidance provided by the FDA, presented an excellent opportunity to upgrade PDS’s environment and equipment in a new space created especially for the function.

The section formulates and analyzes vaccines and medications not available from manufacturers. These products account for one-third of the 800 separate drugs (including placebos and varying strengths) that the CC uses in its research protocols, said George Grimes, Jr., section chief. Section staff register and package all drugs obtained from an outside pharmaceutical company for use in CC clinical trials. “We handle all investigational drugs,” Grimes said. “In the double-blind studies in particular, all the drugs look alike, so we have to be really good about record-keeping and procedures.”

There’s a different room for nearly every step of the manufacturing process, which is a “good manufacturing practice” recommendation because separate spaces allow for better airflow and overall quality control, Grimes said.

The section produces three to four sterile product batches and the same amount of tablets and capsule batches a week, Grimes said, though the batch sizes vary. A vaccine will likely be made 1,000 vials at a time, while the number of capsules produced can run from 50 to 100,000. New equipment in the area is making that process run smoother—a new tablet-making machine has more safety measures than the old one from the 1950s, and the new equipment to make capsules runs at a much faster pace, Grimes said.

Before and after production, the pharmaceuticals and their components go to the section’s analytical lab to make sure they are as they should be—right product, pure grade. “We assay the sample to make sure a five milligram tablet is really five milligrams,” said Grimes. We also do the proper tests to ensure that the tablets and capsules dissolve in the body as they should. Even after the drug has been dispensed to patients, monitoring continues on quarantined samples to assure stability over time.

3 Tesla MRI added

The latest whole-body magnetic resonance imaging technology (MRI) came to the Clinical Center in 2009 by way of the National Institute of Diabetes and Digestive and Kidney Diseases as part of their research involving obese patients. The larger and stronger 3 Tesla MRI allows stronger image signal and faster image acquisitions, said clinician Dr.Ahmed Gharib. The new machine is used 50 percent of the time for NIDDK’s obesity protocol patients and remains open to general use in other NIH studies the other half. The new MRI table is equipped with a coil that receives radiofrequency (necessary for the acquiring the MRI images). In older machines, a coil had to be placed both under and over the patient’s body part of interest. The table now acting as a coil frees space and allows for imaging of more than one part at a time, cutting down on time spent in the MRI and patient adjustment, a benefit for patients who are claustrophobic or have disabilities, Gharib said.
RESPONDING TO THE CLINICAL RESEARCH NURSING NEEDS WITHIN THE ONCOLOGY PROGRAM

There was a significant increase in the number of oncology research participants being admitted to the CC in 2009 because of increased research activity by the National Cancer Institute. In response, Nursing and Patient Care Services worked closely with NCI nursing colleagues to strategize the best way to support this increased activity. Joint planning meetings were convened to review patient flow and clarify services in each patient-care area to best meet research participant and investigator needs. The outcomes of this collaboration included:

- Opening a 12-bed oncology patient care unit on 3SE-N by converting day hospital stations to inpatient beds and increasing staffing.
- Revising the model of care in the outpatient clinics to better support patients who are more acutely ill and requiring urgent care assessment, pre-admission stabilization and support during protocol assessments, and follow-up visits.
- Expanding services in ambulatory care, including increased clinic hours and adding outpatient procedures previously done during day hospital visits.
- Meeting the increased need for nursing staff with a group of oncology-experienced contractors and per diem staff while conducting a focused recruitment of 71 experienced oncology nurses, eight patient-care technicians, and a clinical nurse specialist for surgical oncology/immunotherapy.
- Improving patient flow in the clinic by re-aligning outpatient clinics 12 and 13. The space was reconfigured to preserve patient privacy and confidentiality and better support chronically and often severely ill patients with extensive teaching and counseling needs as well as the needs for discussion, consultation, and image review by the research team.
- Enhancing nursing educational programs to include the Oncology Education Series, the Association of Pediatric Hematology Oncology Chemo-Biotherapy Course, the Oncology Nursing Society Chemo-Biotherapy Course, the End-of-Life Nursing Education Consortium Course, the Advanced Oncology Education Series, and the Peripheral Blood Stem Cell Transplant Course. All these offerings are presented multiple times throughout the year. In collaboration with NCI, the longstanding Cancer Nursing Fellowship Program was extended to two years. The program’s goal is to enable graduating fellows to sit for the Oncology Nursing Society certification exam. To date, all program graduates have achieved the certification. The skill sets for the patient care technicians were also expanded to support the oncology services.
- Working with NCI nursing leadership to develop competencies for the clinical research nurse that will have application nationally, both within the specialty and across all research settings.
This awards program was established in 1999 to integrate the work of basic and clinical scientists on the NIH campus. The program expanded in 2006 to encourage partnerships between intramural and extramural programs. To date, about 500 principal and associate investigators have collaborated on 152 funded projects with about $33 million distributed in total bench-to-bedside funding.

### General Category

**Teams**
- NIDCD, NINDS
  - Johns Hopkins University

**Projects**
- Connectivity Analysis for Investigation of Auditory Impairment in Epilepsy

**Principal Investigators**
- B. Horwitz, NIDCD; W. Theodore, NINDS; D. Boatman, JHU

**Teams**
- NIAID
  - Tufts, Yale

**Projects**
- Searching for Persistence of Infection in Lyme Disease

**Principal Investigators**
- A. Marques, NIAID; L. Hu and S. Telford III, Tufts; P. Krause, Yale

### AIDS Category

**Teams**
- NIDDK, NCI, NEI
  - Prince George's Hospital Center
  - Washington Hospital Center

**Projects**
- MYH9 Genetic Variation in Kidney Disease Among African-Americans

**Principal Investigators**
- J. Kopp, A. Gharib, NIDDK; C. Winkler, NCI; E. Chew, NEI; D. Berhane, Prince George's Hospital Center; J. Light, Washington Hospital Center

**Teams**
- NIDCR, CC

**Projects**
- Development of a Diagnostic Test for Latent Tuberculosis Infection

**Principal Investigators**
- P. Burbelo, NIDCR; J. Kovacs, CC Critical Care Medicine Department

**Teams**
- NIAID, NIDDK, CC
  - Johns Hopkins University

**Projects**
- Cardiometabolic Assessment in HIV

**Principal Investigators**
- C. Hadigan, NIAID; A. Gharib, C. Kong, M. Skarulis, NIDDK; D. Bluemke, CC Radiology and Imaging Sciences; S. Lai, JHU

### Rare Diseases Category

**Teams**
- NIAID, NCI
  - University of Texas—MD Anderson

**Projects**
- Frequency and TCR Diversity of FOXP3+ Regulatory T Cells in Chronic GVHD

**Principal Investigators**
- D. Tran, E. Shevach, NIAID; S. Pavletic, NCI; L. Cooper, University of Texas—MD Anderson

**Teams**
- NINDS
  - University of Pittsburgh
  - Children's National Medical Center

**Projects**
- GABAB Receptor Antagonist SGS-742 Treatment in SSADH Deficiency

**Principal Investigators**
- W. Theodore, NINDS; K. Gibson, Univ of Pittsburgh; P. Pearl, Children's National Medical Center

**Teams**
- NHLBI, NIAID, NIDDK, NHGRI
  - Johns Hopkins University

**Projects**
- Aneurysm Formation in Patients with Mutations in STAT3

**Principal Investigators**
- M. Boehm, L. Beltran, A. Walts, S. Han, NHLBI; A. Freeman, S. Holland, NIAID; A. Gharib, NIDDK; J. Davis, NHGRI; H. Dietz, JHU

**Teams**
- NIAID, NLM
  - Cincinnati Children's Hospital
  - University of Toronto

**Projects**
- Genomic and Stem Cell Approaches to Hemophagocytic Lymphohistiocytosis

**Principal Investigators**
- H. Su, M. Lenardo, NIAID; A. Schaffer, NLM; A. Filipovich, Cincinnati Children's Hospital; J. Zuniga-Pflucker, Univ of Toronto
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<td>NCI</td>
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<td>Fred Hutchinson Cancer Center</td>
<td>Leukotriene Inhibition for the Amelioration of Bronchiolitis Obliterans</td>
<td>R. Gress, NCI; S. Lee, Fred Hutchinson Cancer Center; A. Chen, JHU</td>
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<td>Johns Hopkins University</td>
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<th><strong>NCI (Center for Cancer Research)</strong></th>
<th><strong>NCI (Division of Cancer Epidemiology and Genetics)</strong></th>
<th><strong>University of Toronto</strong></th>
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<td></td>
<td>Repositioning Metformin as an Anti-Cancer Agent in Li-Fraumeni Syndrome</td>
<td>P. Dennis, C. Harris, NCI (CCR); J. Fraumeni, S. Savage, NCI (DCEG); D. Malkin, University of Toronto</td>
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<td>University of South Carolina</td>
<td>Targeting mTOR as a Novel Mechanism-Based Therapy for Head and Neck Cancer</td>
<td>J. S. Gutkind, A. Molinolo, NIDCR; C. Van Waes, NIDCD; P. Dennis, S. Steiner, NCI; T. Veenstra, SAIC-Frederick; T. Day, K. Kirkwood, S. Rosenzweig, Univ of South Carolina</td>
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| **NHLBI, NCI, CC**       | **University of Pittsburgh** | **Hemolysis-Associated Hemostatic Activation in Sickle Cell Disease** | G. Kato, NHLBI; D. Roberts, NCI; J. Lozier, CC Department of Laboratory Medicine; E. Novelli, J. Isenberg, M. Ragni, Univ of Pittsburgh |

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<th>MINORITY HEALTH/RARE DISEASES CATEGORY</th>
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<td>Boston University</td>
<td>Gene Expression Profiling to Predict Sickle Cell Anemia Sub-Phenotypes</td>
<td>J. Taylor, G. Kato, C. Minniti, N. Raghavachari, X. Xu, NHLBI; E. Kings, Boston Univ; V. Gordeuk, P. O’Neal, Howard Univ</td>
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<td>Howard University</td>
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<th><strong>NIMH, NIDDK</strong></th>
<th><strong>University of Michigan</strong></th>
<th>Genetic Markers of CNS Adverse Events During Interferon Treatment</th>
<th>G. Laje, F. McMahon, NIMH; M. Ghany, NIDDK; R. Fontana, Univ of Michigan</th>
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<td><strong>NCI, FDA</strong></td>
<td><strong>University of Maryland</strong></td>
<td>Clopidogrel Pharmacogenetics: Practical Application</td>
<td>W. Figg, NCI; M. Pacanowski, R. Madabushi, FDA; A. Shuldiner, Univ of MD</td>
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<td><strong>NICHD, NIDDK, CC</strong></td>
<td>FTO and Eating in Absence of Hunger</td>
<td>J. Yanovski, J. Han, NICHD; S. Yanovski, NIDDK; N. Sebring, M. Kozlowski, CC Nutrition Department; M. Tanofsky-Kraff, L. Shomaker, USUHS</td>
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Kastner Delivers Astute Clinician Lecture

The Astute Clinician Lecture series honors a US scientist who has observed an unusual occurrence, and by investigating it, has opened an important avenue of research. “You will never understand a system as well as when you have an opportunity to observe when something goes wrong,” said NIH Director Francis Collins in his introduction of this year’s honored scientist, Dr. Daniel Kastner, chief of the National Institute of Arthritis and Musculoskeletal and Skin Diseases Genetics and Genomics Branch, as well as the institute’s clinical director and director of translational research in the intramural research program. Kastner also serves as deputy director of NIH Intramural Clinical Research.

His November 18 lecture was titled “Fever, Genes, and Histories: Adventures in the Genomics of Inflammation.” Said Kastner, “It has been, over the course of the last few years, a real adventure for me.” He led an international consortium that identified the gene causing familial Mediterranean fever in 1997, and his group subsequently discovered that mutations in the p55 tumor necrosis factor receptor cause a dominantly inherited periodic fever syndrome that they named TRAPS (the TNF receptor-associated periodic syndrome). Based on these findings, Kastner proposed the term “autoinflammatory” to describe the family of diseases characterized by seemingly unprovoked episodes of inflammation, without high-tier autoantibodies or antigen-specific T-cells, which are now known to be disorders of the immune system. With NIAMS collaborators, his team has gone on to identify the genetic basis of other Mendelian autoinflammatory diseases, and they follow a large cohort of these patients at the Clinical Center.

The Astute Clinician Lecture Series, part of the NIH Director’s Wednesday afternoon lecture series, is made possible by a donation from the late Dr. Robert W. Miller and his wife, Haruko.

CC staff help increase awareness of clinical research

The Clinical Center Office of Communications, Patient Recruitment, and Public Liaison exhibited at the Aware for All—Baltimore Clinical Research Education Day on May 9, at Johns Hopkins University School of Medicine. The event, which was free and open to the public, provided an opportunity for more than 150 members of the community to attend workshops, presentations, free health screenings, and exhibits. Staffers Mandy Jawara (left) and Omar Echeboy unveiled a new patient recruitment exhibit and were among dozens of exhibitors providing information and resources to the public. Theme for the new materials: The best reasons to volunteer for clinical research are all around you.
The Eighth Annual John Doppman Memorial Lecture for Imaging Sciences hosted a leading researcher who knew the former chairman of the Clinical Center’s Diagnostic Radiology Department well. “He was such a good and loyal friend to many of us,” Dr. Hedvig Hricak said of Doppman, who retired from the CC in 2000 and died that August. Hricak is chairman of the Department of Radiology at Memorial Sloan-Kettering Cancer Center and professor of radiology at the Weill Medical College of Cornell University. She spoke on “Oncologic Imaging: Endless Horizons,” February 25 in Lipsett Amphitheater as part of the CC Grand Rounds series.

New developments give radiologists a clearer, more precise picture, especially useful in cancer research, Hricak pointed out. “As we advance in imaging technology, it is increasingly frightening how little we knew yesterday.” She said that imaging key biological markers and targeted imaging are the next waves of research. “It has never been a better time to be in molecular, oncologic imaging—seeing our work make people better is so rewarding.”

Dr. Elliot K. Fishman presented the Ninth Annual John Doppman Memorial Lecture on December 16. Fishman, professor of radiology and oncology at Johns Hopkins University School of Medicine, and director of the Division of Diagnostic Imaging and the Division of Abdominal Imaging and Computed Body Tomography at The Johns Hopkins Hospital, referenced his shared goal of Doppman’s—to improve patient care and patient outcomes—in his lecture “CTA and 3-D Visualization: Its Evolving Role in Oncologic Imaging.” New technologies that offer arterial and venous views of potential malignancies allow for better tracking of transition, texture, and neovascularity of abnormalities. Such advances in imaging, coupled with advances in surgery, Fishman said, are helping patients with borderline resectable masses choose a treatment method that favors the best possible outcome. “I think in radiology, as Dr. Doppman said 30 years ago, opportunities have never been greater. Challenges have never been more difficult, but the future has never been brighter,” said Fishman.

CTSA PHARMACEUTICAL ASSETS PORTAL: MATCHING ACADEMIA AND INDUSTRY FOR DRUG REPOSITIONING

Drug repositioning—exploring new uses for a drug originally created for another purpose—has been garnering attention in the last few years as the pharmacological effect of some compounds has reached beyond developers’ first focus. The new Clinical and Translational Science Awards (CTSA) Pharmaceutical Assets Portal connects pharmaceutical companies, the national CTSA consortium, and the NIH intramural research community to improve information and expertise exchange regarding investigational drugs shelved for various reasons at the clinical stage of development, so that repositioning can be explored.

Project stakeholders met at the Clinical Center in November to explore issues. Dr. Juan Lertora, director of the Clinical Center’s Clinical Pharmacology Program, presented on how the CC partners with others on drug repositioning and on translational research. “Even for drugs that are currently in use for their original indications, discovery of new biological/molecular targets in many diseases is the underlying reason to explore the actions of old drugs for potential new indications,” said Lertora. Aspirin, for example, is not only for fever and pain anymore, but proven as a successful agent to prevent and treat heart disease.
CC epidemiologist named 2009 Distinguished Teacher

Dr. Tara Palmore (center), deputy hospital epidemiologist at the Clinical Center and associate director of the National Institute of Allergy and Infectious Diseases clinical fellowship in infectious diseases, received the 2009 Distinguished Clinical Teacher Award.

Dr. Grace Chen, co-chair of the CC’s Clinical Fellows Committee, made the presentation. The Distinguished Clinical Teacher Award has been presented each year since 1985 to an NIH faculty member who exemplifies the ideal qualities of a mentor, teacher, clinician, and researcher. The recipient delivers the annual John Laws Decker Memorial Lecture the following summer. “We thank all of our staff for helping to train the next generation of distinguished clinicians,” said Dr. John I. Gallin, who opened the proceedings. Also nominated this year were: Dr. Jose Apud, Dr. Juan Gea Banacloche, Dr. Theo Heller, Dr. John Tisdale, and Dr. Maria Turner.

NIH AND WIKIPEDIA WORKING TOGETHER

Dr. Ronald Summers, chief of the Clinical Center’s Radiology and Imaging Sciences’ Image Processing Group, was among NIH scientists helping kick off a collaboration between NIH and the Wikimedia Foundation, the nonprofit organization that operates the Wikipedia® online encyclopedia. The two groups are joining forces to make health and science information more accessible and reliable, and the collaboration is the first of its kind for both organizations.

“With the broad range of experts from the National Institutes of Health, we see a great opportunity for increasing the quality of all health-related information on Wikipedia,” said Sue Gardner, executive director of the Wikimedia Foundation. “NIH works to ensure that the information it provides on science and health is of the highest quality and reaches the widest audience,” said John Burklow, NIH associate director for communications and public liaison. “We look forward to this opportunity to collaborate with the Wikimedia Foundation and participate in a resource that is used by millions of people around the world.”

To satisfy the public’s growing need for reliable health information, NIH and the Wikimedia Foundation want to increase the availability of accurate medical and health information available to the public. At the same time, they hope to establish strategies to interface the distinct cultures of Wikipedia and the research community. After the Wikipedia Academy, NIH subject matter experts—including Summers—are better able to contribute to Wikipedia and also help develop best practices for future sessions. “I see it as part of my mission as a scientist to communicate,” said Summers.
Staff scientist Jiaqiang Ren samples a milliliter of cell culture media from the cell expansion system once or twice a day to measure glucose and lactate levels, parameters used to estimate cell expansion and, in turn, regulate how fast to feed the cells. The cell expansion system—the cylinder that Ren pulls aspirate from above—replicates the desired amount of bone marrow stromal cells in an average of five to seven days.

New DTM machine reduces contamination, saves labor in cell expansion
The ease and security of automation is coming to bone marrow stromal cell expansion in a new machine in the Clinical Center’s Department of Transfusion Medicine. Reducing the current manual method guarantees less contamination and frees staff time for other procedures.

In the collaborative effort, the department is using a prototype of CardianBCT’s Quantum Cell Expansion System to reproduce human bone marrow stromal cells in an automated, sealed environment. The collaboration is part of the Trans-NIH Bone Marrow Stromal Cell Transplantation Center, created in 2008 to facilitate the use of clinical-grade bone marrow stromal cells prepared using procedures known to maintain their biological activities and to assist investigators in the preparation of protocols that utilize such cells. The trans-NIH group is co-coordinated by Dr. Pamela Robey of the National Institute of Dental and Craniofacial Research and Dr. Harvey G. Klein, chief of transfusion medicine at the Clinical Center.

Bone marrow stromal cells (also called mesenchymal stem cells) form the supportive structure in which the cells that produce human blood reside and play a part in the repair of tissue and bone formation. Patients with auto-immune disorders, acute host-versus-graft disease, and need for bone formation after surgery benefit from the transfusion or direct transplantation of these cells.

In the traditional expansion method, cell processing laboratory staff take a piece of bone or bone marrow aspirate, a sample of the liquid bone marrow portion, and replicate the stromal cells by growing them in flasks and transferring to larger flasks as they grow in number. Staff must monitor the cells’ development and move them by hand. “This process doesn’t lend itself well to a clinical cell processing environment because the system is open. Every time cells are transferred from one flask to another they could become contaminated with bacteria or fungus,” said Dr. David Stroncek, chief of the DTM’s Cell Processing Section.

As an integrated, closed system, the cell expansion system improves efficiency of the stem cell growth process—allowing for larger scale manufacturing of cells with less risk of contamination and better control of the process. The new system produces cells in a sealed container using bioreactor technology, which circulates fluid through cartridges and automatically loads the cells into the cartridge, feeds the cells, and harvests the cells.

“Having a technology that enables the production of large quantities of cells in a reproducible, robust, and closed-system manner is a key to being able to move forward with the clinical validation and subsequent implementation of cellular therapies,” said Klein.

Until the machine’s output is verified as comparable to the expanded stromal cells created through traditional methods, the DTM will continue to make cells for patients using a more traditional flask/cell factory method.
Imaging team reports on H1N1 case
A possible breakthrough in H1N1 influenza diagnosis, radiology imaging was found to aid in eliminating other possible causes of disease in a middle-aged man who later died from the virus.

Dr. Daniel Mollura of the NIH Center for Infectious Disease Imaging, a partnership between Clinical Center Radiology and Imaging Sciences and the National Institute of Allergy and Infectious Diseases, is lead author on published findings of the case in the December 2009 issue of the American Journal of Roentgenology. He and his collaborators report that computed tomography (CT) imaging of severe novel H1N1 contributed to earlier diagnosis and treatment of the infection, suggesting a potential role for imaging in complex cases.

The authors point out that the pandemic nature of the H1N1 outbreak calls for swift reporting of any leads in diagnostic techniques. “More cases will certainly arise as a result of this pandemic, and we hope to study additional cases in the future,” they wrote.

The case in review is that of a man who presented with a fever, fatigue, nausea, diarrhea, and an intermittent cough, and who rapidly lost lung function and died on the fifth day of hospitalization. Two initial nasal swab tests for H1N1 influenza came back negative, but x-ray and CT on the first day showed peripheral patchy opacities in the lungs (patches of opaqueness near the outer edge of the organ), which led to earlier diagnosis and aggressive treatment of novel H1N1—later confirmed by laboratory tests.

The imaging findings suggested atypical infection and “are consistent with and add detail to the characterization of lung injury resulting from H1N1,” the authors wrote. “Early CT may help clinicians recognize cases of severe influenza and monitor response to treatment,” Mollura said. “At the Center for Infectious Disease Imaging at the NIH, the study of influenza is a priority with a focus on achieving early diagnosis and understanding its pathogenesis.”

CC researchers develop new consent for cancer trials
About a third of NIH onsite clinical trials are Phase I studies—those that evaluate a new drug or treatment's safety, determine a safe dosage range, and identify side effects. A team including Dr. Christine Grady, acting head of the Clinical Center Department of Bioethics, recently developed a shorter and simpler consent form for patients participating in Phase I oncology trials.

“Participants need to know that research is different than the regular care that they might be receiving elsewhere. Individuals need to know why it is being done, what it entails, and what the risks and benefits are,” Grady said.

The new consent template was published in the July-August 2009 issue of IRB: Ethics & Human Research. In addition to Grady, the research team included Dr. Shlomo Koyfman from the Department of Radiation at the Cleveland Clinic; Mary S. McCabe, director of the Cancer Survivorship program at Memorial Sloan Kettering Cancer Center; and Dr. Ezekiel Emanuel, chief of the CC Department of Bioethics and on detail as special advisor for health in the White House Office of Management and Budget.

The idea to create a simplified consent form grew out of a study by the CC Department of Bioethics several years ago that collected Phase I oncology trial consent forms from around the country to analyze content. That study team found that some of the consent forms were different and easier to understand than others.

The informed consent process is especially important for individuals enrolled in Phase I oncology trials because of the nature of the trial and the nature of the individuals, Grady said. “Phase I research is controversial because it is done to determine safety and toxicity, yet it involves people who are sick, who have advanced cancer and have exhausted usually all available treatments for their cancer. So there is this confluence of potentially vulnerable people with a study that is designed for purposes that are not to benefit them. You want to be sure that people understand that.”
After reviewing more than 200 consent forms for Phase I oncology trials, the CC, Cleveland Clinic, and Sloan Kettering team created the improved consent template in both English and Spanish by redesigning and rewording it to be specific to Phase I trials and to avoid repetition and utilize simplified language. The new form is divided into identifiable sections framed by first-person questions and presents statistical information in tables. It is also about two pages shorter than the average consent form.

Researchers will use a randomized controlled trial to test the new consent form against a standard template to compare and evaluate patients’ understanding and satisfaction.

**Updated clinical guidelines for HIV-associated opportunistic infections released**

The first complete update in five years of the U.S. guidelines for preventing and treating HIV-associated opportunistic infections was released April 10, 2009, by the National Institutes of Health and the Centers for Disease Control and Prevention in cooperation with the HIV Medicine Association of the Infectious Diseases Society of America (IDSA).

“The scientific community has developed new and more accurate diagnostic tests for HIV-associated opportunistic infections during the past five years, more effective treatments for these infections and better approaches to preventing them,” says Dr. Henry Masur, co-chair of the working group that revised the guidelines. He is chief of the CC Critical Care Medicine Department and a former president of the Infectious Disease Society of America. “The updated guidelines outline these advances for physicians and patients across the United States and beyond.”

The new Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents apply state-of-the-art science and medicine to 29 infectious diseases of concern. More than 140 medical experts contributed their knowledge to this edition of the guidelines.

HIV cripples the immune systems of its human hosts, leaving them more vulnerable than the general population to numerous other infectious diseases. These HIV-associated opportunistic infections are a leading cause of hospitalization and death among HIV-infected individuals in the United States.

The new guidelines combine what were previously two separate publications, one for the prevention of opportunistic infections (last published in 2002) and one for their treatment (first published in 2004).

**Genomic sequencing identifies unexpected bacterial diversity on human skin**

Take a look at your forearm—freckles, hair, maybe a birthmark. Unseen are an average of 44 species of bacteria that populate normal skin and possibly impact the health of one of the body’s first lines of defense against illness and injury.

This bacterial diversity is just one of the findings of an initial study by NIH researchers published in the May 29, 2009, issue of *Science*, an effort to explore the skin’s microbiome—all of the DNA, or genomes, of all the microbes that inhabit human skin.

NIH recently launched the Human Microbiome Project, a part of the NIH Roadmap for Medical Research, to discover what microbial communities exist in different parts of the human body and to explore how these communities change with disease. In addition to skin, that project is sampling the digestive tract, nose, mouth, and vagina.

Drawing on the power of modern DNA sequencing technology and computational analysis, the research team from the National Human Genome Research Institute, the National Cancer Institute, and the Clinical Center uncovered a far more diverse collection of microbes on human skin than had been detected by traditional methods that involved growing microbial samples in the laboratory.

“The advanced DNA techniques are going to give us the information we need to understand these...”
complex microbial communities, and once we understand their relationships to healthy and diseased skin surfaces, we can identify treatments,” said Dr. Patrick Murray, chief of the CC Department of Laboratory Medicine’s Microbiology Service.

**Undiagnosed diseases program continues to solve mysteries**

The Undiagnosed Diseases Program is a partnership of the CC, the National Human Genome Research Institute, and the NIH Office of Rare Diseases Research. Since the program began in 2008, about 140 patients have been brought to the Clinical Center for evaluation. One patient seen in 2009 was Dunham Aurelius of New Mexico—an artist who has been plagued with constant kidney stones. Searching for the reason why brought Aurelius to the Clinical Center. With him came his recent bride, Dr. Michelle Barry, a forensic pathologist at the University of New Mexico Health Sciences Center, who gave a presentation to CC pathology residents.

Aurelius, who creates contemporary sculptures in a variety of materials, first noticed the kidney stones in his early twenties. The stones are produced at an alarming rate and size. His largest ever measured close to three centimeters. Aurelius has a bag full of the stones he has passed. “We’re planning on making jewelry,” Barry joked. “He just makes them like an oyster. We’re trying to get him to make diamonds or pearls; it’d be much more financially beneficial.”

During his evaluation at the Clinical Center, Aurelius saw a team of researchers, including calcium metabolism expert Dr. Michael Collins of the National Institute of Dental and Craniofacial Research. Aurelius said, “From those at the information desk to the doctors, they’re so helpful.” Also impressive was the communication of knowledge, he said. “Everyone is on the same page.”

To prepare the CC pathology residents for the pages of their board certification exams, Barry quizzed the staff on their forensic pathology knowledge. Her titles include assistant professor, associate medical investigator, and autopsy director at the New Mexico Office of the Medical Investigator and University of New Mexico Health Sciences Center in Albuquerque.

The Undiagnosed Disease Program has been popular with the media. In 2009, it’s been covered by outlets that include the Discovery Channel, the *New York Times*, and CNN.
The element of surprise did not affect the favor of The Joint Commission on its site visit in October 2009.

The accrediting and reviewing representatives arrived with no advance warning early the morning of October 6 to begin a three-day investigation into the Clinical Center’s facilities and activities to evaluate our commitment to certain quality standards.

“This is the best hospital I have ever seen,” one of the surveyor reports read. CC Director Dr. John I. Gallin presented The Joint Commission’s findings at a town-hall meeting immediately after the survey results were delivered. The CC received an outstanding score—compared against 301 standards the surveyors identified only six areas requiring improvement—and the compliment, “Awesome!” from another surveyor. The Joint Commission lauded the CC for our culture of safety, commitment to the patient mission, and knowledgeable staff.

Gallin thanked everyone who helped earn such a high rating—the CC staff, institute and center partners, Offices of Research Facilities and Research Services, and the patients—including Patient Advisory Group member Antoinette Royster, who participated in a special session with reviewers. “We may have a fabulous building, but what really makes this place special are all of you,” said Gallin to the crowd listening in Masur Auditorium.

Language interpreter program coordinator Brenda Robles (second from right) and volunteer program coordinator Courtney Duncan (right) greet three volunteer interpreters at an April 2009 reception celebrating National Volunteers Week.
The Clinical Center has recently joined the ranks of hospitals across the country working toward a healthier environment with the creation of the CC Green Team.

“Hospitals in general use tremendous amounts of resources and energy, and there are simple things that we can do to make a big impact,” said Dave Folio, head of the CC Nutrition Department and CC Green Team leader. “At home, you recycle, you shut off the lights when you leave a room. We want to instill that same awareness here at work.”

The CC Green Team looks at how the center conducts its day-to-day activities and recommends earth-friendly initiatives to support the team’s goals of increasing recycling, decreasing paper consumption, and decreasing the amount of electricity used by the CC. The NIH Bethesda campus uses approximately $65.5 million worth of electricity per year, and about 10 percent of that is used by the CC, according to the Office of Research Facilities.

A collaboration with the NIH Environmental Management System, the CC Green Team was formed to comply with an executive order to strengthen federal environmental and energy management and because “it was simply the right thing to do,” Folio said.

Evidence of the Green Team’s efforts can be found throughout the building—from the hallway recycling containers brimming with plastic and paper to the reusable plates on which CC patients receive their food. One recent step to promote a greener CC is the desk-side recycling bin initiative. Staff can request two small, blue bins—one for commingled (cans and bottles) and one for mixed paper—for their desk side. The Green Team has already distributed more than 700 bins and will evaluate the progress of this initiative by measuring the weight of commingled and paper recyclables over time, said Folio.

Employees and visitors can help serve the Green Team mission. When leaving a room for more than a few minutes, turn off the lights. This small step can save roughly three cents an hour, which, considering the CC’s many rooms, can really add up. Employees should recycle ink and toner cartridges in the bins throughout the CC, especially because for each cartridge recycled, $1 goes to NIH charities like Friends of the Clinical Center and The Children’s Inn. Employees can also help reduce paper consumption by decreasing type size to save toner and copying and printing on both sides of paper if possible.
MAKING A DIFFERENCE

Clinical Center volunteers selflessly give their time and efforts to serve the CC mission of quality patient care and clinical research. Their contributions comprise a variety of roles. For many, volunteering is a symbiotic arrangement. Afrooz Nikoobakht helps out in the Pharmacy Department—organizing unit-dose trays, setting up new order medications, and filling prescriptions—while gaining valuable experience toward her pre-pharmacy studies at Montgomery College. Nikoobakht said she has appreciated how helpful her fellow team members have been. “They are very friendly and answer all the questions a new person could ask. They really make you feel part of the team.” Meeting patients who have come to the CC has profoundly affected Nikoobakht. “It really makes me appreciate how precious life is, and how one should not take a moment for granted. I feel very lucky that I am able to be part of an organization like this.”

With work or school, family and friends, it can be hard to fit in a regular volunteer activity. The CC makes an effort to accommodate those interested in helping serve the mission of patient care and clinical research, those like Tara Mahan.

Mahan volunteers with the patient ambassador program and volunteer services coordinator Courtney Duncan found an inpatient unit with high weekend traffic for Mahan, a biomedical engineer from Upper Marlboro. The work she most enjoys is orienting new patients to their surroundings. Mahan walks them through their unit admission packet and shows them how to order meals and use their computer and television. “Volunteering at the NIH is a unique opportunity because of the types of patients that are seen in the facility,” Mahan said. “I am able to give back to the community while walking with patients on their journey of hope.”

One of the greatest repositories for CC volunteers is the brigade of eager, young post-baccalaureates spending a year or two at NIH before starting medical or graduate school. Lindsey Buckingham is one such trainee, using her time in the CC for more than research. Buckingham worked in the Kidney and Electrolyte Metabolism Branch of the National Heart, Lung, and Blood Institute before returning to her alma mater, the University of North Carolina, Chapel Hill, to begin medical school. She served as a Spanish interpreter for Radiology and Imaging Sciences because remaining proficient in Spanish was important to her. She worked with patients to fill out paperwork, explain procedures, and make sure they were comfortable and aware of what is happening. “Many patients come to the NIH with a serious illness, some visiting the United States for the first time. It’s scary and disorienting,” Buckingham said. “It’s a really gratifying experience to connect with people and see their comfort when I can understand them.”
PATIENT SAFETY AWARD GOES TO NEW CONSULT SERVICE

The staff honored, with CC Director Dr. John I. Gallin (front middle), were: (back, from left) Minnie Raju, Windy Wallin, Connie Kotefka, Tye Mullikin, Nancy Munro, Avril Bertrand, Nancy Ames, Deborah Kolakowski, Kimberley Klapec, Patricia Smatlak (front left), Dr. James Shelhamer (front right), and (not shown) Mary Fleury, Pamela Horwitz, Elizabeth Keber, Melanie Reagan, and Dr. Richard Sherry.

Early recognition of, and response to, a patient's worsening condition greatly reduces the likelihood that the patient will require emergency transfer to the intensive care unit or, worse, necessitate a Code Blue situation. This basic patient safety tenet has been realized as a result of the work done by a dedicated group of nurses, physicians, respiratory therapists, and information technology specialists. The Critical Care Medicine Consult Service group worked to establish processes to facilitate nurses and respiratory therapists contacting directly the critical care fellows to request their expertise at the patient's bedside.

To celebrate this work the group has been awarded the 2009 Clinical Center Patient Safety Champion Award. “What you’ve done in creating this new service clearly has made a difference in keeping patients safe and alive,” Clinical Center Director Dr. John I. Gallin told the group in announcing the honor.

This annual award goes to an individual or team who demonstrate a sustained commitment to a safe patient environment. The Critical Care Medicine Consult Service serves that mission by bringing critical care to the bedside when a patient’s condition suddenly worsens.

The seed for the service was planted in 2006 when a patient commented to nurse Patricia Smatlak that the CC could benefit from a rapid response team. “The idea is to respond to a spark before it becomes a fire,” said Smatlak.

INW group named “best team”

Nursing Week 2009 ended with the announcement of the “best team” award, an honor that went to the INW inpatient unit and day hospital group. Eleven nursing teams were evaluated on initiative, adaptability, recruitment, retention, knowledge, and teamwork. “Working together, the sky is the limit” was the competition’s theme. Dr. Clare Hastings, chief of Nursing and Patient Care Services, made the announcement.

“One short year ago, INW was functioning with 50 percent vacancy rate and 40 percent turnover. Through strong recruitment efforts and staff participation in open houses and shadow days, we accomplished the lofty goal of hiring excellent, committed, experienced pediatric nurses,” read the INW nomination. The team was commended for flexibility, adaptability, and constant competency enhancement necessary on a multi-institute unit. Team members include (front row, from left) Roel Cabulang, Meagan VanAsche, Tony Terry, and Susan Eidelheit; back row, from left: Jean Perrelli, Nicole Holland, Nicole Gamba, Michelle Kwiatkowski, Ellen Carroll, and Patricia Smatlak.
The Clinical Center Data Center (CCDC) houses more than 500 networked devices providing both CC and other NIH users continuous access to data and applications. As the technical capabilities of the CC grow, so does the systems need. The CCDC recently began migration to a new location in the Hatfield Building to remedy the physical size, power, and space limitations and geographic risks of the current CCDC in the older part of Building 10.

The new CCDC has been designed with redundant systems to minimize potential risk and maximize potential growth for the next 10 years, assuring system availability in the event of failure of any of the three major systems required for CCDC operation—power, cooling, and network. The design also minimizes physical risk due to environmental issues such as water intrusion from aging building infrastructure and failures.

The older center has lived in a space for more than 25 years that was never designed to hold such equipment. Eight years after conceiving the idea of a move, and three years after a space was designated and design began, testing and acceptance of the new data center was completed on September 19. Migration of equipment into the new space started two days later and is expected to be complete in early 2010.

The bright new space has the capacity for 100 server racks, but initially will be only 70 percent populated to allow for expansion in the next decade. “The physical size of the systems is shrinking, but the power needed is increasing,” said John Kocher of the CC Department of Clinical Research Informatics (DCRI). Server consolidation and virtualization will further reduce the physical footprint, allowing room for growth. Even though these newer, smaller systems take up less space, they have larger power and cooling requirements. Those projected increases were designed into the new CCDC infrastructure to ensure the CC would not outgrow the new space.

The power for the data center comes from two 450-kilowatt uninterruptable-power-supplies. They run concurrently to share the power load, but either could handle the entire CCDC power needs. Different power feeds from Pepco work to keep at least one up and running. Just in case it is needed, a 1.5-megawatt generator looms outside the CC ambulatory entrance. It can generate enough power to support a small community, said Kocher. As a last resort, if there is a problem with the dedicated CCDC generator, the data center can run off the CRC emergency generator system.

A major improvement of the new space is protection from the frequent flooding that has plagued the old Building 10 data center. An internal tin roof protects the new set-up by catching any water from a leak and sending it through a gutter to the hallway, away from the important equipment. Water sensors have been installed both in the internal roof and under the raised floor to give an early indication of potential water-related issues.
MONITORS SHOWCASE RESEARCH AND CC EVENTS

Newly installed monitors around the Clinical Center are the latest way to learn what is happening in the CC. Two screens in the atrium display upcoming lectures and meetings, briefs on CC programs such as Recycled Reads for magazine donation, and abstracts of research findings. Timothy Jancel (left) of the CC Pharmacy Department, Janine Daub of the National Institute of Allergy and Infectious Diseases, and Dr. Phillip Arlen of the National Cancer Institute pause before an abstract from one of their peers.

HOSPITALITY SERVICES REORGANIZES TO DELIVER QUALITY CUSTOMER SERVICE

A reorganization of Hospitality Services has led to a variety of changes that improve the patient experience—from the front door to the bedside.

Previously under the Office of Organizational Development, Hospitality Services branched off in early 2009 with a broader goal of helping the Clinical Center deliver outstanding customer service consistently and seamlessly across the front line. The office now reports directly to Maureen Gormley, CC chief operating officer, who continues to focus on improvement of service excellence across the CC.

The reorganized Hospitality Services continues to be led by CAPT Denise Ford. Responsibilities include customer service representatives at hospitality desks and the patient entrance at West Drive, staff at reception desks in front-line departments, patient ambassador volunteers, and the patient escort staff. In an effort to enhance consummate service throughout the patient experience, Ford established a partnership with Gina Mattia, the chief medical technologist of phlebotomy services, so that shared customer service standards were developed for phlebotomy and the other front-line services. This service excellence team now spans from the north lobby’s hospitality desk to the front desks of phlebotomy, the EKG/heart station, radiology, and nuclear medicine.

Small changes have made significant differences. Hospitality Services now handles scheduling for radiology, nuclear medicine, and pre-anesthesia services. The addition of a cancel option to the automated schedule-by-phone system has allowed appointments to be quickly cancelled if a patient’s schedule changes. Since approximately 20 percent of patients do not arrive for appointments, this approach has the potential to substantially reduce the patient backlog, allowing better access for other patients. More than 100 additional appointment slots were freed up for Radiology and Imaging Sciences procedures in the first month that the cancel option system was in place.

Hospitality Services also refurbished signage instructing patients on how to contact the radiology technicians for after-hours services, thereby decreasing their wait time. “It’s the little things that make the experience easier and smoother for the patients,” said Ford.
STAFFERS JOIN TEAM NIH TO RACE FOR A CURE

More than 40 staffers turned out on a sunny Saturday morning for the 2009 Susan G. Komen Global Race for the Cure on June 6. Team NIH, led by Pat Piringer, special assistant to the CC director, joined a crowd of nearly 45,000 people who ran or walked the 5 kilometers (3.1 miles) to support the fight against breast cancer. Susan G. Komen for the Cure was founded in 1982 by Nancy G. Brinker after she promised her dying sister she would do everything in her power to end breast cancer. Today, Komen for the Cure is the world’s largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all, and energize science to find the cures. With more than $1.3 billion invested to date, Susan G. Komen for the Cure is the world’s single largest source of nonprofit funds dedicated to curing breast cancer—second only to the US government.

SESSION PROMOTES PARTNERSHIPS WITH VET-OWNED BUSINESSES

The Clinical Center Office of Purchasing and Contracts hosted an outreach session in August to encourage CC partnerships with service-disabled veteran-owned small businesses—“Partnering for Success with the NIH Clinical Center.”

“We have a really dedicated and caring team of professionals in the Clinical Center,” Maureen Gormley, CC chief operating officer, said, welcoming the group. “One of the reasons that we wanted to put this forum on today is so that you could get to know us and we could get to know you.”

Session attendees received advice on forming relationships with a large federal institution like NIH from Annette Owens-Scarboro, small business specialist to NIH from the DHHS Office of Small and Disadvantaged Business Utilization. “This was an opportunity to demonstrate our commitment to go that extra mile to expand small business opportunities and to provide vendors additional information that may be useful in their efforts to obtain contract awards to provide supplies and services to the Clinical Center,” said Janice Brunson, deputy director of the CC Office of Purchasing and Contracts.

“We pride ourselves on being real people; we are different than a big office-building-type setting,” Gormley said. “We are looking forward to establishing relationships that, down the road, can be mutually beneficial.”

New ways to keep informed

Interested in the Clinical Center and its activities? Explore the new ways CC information is being shared. Podcasts feature Clinical Center Grand Rounds, along with news and information about CC programs. More than one thousand individuals follow the Clinical Center’s Twitter site. There are also Twitter sites for patient recruitment and for medical education and training. A Clinical Center Facebook page is also available. For links to all, go to the Clinical Center’s Web site, http://clinicalcenter.nih.gov.

Pushing to the maximus

The CC Rehabilitation Medicine Department’s team for September’s NIH Relay ran to the theme of “pushing our gluteus to the maximus.” It worked. The group placed tenth in the competition that included 105 teams. Rehab medicine team members, who each covered a half mile, included Abraham Behnam, William Sipprell, Melissa Luhmann, Laura Maring, and Dr. Hyung Park.
Training the Next Generation

FROM LOCAL TO GLOBAL: CLINICAL RESEARCH TRAINING EXPANDS

Only six years ago, the Clinical Center established the Office of Clinical Research Training and Medical Education (OCRTME), which develops, administers, and evaluates clinical research training initiatives. Since then, the training and medical education offered by the Clinical Center has gone from Bethesda to Beijing and many destinations in between.

Under the direction of Dr. Frederick P. Ognibene, OCRTME has made great strides in advancing the educational component of the CC mission. “We know that training the next generation of clinician-scientists is not going to be accomplished solely in Bethesda,” said Ognibene, CC deputy director for educational affairs and strategic partnerships. “We have to increase the availability of training around the world and forge partnerships with a variety of institutions.” From existing courses to new programs, 2009 raised the bar of clinical research training.

INTERNATIONAL ACCESS

Imagine being several continents away, but viewing a training taught in the United States at the NIH Clinical Center. That is exactly what students at the Dow University of Health Sciences in Karachi, Pakistan, do every Monday and Tuesday during the fall semester. Thanks to improved technology, the CC is able to broadcast its most popular courses, Introduction to the Principles and Practice of Clinical Research (IPPCR) and Principles of Clinical Pharmacology, to remote sites around the world.

Twenty-six remote sites observed the 2009-10 IPPCR course, including ten international locations such as the Universidade Federal de Santa Maria in Brazil and the Dong-A University Medical College in Korea. The CC makes content available for students via live stream and archived content on the web for the five sites without a live broadcast. About 62 percent of students participate at NIH or other locations within the United States. Approximately 38 percent participate at a site around the globe.

A record number (1,296) of students enrolled in IPPCR in 2009-10, which demonstrates the strong and sustained interest in the subject matter and the good reputation of the course. And the word keeps spreading. In April 2009, NIH faculty, including CC Director Dr. John I. Gallin, conducted a week of the IPPCR course in person at West China University in Chengdu, China. Students then follow the course through the archived material either in DVDs or stored online and keep in touch with faculty as needed.

Designed to meet the needs of researchers who have an interest in the clinical pharmacologic aspects of contemporary drug development and utilization, the Principles of Pharmacology (PCP) course is entering its 11th year. The course has also reached students far away from the NIH.

IPPCR PARTICIPATION BY LOCATION

<table>
<thead>
<tr>
<th>Location</th>
<th>Participation</th>
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<tbody>
<tr>
<td>NIH</td>
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<tr>
<td>United States</td>
<td>345</td>
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<tr>
<td>Latin or South America</td>
<td>245</td>
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<td>Asia</td>
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<td>Africa</td>
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Twenty-one remote sites, including four international, and a record 813 students participated in the 2009-10 course.

The interest in the subject matter has grown so much that a demand has emerged abroad. In November 2009, Dr. Juan Lertora, Director of Clinical Pharmacology at the CC, and others from NIH led a week-long PCP course in Beijing, China. “Our goal was to share the knowledge and the high standards in place at the NIH Clinical Center for the study of new drugs in human subjects and their rational use in therapeutics,” Dr. Lertora said. “I sensed a great deal of interest in the field and in all aspects of the drug development process, judging from the questions we received from an audience of approximately 140 physicians, pharmacists, and pharmacologists working at academic, private, and governmental institutions in China.” With the lively discussion and strong interest in the topic, Dr. Lertora expects this to be the beginning of an exciting partnership.

TWO COURSES GO TO CHINA IN 2009

In April 2009, NIH faculty, including CC Director Dr. John I. Gallin, conducted a week of the Introduction to the Principles and Practice of Clinical Research course in-person at West China University in Chengdu. In November, Dr. Juan Lertora (second from right), director of CC Clinical Pharmacology, led a week-long Principles of Clinical Pharmacology course in Beijing. With Lertora are (from left) Arthur J. Atkinson, Jr., Northwestern University; Shiew-Mei Huang, FDA Office of Clinical Pharmacology & Biopharmaceutics; Frank Gonzalez, National Cancer Institute; and Tim Shi, GlobalMD. Not pictured is Diane Mould, Projections Research, Inc. The course is taught by faculty members from NIH and guest faculty from FDA, the pharmaceutical industry, and several academic institutions from across the United States.

GRADUATE MEDICAL EDUCATION BROADENS

The Clinical Center, as the Accreditation Council for Graduate Medical Education (ACGME) accredited sponsor of graduate medical education at NIH, made strides to bolster Graduate Medical Education (GME) offered to residents and fellows who study at NIH. The Medical Biochemical Genetics program was ACGME-accredited in late 2008 and has proven to be a trailblazer in the GME realm. As one of the few programs of its kind in the world, the Medical Biochemical Genetics program has a long track record of producing research leaders in the field. In 2009, two other programs became ACGME-accredited, bringing the NIH’s total to 17 accredited programs.

The Vascular Neurology and the Hospice & Palliative Care programs are new in 2009 and have made a significant footprint. For example, the Hospice & Palliative Care program has become one of the largest of its kind through its partnership with Capital Hospice of Washington, DC. Expansion of GME programs furthers the Clinical Center’s mission to educate a pipeline of clinician-scientists. With more GME programs available, researchers are better able to address the needs of patients. Also, specialty trainings such as Vascular Neurology allow fellows to enhance their knowledge of a specialty area and eventually achieve board certification.
Medical, dental, and veterinary students from across the country gathered at NIH in November for the CIST Forum, offering a chance to share best practices and contact information with their likely future collaborators.

With all of the international interest and activity around clinical research, the CC does not forget the importance of training the cohort of interested scientists in medical schools in the United States. On November 5 and 6, 2009, a group of 268 students from 67 schools around the country descended on the NIH campus for the Seventh Annual Clinical Investigator Student Trainee (CIST) Forum. Students gathered to compare notes, network with peers and established researchers, and hear from distinguished speakers, from NIH IC Directors to recent program alumni.

Invited were medical, dental, and veterinary students participating in year-long research and enrichment programs: Howard Hughes Medical Institute (HHMI)-NIH research scholars and HHMI medical fellows, Doris Duke Charitable Foundation (DDCF) clinical research fellows, National Center for Research Resources/Clinical and Translational Science Award-sponsored students in year-long research programs, NIH Clinical Research Training Program (CRTP) fellows, Sarnoff Cardiovascular Research Foundation fellows, fellows in the applied epidemiology fellowship at the Centers for Disease Control and Prevention, Fogarty International clinical research scholars, and the NIH MD/PhD Partnership Training Program fellows.

All 30 of the CC’s own Clinical Research Training Program (CRTP) class of 2009-10 attended the CIST Forum. One of the CC’s longest standing programs, the CRTP was founded in 1997 and is supported jointly by the NIH and the Foundation for NIH through grants from Pfizer Inc as part of the company’s commitment to public-private partnerships. The CIST Forum is an opportunity for CRTP fellows to expand their network beyond NIH and cultivate relationships with young, motivated researchers like themselves.

Networking was a major theme of the two-day forum, which also featured a panel on loan repayment and research funding opportunities, and career advice from clinician-scientists who recently completed their residency and sub-specialty trainings, as well as a keynote speech from dean of the Duke University School of Medicine, Dr. Nancy Andrews. New this year, organizers utilized the technology of micro-blogging site Twitter and a collaborative online forum to connect with the audience and encourage conversation.

In line with the CC’s emphasis on collaboration to make clinical research training a success, the CIST Forum has always been a team effort. “It is important to stress that even though the event was held on the NIH campus, the forum is really based on partnerships, and the event could not have been done as successfully without the collaboration and input from all the participating programs, as well as significant input from a number of NIH and CC staff,” explained Dr. Frederick P. Ognibene.
Dr. Nancy Andrews, dean of the Duke University School of Medicine, was the keynote speaker at the Clinical Investigator Student Trainee (CIST) Forum, a gathering of future clinician-scientists in year-long research fellowships.

Andrews, the first and only female dean of a top-ten medical school, spoke on her research background, her perspectives on health-care, and her experiences as a woman in science.

She received her bachelor’s degree in molecular biophysics and her master of science in biochemistry from Yale University, her doctorate in biology from Massachusetts Institute of Technology, and her medical degree from Harvard Medical School. Andrews completed her internship and residency in pediatrics at Children’s Hospital Boston, and her hematology/oncology fellowship at Children’s Hospital and the Dana-Farber Cancer Institute.

She was a full professor of pediatrics and dean for basic sciences and graduate studies at Harvard Medical School before she was appointed vice chancellor for academic affairs and dean of the Duke University School of Medicine in 2007.

“I remember my high school biology teacher telling us it would never be possible to sequence DNA,” she began, before telling the CIST Forum attendees that in their careers they would likely see genomic sequencing as a routinely analyzed part of a patient’s medical record. “The lesson in that is that you should never say never in science and that you should be very ambitious in your goals,” Andrews said. “Because unless you aim high, you have no chance of getting there.”

She explained her choice of iron biology as a research focus: “I could do something that was unique and interesting and not something that thousands of other people would be thinking of doing.”

Andrews used patient case studies to illustrate the value of investigative instincts and collaboration with peers who offer complementing specialties.

She recommended attention to access of health-care delivery. “We also need to be thinking of course about preventing disease in the first place and changing medicine so that it becomes more proactive and less reactive—working toward preserving health rather than treating disease.”

Questions from female trainees in the audience asked for advice on overcoming bias and on balancing a successful career with a strong home life. “Until we make careers and academic positions and places in medical school classes truly accessible to everybody we’re losing out on a lot of talent,” Andrews responded.

“There are myths out there about how hard it is to have a family and a career, and I just don’t think that’s really true anymore,” she said. “Most of the time it’s probably more manageable than young women are told.”

**Dietetic interns graduate**

The NIH Dietetic Internship Program through the Clinical Center Nutrition Department graduated three at a ceremony in July 2009. LCDR Merel Kozlosky, program director, acknowledged (sitting from left) Sara Hauck, Kelly Verdin, and Kimberly Wong for completing the “rigorous and renowned program” and thanked the “significant groups in their journey,” including preceptors, family, and nutrition staff. In attendance were dietitians (from left): CAPT Nancy Sebring; Marnie Dobbin; Kozlosky; LCDR Jennifer Graf; CAPT Madeline Michael, chief of Clinical Nutrition Services; Kristy Suhr; Beth Moylan; Kirsten Zambell; LT Rachael Drabot; and Jennifer Widger, chief of the Food Service Section.
About 50 scholars, supported through the National Center for Research Resources via an institutional career development award program, stopped at the Clinical Center in April while in Washington to attend the 2009 National Clinical & Translational Research Education Annual Meeting. CC Director Dr. John I. Gallin welcomed the trainees, including those at right representing the Mayo Clinic; Harvard University; the Albert Einstein College of Medicine of Yeshiva University; and the Universities of Minnesota, Pittsburgh, and Colorado. “I wish you phenomenal luck, though it won’t be luck if you take advantage of all the opportunity in front of you,” Gallin told the scholars, as part of a presentation including an overview of the CC. The scholars, selected to receive support to pursue multidisciplinary clinical research with training and mentoring built in, also enjoyed a tour of the CC while at NIH.

ARRA supports new generation of clinical researchers

The American Recovery and Reinvestment Act of 2009 (ARRA) is helping support the next generation of clinician-scientists. ARRA funded six Clinical Center summer Intramural Research Training Awards, providing opportunities for students to work side-by-side with CC staff in an environment devoted exclusively to translational research.

The act allocates $21 million over two years for educational opportunities in NIH-funded laboratories for students and science educators with the goal of creating more jobs, supporting economic development, and accelerating the pace and achievement of scientific research. The money will also encourage students to pursue clinical research-related career fields. The six CC summer students worked in the Department of Transfusion Medicine; the Rehabilitation Medicine Department; the Department of Laboratory Medicine; and the Office of Communications, Patient Recruitment, and Public Liaison. “This additional support from ARRA provided the Clinical Center with a wonderful opportunity to offer the rich research environment in these Clinical Center departments to six excellent students,” said Dr. Frederick Ogimigene, CC deputy director for education affairs and strategic partnerships.

Hilda Tejero, a medical student at The George Washington University, worked in the Department of Transfusion Medicine looking at the transmission of hepatitis C.
INVESTIGATORS GREET CLINICAL FELLOWS

The Clinical Center welcomed a new crop of clinical fellows at a reception July 8 after a day of orientation. Dr. Constantine Stratakis (left)—acting scientific director, head of the Program on Developmental Endocrinology and Genetics, and director of the Training Program on Pediatric Endocrinology at the National Institute of Child Health and Human Development—and Dr. Richard G. Wyatt, deputy director of the NIH Office of Intramural Research, mingled with new fellows, including Dr. Fariha Kamran (right) and Dr. Alison Boyce. Both are starting a clinical fellowship in pediatric endocrinology with NICHD. Kamran graduated from King Edward Medical College in Pakistan and did her residency at Nassau University Medical Center. Boyce graduated and completed her residency at Eastern Virginia Medical School.

KOREAN TRIALS CENTER LEADERS VISIT THE CC

Leaders of the Inha University Clinical Trials Center at Inha University Hospital in Incheon, South Korea, visited the Clinical Center in April to learn about the operations here. Dr. Cheol-Woo Kim (back row, middle) of Inha University Hospital is in a fellowship with Dr. Juan Lertora (front right), director of the CC clinical pharmacology program. Dr. Clare Hastings (front left), chief of Nursing and Patient Care Services; CC Director Dr. John I. Gallin (front middle); and Dr. Shyamasundaran Kottilil (back right), staff clinician with the National Institute of Allergy and Infectious Diseases (with whom Kim has worked), presented CC details and programs. Kim plans to expand the clinical pharmacology department in his home hospital upon return later this year. Making the trip to visit and support their colleague were (from left) chief nurse Eunyoung Kim, clinical pharmacologist Dr. Ju-Hee Kang, and center director Dr. Moon Suk Nam. The Inha University Clinical Trials Center opened in 2006 and recently expanded to include a 36-bed research ward, three clinics, and outpatient services. The center is comparable to the 78 NIH-supported General Clinical Research Centers across the country.
**President Barack Obama visits the Clinical Center**

“Welcome to the House of Hope,” said Susan Butler, a long-time Clinical Center patient and 14-year survivor of simultaneous breast and ovarian cancer, in greeting President Barack Obama as he arrived at the Clinical Center on September 30, 2009.

Obama traveled with Department of Health and Human Services Secretary Kathleen Sebelius to speak to the NIH community. “I’m here to talk about our nation’s commitment to research,” Obama said. “The work you do is not easy. It takes a great deal of patience and persistence. But it holds incredible promise for the health of our people and the future of our nation and our world…Today we’re announcing that we’ve awarded $5 billion—that’s with a ‘b’—in grants through the Recovery Act to conduct cutting-edge research all across America, to unlock treatments to diseases that have long plagued humanity, to save and enrich the lives of people all over the world. This represents the single largest boost to biomedical research in history.”

NIH Director Dr. Francis Collins said of Obama during the visit, “We’re very grateful to have a President who values science, respects its independence, and understands its huge potential for improving Americans’ lives.”

(Top) One of the first faces President Barack Obama saw upon entering the Clinical Center on September 30 was that of Susan Butler, longtime CC patient.

(Above) NIH Director Dr. Francis Collins (left) briefs Obama while in the lab of NCI’s Dr. Marston Linehan (middle).
Rare diseases group honors Gallin’s contributions

Clinical Center Director Dr. John I. Gallin was among those honored by the National Organization for Rare Disorders at its 2009 NORD Partners in Progress Gala at the National Press Club in Washington, DC, in May 2009. Gallin received the National Health Leadership Award, and NORD gave its Lifetime Achievement Award to Sen. Edward M. Kennedy. NORD also honored Social Security Commissioner Michael J. Astrue, Discovery Health, and several treatment-developing companies for significant achievements to improve the lives of people with rare diseases.

NORD represents the nearly 30 million people in the United States who have rare diseases—that is one that affects fewer than 200,000 Americans—their families, and the patient organizations that serve them. “Dr. Gallin represents the unique blend of science and humanism that is so characteristic of the physician/researchers who study rare diseases and treat the individuals affected by them. Although dedicated to furthering scientific understanding of these diseases, he remains supremely aware of the emotional turmoil that patients participating in clinical trials may be experiencing,” the organization wrote in a publication for the gala.

The gala also included a special tribute to Patricia Delaney Klafath, known as Patty Delaney to her friends and coworkers and to the many patients and patient families she helped as associate director for the Cancer Liaison Program at the US Food and Drug Administration. Delaney was a founding member of the CC Patient Advisory Group from 1998 to her death in June 2008 of acute leukemia.

Grady named to new bioethics role

Dr. Christine Grady has been named deputy chief of the Clinical Center’s Bioethics Department. While Bioethics Chief Dr. Ezekiel Emanuel is on an extended detail to the Office of Management and Budget, Grady is also serving as acting chief of the department. As special advisor to the director for health policy, Emanuel is working on a variety of health policy issues but mainly leading the Office of Management and Budget’s health-care reform efforts.

Grady joined the CC in 1983 as a clinical nurse specialist, focused primarily on HIV and other immunological and infectious diseases. After a few years as assistant director for clinical science at the National Institute of Nursing Research and earning a doctorate in philosophy, she returned to the CC to join the Bioethics Department, where she has served as the head of the Section on Human Subjects Research for the last 10 years. As a tenured scientist, Grady’s research areas include informed consent, subject recruitment, incentives, vulnerability, and international research ethics.

Ognibene assumes new role in education, partnerships

Dr. Frederick P. Ognibene has been named Clinical Center deputy director for educational affairs and strategic partnerships. Since May 2003, Ognibene had served as director of the CC Office of Clinical Research Training and Medical Education and maintains that role. Ognibene has worked with CC Director Dr. John I. Gallin to further the development and implementation of global training for clinical investigators in the principles of clinical research.

A graduate of Cornell University Medical College, Ognibene came to NIH in 1982 as a clinical fellow and later became a tenured member of the senior staff in the CC’s Critical Care Medicine Department, a position held until 2003. Ognibene was an active clinical investigator focusing on pulmonary complications of immunosuppressed patients. In 2007, he was president of the Society of Critical Care Medicine.
Recreation therapist named clinician of the year

Clinical Center recreation therapist Robin Greenfield was named Clinician of the Year by the American Therapeutic Recreation Association (ATRA) at its annual conference in Minneapolis in October 2009. With more than 24 years in the field, she returned to the NIH earlier in 2009 (after working for the CC from 1988 to 1997) following stints in Texas, Georgia, and Louisiana. She was nominated for her “ability to assess the patient thoroughly and accurately” and for “researching the appropriate intervention to use with the population she is going to serve in order to provide outcome-oriented interventions.” The ATRA Frank N. Brasile Clinician of the Year is given annually to one distinctive member of the association.

Goldspiel recognized

Dr. Barry Goldspiel, deputy chief of the Clinical Center Pharmacy Department, received the 2009 Hematology/Oncology Pharmacy Association Award of Excellence, the association’s highest honor. The award recognizes a HOPA member who has made a significant, sustained contribution to or provided excellent leadership in improving or supporting hematology/oncology pharmacy. Goldspiel was cited as “a recognized leader in oncology pharmacy who has created the opportunities for the profession to grow to meet the evolving needs of patient care.” HOPA 2008-2009 President Cindy O’Bryant presented Goldspiel’s award.

Platelet donor marks 400th draw

Robert Prior understands selflessness. “You can’t always take, you have to give sometimes,” Prior said while making his 400th donation to the NIH Blood Bank’s platelet center—a Blood Bank record. “I do it to give something back,” said Prior. “It makes me feel good to know I did what I can.”

Prior first donated blood to the American Red Cross as an 18-year-old volunteer firefighter. He started making platelet donations at NIH in 1978 every Saturday. He now makes the trip from his home in Fairfax, Va., once a month. Platelets are colorless, clotting agents that travel in a person’s blood. Patients with diseases such as aplastic anemia or who are undergoing cancer treatment cannot produce their own platelets. His commitment to being a donor was strengthened 20 years ago when his son was diagnosed with Wilms’ tumor. “I realized how much he was depending on other people,” Prior said.

Robert Prior (second from left) of Fairfax, Va., was honored with a plaque commemorating his 400th platelet donation to the NIH Blood Bank on Feb. 23, 2009. He has given at least once a month since 1978. With him are (from left) Dr. Susan Leitman, chief of Blood Services, and Blood Bank employees Janet Miranda, Phyllis Byrne, Zulida Rached, Janeen Thomas-Sanders, Rosella Freeman, Hal Wilkins, and Juan Salgado. “Next visit I’ll be starting my next 400,” he quipped.
First fellows graduate

The Clinical Center Nursing and Patient Care Services Neuropsychiatry Nurse Fellowship Program graduated its first class in August 2009. Program coordinator Julie Kohn and Dr. Clare Hastings, chief of Nursing and Patient Care Services, presented eight nurses with a certificate of completion. Offering congratulations were leaders of the programs the graduating nurses serve—Dr. Maryland Pao, clinical director of the National Institute of Mental Health; Dr. David Ted George, chief of the National Institute on Alcohol Abuse and Alcoholism’s Section of Clinical Assessment and Treatment Evaluation; and Bruce Steakley, nurse manager of the Child and Adolescent Psychiatric-Mental Health Research Unit and the Psychiatric-Mental Health Outpatient Research Program. George instructed the class to overcome the “boring routines, the busyness, the hierarchies” by serving a greater purpose. “We all deal with everyday-ness,” he said. “Get a mission. Have a focus—something you’re driving toward. Number one should be patient care.”

Book collection spotlights NIH authors

A display outside the medical board room on the fourth floor of the Hatfield Building showcases a sampling of textbooks recently published by intramural clinician-scientists at NIH. Rachael Schacherer, special assistant to the NIH CC chief financial officer, reviews some of the literature in the collection.
Presidential management, administrative fellows flourish at the Clinical Center

Management guru Peter Drucker once said, “Management is doing things right; leadership is doing the right things.” Learning to be a good manager is only the beginning for most Presidential Management Fellows (PMFs). As their careers progress, these motivated colleagues often stand out not only because of their management skills, but also because of their ability to lead.

The PMF program, sponsored by the Office of Personnel Management, aims to attract outstanding individuals into public service for a two-year, on-the-job training experience, preparing them to lead public programs and policy development. Individuals are eligible to apply for the program during their last year of graduate school. After two years of leadership training, mentoring, and rotational experiences around the federal government, PMFs will likely convert to permanent positions within their home agency. The Clinical Center offers rotational opportunities for PMFs and other administrative interns in a variety of assignments across the organization. Paired with CC mentors, the fellows complete a project within a three-to-six month rotational experience. Fellows are often drawn to rotations at the CC because, as one fellow put it, “its educated staff not only do things right; they’re also focused on doing the right things.”

In an effort to fuel a healthy pipeline of future leaders, the Clinical Center has attracted outstanding fellows to its ranks. Melissa Moore, chief of the CC Office of Management Analysis and Reporting (OMAR), began her government career in 2000 as a PMF who rotated with the Department of Health and Human Services budget office and various NIH institutes. Moore joined the CC Office of Financial Resources Management in 2002 after completing the program and later was selected to lead her current office when it was established.

Two recent PMF program graduates have joined the CC staff: Rebekah Geiger and Virginia Hill. Geiger came to the Clinical Center in 2008 as a special assistant to the chief operating officer, using her expertise in management analysis and project management to ensure the CC achieves its operational goals. Virginia Hill, who works at the special assistant to the deputy director for educational affairs and strategic partnerships, completed the program in August 2009 with a focus on communications and public affairs.

Another program that recruits enthusiastic candidates is the Administrative Fellows program. Tina Comissiong was a member of the program’s inaugural class and graduated in 2009. As an administrative officer, Comissiong provides vital managerial support to the CC office of Clinical Research Training and Medical Education and the Social Work Department. More information about NIH-supported internship programs is online, http://www.jobs.nih.gov/vacancies/student/default.htm.

Finding the balance

Female fellows gathered in the Clinical Center’s Duke Room last spring for a forum on work/life balance sponsored by the National Institute of Child Health and Human Development and the CC’s Office of Clinical Research Training and Medical Education.

Panelists Dr. Donna Krasnewich, National Human Genome Research Institute deputy clinical director; Dr. Tara Palmore, CC deputy hospital epidemiologist and associate director of the National Institute of Allergy and Infectious Disease’s Infectious Diseases Training Program; and Dr. Sara Spence, National Institute of Mental Health staff clinician, spoke on balancing career, social life, relationships, ambition, and family. Their reflections on moving up the academic and NIH ladders while maintaining sanity and stability at home helped the young researchers present for the forum. “We needed to hear how successful people manage a career and a home and social life,” said Dr. Radha Nandagopal, pediatric endocrine fellow and one of the event’s organizers.
First inductee to the Blood Donor Hall of Fame dies

The first inductee to the NIH Blood Donor Hall of Fame, Howard Drew, died April 15, 2009. Drew, who worked as a reference librarian at the National Library of Medicine, was named the Guinness world record holder for most blood donated in 2003—with 213 units, or about 28 gallons, to his credit. He was also the first to donate 100 times to the NIH Blood Bank. His first donation was made in 1943 while stationed in England with the US Army early in his 36-year military career. In 2000 Drew recorded a series of public service announcements on blood donation with Congress and the US Surgeon General.

“I believe in the importance of community service, and nothing is as fulfilling as saving lives by donating blood,” Drew, who lived in the District of Columbia, said in one announcement. Before his last donation on April 5, 2005, he tried to donate every two months. “Mr. Drew was committed to being on the front line in terms of saving lives, first with his heroic actions in the military service, and then continuing with his deep and passionate commitment to blood donation. He broke so many barriers and records in the process. The Department of Transfusion Medicine has lost a great friend and a wonderful human being,” said Dr. Susan Leitman, Blood Services Section chief.

CC staff honored with NIH Director’s Awards

Receiving a 2009 NIH Director’s Award were:

- **Denise Ford**, chief, Hospitality Services: Mentoring—for outstanding contributions as a mentor, teacher, and leader of employees and volunteers in support of excellent customer service across the CC.

- **Dr. James Shelhamer**, deputy chief, Critical Care Medicine Department: Scientific/Medical—for extraordinary contributions to the understanding of pulmonary physiology.

- **Dr. Robert Wesley**, chief, Biostatistics Service: Scientific/Medical—for extraordinary contributions to the design and analysis of clinical research projects.

- **Dr. David Henderson**, deputy director for clinical care: Administrative—for use of novel leadership strategies to facilitate high quality clinical research and for the application of epidemiological methods to enhance patient safety.

- **Karen Kaczorowski**, deputy chief nurse officer, Ambulatory Care Services: Administrative—for outstanding work on strategic initiatives.

- **CC Patient Travel Team (Maureen Gormley, John McKeepy, Dr. Adrienne Farrar, Kim Jarema, Karen Kaczorowski, Sydney Jones, Bridget Moore)**: for exceptional teamwork in creating a new administrative infrastructure to implement a uniform and equitable NIH patient travel policy.

- **NIDA RTX Development Project Members (Dr. Gopal Potti, Dr. George Grimes, Judith Starling, Dr. Andrew Mannes)**: for advancing resiniferatoxin to a successful IND approval, enabling its evaluation in clinical trials as a treatment for intractable pain.

- **Walter Jones**, lead for diversity management and minority outreach, Office of Clinical Research Training and Medical Education: as a member of the NIH Health Disparities Summit group for contributions in planning and coordinating the first NIH Summit: The Science of Eliminating Health Disparities.
Organization and Governance

ADVISORY BOARD FOR CLINICAL RESEARCH
NATIONAL INSTITUTES OF HEALTH (2009–2010)

Governance

The NIH Advisory Board for Clinical Research oversees the Clinical Center’s resources, planning, and operations. The Board also advises on NIH’s overall intramural program, including priority setting, the integration and implementation of research programs of the individual institutes and centers, and overall strategic planning for the intramural program.

Comprised of NIH clinical and scientific leaders and outside experts in management of health care and clinical research, the Board advises the NIH deputy director for intramural research and the Clinical Center director and reports to the NIH director.

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National Institute of Neurological Disorders and Stroke (NINDS)
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NIH Clinical Center (CC)