PROFILE 2008

DIRECTOR'S ANNUAL REPORT • NIH CLINICAL CENTER

There's no other hospital like it

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health


CLINICAL
CENTER

PROFILE 2008

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OUR VISION

The NIH Clinical Center will serve as the nation's premier research hospital for conducting clinical research to improve the health of humankind.

The Clinical Center will also serve as a national resource for clinical research by fostering dynamic interactions with outside partners; developing diagnostic and therapeutic interventions; enhancing systems to ensure the safe, efficient, and ethical conduct of clinical research; training clinical researchers; and leading the clinical research response to the nation's emerging public health needs.

OUR MISSION

As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates:

- Development of diagnostic and therapeutic interventions
- Training of clinical researchers
- Development of processes to ensure the safe, efficient, and ethical conduct of clinical research.

The Clinical Center achieves this mission through a culture that fosters collaboration, innovation, diversity, and the highest ethical standards.

STRENGTHENING FOUNDATIONS

The Clinical Center is a key resource in support of clinical research conducted at the National Institutes of Health in Bethesda, Maryland. It's also a unique resource. All patients volunteer to participate in clinical research protocols here. Nearly half of those protocols are natural history studies, most of which involve rare diseases. The majority of the clinical trials are the early phase 1 or 2 trials to evaluate the safety or effectiveness of a new drug or treatment.

Translating ideas from the laboratory into better health and health care has been the Clinical Center's focus since the facility was established as the nation's clinical research hospital in 1953. Over these decades, clinical research carried out here has bolstered the body of medical knowledge in incalculable ways. Our ability to create and maintain an environment that nurtures collaboration and innovation in medical discovery will help sustain future progress.

Strengthening our capability to help train the next generation of clinician-researchers in innovative ways is essential. Identifying and implementing new approaches in organizational efficiency and effectiveness are fundamental priorities.

The dedication and commitment of the Clinical Center team provide a strong foundation for the challenges and opportunities we face in 2008. Our patients, invaluable partners in medical discovery, look to you—and find—comfort, support, and hope.

John I. Gallin, MD
Director, NIH Clinical Center

In 2007 we:

- **Improved the environment** for Clinical Center patients, staff, and visitors through a renewed commitment to a smoke-free Clinical Center.
- **Enhanced services for patients** by introducing an online resource to provide feedback on services and implementing new approaches to minimize wait times for appointments and procedures.
- **Expanded CRIS,** the Clinical Research Information System, and retired MIS, the Medical Information System.
- **Improved the physical facility** and our ability to manage critical projects with the NIH Office of Research Facilities.
- **Opened the NIH Metabolic Clinical Research Unit** that will allow researchers to comprehensively study factors that contribute to obesity and associated diseases.
- **Made strides in our ability to benchmark costs** throughout the organization and use that information to more precisely manage resources and project resource use.
- **Merged training and education programs** from the NIH Office of Intramural Research and the Clinical Center to form an expanded CC Office of Clinical Research Training and Medical Education.
- **Explored the role of the Clinical Center** with colleagues and collaborators throughout NIH and through the Clinical and Translational Science Award network, culminating in a mid-year mini-retreat of NIH institute directors to define options.
- **Conducted a review of the Bench-to-Bedside program,** begun in 1999, resulting in a renewed commitment to fostering these projects.

There's no other hospital like it

PROACTIVE ENFORCEMENT CLEARS THE AIR

For the Clinical Center, it was a collective New Year's Resolution—a renewed commitment to a smoke-free Clinical Center.

"Our patients, staff and visitors want and deserve this," said Dr. John I. Gallin, CC director, in announcing an initiative to eliminate smoking in and around building 10 on Jan. 2, 2007, through proactive enforcement of no-smoking policies. "The work conducted here is dedicated to improving the health of the nation, but I receive numerous complaints from individuals exposed to second-hand smoke, especially at hospital entrances. This is a problem we can fix together."

Smoking is not permitted inside any NIH building. At the Clinical Center, it's also prohibited within 100 feet of any entrance and anywhere between the north entrance of the Hatfield Center and Center Drive, including the stairways to the Children's Inn.

New signs help ensure that no-smoking areas are clearly identified. Red house-shaped posters throughout the CC serve as reminders. A CC-hired security guard monitors the outside no-smoking areas and—when appropriate—offers information about smoking cessation. The NIH police continue to monitor inside areas, including underground garages and stairwells.

NEW STANDARDS GUIDE PATIENT CARE

The Medical Executive Committee (MEC) has issued *Standards for Patient Care at the NIH Clinical Center* to address essential principles and processes concerning the clinical care of the volunteers who participate in clinical research here and to foster commitment to excellence in patient care. The standards offer guidance on objective measurement of medical staff competence, preadmission planning, multidisciplinary patient care, and the importance of clear and timely communication with referring physicians. Dr. Richard Cannon, National Heart, Lung, and Blood Institute clinical director and former MEC chair, coordinated the preparation of the standards. The standards are online, along with *Guidelines for the Conduct of Research in the Intramural Research Program at NIH* and *A Guide to Training and Mentoring in the Intramural Research Program at NIH*, http://www.cc.nih. gov/ccc/patientcare/summary.shtml.

CC food service worker Andre Russell delivers a tray including several items on the new menu (at left), including a tortilla-crusted tilapia with chipotle and lime, brown rice, steamed vegetable blend, spinach salad, and a seasonal fruit plate.

PHYSICAL ENVIRONMENT IMPROVEMENTS

Enchanced oversight. A new position created in the NIH Office of Research Facilities—chief of the hospital physical environment—will bring greater responsiveness and flexibility in ensuring that the hospital space meets life-safety requirements set by the Joint Commission. This new position, which also focuses on building-related construction and maintenance, will report to both the director of the Clinical Center and to the director of NIH research facilities.

Atrium project. Glass partitions and stainless steel mesh now surround the Hatfield building's atrium on all levels. The architects who designed the building worked with CC staff and stakeholders to design the alteration, which was added as a safety precaution. The final result allows critical air flow and preserves transparency throughout the atrium's dramatic open spaces.

Clinic work. Renovations and realignments of the outpatient clinics moved forward in 2007. First to undergo transformation, which includes increasing the number of exam and patient consultation rooms, was outpatient clinic 11. The former surgical intensive care unit, 2J, has been refurbished to serve as clinic space as areas are shut down to accommodate the work. Also scheduled for renovations are outpatient clinics 1, 5, 12, and 13. Remaining clinics (3, 4, 7, 8, 9, and 10) will be spruced up with new paint, flooring and ceilings, along with new furniture for the waiting rooms.

NUTRITION DEPARTMENT UPGRADES PATIENT MENUS, ROOM SERVICE ORDERING SYSTEM

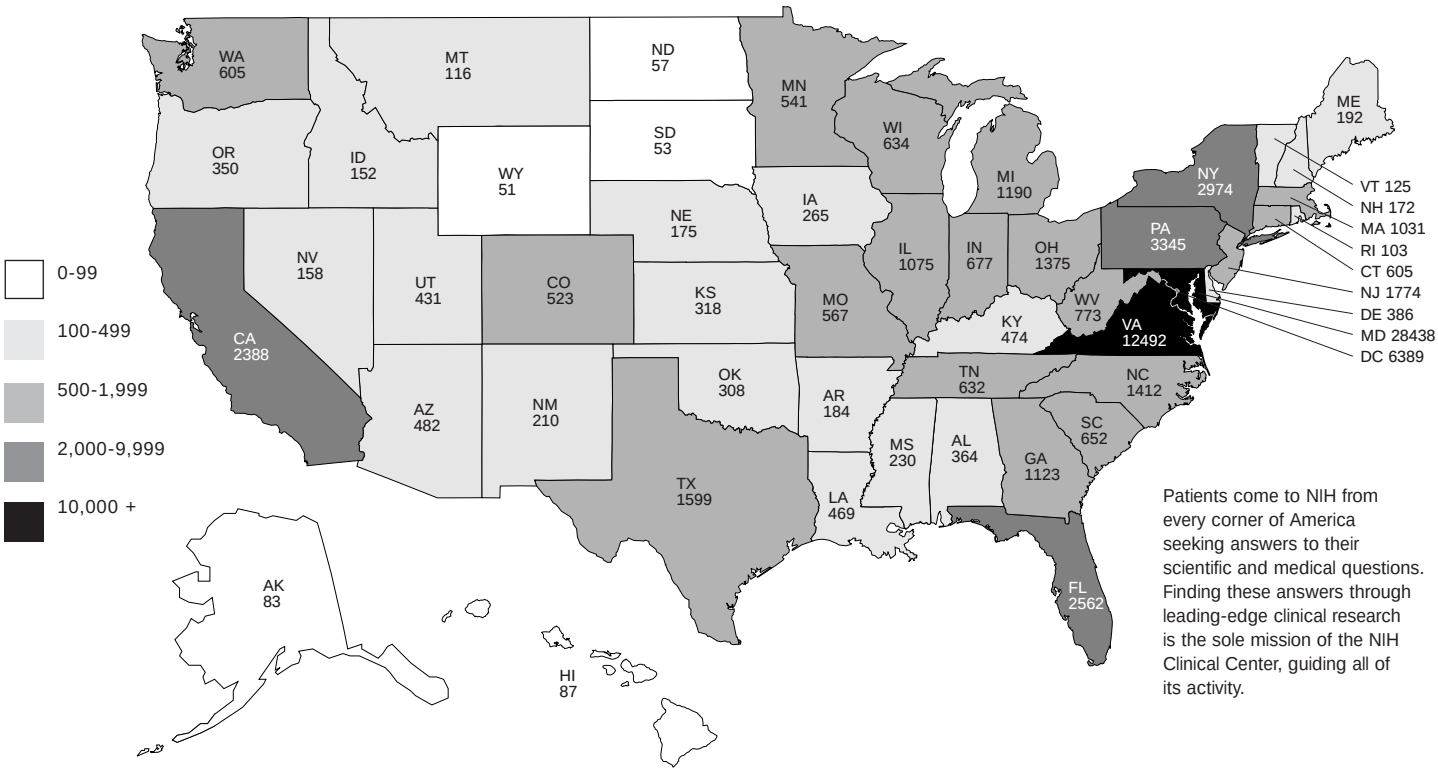
Clinical Center patients had 60 more food items to choose from when the Nutrition Department introduced its revised standard room service dining menu in June. The new selections offer more vegetarian and whole grain items. The menus also upgrade the quality of several foods, including soups and cheeses; expand selections of herbal teas and baked potato toppings; and list flavors available for ice cream, popsicles, and gelatin. This is the second major redesign of the room service menu system since 2002.

The project involved a great deal of behind-the-scenes work, such as tasting items, comparing ingredients and cost, coding each offering according to compliance with different diets, and training cooks and call center technicians.

David Folio, chief of the Nutrition Department, said ideas for the new menu were gathered from a variety of sources, including patient surveys, meal rounds by department staff, and feedback by the Patient Advisory Group and clinical dietitians. Incoming patients find the new standard menu on tray tables in their rooms. The Housekeeping and Fabric Care Department places a menu when a room is cleaned after a patient is discharged.

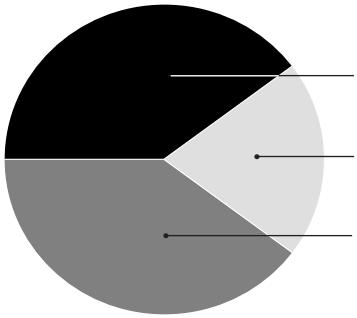
The department redesigned its 30 specialized printed menus to make them physically larger with a larger type size and a more spacious layout. The CC offers more than 160 different diets. Nutrition's computer system coordinates them and makes the room service program possible.

HOME STATES OF ALL ACTIVE CLINICAL CENTER PATIENTS



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.

WORKFORCE DISTRIBUTION



Nursing & patient care/support services 41%

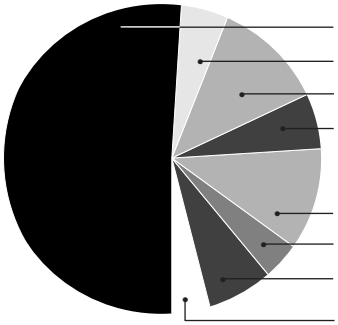
Administrative & operations 19%

Clinical departments & imaging sciences departments 40%

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

FY2007 BUDGET BY MAJOR CATEGORY

$344.8 million



Salaries and benefits 51%

NIH assessments 5%

Drugs 12%

Contracts (labor) 6%

Contracts (non-labor) 11%

Equipment 4%

Supplies 7%

All other 4%

(Includes travel, training, rentals, and printing.)

PATIENT ACTIVITY

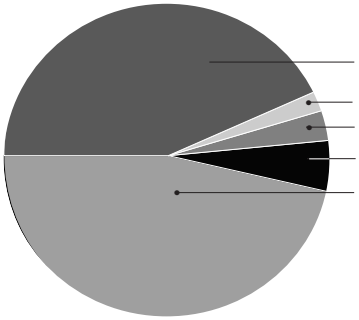
Admissions	05	6,619	4.7% decrease
	06	6,096	7.9% decrease
	07	5,825	4.4% decrease
New patients	05	9,711	9.5% decrease
	06	9,263	4.6% decrease
	07	9,435	1.9% increase
Inpatient days	05	57,718	0.1% decrease
	06	51,575	10.6% decrease
	07	51,189	0.7% decrease
Average length of stay (days)	05	8.8	3.5% increase
	06	8.3	5.7% decrease
	07	8.6	3.7% increase
Outpatient visits	05	105,004	2.8% decrease
	06	95,151	9.4% decrease
	07	90,889	4.5% decrease

CLINICAL ACTIVITY FOR FY 2001–2007

Active Protocols	01	1,122
	02	1,165
	03	1,239
	04	1,329
	05	1,357
	06	1,372
	07	1.390
New Protocols	01	250
	02	305
	03	306
	04	288
	05	245
	06	251
	07	227
Principal Investigators	01	417
	02	437
	03	450
	04	474
	05	487
	06	505
	07	484

PROTOCOLS BY RESEARCH TYPE

(onsite intramural protocols, fiscal year 2007)



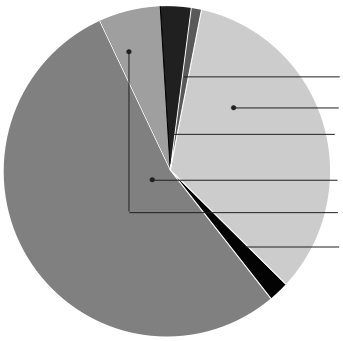
Total active protocols: 1,390

Clinical trials: 605 (43%)
Training: 31 (2%)
Sample data analysis 39 (3%)
Screening: 68 (5%)
Natural history (disease pathogenesis): 642 (46%)

(Five 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 healthcare professionals to follow particular types of patients.

Breakdown of clinical trials



Total clinical trials: 605

Phase 0: 6 (>1%)
Phase I: 204 (34%)
Phase I-2: 15 (2%)
Phase 2: 323 (53%)
Phase 3: 38 (6%)
Phase 4 19 (3%)

Clinical trials proceed through four phases

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.

IMAGING IMPROVEMENTS

Installation of three new MRIs in Diagnostic Radiology in early May signaled a major milestone in a multi-year project to enhance the department's physical space and technological capability. Clustering the MRIs on the first floor of the Magnuson building will centralize MRI clinical research in one section, facilitating sharing of tools and exchange of information. This clustering helps limit the need for costly new steel shielding, extra structural fortification, and potential displacement of other functioning units. It also will be easier to replace equipment in future upgrades.

These MRIs—weighing 10,000 pounds each—arrived in an elaborate logistical ballet involving a team of more than 20 from NIH and the manufacturer. Special permits and road closures were required for travel to campus. Once here, the eight-foot-tall MRIs were painstakingly maneuvered and rotated through the CC's seven-foot-tall doors and ceilings, requiring even temporary relocations of walls.

The children's playground and ground-level glass door passageway on the west side of the Hatfield building were closed for a few days in late September during the preparation for and delivery of a new PET trace cyclotron to the Clinical Center. At 28 tons, the new computer-controlled cyclotron weighs about half as much as the manually operated one it replaced. It is identical to a machine installed in 2002 and complements the remaining large CS-30 cyclotron installed in 1985. Staff conducted soil compression tests to ensure that the soil between the playground and the CC could support the weight of the crane and the trucks that would move the machines. The new cyclotron arrived on three tractor trailers. A 300-ton crane lifted out the old cyclotron and lowered in the new one.

The NIH Clinical Center created the Bench-to-Bedside awards program in 1999 to speed translation of promising laboratory discoveries into new medical treatments by encouraging collaborations among basic scientists and clinical investigators. The program has been open to research teams made up of intramural and extramural partners for two years and in 2007 a comprehensive review of the program was completed.

Teams	Project
RARE DISEASES	
NHLBI, CC, INOVA Fairfax Hospital	• Antiproliferative Therapy for Severe Pulmonary Arterial Hypertension
NICHD, University of Oxford (UK)	• Characterization of Glycosphingolipid Accumulation in Smith-Lemli-Opitz Syndrome and Treatment with N-butyldsoxynojirimycin
NHLBI, CC, University of Maryland	• Life-Threatening Pulmonary Complications of Organ Transplantation: An Investigation of the Pathogenesis of Bronchiolitis Obliterans and Its Novel Treatment with Aerosolized Liposomal Cyclosporine A
NIAID, Uniformed Services University of the Health Sciences, NCI, NHGRI, CC, University of California, San Francisco	• Role of Pathogen-specific IgE and histamine release in the hyper-IgE syndrome
NICHD, NEI, NIDCR, NIMH, NIDDK, Georgetown University Medical Center, Uniformed Services University of the Health Sciences	• WAGR Syndrome: Clinical Characterization and Correlation with Genotype
NHLBI, NCI, University of Virginia	• Sensitivity and resistance to Rituximab therapy in SLL/CLL: the role of antigenic modulation, immune effector mechanisms and direct pro-apoptotic signaling
NINDS, University of Pennsylvania	• Quantification of urinary oxidized lipids, 8-hydroxyguanine, and 8-hydroxy-2'-deoxyguanosine in Friedreich ataxia patients undergoing idebenone treatment in a phase II double-blind placebo-controlled study
NINDS, NIDDK	• Translational Studies of Hereditary Spastic Paraplegias types SPG4 and SPG20
NICHD, Cleveland Clinic Genomic Medicine Institute	• Genetics of inherited paragangliomas and gastric stromal tumors associated with adrenal and other tumors
GENERAL CATEGORY	
NCI, Hackensack University Medical Center	• Dynamic Measurement and modeling of Immune Homeostasis and Reconstitution in Pre-clinical and Clinical Studies of Cytokine Therapy and Allogeneic Hematopoietic Stem Cell Transplantation (AHSCT).
AIDS	
NIAID, CC, University of Toronto, George Washington University	• Intensification of Antiretroviral Therapy Using HIV Integrase Inhibitor (MK-0518) to Assess Decay of Viral Reservoirs in Peripheral Blood and Gut-Associated Lymphoid Tissue of Chronically Infected Patients
NIDCR, CC	• Humoral Response Profiling of Viral and Cellular Tumor Antigens for Predicting, Diagnosing, and Monitoring HIV Malignancies
NIAID, CC, Massachusetts General Hospital	• 1H Magnetic Resonance Spectroscopy for Quantification of Hepatic Triglyceride Content: Validation and Application in HIV-infected Patients
NIAID, University of Washington	• Development of Immunotoxins against Kaposi's Sarcoma Associated Herpesvirus for Treatment of Multicentric Castleman's Disease (MCD)
MINORITY HEALTH & HEALTH DISPARITIES CATEGORY	
NIDDK, UCLA	• Effects of Beta Cell Rest in Young Individuals with Type 2 Diabetes and in Relevant Animal Model
NHLBI, Johns Hopkins University	• Identification of Predictive Biomarkers of Asthma Exacerbations in Exhaled Breath Condensates from High Risk Patients
NIDDK, NHLBI, Harvard School of Public Health	• Ethnic Differences in Triglyceride Levels and Vascular Disease: A Study of Premenopausal African American and Caucasian Women
NHLBI, CC	• Contribution of Stromal Free Hemoglobin, Red Cell Membranes, and Red Cell Lysate on Nitric Oxide Inactivation in the Chronic Hemolytic State
WOMEN'S HEALTH CATEGORY	
NCI, Gynecologic Oncology Group, University of Miami, University of Oklahoma	• Targeting HPV E2 as a vaccine against HPV mediated CIN1 and CIN2

At the opening ceremony were (left to right) National Institute of Diabetes and Digestive and Kidney Diseases Director Dr. Griffin Rodgers; CC Director Dr. John I. Gallin; NIDDK Scientific Director Dr. Marvin Gershengorn; Dr. Monica Skarulis, director of NIDDK's metabolic research core; NIH Deputy Director for Intramural Research Dr. Michael Gottesman; and NIH Director Dr. Elias Zerhouni.

The new NIH Metabolic Clinical Research Unit, which houses specialized, state-of-the-art facilities for comprehensive research on factors driving obesity, opened with a ribbon-cutting ceremony in January 2007. The unit's fifth floor facility includes ten private inpatient rooms, a metabolic kitchen, an exercise room, specialized vending machines, and a communal dining area. The design of each inpatient room on the unit took into account the needs of the patient volunteers, with specially reinforced construction, amenities, and equipment. The metabolic kitchen allows dietitians to precisely control and analyze the composition of patient meals to calculate the exact nutrients consumed.

Exercise testing equipment, physical activity monitors, and body composition measurement tools are key resources for clinical research protocols. The fitness equipment, including a treadmill and stationary upright and recumbent bikes, allows researchers to conduct stress and pulmonary function tests to observe the effects of exercise on weight loss. Three "Rapid Response Respiratory Suites," located on the seventh floor, allow researchers to measure volunteer's energy metabolism over 24 hours using non-invasive means and compare comprehensive physiological measurements. By analyzing air composition in the suite, researchers will be able to determine how much energy on a minute-to-minute basis a volunteer burns while sleeping, eating, or exercising, and whether the energy comes from carbohydrate, protein, or fat. The metabolic suites also feature custom-designed vacuum-sealed portholes, or "isolette systems," through which measured food and other items can be passed and blood samples taken without disrupting physiological measurements.

Vaccine research capability

As part of an ongoing collaboration with the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, design and construction began in 2007 on a new outpatient vaccine facility. Also in 2007, work began on a special inpatient clinical studies unit. When completed, the components will house the Vaccine Research Center's clinical vaccine testing clinic within the CC and be available to other NIH clinical programs involving testing of novel vaccine candidates. The facility also will provide additional capability for containment of infectious diseases.

Primary investigator Dr. Leslie Biesecker (left) and Flavia Facio, genetic counselor and lead associate investigator, meet with patient volunteer Alan Freeman, who is participating in the ClinSeq clinical trial.

Human genome sequencing study enrolls first patient at CC

Alan Freeman, a 48-year-old electric utility company employee from Silver Spring, in early 2007 became the first of 1,000 participants to enroll in a study led by the National Human Genome Research Institute to test the use of human genome sequencing in a clinical research setting. The investigation—dubbed the ClinSeq study—uses high-throughput DNA sequencing to determine whether tiny changes in selected genes may indicate predisposition to or onset of common diseases. Initially, the study will focus on the 200 to 400 genes connected to coronary heart disease and will follow participants for as many as 10 years.

"My family has lost some to heart attacks," Freeman said, noting that he was told about the study by his cardiologist, whom he was seeing for a heart checkup prompted by some undiagnosed chest pains. Study goals include detecting genetic changes that increase the risk for cardiovascular disease, developing the process by which genomic sequencing can be used as part of medical care, and assessing whether participants want to learn genetic information and how they respond to this information.

The study also explores the use of large-scale genome sequencing, a tool once reserved for basic bench research, as a potential test that clinical researchers can use with their patients. Participants also receive education about understanding and interpreting genotype information. Although the researchers will monitor some indicators of participant's interest in genetic test data and their responses to those data, the study primarily focuses on clinical research application of sequencing technology—not behavior.

Dr. Leslie Biesecker, chief of the genetic disease research branch at NHGRI, conducts the ClinSeq study with a team of NIH researchers. "ClinSeq is the first study in which results from high-throughput sequencing will be communicated back to individual patients," he said. Collaborators include researchers from the CC, National Heart, Lung, and Blood Institute, the National Institute of Biomedical Imaging and Bioengineering, and the NIH Intramural Sequencing Center.

Alan Remaley, an investigator in the CC Department of Laboratory Medicine who helped draft the gene list and design the study, is assisting with the study in two ways: performing the standard lab tests for coronary heart disease and conducting new serum tests for proposed coronary heart disease markers that will be banked for future studies. "This will probably be the most comprehensive study to sequence genes involving a complete DNA-sequencing approach for cardiovascular disease risk," Remaley said.

The study's first participant shares the researchers' curiosity and excitement. "I am by nature curious. I have been following human genome research because of my coronary problems and heart," Freeman said. "Just the fact that they can look at a gene and perhaps even treat you before a problem occurs—just the fact they are headed that way—fascinates me."

Virtual environment lab opens at the CC

The National Human Genome Research Institute's Immersive Virtual Environment Testing Area, located near the Occupational Medical Service's sixth floor clinic, opened in June to conduct the first of many social and behavioral research studies at the Clinical Center.

The concept of using virtual reality technology in research and health care is not new. But the research lab is the first facility to combine the two and ask questions about how to promote health, prevent disease, and improve health care, according to NHGRI staff.

Social and Behavioral Research Branch investigator Dr. Kim Kaphingst's protocol, "Using Virtual Reality to Test Communication Strategies for Genomic Concepts," will be the first study to use the new lab.

Study participants will be healthy adult volunteers without specialized genetics knowledge so that the study can see how the general public learns best about the topic. Each participant will answer an initial questionnaire, complete one 15-minute activity in the virtual arena, and then complete a test of how they remember the content that was presented or apply that material to new situations.

To preserve the integrity of the study, the investigators can't reveal the topics of the virtual reality environments, except to say that they deal with genetics. Participants will see the virtual environment through a headpiece and use a handheld pointer, which functions as an extension of the hand, to make selections in the computer-generated scenarios. An investigator in the room with the participant sees the images in the headpiece on a computer screen.

NHGRI plans future studies exploring how to teach genomic concepts, the understanding of disease risk, influences on physician-patient interactions in clinical environments, and the potential role of genetic information in improving clinical outcomes for people with stigmatized diseases, such as obesity.

NHGRI Social and Behavioral Research Branch staff scientist Dr. Susan Persky observes NHGRI scientific director Dr. Eric Green interacting in a virtual environment through a headpiece displaying computer-generated 3-D images and a handheld pointer.

CC neuroradiologist and lead study author Dr. John Butman.

CC imaging study focuses on von Hippel-Lindau patients' hearing

The results of an imaging study conducted at the Clinical Center could help doctors protect and preserve the hearing of people with the rare genetic disorder von Hippel-Lindau disease (VHL).

VHL causes the abnormal growth of benign and cancerous tumors in numerous parts of the body. This imaging study focused on endolymphatic sac tumors (ELSTs). The connection between ELSTs and hearing loss has been a curiosity because the endolympatic sac is on the temporal bone that contains the ear but is not part of the inner ear associated with hearing. Some cases of hearing loss in VHL can be attributed to large tumors on the sac that invade the hearing apparatus. But CC neuroradiologist and lead study author Dr. John Butman noticed, and set out to explain, why some patients lost hearing when they had only a very small tumor outside the sensory part of the ear.

He says he could see blood flowing from the endolymphatic sac into the inner ear in about half of the small tumors he imaged. Researchers then talked to patients to correlate the images with their symptoms. "It turned out virtually all patients who had evidence of bleeding had a sudden hearing loss," Butman explains. "For example, they were talking on the phone and suddenly their hearing went out, which is characteristic of a hemorrhage."

Other patients with small tumors experienced gradual hearing loss, but no bleeding. Butman says in those cases the ELST was disrupting the flow of fluids in the inner ear and causing and condition known as endolymphatic hydrops, which creates pressure, ringing in the ears, vertigo, and gradual hearing loss.

NINDS neurosurgeon Dr. Russell Lonser, senior author on the study, says the findings prompted a change in thinking about how to manage these tumors. Previous practice was a wait-and-see approach. Given that the tumors were benign, slow-growing, and their natural history was unknown, doctors monitored their growth and did not remove them until they became big enough to threaten hearing.

"It was believed these tumors probably would be best observed," Lonser says, "Now we believe they probably should be operated on very early on, as soon they are identified on imaging." Butman used CT imaging to study the bone and MR technology for the soft tissue and inner ear. He studied the inner ear with an imaging technique that is typically used for the brain to detect some of the cases of hemorrhage.

"Part of radiology is solving puzzles," Butman says. "Being able to figure out most of the story from imaging findings alone is very satisfying. Then having the clinical findings correlate so well with the imaging gives a sense of the solution to the puzzle. The fact that this has affected the thinking on how to manage patients is very nice."

Dr. Barbara Bryant gives Maureen McDonnell her pack of iron supplements when she comes to donate.

Iron-deficient NIH blood bank donors receive something extra

Some donors at the NIH blood bank are getting something extra at the end of their visit—a packet of oral iron supplements as part of a novel protocol.

Clinical Center researchers are giving iron supplements to donors with low iron and low hemoglobin levels. Researchers want to know if this could help treat and prevent iron deficiency in people who donate regularly or would like to donate regularly.

Dr. Barbara Bryant, a clinical fellow in the CC Department of Transfusion Medicine, is the principal investigator of the study known as IRON, which stands for Iron Replacement or Not. She says the NIH blood bank may be the only blood bank doing a large-scale study on iron replacement for donors.

"If we prove that iron replacement for donors can be done safely and efficiently in blood banks, it has the potential to increase the blood supply by decreasing the number of donors who are deferred," explains Bryant.

When people donate blood, they lose about one-quarter of the storage iron in their body. Some people rebuild their iron stores quickly, through diet, and are ready to donate again in about two months. But other people do not rebound as quickly. If people are iron depleted or deficient, it will show up during the donation screening process, when a fingerstick blood test is done to measure hemoglobin levels. People who do not meet the required hemoglobin level for giving blood are temporarily deferred from donating—sent home and told to come back and try again in a month or two.

At the NIH blood bank, people who do not pass hemoglobin screening are invited to talk with Bryant and colleagues about participating in her study. But before passing out iron pills, Bryant does an extensive screening questionnaire and more blood work to make sure there is no serious underlying problem causing the low hemoglobin levels. If nothing abnormal is found, people are then asked to be part of her protocol. Participants take supplements for 60 days, return for follow-up, and if they pass their hemoglobin screening, they are allowed to donate.

Maureen McDonnell, a management analyst in the CC Office of Organizational Development, says she had low hemoglobin during her three pregnancies so she was not surprised by her fingerstick test result at the NIH blood bank. She now is taking iron supplements as part of the study and says she is experiencing the benefits of the boost in iron. "I don't feel as tired mid-day. I am much more energetic. And, I've been able to donate again, so that feels good too."

Both men and women can become iron depleted or deficient. But Bryant says the problem is more common in women, particularly those who are pre-menopausal.

"I like studying blood," Bryant says of her career in blood banking, first as a technologist and now a clinician. She says having a good supply of blood is a huge challenge and deferring donors is frustrating to donors and blood centers. "The practice of giving iron replacement to donors is probably a good thing," Bryant says. "The blood banking community has acknowledged it, but nobody has had the resources to do this study. That's where we came in. This is a fabulous opportunity here at the NIH."

Hutchinson's cake reads "Happy 30th to Mr. H. and his virus." With him are (back row, from left) Dr. Barbara Rehermann, NIDDK; Dr. Harvey Alter, CC; Dr. T. Jake Liang, NIDDK; Dr. Robert Purcell, NIAID; Dr. Patrizia Farci, NIAID; and Dr. Susan Leitman, CC. In front are Kimiyo and William Hutchinson and Cathy Schechterly, CC.

Trailblazer marks 30 years as a hepatitis clinical research participant

July 25, 2007, was a milestone for William Hutchinson. It was about 30 years ago that he contracted hepatitis, beginning a unique clinical research relationship with scientists around the globe.

As result, he has contributed more than any other patient in the world to NIH researchers' understanding of the hepatitis C virus. Although Hutchinson has attended lectures at NIH where researchers with a technical interest in his blood convened, this was the first time that he met the researchers who had pored over his cells.

Hutchinson, now 90, thinks it was his career of international travel and diplomacy that prepared him for these past three decades of his life and the resulting renown among medical researchers across the globe. Before he retired in 1973, Hutchinson served as a public affairs officer for the U.S. government in countless countries. He estimates that he spent time in about 25 African countries, where he'd encounter indigenous infectious disease strains with every river and valley he crossed.

Unbeknownst to him, Hutchinson's immune system grew stronger and developed antibodies as he traveled the globe. "It did a remarkable job on my immune system to live in so many different places," Hutchinson said.

An avid hiker and mountain climber, Hutchinson first came to the NIH Clinical Center in April 1977 when he had a heart attack on a trail in New Hampshire. He received 18 units of blood following his open heart surgery, and one of them was contaminated with what is now called hepatitis C, then known only as non-A/non-B hepatitis. There was no way to screen the blood supply for hepatitis at that time, because no screening test existed. Although the virus remains in his bloodstream, Hutchinson has no symptoms related to the infection, and liver biopsies have shown that he has had no disease progression in 30 years. Hutchinson's immune system has contained the virus, but not eradicated it. Investigators continue to study this balance between virus and host.

Dr. Harvey Alter, chief of the CC Department of Transfusion Medicine's infectious disease section, said Hutchinson was the right patient at the right time in the right place. "Because he was being followed in an NIH protocol, we detected the onset of hepatitis very early in its course and obtained a plasma sample just when, as we later found, his virus was growing rapidly and was in its most infectious state," Alter said. Working closely with the lab of Dr. Robert Purcell in the National

Institute of Allergy and Infectious Diseases (NIAID), Alter divided the plasma into vials to determine the titer of the virus, estimate its size and density, show that it had a lipid envelope and physically characterize the virus even before researchers knew what it was. NIAID's Dr. Patrizia Farci cloned the Hutchinson (H) strain virus and demonstrated that his viral agent contained a large family of closely related viral variants, rather than a single agent, so that antibodies to the virus would not be able to contain all the variants present in his blood. Because of this unique characteristic of the H strain virus, it became the standard challenge dose for most subsequent studies of prototype hepatitis C vaccines and has been used to develop tissue culture models. "All this was possible because of Hutchinson's interest in science and his willingness to provide blood samples and to allow investigators to distribute them to laboratories throughout the world. Hutchinson's name is known throughout the global hepatitis community and we are all indebted to him," Alter said.

Hutchinson says he's pleased that his blood could be useful, even if his involvement with clinical research was mostly an accident. "If my blood saves even one life, that's good. If it saves more, so much the better."

The NIH researchers who gathered to meet Hutchinson assured him of how much they, and other hepatitis patients, have learned from him. Alter told Hutchinson that researchers are working with purified antibodies isolated from his blood to measure their ability to neutralize the virus and to see if these antibodies could be useful as a prototype therapeutic agent. The group presented Hutchinson with a framed aerial photo of NIH for his 30 years of participation in clinical research, as well as a letter that they all signed expressing their deep gratitude for "his selfless and unwavering willingness to be a research subject. His efforts have helped to diminish the risks and chronic consequences of this highly prevalent infection and to vastly improve the safety of the blood supply."

Dr. Alter received a 2000 Lasker Award for clinical medical research, an award he shares with Dr. Michael Houghton, a scientist with the Chiron Corporation. It recognizes Dr. Alter's ongoing studies to uncover the causes and reduce the risks of transfusion-associated hepatitis and Dr. Houghton's continuing work in molecular biology to isolate the virus, hepatitis C. Thirty years ago, Dr. Alter spearheaded a project at the NIH Clinical Center that created a storehouse of blood samples used to uncover the causes and reduce the risk of transfusion-associated hepatitis. Before this, about a third of transfused people received tainted blood, which later inflamed their livers, producing a condition known as hepatitis. Because of Dr. Alter's work, the U.S. instituted blood and donor screening programs that have served to increase the safety of the nation's blood supply.

Presidential visit

President George W. Bush visited the Clinical Center on Jan. 17. While here he met with staff and patients, including Dale Miller of Montana. During the visit, Bush's fifth to NIH, he said, "I love coming to the NIH. It is an amazing place because it is full of decent, caring, smart people, all aiming to save lives. And I truly believe the NIH is one of America's greatest assets. And it needs to be nourished." (White House photo by Eric Draper)

Tim Maloney and Susan Houston, Department of Clinical Research Informatics, stand behind a palette stacked with 128 disk drives from MIS.

MIS has left the building

The Clinical Center surplused the Medical Information System (MIS) mainframe in September. It had served the hospital since June 1976. The CC was the nation's fifth hospital to install the system and the first to configure and enhance it to support protocol-based clinical research. MIS allowed physician order entry, result reporting, medication administration, and nursing documentation long before others began using electronic medical records—and provided access to patient data at rates difficult to match even after 30 years.

CRIS, the Clinical Research Information System, replaced most of MIS in 2005, but MIS continued to be used for patient registration and for managing admission, discharge, and transfers until late in 2007.

Dr. Jon McKeeby, CC CIO, marked the historic transition by lauding the enduring efforts of Dr. Thomas Lewis—the "heart and soul of MIS" since the beginning. Lewis, former associate director of information systems and currently a consultant to the Department of Clinical Research Informatics, led the original MIS selection and implementation team.

"As you might imagine," said Lewis, "the step from a billing-oriented, community hospital to the complex research-oriented CC environment was large and with significant risk." It was a risk work taking. Lewis credits staff involved in clinical programs—even for brief periods—during MIS's lifespan who "worked hard to use, contribute to, critique, explore, and expand the use and advancement of information technology for better patient care and clinical research. This is a group of literally thousands of individuals, many of whom may not even realize how much they contributed, to patients, the CC, the NIH, and beyond."

CRIS I enhanced, CRIS II envisioned

Significant upgrades to the Clinical Research Information System in 2007 included the ability to use CRIS for physician progress notes, expanded capability for medical record documentation, and improvements to how clinical summaries can be viewed. Planning is under way for CRIS II, which will be a clinical research data repository comprising clinical and research information by patient, protocol or disease state. This resource will help identify promising new avenues for research and foster data sharing across institutes and with extramural collaborators. The Clinical Center created a new position to oversee CRIS II and, through a dual appointment with the National Library of Medicine, to guide development of an NIH intramural training program in medical informatics.

Dr. James J. Cimino has been named chief of this new Laboratory for Informatics Development. He comes to NIH from Columbia University where he was as professor of bioinformatics and medicine. (For more, **Go to:** page 34)

Clinical research & NIH on the web

The Clinical Center introduced a new Web site in 2007 that offers a broad overview of clinical research for the public. It includes options for participating, questions to ask if considering joining a trial, ethical issues to explore, and how to find out details on trials conducted at the Clinical Center and around the country.
Go to: http://clinicalresearch.nih.gov.

Joyce Bohn, who came from a family of 10 children and couldn't afford college, was one of several in the group who received a year of tuition at American University in exchange for her services as a healthy control subject. Bohn bonded so closely with her roommate, an osteoporosis patient, that she loaned Bohn all of her university expenses without interest so she could continue her studies and the two friends would not be separated. "My life changed tremendously because of NIH," Bohn said, wiping away her tears.

MENNONITE, BRETHREN HEALTHY VOLUNTEER GROUPS REUNITE

Eating only lima beans. Sleeping with weights on your eyes. Drinking a mixture of corn oil and skim milk. It might seem strange now, but these were some of the diets that a group of Mennonites and Church of the Brethren members who served as healthy volunteers consumed while participating in clinical research studies at the Clinical Center from 1954 to 1975. About 25 volunteers, together with their family members, reunited here on Sept. 8, 2007, and traced how their contributions decades ago changed the course of clinical research for the better.

The reunion, spearheaded by Dr. Jim Conrad, a member of the Mennonite Church from Perkasie, Pa., provided an opportunity for the group to reflect on their experiences as "creatures made in the image of God need to express God's love by how we live our lives." For these faith communities, service to those who are ill provides a powerful metaphor for assisting brothers and sisters in need by choosing "another way of living." Both groups are recognized peace churches affiliated with the National Service Board for Religious Objectors, now the Center on Conscience & War.

One of the volunteers recounted how his mother often said to him, "Someday you'll serve your country in the Brethren Volunteer Service (BVS) instead of the military." Local draft boards accepted boys' participation in public service projects in lieu of military service. Girls from both churches generally contributed one or two years to youth service activities, such as medical or social work.

CC Director Dr. John I. Gallin noted that like many of the researchers in his generation who joined the U.S. Public Health Service, healthy Mennonite and Brethren volunteers also share a commitment to "save life and not destroy it," to quote former president Franklin D. Roosevelt's 1940 NIH dedication speech. Although many came to the Public Health Service during the Vietnam War from 1959 to 1975, the Mennonite and Brethren volunteers came to NIH as early as the Korean War in 1954.

Mandy Jawara from the CC Office of Communications, Patient Recruitment & Public Liaison updated the group on the Clinical Research Volunteer Program, which began in 1954 as a collaboration between NIH and the Mennonite and Brethren church's service agencies, which in turn formed their own volunteer services. Until 2006, 50 to 100 students a year came to live at the CC while participating in clinical research and earning academic credit for their service. Jawara, who coordinates the program, said that although it has changed—healthy volunteer students no longer live on the patient care units—its mission of providing assistance to NIH investigators whose research involves healthy volunteers remains the same.

In his welcome to the group, Gallin described the numerous medical advances from CC history—none of which would have been possible without healthy volunteers' participation as control subjects. "We will never be able to thank you appropriately. Your contributions to society have been enormous," Gallin said. Dr. Allan Mirsky, National Institute of Mental Health, and Dr. Robert Shamburek, National Heart, Lung, and Blood Institute, detailed how the volunteers' participation in mental and cardiac health research has affected medical knowledge.

According to Mirsky, many volunteer control patients helped NIMH researchers to standardize tests of attention, in part by participating in a 1956 study that has been cited in the literature more than 1,000 times and led to the development of the continuous performance test (CPT).

Reunion participants look at photos and newspaper clips documenting their experiences as research volunteers.

Thanks to these volunteer control patients, NIMH researchers also compared psychological test performance in seizure disorder patients; described behavioral effects of the first effective anti-psychotic drugs used to treat schizophrenia; contrasted behavioral and physiological effects of anti-psychotic drugs and sedatives; contrasted effects of anti-psychotic drugs in healthy volunteers and patients; and described effects of stimulant drugs in healthy volunteers through sleep deprivation studies. Mirsky reminisced about coming to campus in the middle of the night to play billiards with a BVS volunteer who hadn't slept for 70 hours. "She couldn't do a CPT, but she could complete more challenging tests, including beating me at pool!"

Many cardiovascular and lipid concepts now taken for granted were major new findings from protocols in the 1960s. The NHLBI investigators leading protocols involving these volunteer control patients reads like a who's who list of leaders in the field of lipid research:

- Drs. Michael Brown and Joseph Goldstein, who won the 1985 Nobel Prize for their work with cholesterol that led to the development of statins;
- Eugene Braunwald, the first Heart Institute chief of cardiology, author of more than 1,000 publications, and editor of the definitive text, Braunwald's "Heart Disease;"
- Frederic Bartter, discoverer of five different metabolic syndromes; and
- Donald Fredrickson and Robert Levy, the first to describe the movement of HDL and LDL through the blood stream.

The Amish and Mennonite populations have the highest percentage of a rare genetic disorder called sitosterolemia, in which plant cholesterol becomes extremely high because the body is unable to excrete it into the bile for removal from the body. By observing volunteers from these communities, researchers developed drugs to block cholesterol's absorption in the intestines that are now used in millions of patients with ordinary cholesterol disorders. Marian Payne, a normal volunteer in 1956 who returned to the CC in the late 1990s as a sitosterolemia patient and participated in investigational treatments, said that if it wasn't for NIH's research, "I wouldn't be here today or be in the health I enjoy today."

Shamburek also unearthed hundreds of historic documents to show the group, including media coverage from the time, much of which brought exclamations from his audience as several people present recognized themselves. After tours of the new Hatfield Building, the group reconvened to tell stories of their experiences and pore over photos and articles brought to share with the group. Their recollections shared a common theme: how much their life changed as a result of coming to the CC. Carson Good discovered the social work profession, which became his career path, during his time at the CC. Two couples in the group—Marilyn and Dave Verbeck and George and Judy Reimer—met at the CC and married shortly after their time here.

The volunteers, all of whom were 18 years or older, many of them away from their rural community for the first time when they came to NIH, especially appreciated the exposure to diverse cultures in the Washington, DC, area that they enjoyed in their free time, such as attending Washington Senators baseball games, boating on the Potomac, or attending concerts and sporting events. One participant said, "The culture and social learning we received while at NIH molded our lives to this very day."

ASTUTE CLINICAN LECTURER
A NOTED HEMATOLOGIST

"Harnessing the power of the scientific method to promote health and alleviate suffering from disease is humankind's proudest achievement," said Dr. Barry Coller, vice president for medical affairs at the Rockefeller University, in presenting 2007's Astute Clinician Lecture at the Clinical Center in November.

"What excites me about translational research," he added, "is the ability to unite humanism and science in the service of medicine." The title of his lecture, "From the Rivers of Babylon to the Coronary Blood Stream," is taken from Psalm 137, an apt reference to a rare platelet disorder—Glanzmann thrombasthenia—that helped trigged his interest in cardiovascular research.

The rivers of Babylon refer to an area near modern-day Baghdad where, in ancient times, captives from Jerusalem were held. Over the centuries, members of this Jewish community in Iraq intermarried, which ultimately led to a high frequency of the recessive disorder. It affects about one person in a million and involves lifelong excessive bleeding. Clinical observations have contributed to the development of therapeutic and diagnostic strategies for coronary artery disease, one of the most common causes of death in the world. Coller studied a defect in these patients' platelets that affects the platelets' ability to aggregate. Based on this knowledge, Coller's laboratory developed an antibody that blocks the ability of normal platelets to aggregate.

A derivative of that antibody (abciximab) received FDA approval in 1994 and has been used to treat more than two million patients worldwide to prevent complications of coronary interventions such as angioplasty and stent insertion. Treatment with abciximab prevents clots from forming in stents used to open the diseased arteries in patients with heart attacks. A recipient or co-recipient of 13 U.S. patents, Coller also developed an assay to assess platelet function and has received FDA approval to monitor antiplatelet therapy with aspirin and other agents.

Coller has received numerous awards, including the American Society of Hematology's Henry M. Stratton Medal and the Robert J. and Claire Pasarow Foundation Award for Cardiovascular Research in 2005. His antibody in 1995 was named best new therapeutic product by the Biotechnology Industry Organization and innovation of the year by Pharmazeutische Zeitung. In 1997 he was named inventor of the year by the New York Intellectual Property Law Association and received the International Society on Thrombosis and Haemostasis' distinguished career award.

Coller, who also serves as David Rockefeller Professor of Medicine, head of Laboratory of Blood and Vascular Biology, and physician-in-chief of the Rockefeller University Hospital, is a member of the Association of American Physicians, the Institute of Medicine of the National Academies, and the National Academy of Sciences. He is a Fellow of the New York Academy of Medicine, the American Association for the Advancement of Science, and the American Academy of Arts & Sciences, and a Master of the American College of Physicians. He has served as a member of National Heart, Lung, and Blood Institute's Board of Extramural Advisors and co-chair of NIH's Advisory Board for Clinical Research. He also worked at the Clinical Center from 1972 to 1976 in the Clinical Pathology Department's Hematology Service.

The Astute Clinician Lecture was established through a gift from the late Dr. Robert W. Miller and his wife, Haruko. It honors a U.S. scientist who has observed an unusual clinical occurrence, and by investigating it, has opened an important new avenue of research.

CLINICAL RESEARCH NURSING 2010

Nursing and Patient Care Services in 2007 launched a four-year strategic plan to strengthen nursing practice and expand contributions to clinical research at the Clinical Center. This plan—Clinical Research Nursing 2010—was guided by the vision that the Clinical Center will lead the nation in developing a specialty practice model for Clinical Research Nursing.

As part of the effort, teams addressed eight charter projects defined for 2007, each focusing on a key issue identified by clinical staff as a priority or through the Nursing operational review. The CRN 2010 Teams, as they came to be called, were launched in March and presented results and findings in December, including: confirmation and refinement of primary nursing as the Clinical Center's clinical research nursing model of care; delineation of outcomes and results from more than 20 evidence-based practice projects carried out in 2006 and 2007; pilot testing of a clinical research nursing intensity measurement tool in all clinical areas; proposal for a process and documentation tools to promote continuity across care settings; proposal of a framework and organizational structure to strengthen communication and education for research participants and their families; collaboration with nurses from the institutes with large numbers of nurses to define, categorize, and clarify the various roles nurses perform at the CC and throughout NIH in support of research; assessment and resolution of documentation of clinical and research activities in the Clinical Research Information System; and a proposal of structured approaches to improving consistency of communication and performance across all clinical care areas.

A critical success factor for CRN 2010 has been collaboration with clinical research nursing colleagues around the country, primarily those who were in leadership roles with the General Clinical Research Center / Clinical and Translational Science Awards (GCRC/CTSA) network.

Informal collaboration was formalized through the creation of the Clinical Research Nursing Consortium, which includes nurse leaders from the Clinical Center, GCRCs, CTSAs, academic centers (including those in England and Switzerland), and the National Center for Research Resources. The consortium's Think Tank met three times at Rockefeller University in New York City to draft ideas for a White Paper on the importance and role of nurses in clinical research and to create practice and management tools that support specialty development. Dr. Clare Hastings, Chief Nurse for the Clinical Center, has taken a leadership role in this group, and presented the specialty development work being done at the Clinical Center at the GCRC nurse manager meeting in March and the American Academy of Nursing meeting in November.

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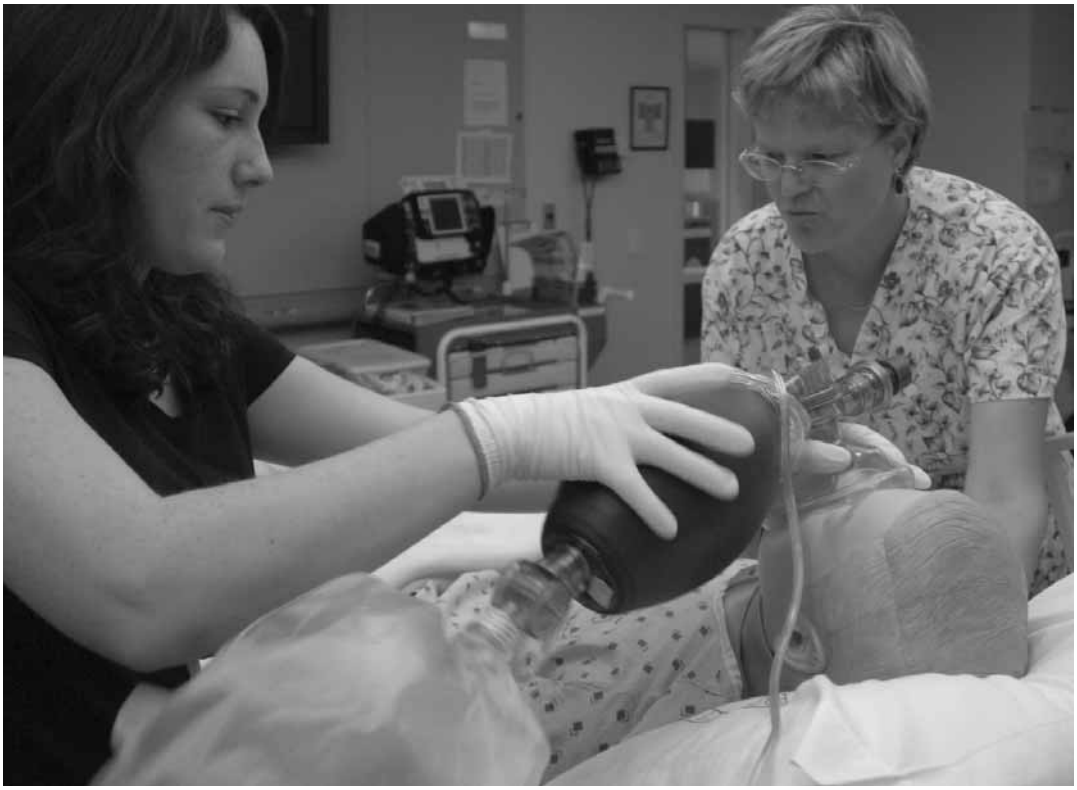
ICU CRIS TEAM WINS CC PATIENT SAFETY CHAMPION AWARD

The ICU CRIS interdisciplinary team on May 8 received the CC's third Patient Safety Champion Award, which is given annually to individuals or teams demonstrating a sustained commitment to a safe patient environment. The team, created in 2004, identified and implemented several initiatives to benefit patients in the ICU and throughout the CC. These included a CRIS medication start time alert; the ability to view results in some order forms to avoid duplicate blood draws; 18 computers on wheels for bedside nurse access to patient data; a critical care assessment flow sheet to standardize ICU patient information; and the ICU profiles and continuous venous-venous hemofiltration order sets.

ICU CRIS team members and additional ICU and CC staff at the award presentation included (Back row, from left): Brad Moriyama, Dr. James Shelhamer, Dr. Naomi O'Grady, Connie Kotefka, Dr. Peter Eichacker, Dr. David Vitberg, Deborah Kolakowski, Christine Callahan, CC Director Dr. John I. Gallin, Gina Ford, Susy Postal, Dr. Henry Masur, Dr. John Beigel, Carrie Patricola, and Lauren Stringi. (Front row, from left): Therese Kent, Nancy Ames, Pamela Horwitz, Parvin Safavi, and Gloria Cruz.

THE REAL THING?



Rose Simpson (left) and Wendy Moore, both clinical research nurses on 3NE, participate in a live-action scenario in the clinical simulation classroom, 4th floor of the Hatfield building. Critical Care Medicine launched the service, which features high-fidelity, full-body mannequin, more advanced than the basic models used for CPR training. It can simulate emergency events, such as a blocked airway, cardiac arrest, or internal bleeding after surgery. The mannequins can also be used to practice chest tube insertion, tracheostomies, and periocardiocentesis. The mannequin—called William Simman for a male patient or Wilma Simman for a female patient—can also be shocked and intubated and can produce a variety of life-like heart and breath sounds.

DATA TRANSFORMATION

The Departments of Laboratory Medicine and Social Work participated in a pilot project to improve the collection and automation of management data. The pilot phase and its follow-on projects involving other CC departments will yield a new structure to more precisely define and predict the costs of conducting clinical research, enable benchmarking of Clinical Center services that are similar to other hospitals, and delineate costs that are unique to a clinical research environment. CC managers and the NIH scientific community can use this information to make more informed decisions about directions for research and to identify efficiencies.

FIFTH CIST FORUM FOCUSES ON OPPORTUNITIES, INSIGHTS ABOUT CLINICAL RESEARCH CAREERS

Approximately 275 medical and dental students from across the country recently attended the fifth annual Clinical Investigator Student Trainee (CIST) Forum at NIH in November 2007. The forum is designed for students who are participating in clinical and research fellowships at academic medical centers and NIH and is structured to further engage and encourage them as they become the next generation of clinician-scientists. The two-day event included presentations by well-known researchers from inside and outside the NIH and gave students the opportunity to network with their peers and with established clinical investigators.

"You are the future physician-scientists," Dr. Michael Gottesman, NIH deputy director for intramural research, said in his welcome to the group. "We invited you here so we could get to know you and have you get to know us and each other. The people sitting next to you will review your papers and your grants and give you comments, so it's important for you to begin creating networks now." Dr. John I. Gallin, CC director, invited the students to tour the Clinical Center, "a gift that you as taxpayers and future clinical researchers, have all given to yourselves."

The breaks between presentations provided opportunities for students to get to know each other and share research interests.

A highlight of the program was a keynote address by NIAID Director Dr. Anthony S. Fauci. He said his undergraduate studies of the humanities including Greek philosophy, Latin, and French—with the minimum amount of pre-medical school courses—influenced how he thought about diseases and global health issues. Fauci said he was absolutely convinced that he wanted to return to New York to practice until he heard about the Public Health Service during a presentation on military service options given by a Marine captain. This brought him to NIH before the discovery of HIV/AIDS, the disease that would define his career. "Never in my wildest dreams would I have thought I would later be working for presidents and Congress," Fauci said.

According to Fauci, the "extraordinary payback" in scientific understanding, new treatments, and lives saved as a result of the funding and focus dedicated to HIV/AIDS is an excellent example of what is possible with a great investment in clinical research. He noted that there are currently 25 FDA-approved drugs for HIV/AIDS—more than the sum total of drugs for every other viral disease combined. Fauci asked, "If we put the money and focus into HIV/AIDS research, why can't we put it into other infectious diseases?"

Fauci advised students to think beyond publishing the next prestigious paper. "It takes a collective commitment from the scientific community. No one individual scientist can conduct the basic research, develop a useable product for people, and deliver it to those who really need it. At some point, you have to collaborate with colleagues in the biotechnology and pharmaceutical industries, but as those making the discoveries, you can have a say in how the treatments based on those advances are used."

Forum panels included updates in cardiovascular diseases, moderated by Dana Boyd, executive director of the Sarnoff Cardiovascular Research Foundation; practical tips for career development, including funding support, grants, and loan repayment, moderated by Gallin; and how to succeed

NIAID Director Dr. Anthony Fauci, who gave the keynote address at the fifth CIST forum, answers student questions after his lecture.

as a physician-scientist, moderated by Dr. Frederick P. Ognibene, director of the CC Office of Clinical Research Training and Medical Education and the lead organizer of this annual event.

This year the program expanded by inviting medical students from the Centers for Disease Control and Prevention Applied Epidemiology Program, the NIH MD/PhD Partnership Training Program, and institutions that have received NIH Clinical and Translational Science Awards. They joined participants from Howard Hughes Medical Institute-NIH Research Scholars and Fellows, Doris Duke Clinical Research Program Fellows, Fogarty International Clinical Research Scholars, NIH CRTP Fellows, and Sarnoff Cardiovascular Research Foundation Fellows.

OFFICE OF CLINICAL RESEARCH TRAINING AND MEDICAL EDUCATION:

The Clinical Center programs to train the next generation of clinical researchers continue to expand. Established in 2003, the Office of Clinical Research Training and Medical Education offers three courses (Introduction to the Principles and Practice of Clinical Research, Principles of Clinical Pharmacology, and the required Clinical Research Training for principal investigators) and manages the NIH-Duke program in clinical research leading to a Master's degree, Clinical Center Grand Rounds, and the Annual Clinical Fellows' Orientation. More than 25,000 students worldwide have participated in CC clinical research educational programs, most of which are online.

In 2007/2008, there are 836 enrollees (390 NIH/446 from remote sites) in the Introduction to the Principles and Practice of Clinical Research course and 596 enrollees (372 NIH/224 from remote sites) for the Principles of Clinical Pharmacology course.

In 2007, the Medical Education Program in the NIH Office of Intramural Research merged with the CC office. Responsibilities now include the Accreditation Council for Graduate Medical Education fellowships, the Clinical Research Training Program for medical and dental students, the Clinical Elective Program for medical and dental students, the Resident Elective Program, and Continuing Medical Education.

CLINICAL RESEARCH TRAINING PROGRAM 10-YEAR REUNION

Members of the Clinical Research Training Program class of 2005-2006 (from left) Alison Rager; Bryan Traughber; Ezinma Achebe; Mehrdad Alemozaffar; CRTP Director Dr. Frederick P. Ognibene; Tony Wang; NIH Director Dr. Elias Zerhouni; Obinna Emechebe-Kennedy; Clint Allen; Frank Hwang; Lan Chang; Richard Robison; and Veronique Nussenblatt.

"You are the people who will form the bridge and provide the most valuable part of translational medicine. You are the vanguard of innovation in health," said Dr. Elias Zerhouni, NIH director, speaking to alumni and current fellows in the NIH Clinical Research Training Program (CRTP). He presented the keynote address during a dinner that capped the program's 10th year reunion in March 2007.

"What is important in life is not what organization you belong to, but the values that you hold. If the values are there, things will happen," he said, expressing appreciation to the fellows for "translating their passion for clinical research, which is critical to the well-being of human kind, for the benefit of others in the world."

The program's strengths, Zerhouni said, include creating friendships and networks that will last a lifetime, uniting "like minds with like values coming together for something greater than themselves," and providing a "thinking space" with mentors and facilities to encourage scientific innovation. He advised the group to "remember key mentors" and to have the courage to take risks to follow their dreams. "You never know what turns your life will take, if you're willing to take a path that no one else will take."

During the reunion, current and alumni fellows heard updates on the clinical and translational research agendas from the directors of the CC, NIAID, NIDDK, NHGRI, NIMH and NCRR. Many alumni took to heart the quote NHGRI Director Dr. Francis Collins shared at the conclusion of his presentation: "As for the future, your task is not to foresee, but to enable it," he said, citing Antoine de Saint-Exupery.

Reflecting on how things have changed since the first class came to campus, Dr. John I. Gallin, CC director, traced Clinical Center accomplishments that have occurred since the birth of program, noting "this has been an era of extraordinary growth and transition." Milestones include celebration of the CC's 50th anniversary in 2003; opening of the new hospital, the Mark O. Hatfield Clinical Research Center, in 2004; and responses to the Katrina disaster in 2005.

During the alumni panel on career development post-CRTP, several speakers echoed stressed opportunities the program offers for professional growth. Dr. Lynn Henry (CRTP 1999-2000) said she came to the program thinking she wanted to work in infectious diseases. Exposure to various clinical and translational research opportunities as a fellow led her in a different direction. She's now a hematology/oncology fellow at the University of Michigan Comprehensive Cancer Center.

"I don't think I could have planned a more perfect route, and nine years ago I wouldn't have guessed that this would be my research," said Dr. Stacy Suskauer (CRTP 1998-1999), pediatric rehabilitation fellow at the Kennedy Krieger Institute and Johns Hopkins School of Medicine. "At some point, you have to bring up the younger generation of clinical researchers, which is why we

have this fabulous program," Dr. Stefan Weiss (CRTP 1999-2000), senior medical director at Connetics Corporation, said. Weiss described his "alternative track," beginning with work as a CRTP fellow with Dr. Ezekiel Emanuel, chief of the CC Bioethics Department, followed by specialization in dermatology and learning business development in the pharmaceutical industry.

Nine former CRTP fellows have returned or will return to NIH for additional fellowship programs, post-residency training in NCI, NINDS, NIAID, and the CC. Several fellows credited CRTP with helping them create contacts and networks that are still fruitful today. Dr. Jonathan Samuels (1997-1998), assistant attending physician and clinical instructor in medicine for the Division of Rheumatology at New York University Hospital for Joint Diseases, described a current collaboration with a colleague he met at NIH who is now in Oklahoma. Dr. Uri Lopatin (1997-1998), associate director, hepatology branch, Schering-Plough, called CRTP a "great learning experience with fabulous role models and mentors that creates a network of people," many of whom remain in contact years later. The experience is "very enabling for those who begin a very long, difficult road. It's an invaluable resource to have a community of peers. It's a wide, wide world full of really smart people who all have something to offer the clinical endeavor."

At the event's keynote dinner, The Honorable John E. Porter, vice chair of the board of directors for the Foundation for NIH, acknowledged the "risks and real sacrifices" made by the fellows to pursue their vocation of helping patients. "The Foundation for NIH takes pride in your persistence and the excellence of your work," Porter said, adding that scientists have the utmost of America's respect. Pfizer Chief Medical Officer Dr. Joseph Feczko praised the endurance and expansion of CRTP. "Seeing the success of this—where you've all ended up or are going—is a tremendous credit to you and to this program," Feczko said. The Foundation for NIH and Pfizer Inc sponsored the reunion.

PROGRAM HISTORY

Two hundred and twenty medical and dental students representing 68 schools have participated in the Clinical Research Training Program since it was established in 1997. Former NIH Director Dr. Harold Varmus instituted the program to provide creative, research-oriented students with an opportunity to become involved in clinical research early in their careers. According to Dr. Frederick P. Ognibene, director of the CC Office of Clinical Research Training and Medical Education and of CRTP, "During the CRTP year the students learn the principles of clinical research and conduct either clinical or translational research alongside energetic NIH investigators who serve as mentors. It's truly a life-changing experience that would be hard to replicate elsewhere."

Support from Pfizer Inc allowed the program to grow to 15 students annually starting with the 1998-1999 class. The company renewed its commitment four times, most recently in late 2006 for another three-year cycle. "The partnership between Pfizer and the Foundation extends back to 1998—nearly to the birth of the Foundation—and includes contributions, pledges, and in-kind gifts totaling $38.9 million, including $7.4 million in support of CRTP," said Amy McGuire, executive director of the Foundation for NIH. In 2004, the NIH Roadmap provided additional funds and allowed the program to increase in size from 15 to 30 students.

DISTINGUISHED CLINICAL TEACHER

Dr. Elaine Jaffe delivered the 2007 John Laws Decker Memorial Lecture in June. Named the NIH Fellows Committee's 2006 Distinguished Clinical Teacher—the highest honor bestowed collectively on an NIH senior clinician, staff clinician, or tenure/tenure-track clinical investigator by the NIH Clinical Fellows—Jaffe was invited to deliver the 2007 address.

Chief of the Hematopathology Section and acting chief of the Laboratory of Pathology at NCI's Center for Cancer Research, Jaffe came to NIH in 1970 as a resident in anatomic pathology and has been a senior investigator since 1974. Her current area of expertise is in the relationships between the immune system and malignant lymphomas and leukemia. In her lecture, Jaffe described how microscopy complements molecular diagnostic technologies and illustrated its role in describing Hodgkin's disease, anaplastic large cell lymphoma, and in situ follicular lymphoma. John Laws Decker began his career at NIH in 1965 as chief of the Arthritis and Rheumatism Branch, which is now NIAMS. He was director of the NIH Clinical Center from 1983 to 1990 and was named scientist emeritus.

MIRABAL SISTERS' MIDDLE SCHOOL STUDENTS EXPLORE CLINICAL CENTER

Middle school students from the Mirabal Sisters Campus, a community school operating in Harlem, New York, in collaboration with The Children's Aid Society, spent a May afternoon at the Clinical Center exploring some of the diagnostic and therapeutic tools available to clinical researchers. After a welcome and introduction from CC Director Dr. John I. Gallin, who compared the workings of a clinical research hospital to a city, the students participated in interactive presentations about DNA, science and probability, using virtual colonoscopy to find polyps, and laboratory medicine.

TAKE YOUR CHILD TO WORK DAY CONNECTS EARTH, HEALTH

NIH's combined Take Your Child to Work Day and Earth Day observances in April gave children and their grownups the opportunity to explore biomedical research, environmental awareness, and the connections between the two. Laetitia Sangwa and her brother Dan enjoyed looking through the microscopes in the CC's Department of Laboratory Medicine.

PHYSICAL THERAPY IN ACTION

About 70 seventh grade students from Roberto Clemente Middle School's math, science, and computer science magnet program in Germantown toured the Clinical Center's Rehabilitation Medicine Department in March. They learned about the role physical therapy plays in patient rehabilitation and clinical research. CC patient Bernadia Lovely (right) talked to the students, including Jamie Palmer, Victor Ying, Tiffany Le, Anika Jain, and Rakhee Jain, about her diagnosis with osteosarcoma, a pediatric cancer, and her experiences. Lovely, a college art major, wants to become a cartoonist and works with an art therapist to express herself during her treatment. She's also writing a book about her life, what she has learned, and how she has grown from her experience with cancer. "People think of having cancer as being the end of the world. But it's not."

SCIENCE FAIR WINNERS VISIT

The 12 winners of the Bushy Park Elementary School's science fair toured the Clinical Center on May 18. Dr. Gregory Kato, staff clinician in CC Critical Care Medicine Department and director of NHLBI's Sickle Cell Vascular Disease Unit, collaborated in judging the projects and hosted the students, who ranged in age from kindergarten through fifth grade.

NHLBI nurse Inez Ernst gave the young visitors toy stethoscopes to keep, taught them how to listen to their heart beats and demonstrated an echocardiogram. Joshua Joseph and Candice Bereal, Clinical Research Training Program medical students, showed the students a method of testing blood circulation in the forearm. Kato involved the students in microplate protein assays. Dr. Nalini Raghavachari of CCMD and the NHLBI Genomics Core Facility, assisted by NHLBI's Ronald Cooper, demonstrated gene expression microarray analysis and use of robotics.

The students learned about gait analysis in the CC Rehabilitation Medicine Department's Clinical Movement Analysis Laboratory from Physical Disabilities Branch members Alex Razzook and Dr. Saryn Goldberg.

International health leaders visit the CC and NIH

The ministers, secretaries, and commissioners of health from Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the European Union completed their eighth ministerial meeting—the first to be held in the US—of the Global Health Security Initiative (GHSI) in November. HHS was the official host, with most events occurring at NIH. During special tours of the Clinical Center, ministers and their staffs visited a patient room outfitted with supplies and equipment that typify components of the 250-bed contingency hospital housed at the CC.

Accommodating a surge in demand for medical services is the CC's primary role as a member of the NIH emergency preparedness partnership with Suburban Hospital, National Naval Medical Center, and National Library of Medicine. Dr. John I. Gallin, CC director, discussed the partnership and surge capability with attendees, including Roselyn Bachelot-Narquin, France's health minister (above right).

Created in 2001, GHSI is a partnership to strengthen public health preparedness and response globally to the threat of international chemical, biological, and radio-nuclear terrorism, as well as pandemic flu.

Chan elected to IOM

The Institute of Medicine elected Dr. Leighton Chan, chief of the Clinical Center Rehabilitation Medicine Department, as one of 65 new members in October.

IOM membership, now totaling 1,538, is considered one of the highest honors in the fields of medicine and health. The criteria for election are distinguished professional achievement in a field related to medicine and health; demonstrated and continued involvement with the issues of health care, prevention of disease, education, or research; skills and resources likely to contribute to the Institute's tasks of assessing current knowledge, conducting studies, and considering policy issues; and willingness to be an active IOM participant.

Unique for its structure as both an honorific membership and advisory organization, IOM was established in 1970 by the National Academy of Sciences and is recognized as a resource for independent, scientifically informed analysis and health recommendations. With their election, members make a commitment to devote a significant amount of volunteer time as members of IOM committees, which engage in a range of studies on health policy issues.

New chief, new lab

Dr. James J. Cimino has been named chief of the Clinical Center's new Laboratory for Informatics Development and will lead the development and implementation of CRIS II, a clinical research data repository. Through a dual appointment to the National Library of Medicine, Cimino will also spearhead development of an NIH intramural training program in medical informatics.

He comes to NIH from Columbia University where he was a professor of bioinformatics and medicine. Cimino's primary areas of research interests include medical concept representation and using it to support clinical decision-making. Since 1991, he has received significant grant support, primarily through the NLM, as principal investigator on projects to begin the development of the Unified Medical Language System (UMLS), a resource NLM says is to facilitate the development of computer systems that behave as if they "understand" the meaning of the language of biomedicine and health. His latest work involves infobuttons, which are automated, context-sensitive links inserted into clinical information systems to anticipate and resolve the information needs of clinicians as they provide patient care.

Cimino has been an active member of the NLM Board of Scientific Counselors, co-chair of the HL-7 Vocabulary Technical Committee, and on the board of the American Medical Informatics Association. He is currently an associate editor of the *Journal of Biomedical Informatics* and on the editorial board of *BioMed Central*. Cimino has published more than 250 peer-reviewed articles on medical informatics and is the co-editor of the leading text for medical informatics "Biomedical Informatics: Computer Applications in Health Care and Biomedicine," published in 2006.

A graduate of Brown University, Cimino earned the MD degree at New York Medical College. He interned and completed residency training in medicine at Saint Vincent's Hospital in New York. He went on to complete a research fellowship in medical informatics at Massachusetts General Hospital and in biostatistics at Harvard.

He is a fellow of the American College of Medical Informatics and the American College of Physicians. In 2006 he received the Medal of Honor from the New York Medical College and was elected to fellowship in the New York Academy of Medicine.

Two CC leaders head national societies
Dr. Frederick P. Ognibene (left), director of the CC Office of Clinical Research Training and Medical Education, became the 37th president of the Society of Critical Care Medicine (SCCM) in February 2007. With more than 13,000 members worldwide, the Society is the only professional organization devoted exclusively to the advancement of multi-professional intensive care through excellence in patient care, professional education, public education, research, and advocacy.

Dr. Henry Masur (right), chief of the CC Critical Care Medicine Department, is current president of Infectious Diseases Society of America (IDSA). IDSA represents about 8,000 infectious disease specialists and seeks to improve health by promoting excellence in infectious disease patient care, education, research, public health, and prevention.

Shirley Winford, Floride Canter, Harry Canter, and CC patient Clenton Winford visit over coffee and cookies from the Red Cross hospitality cart.

Long-time volunteers say good-bye

Clinic waiting rooms throughout the Clinical Center became a little quieter in November after Floride, Harry, and Susan Canter—a family that has given more than 25 years of service and friendship to CC patients and staff—spent their last day as volunteers.

Floride, American Red Cross chairwoman at the CC, served a continental breakfast to the phlebotomy patients each morning before making rounds with a hospitality cart. Her husband, Harry, a 14-year volunteer, worked at NIH for 43 years before retiring as chief of the research, analysis, and evaluation branch in NCI's Division of Extramural Activities. Their daughter Susan has volunteered at NIH for about 15 years.

"Very few people can greet anyone, anywhere better than Floride," Harry said. "She can open her heart to everyone. It's the best part of her personality." Monica Sullivan, a volunteer Spanish interpreter at the CC since 1988, agreed that Floride's friendliness and kindness are her greatest gifts to patients, volunteers, and staff. "She always has something nice to say about everybody and tries to help in any way possible."

Andrea Rander, director of volunteer services and language interpreters programs at the CC, called the Canters "the epitome of volunteerism" and an inspiration to her, as well as volunteers and staff. "I cannot convey enough thanks for all the hours they have devoted to our volunteer program: Floride more than 27,000; Harry 15,000. Rarely has either Floride or Harry said 'no' to any chore asked of them. They have passed along this spirit of service to their daughter Susan, who also added to the beauty of volunteer services at the Clinical Center. I will miss them individually and as a family. They are irreplaceable."

CC and Red Cross staff feel the same way. "I cannot imagine more generous people," said CC patient representative Laura Cearnal. "Perhaps even more important than the many services they've provided to CC patients and families is the spirit in which their service is offered. They approach every task with a can-do attitude and a willingness to do whatever it takes. They are an inspiration and so steady." The family has move to Harrisonburg, Va., where Floride and Harry grew up and met 60 years ago. When asked what they'll do in their new town, Floride immediately responds, "We're going to volunteer! Most likely at the new hospital."

Spiritual Ministry chief named

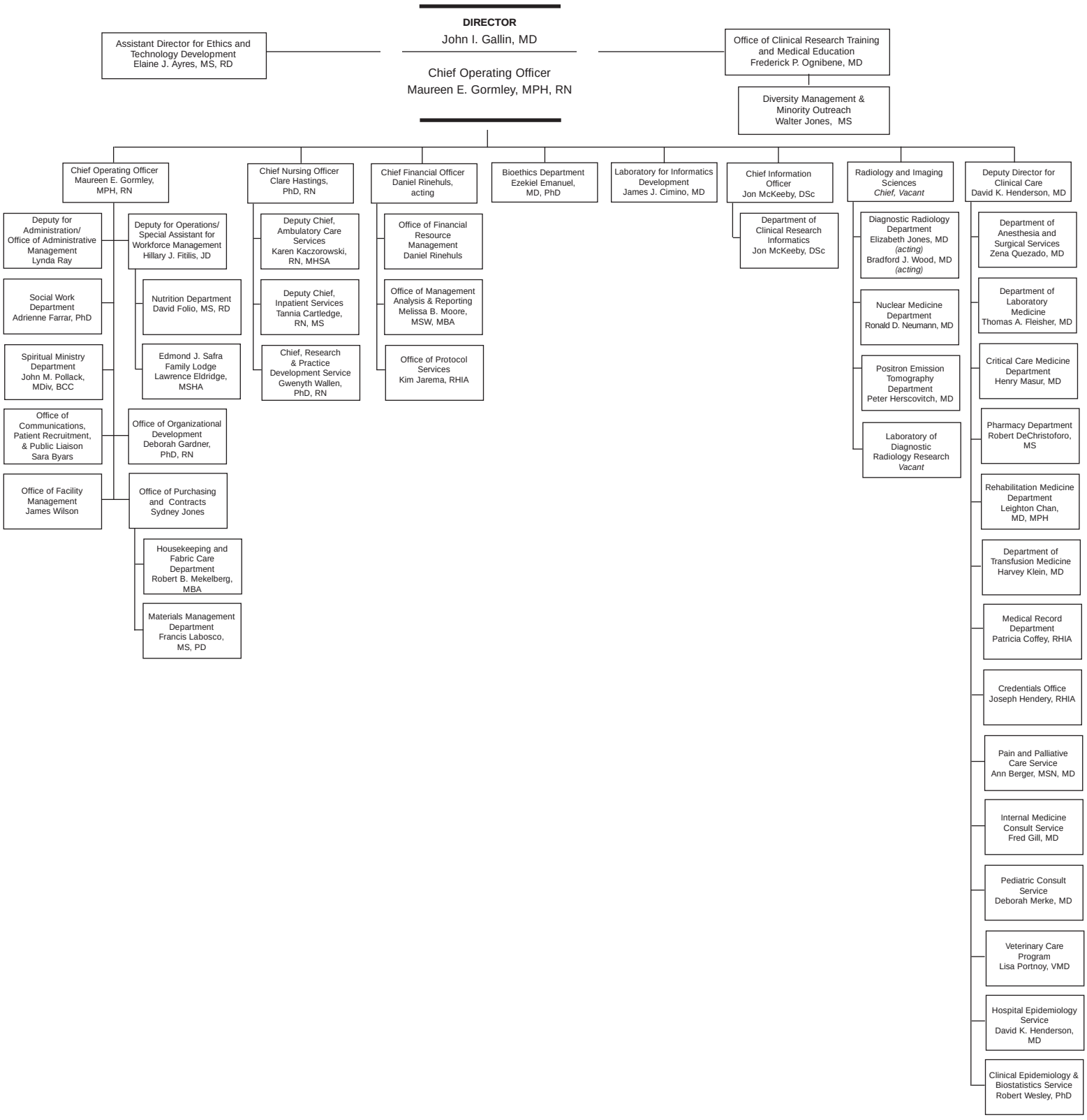
John M. Pollack has been named chief of the Spiritual Ministry Department. He had been director of Pastoral Care and Mission Operations at Holy Cross Hospital in Silver Spring, Maryland, where he served on the hospital's Ethical Advisory, Perinatal Ethics, and Ethics Education Committees. He has been active in Holy Cross Hospital's end-of-life care initiatives, including initial implementation of a hospital-based palliative care service and launching an annual conference series, "Conversations for the End-of-Life," which focused on issues of death and dying as they relate to various types of caregivers in the community. For several years he was staff chaplain for Holy Cross Home Care and Hospice, a community-based hospice program serving hospice patients and their families in Montgomery and Prince George's Counties.

Pollack holds a BS degree in accounting from the Pennsylvania State University and a master of divinity degree from the Union Theological Seminary in the City of New York. He completed chaplaincy training at Sibley Memorial Hospital and Georgetown University Medical Center in Washington, DC.

He is board certified as a chaplain through the National Association of Catholic Chaplains. As a member of the association he has been active in the chaplain certification process and recently joined their Board of Directors.

NIH CLINICAL CENTER

Organization Chart



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NATIONAL INSTITUTES OF HEALTH (2007–2008)

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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 a mixture 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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