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PROFILE 2007

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

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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. It will also serve as a national resource for clinical research by 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 the

- 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.

EXPANDED PARTNERSHIPS, NEW OPPORTUNITIES

The NIH Clinical Center offers an unparalleled environment for clinical and translational science through its unique complement of resources and expertise—in clinical care, research support, informatics, and clinical research training. Sharing that environment through extramural collaborations—new forms of partnership launched in 2006—offers exciting new opportunities to advance biomedical research.

For the first time, NIH's bench-to-bedside program, which is designed to speed the translation of promising laboratory discoveries into new medical treatments, was opened to research teams that included extramural collaborators from medical schools, health-care organizations, and private industry. All but one of the 19 projects that received funding involved extramural partners.

Through its national Clinical and Translational Science Awards (CTSA) consortium, NIH aims to transform how clinical and translational research is conducted. Clinical Center staff members are actively involved in this consortium, which will ultimately help accelerate the translation of new laboratory discoveries into better treatments for patients.

Clinical Center training programs in clinical research continue to attract participants from around the world. These programs are mission priorities because they help ensure that clinician-scientists have the knowledge and skill to conduct safe, effective, ethical, well-targeted research.

In 2006, the Clinical Center team successfully underwent its first JCAHO accreditation survey in our new hospital, the Mark O. Hatfield Clinical Research Center. The JCAHO surveyors arrived early on September 26, to conduct the first unannounced survey of the hospital. At the end of three days, we received an outstanding report. The surveyors were impressed with the excellent work our collaborative team does in a large and complex organization and noted the staff's palpable commitment to the Clinical Center's mission and to supporting each other. I commend and thank our staff for this sustained commitment to excellence.

I also thank the many employees, contractors, and volunteers who make the clinical research conducted at the Clinical Center a beacon of hope for people everywhere. As always, our most important partners in clinical research are the patient volunteers through whom we study various diseases and medical conditions and the healthy volunteers who serve as controls in those clinical studies. They not only make the research possible but also remind us of our mission to improve human health.

John I. Gallin, MD
Director, NIH Clinical Center

In 2006 we:

Expanded collaborations with partners outside NIH. The Clinical Center is sharing its unique resources and expertise with the extramural community by developing new programs and expanding old ones. In 2006, the NIH bench-to-bedside program, created at the Clinical Center in 1999, was extended to extramural collaborators for the first time.

Strengthened organizational effectiveness. Budget constraints over the last few years have challenged Clinical Center staff to do more with less. Several projects have focused on improving organizational operations and efficiency to meet the challenge head on, including a CC-wide benchmarking survey, creation of a think tank for more effective use of protocol resources, operational reviews (beginning with the imaging sciences and nursing departments), and specialized leadership training and consultation for managers and supervisors.

Successfully completed JCAHO survey. In September, a survey team from the Joint Commission on Accreditation of Healthcare Organizations arrived unannounced to conduct the Clinical Center's first accreditation survey since the new hospital opened. The JCAHO surveyors praised the excellent work our collaborative team does in a large and complex organization and our unwavering dedication to the Clinical Center's mission and support for each other.

Enhanced patient services. Easing and enriching the Clinical Center experience for patient volunteers, our invaluable partners in discovery, is always a high priority. In 2006, in response to suggestions from patients, the CC shortened wait times in the clinics, expanded patients' access to computers in the business center, and created a larger new space for the patient library.

Improved support for clinical research. The Clinical Center's legacy as a world center for medical advances continued in 2006. The new hospital, the Mark O. Hatfield Clinical Research Center, opened to patients in 2005, providing state-of-the-art technology in a healing environment designed for patient comfort. This year, the CC supported the implementation of new and expanded clinical research programs, including studies in obesity, vaccine development, and childhood autism.

IMPROVING THE PATIENT EXPERIENCE

Patients at the NIH Clinical Center are active partners in both clinical research and patient care. Improving their experiences here is a continuing priority. The Patient Advisory Group—all current or former patients or patient family members—provides important feedback on what works well for patients and what doesn't. In 2006, the Patient Advisory Group provided advice and feedback on relocating the patient library, shortening clinic wait times, improving room service menus, and making use of information technology easier—for example, by enhancing bedside access to computers and keeping the popular business center for patients and families open longer.

Several group members have represented the patient's perspective in at least two other Clinical Center venues. One member of the Patient Advisory Group participates in meetings of the NIH Advisory Board for Clinical Research. Patients' voices are also heard in two important Clinical Center courses: "Introduction to the Principles and Practice of Clinical Research" and "The Ethical and Regulatory Aspects of Clinical Research," bringing home to participants the practical realities of the patient's role in clinical research.

A focus for 2006 has been shortening waiting times for patients, an ongoing project led by Nursing and Patient Care Services. In a major shift—supported by a new computerized scheduling system—clinic patients were given specific appointment times, eliminating inefficient 'block' scheduling. Clinic staff are implementing changes and continuing to evaluate patient flow and identify areas for improvement. In mid-2006, they conducted a patient shadowing project, tracing the patient experience in an effort to pinpoint typical needs or problem points. Regular outpatient satisfaction surveys were re-instituted in 2006. These surveys, administered to a continuous sample of patients, help keep us informed about how patients regard Clinical Center services.

In 2006, Clinical Center design teams began planning for renovations in the outpatient clinics and a redesign of the ambulatory surgery suite. Work will be done to update clinic exam rooms, ensure space for confidential conferences between patients and care providers, and provide ample waiting areas.

NEW PATIENT LIBRARY

"It's a welcoming, light-filled environment for patients and their families," said Marie Kaplan, head librarian, describing the new seventh floor location for the patient library. "We're thrilled to be serving their information needs in this beautiful, spacious setting." The Patient Library, now 1,250 square feet, opened in October in room 7-1580. Also expanded were its hours—until 9 pm Monday through Thursday.

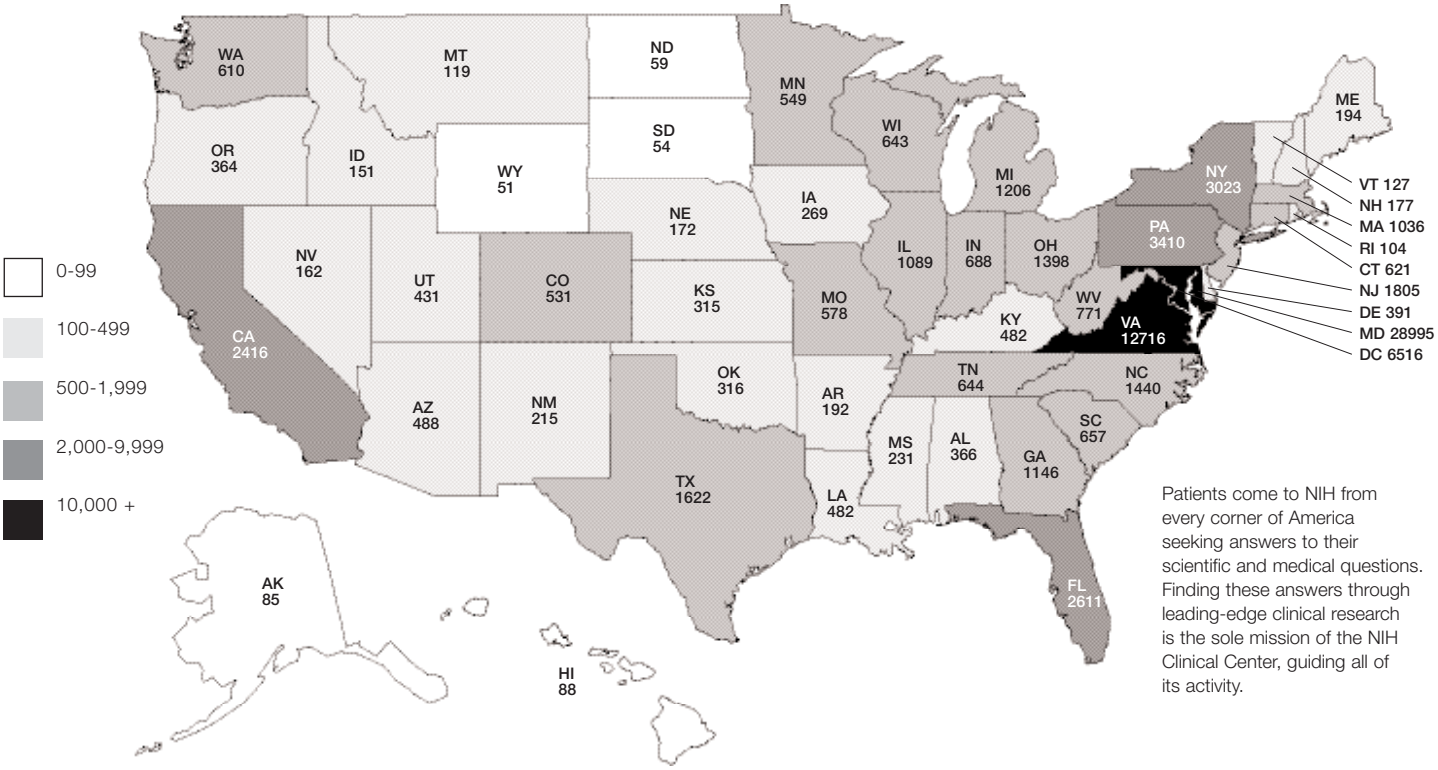
The library had been located in a smaller space on the same floor when patients moved to the Hatfield building in 2005—quarters that soon proved too cramped. "The Clinical Center's patient advisory group suggested that a new location was needed and worked with us as we explored options," said Dr. John I. Gallin, CC director. The fix was a simple space trade with other programs sponsored by the Rehabilitation Medicine Department.

Patients can browse the library's collection of 6,500 items in the sunny space in the northwest corner of the Hatfield building's top floor. The library will also continue its popular honor-return system, with books and magazines located in new shelving in the seating areas outside the library. These resources are available for patient access around the clock.

FOUR-LEGGED VISITORS PROVIDE MORE THAN JUST SMILES

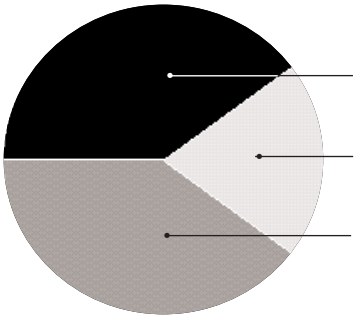
Pediatric patient Ana Lucia Garcia welcomes her four-legged visitor, Ross, and his handler, National Capital Therapy Dogs volunteer Barbara Murgo. Ross is one of more than a dozen dogs that visit patients here. The recreation therapy section of the Rehabilitation Medicine Department started an animal-assisted therapy program in 1989. In the beginning, the dogs came once a month and visited only pediatric patients. Now the dogs come once a week to visit units throughout the CC, averaging 1,200 visits a year.

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.

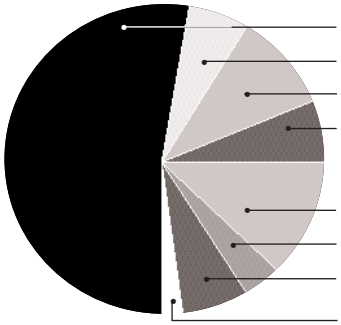
WORKFORCE DISTRIBUTION



The Clinical Center has a staff of approximately 2,000; 80% work with patients, as the graph shows. Another 20% work in administration and operations.

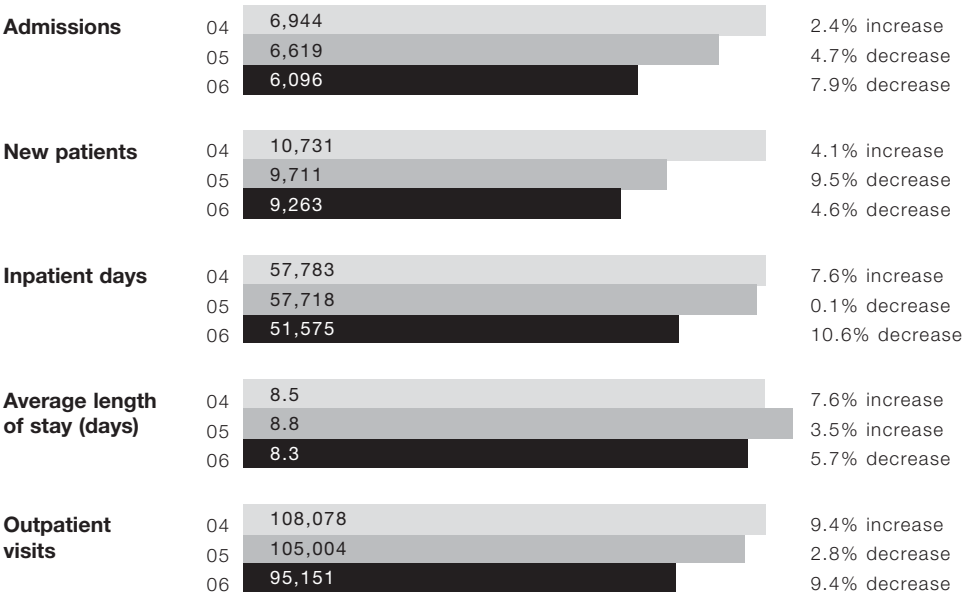
FY2006 BUDGET BY MAJOR CATEGORY

$335.9 million

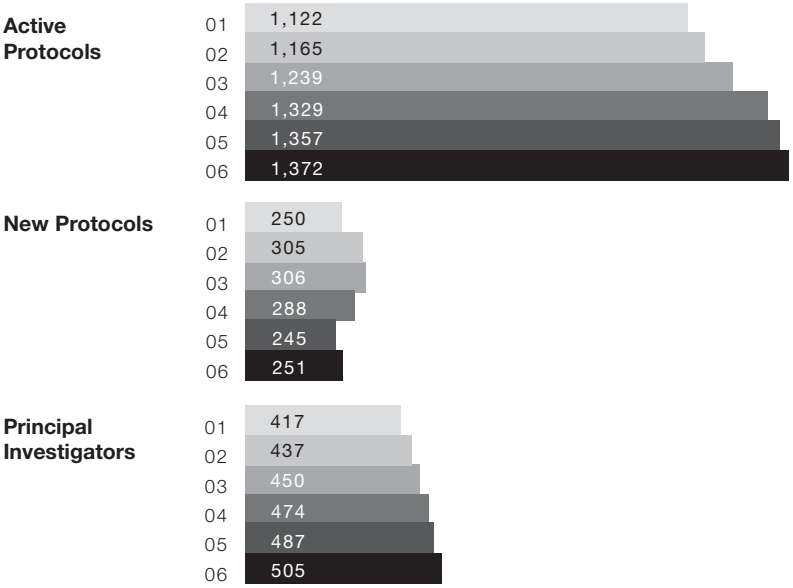


Includes travel, training, rentals, and printing.

PATIENT ACTIVITY



CLINICAL ACTIVITY FOR FY 2001–2006



SPECIAL CONCERT FOR SAFRA LODGE GUESTS

Marvin Hamlisch, principal pops conductor of the National Symphony Orchestra, offered a special holiday concert for patients and their loved ones at the Safra Family Lodge in December. Opera singer Angela M. Brown and trumpeter Brandon Ridenour also performed. All three were in town for a series of "Happy Holidays" concerts at the Kennedy Center. This was the second year Hamlisch put on a holiday show at the Lodge. "We look forward to coming here," he told the audience. "You are inspirational to us."

BEDSIDE COMPUTERS

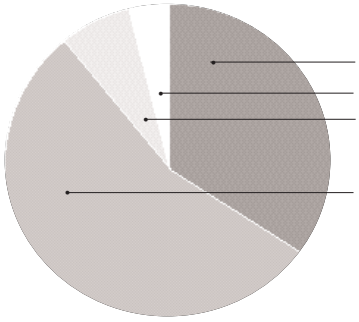
The patient portal on bedside computers and in outpatient areas provides an internet gateway to significant educational and informative resources for patients. Information presented covers important aspects of the patient care and research experiences and offers a variety of patient education materials, including collections developed specifically for Clinical Center patients and educational videos. The site includes an application that allows patients to develop Web pages to use to keep in touch with family members and loved ones while they are hospitalized.

LANGUAGE INTERPRETER INTERNS HELP BRIDGE LANGUAGE GAP

LCDR Stacy Barley, a clinical nurse, conducts an examination with the help of former CC interpreter José Rosado-Santiago and Alma Luisa Andrade, an intern with the CC Language Interpreters Program for spring 2006. The interns are part of a national program sponsored by the Hispanic Association of Colleges and Universities. One student is chosen for the CC program each fall and spring semester and summer break. The interns undergo specialized training and work with seasoned CC interpreters before working on their own. "My biggest challenge is understanding each situation and, optimally, each patient's disorder as well as possible treatments or procedures, risks, expected outcomes, and what the doctors wish to convey to the patients" said Andrade, a senior at the University of Arizona. Born in Mexico and raised in Tucson, Andrade is fluent in both Spanish and Portuguese.

PROTOCOLS BY RESEARCH TYPE

(onsite intramural protocols, fiscal year 2006)



Total active protocols: 1,372

Clinical trials: 602 (44%)

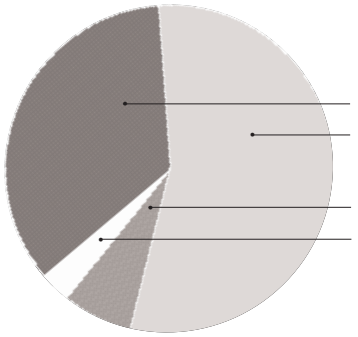
Training: 35 (3%)

Screening: 67 (5%)

Natural history (disease pathogenesis): 668 (48%)

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: 602

Phase I: 212 (35%)

Phase II: 330 (55%)

Phase III: 40 (7%)

Phase IV: 18 (3%)

Note: Two trials are Phase O.

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.

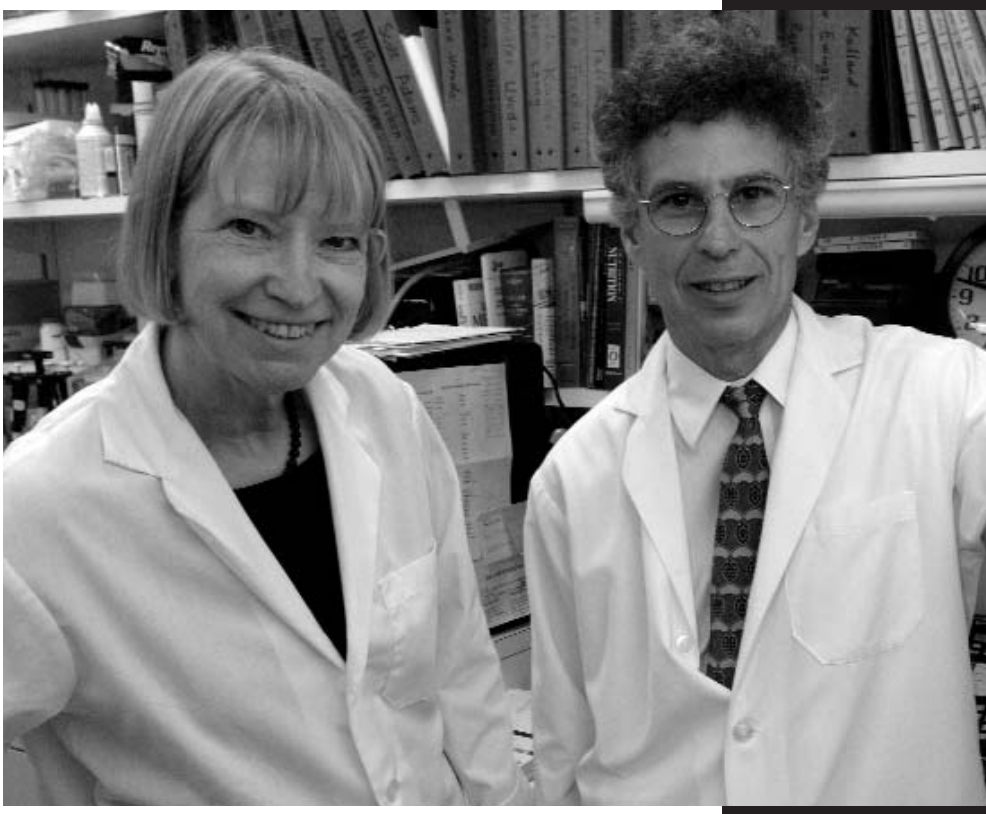
NIH EXPANDS BENCH-TO-BEDSIDE RESEARCH

NIH provided nearly $4 million in funding for 19 bench-to-bedside medical research projects in 2006. For the first time, applications for these awards were open to research teams partnering intramural NIH researchers with extramural collaborators from medical schools, health-care organizations, and private industry. All but one project included extramural partners; nine involved researchers from two or more NIH institutes or centers. First given in 1999, the bench-to-bedside awards were designed to speed the translation of promising laboratory discoveries into new medical treatments.

"The new bench-to-bedside awards program is a good example of NIH's commitment to transforming medicine through discovery," says Dr. Elias A. Zerhouni, NIH director. "It encourages innovative partnerships between extramural and intramural researchers and opens new opportunities for advancing medical science."

The bench-to-bedside research program was created within the Clinical Center to encourage collaborations between basic scientists in the laboratories and clinical investigators who work with patients, says Dr. John I. Gallin, CC director. "A hallmark of this program has been support for projects that involve partnerships between basic and clinical scientists from across institutes at NIH. The new component started this year profoundly expands the partnerships in medical research to other government and non-government scientists."

This is the first year projects were specifically funded in women's health and in minority health and health disparities. Selection criteria included the quality of the science, promise for becoming an active clinical trial, and potential for offering a new medical treatment or better understanding of an important disease process. Project teams receive up to $200,000 over two years to support their work.



Primary investigators
Dr. Maret G. Traber (left), Oregon State University, and Dr. Mark A. Levine (right), NIDDK, received a bench-to-bedside award for their research project on women's health, "Vitamin E Pharmacokinetics and Oxidative Biomarkers in Normal and Obese Women."

Teams	Project
RARE DISEASES	
NHLBI, NIH Clinical Center, Harvard University, Georgetown University Medical Center, National Naval Medical Center, Salisbury District Hospital, U.K.	• Role of Cyclin D1 in Myelodysplasia
NHLBI, NCI, NIH Clinical Center, Walter Reed Army Medical Center	• Exploring the Anti-Tumor Effects of *in vitro* Expanded Natural Killer (NK) Cells Against Renal Cell Carcinoma Sensitized to NK-TRAIL Cytotoxicity with Bortezomib
NHLBI, MD Anderson Cancer Center, NIDDK, Medical College of Virginia	• A New Global Function for a Rare Disease Gene: Clinical Significance of the Regulation of Mitochondrial Respiration by Tumor Suppressor p53 in Li-Fraumeni Syndrome
NCI, NHLBI, NINDS, Sloan-Kettering Cancer Center	• Therapeutic Approaches for Cancer Stem Cells in Small Cell Neuroendocrine Carcinomas
NCI, University of Southern California, the Barbara Ann Karmanos Cancer Center and Wayne State University, the Fred Hutchinson Cancer Research Center, University of Washington, Mayo Clinic College of Medicine	• High Density Genotyping in Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma – Translating Etiologic Clues into Prognostic Relevance Within the NCI-SEER NHL Case Control Study
NIH Clinical Center, NCI, University of Toronto/ Ontario Cancer Institute, University of Illinois	• Novel Suicide Gene-Modified Donor Th2 Cells for GVHD Prevention
NIDDK, NHLBI, University of Maryland	• A Nutrigenomics Intervention for the Study of the Role of Dietary Sitosterol on Lipid, Glucose and Energy Metabolism
NHLBI, NIH Clinical Center, NCI, NIDDK, Drexel University	• Pilot Trial of Intravenous Nitrite for Sickle Cell Vaso-Occlusive Pain Crisis
AIDS	
NIAID, St. Michael's Medical Center	• The Effect of HIV-1 Infection on Endogenous miRNA Expression *in vivo*
NCI, Johns Hopkins University, NIAID	• Genetic Characteristics of HIV-1 During Suppressive Antiretroviral Therapy
NIH Clinical Center, NCI, San Francisco General Hospital, Science Applications International Corporation, Mulago Hospital, Makerere University	• Evaluation of Molecular Methods for the Non-Invasive Diagnosis of Pneumocystis and Tuberculosis and Molecular Evaluation of Non-subtype B HIV Quasispecies in the Lung
NIDDK, Children's National Medical Center	• Microalbuminuria and Podocyturia in Patients with HIV disease: Detection, Characterization, and Therapy
MINORITY HEALTH AND HEALTH DISPARATIES	
NHLBI, NIH Clinical Center, Ahmadu Bello University Teaching Hospital, Nigeria	• Hemolysis, HIV/AIDS and Parasitic Infections Associated Secondary Pulmonary Arterial Hypertension in Sickle Cell Diseases
NIDA, University of Pennsylvania	• Novel Bench-to-Bedside Research Methods for Drug Addiction: Development, Validation and Application
NHGRI, Fred Hutchinson Cancer Research Center	• Breast Cancer Among African American Women: The role of Missense Changes in the BRCA1 and BRCA2 Breast Cancer Susceptibility Genes Using a Population-Based Approach
NICHD, NIDDK, University of Wisconsin	• Melanocortin 3 Receptor Mutations as an Etiology for Obesity in African American and Caucasian Children
WOMEN'S HEALTH	
NIDDK, Oregon State University	• Vitamin E Pharmacokinetics and Oxidative Biomarkers in Normal and Obese Women
GENERAL (INSTITUTE AND NCRR)	
NIDDK, Washington Hospital Center	• Immunosuppression Minimization by Biological Response Monitoring
NINDS, NEI, Johns Hopkins School of Medicine, University of Pennsylvania	• A Preliminary Assessment of the Use of Ocular Coherence Tomography and Magnetic Resonance Imaging as Outcome Measures for Studying the Optic Nerve in Studies of Neuroprotection in Multiple Sclerosis

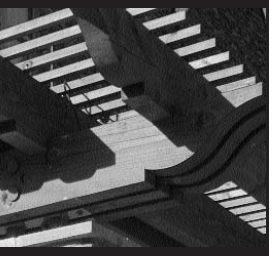
The state-of-the art NIH Metabolic Clinical Research Unit will allow researchers from across NIH to study factors that contribute to obesity and associated diseases. The unit is an important component of the NIH Strategic Plan for Obesity Research. The National Institute of Diabetes and Digestive and Kidney Diseases, working closely with the Clinical Center, led the effort to construct the unit. It's designed to bring together experts from the fields of metabolism, endocrinology, nutrition, cardiovascular biology, gastroenterology, hepatology, genetics, and the behavioral sciences.

Unit components are located on two floors of the Hatfield building. On the 5th floor are 10 inpatient rooms, a metabolic kitchen, an exercise room, and dining areas. The metabolic kitchen allows dietitians to precisely control the makeup of patient meals. Vending machines will be used in some studies to monitor aspects of food choice. The unit's three metabolic suites have been installed on the 7th floor. These self-contained suites allow researchers to study a patient's energy metabolism over the course of 24 hours using non-invasive and comprehensive physiological measurements.

NIDDK's Dr. Kong Chen (above), a biomedical engineer and a clinical investigator, makes sure that the unit's equipment is appropriately calibrated so that protocol-related physiological measurements are complete and precise. Exercise testing equipment, physical activity monitors, body composition measurement systems such as the Bod Pod and DXA, and the three metabolic suites are key resources for clinical research protocols.

Clinical Center research dietitians, including LT Merel Kozlosky (above) and LT Blakeley Denkinger (right), will play central roles in the studies conducted in the new unit. In the metabolic kitchen, cooks use highly controlled preparation techniques and precision weighing of portions for patient meals. Some studies involve offering patients an array of foods to help researchers determine how appetite is influenced by various factors. Foods offered via computerized research vending machines will help researchers track a variety of eating behaviors.

Patient rooms are designed for comfort and safety.



INFORMATION TECHNOLOGY ADVANCES

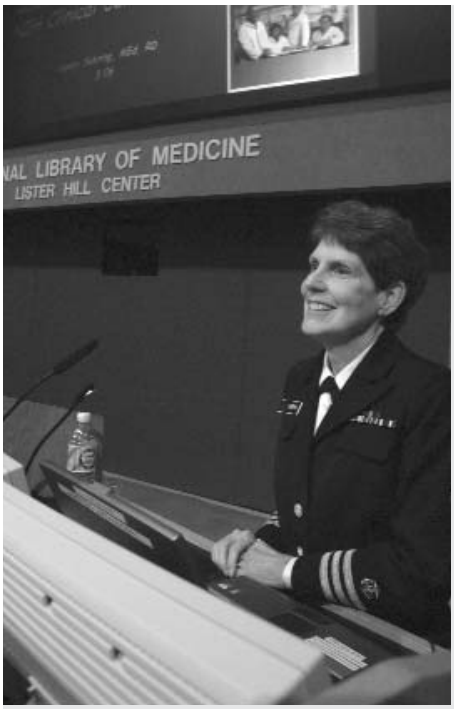
ProtoType. This Web-based clinical protocol writing tool provides investigators with a standard protocol structure, online help, and templates of suggested language. Investigators use it to put ideas for new protocols into the proper format to satisfy regulations and facilitate review. ProtoType's 2006 enhancements included a more intuitive user interface for protocol writing and a more complete consent-writing module. Several institutes use ProtoType and others are evaluating whether or not to mandate its use for all new protocols.

CRIS, the Clinical Research Information System implemented in 2004, continued to grow and evolve in 2006 to make sure it met user requirements, supported changing protocol needs, and accommodated the addition of interfaces from ancillary Clinical Center and institute systems. New components include a perioperative information system that automates surgical scheduling and facilitates documentation of human resources, equipment, and supplies used on scheduled procedures; a system for admissions/transfer/discharge, which handles new patient registrations and inpatient admissions; and enhancements of the clinical documentation and order entry functions. Work now under way on a pharmacy system will support the internal work of the Pharmacy Department.

The last module of the CRIS system is a "data mart," which will pool all of the data, text, and images from CRIS and make them available to clinical researchers via institute clinical research systems. CRIS allows access to information based on a single patient. The data mart will allow analysis of data from multiple patients across one protocol or many protocols, and will lay the foundation for a larger clinical research data warehouse.

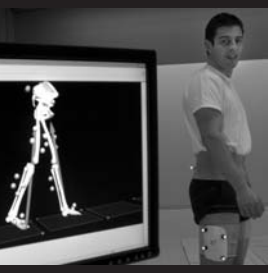
CELEBRATING NURSING SCIENCE

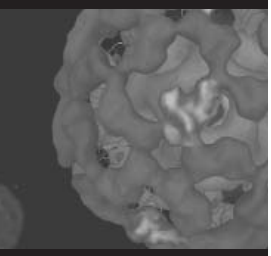
As part of the year-long celebration marking the 20th anniversary of the National Institute of Nursing Research, NINR and the Clinical Center's Nursing and Patient Care Services hosted the conference "Celebrating Nursing Science: The Research-Practice Link" on June 16 to mark achievements in clinical nursing research and their application to practice. Dr. Patricia Grady (left), director of NINR, and Dr. Clare Hastings (right), chief of CC Nursing and Patient Care Services, were on hand to introduce the event's keynote speaker—Dr. Christine Miaskowski, professor and chair of the Department of Physiological Nursing at the University of California, San Francisco, School of Nursing.



RESEARCH DIETITIANS

About 80 dietetic interns, registered dietitians, graduate students and nutrition professors gathered on the NIH campus on March 23 for Nutrition Research Day. Hosted by the CC Nutrition Department, the annual event brings area dietetic interns to NIH to introduce them to the world of federal nutrition research and—more specifically—to the role of research dietitians at the CC. This year, Research Day was coupled with the NCI Division of Cancer Prevention's weeklong nutrition practicum, which offered dietetic interns and visiting students and professors the opportunity to participate in an intense, five-day learning session and gain practical experience as part of their academic program. Among the speakers was CDR Nancy Sebring (left). Describing the research protocols and nutrition services provided at the CC, she gave students a glimpse into the daily life of a CC dietitian, describing how many of them split their time between patient care and research support. Other dietitians then described their involvement in research studies, including specific research diets and pediatric obesity protocols.





Dr. Deborah Merke (left) is able to see more patients like Zachary Ward because of foundation funding.

Grant to CC pediatric program will help expand congenital adrenal hyperplasia research

Two foundations are helping expand NIH research into congenital adrenal hyperplasia. Dr. Deborah Merke, chief of pediatric services for the CC, has received more funding for her natural history study of patients with the rare disease. The nonprofit Congenital Adrenal Hyperplasia Research Education and Support (CARES) Foundation began funding this research at the Clinical Center in 2005. An additional $50,000 grant from the family foundation Peregrine Charities will allow Merke to include nurse practitioner Carol Van Ryzin on the research team. "Having a nurse practitioner dedicated solely to this clinical research has been invaluable," says Merke. "It allows us to see more patients with congenital adrenal hyperplasia and to start new clinical research studies that otherwise would not have been possible."

Merke's study, sponsored by NICHD, will chronicle aspects of development over several years. Researchers want to learn which physiological processes are affected by the disease and why, to help scientists design treatments to address the underlying problems, not just symptoms. CARES funding has helped Merke see so many more patients (101 in a nine-month period) that she was able to expand the research and collaborate with other institutes.

Study finds potential marker to identify sickle cell patients at high risk for complications

Researchers studying sickle cell disease have found that an enzyme that can be measured by a simple blood test may help indicate whether a patient has a high risk of developing certain serious complications associated with the disease.

The study, led by researchers from CC and NHLBI, say the enzyme lactate dehydrogenase (LDH) appears to hold promise in patients with sickle cell disease as a marker for risk of pulmonary hypertension and other complications, including early death. Pulmonary hypertension—abnormally high blood pressure in the lungs—is common in sickle cell disease.

"Our findings suggest that patients with sickle cell disease and high LDH levels should have especially careful monitoring for pulmonary hypertension, a life-threatening complication," says Dr. Gregory Kato, a clinician in the CC Department of Critical Care Medicine and director of the Sickle Cell Vascular Disease Unit in the NHLBI Vascular Medicine Branch.

A hereditary blood disorder, sickle cell disease in the United States is most prevalent in blacks. An abnormal type of hemoglobin inside red blood cells distorts their shape and interferes with blood flow. The enzyme LDH investigated in the study is found throughout the body, especially in red blood cells, the heart, liver, lungs, and muscle. A blood test measuring LDH levels is readily available and commonly used to determine tissue damage, whatever the cause.

Researchers at the Children's Hospital and Research Center in Oakland, California, and the University of Pittsburgh School of Medicine participated in this study.

NIH researchers examine drug interaction that may increase bone damage risk in HIV patients

A study led by Dr. Scott Penzak, CC pharmacist, indicates that a corticosteroid medication, prednisone, taken with an HIV protease inhibitor, ritonavir, may increase the risk of bone damage in HIV-infected patients. The drug interaction may also increase the risk of Cushing's syndrome, a hormonal disorder caused by prolonged exposure of the body's tissues to high levels of steroids. The combination of drugs significantly increased the concentrations of prednisolonethe—the active form of prednisone—in the systems of healthy volunteers.

Corticosteroids are used to treat a number of conditions, including severe allergies, skin problems, asthma, and arthritis. They provide relief from swelling, redness, itching, and allergic reactions. "Physicians have noted bone lesions on scans of HIV patients treated with steroids for inflammation," says Penzak. "We wanted to find out if the problems might be at least partially explained by an interaction between the steroids and HIV drugs."

Researchers tested variously timed combinations of the two drugs on ten healthy volunteers, taking blood samples after each dose of prednisone to determine steroid levels. Prednisolone concentrations were 41 percent higher than the baseline amount after the drugs were taken together four days into the ritonavir regimen and 30 percent higher after the drugs were taken together 14 days into the regimen.

Raul Alfaro (left), study team member, and Dr. Scott Penzak (right), lead author, found that when HIV-infected patients take a steroid medication with an HIV protease inhibitor, there may be an increased risk of bone damage and Cushing's syndrome.

"These are statistically significant increases," says Penzak. "They indicate that when the drugs are taken together, steroid concentrations in the body may rise to levels that cause side effects in some individuals." These results serve as a caution to clinicians treating HIV patients on concurrent steroid therapy," says Penzak. "They may choose to start with lower steroid doses or increase their level of toxicity monitoring compared with steroid recipients who are not taking protease inhibitors."

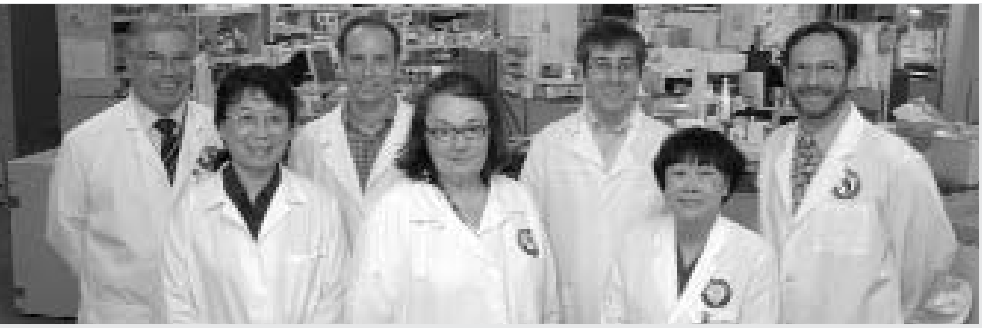
The team, which includes investigators from the Clinical Center and the National Institute of Allergy and Infectious Diseases, plans to continue studies of the blood levels of individuals on steroids and other HIV medications.

Nursing, Indian Health Collaboration

Nursing and Patient Care Services and the Indian Health Service collaborated in 2006 to begin training staff at Indian Health Service clinical facilities on the conduct of research and evidence-based practice projects. This is part of a joint agenda to increase clinical nursing research capabilities in the IHS and supports their quest for Magnet Hospital recognition, which is granted by the American Nurses Association to hospitals that demonstrate an outstanding practice environment for professional nursing. Nurse executives and staff from Hastings Indian Medical Center in Tahlequah, Oklahoma, visited NIH for training in June.

A $50,000 intramural grant was awarded by the National Center of Minority Health and Health Disparities in July to further support interagency collaboration with the Indian Health Service, specifically creating a clinical research infrastructure and expanding nursing research capabilities to address health disparities in American Indians and Alaska Natives. In August, two-day training workshops were held at the Acoma Canoncito Laguna Hospital Service Unit and at the Northern Navajo Medical Center, both in New Mexico. In November, Clinical Center nursing leaders and nurse researchers from the Native Alaska North American Indian Nurses Association (NANAINA) met in Tempe, Arizona, after the NANAINA Annual Summit, to set the agenda for a training workshop to be funded by the grant and held in Bethesda in April 2007.

"FINDING AN ORGANISM THAT HAS NOT BEEN FOUND BEFORE—AND IS KNOWN TO BE A PATHOGEN IN SOME INDIVIDUALS—SUGGESTS THAT WE MAY HAVE SEEN ONLY THE TIP OF THE ICEBERG," **says Steven M. Holland, MD**



Working together in the bacterium discovery and identification were (back row from left) Drs. Patrick Murray, Adrian Zelazny, David E. Greenberg, and Steven Holland. In front are Dr. Li Ding, Frida Stock, and Alexandra Wong.

Discovery of a new bacterium may be only tip of iceberg

Dr. Patrick Murray, chief of the Microbiology Service in the CC's Department of Laboratory Medicine, remembers the day a medical technologist ran into his office and announced she had found an organism she could not identify. Technologist Alexandra Wong recalls that day, too. "I grabbed Dr. Murray and said we may have something unusual here."

They did.

With the resources and collaboration that are hallmarks of the CC environment, NIH researchers from NIAID and the CC went on to make a rare discovery. They identified a new bacterium that causes human disease.

"Novel organisms are being found all the time, but it's quite rare to find an organism that actually causes disease in a human being," explains NIAID's Dr. David Greenberg. "This has been exciting." Greenberg, a physician, is the lead author of a recently published study of the new bacterium. A clinical fellow working with Dr. Steven Holland, chief of NIAID's Laboratory of Clinical Infectious Diseases, Greenberg has been part of this scientific journey from the start.

It began in 2003 when a man with chronic granulomatous disease (CGD) was hospitalized in the CC. CGD is a genetic immune disorder that affects about one in 250,000 people worldwide. People with CGD are susceptible to serious infections of the skin, lungs, bones, and lymph nodes. They may also experience obstructive and inflammatory lesions in the digestive and urinary tracts.

The 39-year-old patient had fever, chills, fatigue, and weight loss, and later developed swollen lymph nodes. When doctors at other medical centers could not make a diagnosis, he was referred to the CC. As part of his diagnostic workup, several of his lymph nodes were removed and sent to the microbiology lab, which does diagnostic testing for CC patients and develops tests for clinical research protocols.

Wong, with research technologist Frida Stock and Fogarty fellow Dr. Adrian Zelazny, became the microbiology service team that worked tirelessly and creatively to isolate and identify the organism.

When cultures were done, an organism could be seen growing on a plate, but conventional tests did not reveal what it was. Lab staffers then turned to genetic sequencing and concluded that the bacterium was a novel member of the *Acetobacteraceae* family. This family of bacteria is prevalent in the environment but had not been associated with human disease before.

"That's how we knew we had something unique," says Murray, whose doctorate is in microbiology and immunology. He credits the technology in the lab and the tenacity of the scientists for making the identification. Murray says other labs might have discounted the organism as just a contaminant when conventional tests could not determine what it was. "But we could go on because we have the resources to perform gene sequencing," he says. "If we don't get an identification by traditional biochemical tests, we send it right to sequencing. It's a very powerful tool to help us classify organisms."

"Without the microbiologists, none of this would have happened," says Holland, "We couldn't have done it without them."

Identifying the organism and verifying its novelty were important steps in discovery. Holland and his team from NIAID and the CC then wanted to know if this bacterium was causing disease in the patient and whether it was associated with chronic granulomatous disease. Dr. Li Ding and other researchers in Holland's lab confirmed that the organism was relevant to the patient and the disease.

Since that initial discovery in the 39-year-old patient, researchers found the bacterium in two other CGD patients at the CC and have been told of a case in another state. The scientists say learning about the case outside of Bethesda is gratifying because it indicates a broader occurrence. It's possible the organism accounts for a significant number of infectious episodes in CGD patients for whom doctors have never had a clear diagnosis. So the findings may prove to be very important for people with that disease.

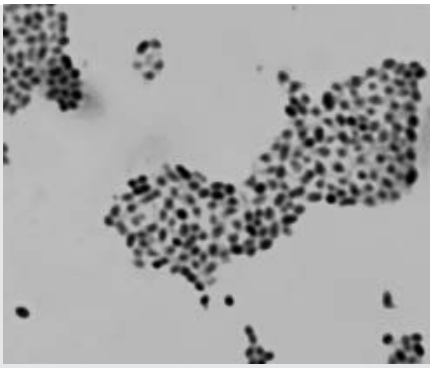
Researchers want to know if the bacterium also plays a role in other diseases—such as Crohn's disease or rheumatoid arthritis—for which infectious causes have been proposed but not demonstrated. "Finding an organism that has not been found before—and is known to be a pathogen in some individuals—suggests that we may have seen only the tip of the iceberg," says Holland. Because of the discovery, the work in Holland's lab is taking a new direction. His team has developed new collaborations and new techniques to learn more about the organism and the impact it may have on health.

Greenberg is developing a screening test to find out how many people, with and without CGD, have been exposed to the organism. The team wants to know how prevalent the bacterium is in the environment, where exactly it comes from, and why it appears to favor CGD patients as a host.

Researchers have much more to learn, but the collaboration between Holland's team and the microbiology service has already had an impact on CGD patients here. The CC's microbiology lab does antibiotic susceptibility testing that helps doctors determine treatments for patients. During the first patient's course of therapy, antibiotic susceptibility testing led the team to use previously untried antibiotics that proved successful. Because of what they learned in that first case, doctors were able to use that treatment from the beginning on the two patients identified later.

"It's a nice personal feeling when you have contributed to the better health of patients," says Zelazny. "Now when patients with the same underlying disease are admitted here or to any other hospital, microbiology labs will know to look for this type of bacteria." He is thankful for a work environment that encourages discovery. "NIH has the people, the resources, and the right setting for different people to come together. I was very fortunate to be here at the right time and to meet the right people." Zelazny will be moving from microbiology to Holland's lab to continue work on this project, in what Greenberg calls "a fantastic partnership." Greenberg, Zelazny, Holland, and Murray named the new bacterium. After many brainstorming sessions, they chose *Granulibacter bethesdensis,* in recognition of chronic granulomatous disease and of Bethesda, the town where the bacterium was discovered.

The three CGD patients known to have the bacterial infection are all said to be doing well. "One patient hung a picture of Granulibacter in the foyer of his house," says Greenberg, "So there's some semblance of pride that he was one of the patients with a novel pathogen."



Third-party reimbursement

Exploring new options for coping with tight budgets is a priority at the Clinical Center. The feasibility of billing insurance companies for patient-care services rendered during clinical trial participation was examined in a comprehensive study completed in 2006. The NIH Advisory Board for Clinical Research recommended to the NIH Director that this option not be pursued at this time because of the nature of the CC's research portfolio, the relatively low projected revenue, and how collections may affect patient volunteers.

Benchmarking

The Clinical Center's benchmarking project was an outgrowth of cost-containment efforts; delineating costs of services and comparing them with costs for similar organizations offers a way to gauge efficiency. In the Clinical Center's benchmarking effort, expenses were categorized as clinical care services, patient support services, imaging, nursing, information technology and administration. Services unique to clinical research were identified so that the CC's budget expenditures could be compared directly with similar organizations. Future efforts will focus on developing national benchmarks for clinical research.

NURSES WEEK

A keynote address from Dr. Patricia Benner, acclaimed author and professor at the University of California, San Francisco's School of Nursing, kicked off 2006 Nurses Week activities at the Clinical Center in May. The week concluded with an awards ceremony and reception. Based on nominations submitted by their colleagues, the nurses of 3NW received the Team Excellence Award. "You are one of the most active groups to affect nursing practice here," said Dr. Clare Hastings, Nursing and Patient Care Services chief. "You ensure flawless patient experience every day." Pictured from left are Clara Borrell, Barbara Rawlings, Jennifer Breeskin, Keith Marin, Leigh Kiger, Tye Mullikin, Clare Hastings, Debbie Nathan, and Lori McIntyre. The 3NE nursing team for oncology/hematology was recognized as the runner-up.

MIXING CREATIVITY AND COLLABORATION

The annual gingerbread house decorating contest drew long lines and lots of oohs and aahs from patients, visitors, and staff. Twenty-eight houses created by staff teams representing a dozen different departments were put on display in the Clinical Center atrium in December. The contest attracted so much interest that more than 1,900 ballots were cast during the week the houses were on display. The Recognition and Retention Committee of Nursing and Patient Care Services began the contest three years ago, with nursing units participating. It was open to all CC staff the next year. Taking first-place honors in 2006 was 5NW. Representing the team at the announcement (left to right): Subramania Varadarajan, Diana Chepurko, Noreen Giganti, Joyce Linderman, Yumi Lee, Catherine Seamon, and Lisa Twedt. Not pictured is gingerbread house designer Philip Bernaldez.

Leadership development
As part of its 2006 leadership development program, the Clinical Center piloted a six-month program in personalized executive coaching offered to six senior managers. Executive coaching gives participating individuals a tailored opportunity to develop the skills they need to support development of effective leadership competencies. One way to support effective workforce succession planning, the program will be offered again in 2007 to six Clinical Center senior managers.

VOLUNTEERS HONORED

As part of National Volunteers Week 2006, the Clinical Center celebrated the more than 200 volunteers currently working here, including (back row, from left) Dr. Joe Held, Patricia Cosgrove, Betty Sanders, and Fay Darya; (front row, from left) Dr. Franz Jemio, Dalia Isicoff, and Michael Harris-Love. Programs supported by CC volunteers include the Red Cross, the animal therapy program, the family friend program, and the language interpreters.

PATIENT SAFETY CHAMPIONS

Drs. JoAnn Lee and Hilary Eichelsdorfer of the CC pharmacy department received the 2006 Clinical Center patient safety champion award for their sustained commitment to creating and maintaining a safe environment for patients. Shown with them here are Andrew Wilson, pharmacy chief, and John I. Gallin, CC director. The pharmacists distribute medications to, and counsel, HIV patients.

As clinical liaison, Lee splits her time between the outpatient pharmacy and the clinic, working at the pharmacy window as well as attending weekly meetings in the clinic to discuss patient issues with the nurses. Lee says she appreciates the dual responsibility because it allows her to get to know the conditions of the patients whose drug orders she manages.

Eichelsdorfer, who is outpatient pharmacist, assumes Lee's duties when needed. She says that the OP8 method of processing and filling medication requests has proved to be efficient and beneficial to the patients. In a typical pharmacy, a physician requests a specific medication for a patient and the prescription is printed in the pharmacy, where a pharmacist checks the label and counsels the patient, when needed. "In addition, we take an extra step," says Eichelsdorfer. "After the labels come off the printer, we screen them all to make sure they correspond with a patient's profile. We are able to prevent errors right away."

This extra step succeeds in the OP8 environment because Lee and Eichelsdorfer have daily contact with the patients and nurses. Because they get to know the patients as individuals—learning the various details of their conditions, treatments, and histories—they are better equipped to notice an error or inconsistency in their prescriptions. "HIV patients are on a complex drug regimen," says Lee. "By having a couple of pharmacists dedicated to this particular treatment, we are more familiar with the intricacies. Patients feel more comfortable knowing they are dealing with someone who knows their individual treatment program."

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BERWICK LECTURE LOOKS AT HEALTH-CARE NEEDS

Meeting need is the essence of quality, said Dr. Donald Berwick (below) president and CEO of the Institute for Healthcare Improvement, during a Great Teachers lecture, part of CC Grand Rounds, in January. The search for quality improvement in health care—making things better—begins by understanding what the needs are and acting on them.

Health care, Berwick explained, should be safe, effective, patient-centered, timely, efficient, and equitable—the six dimensions of health-care 'needs' described in the Institute of Medicine's 2001 report, "Crossing the Quality Chasm." Health care is effective, he said, "when we match what we do to the known science base. Timeliness means not making anybody wait—not caregivers or patients. Efficiency is not wasting money or time or ideas or spirit." These aspects of health care translate to what Berwick calls the 'no-needless' list. "The health-care system I want and envision has no needless deaths, no needless pain, no helplessness on the part of the workforce, the family or the patient, no unwanted waiting, no waste—for anyone. That's where we are headed."

HEALTH CARE IS EFFECTIVE, "WHEN WE MATCH WHAT WE DO TO THE KNOWN SCIENCE BASE."

CONTINGENCY HOSPITAL OFFERS NEW RESOURCE TO SUPPORT PREPAREDNESS

CAPT Elaine Ayres inspects contingency hospital inventory.

CC's emergency response capability

The terrorist attacks on September 11, 2001, were a major impetus for the emergency-response partnership formed in 2004 by the NIH Clinical Center and its neighbors, the National Naval Medical Center and Suburban Hospital.

"The partnership hospitals have complementary strengths," says Dr. John I. Gallin, CC director. "Physicians from the NIH Clinical Center represent almost every medical and surgical specialty and subspecialty. The skilled Naval Medical Center staff are trained to respond to all kinds of emergencies, and Suburban Hospital is a level II trauma center."

Accommodating a surge in demand for medical services is the Clinical Center's major role under the partnership. Navy and Suburban can transfer or divert certain types of patients to the CC so incoming sick and injured can receive care at the best facility.

This collaboration is special in that it includes hospitals from the private, government, and military sectors. Recognizing the partnership's potential early on, DHHS delivered a 250-bed contingency hospital for its support. The contingency hospital—200 containers covering 3,000 square feet—comprises pre-positioned supplies and equipment ready for quick set-up within the Clinical Center. This "within the walls" deployment is both practical and unique, notes Dr. David K. Henderson, the CC's deputy director for clinical care and liaison for the partnership. "We have space to put the beds and we have staff from throughout NIH who have volunteered to provide the care."

The CC was to have received the nation's first of 10 such pre-positioned hospitals in 2005, but supplies and equipment being assembled in Atlanta were redirected to areas affected by Hurricane Katrina, explains Elaine Ayres, project officer for the contingency hospital.

"The inventory, tailored to supplement what we already have at the CC, allows us to be self-sufficient for at least 72 hours," says Ayres. If the hospital were activated in response to an emergency, staff here would simply unpack the 200 containers and set up the beds, equipment, and supplies in pre-determined areas throughout building 10.

The boxes are color coded, meticulously inventoried, and precisely arranged to simplify logistics. They include everything from beds for patients and cots for staff to IV poles and blood pressure cuffs. There are no pharmaceuticals and there are few supplies that can't be stored indefinitely.

Ayres, CC assistant director for ethics and technology development, was the Public Health Service team leader for another contingency hospital sent to Mississippi in the aftermath of Katrina and staffed by NIH volunteers. The experience provided invaluable insight into how such resources can best be set up and used, says Ayres.

The members of the Emergency Preparedness Partnership staged their third preparedness drill in December 2006. The previous exercises provided opportunities to practice and refine response processes under fairly realistic circumstances. "Our goal is to be flexible and creative in our response to emergencies," says Henderson.

EMERGENCY DRILL TESTS STAFF READINESS

A simulated fire and patient evacuation drill held in June tested the Clinical Center level of emergency preparedness. Although CC staff knew the drill was scheduled, the location of the simulated emergency—a fire—was not known until the alarm sounded in the patient-care unit midday. The drill focused on the CC's communication strategies, unit evacuation procedures, and emergency plans.

Training the Next Generation

Training clinical researchers of the future

Much of what clinical researchers learn, they learn by doing and through collaborations and interactions with mentors and colleagues. But with the growing complexity of medicine, medical research, and the regulatory environment governing them, the Clinical Center some time ago recognized the need for formal training as well—a need that in the early 1990s was not being met.

A formal curriculum in clinical research has been developed at the Clinical Center and consists of four courses:

- Introduction to the Principles and Practice of Clinical Research
- Ethical and Regulatory Aspects of Clinical Research
- Clinical Research Training and
- Principles of Clinical Pharmacology.

In 1995, the Clinical Center introduced the course *Introduction to the Principles and Practice of Clinical Research (IPPCR)*, to provide formal training on how to effectively design a clinical trial and implement clinical protocols, in full awareness of ethical and regulatory issues. The course teaches researchers how to design a good clinical trial. It covers epidemiological methods, study design and development, protocol preparation, patient monitoring, quality assurance, and FDA issues. New material helps students navigate regulatory procedures, the grants process, and such practical aspects of research as patient perspectives and how to deal with the media.

The year IPPCR was first offered as a pilot, 25 students enrolled in the course, held at NIH. The second year, enrollment at NIH jumped to 216. By 1997/98, distance learning technology made it possible to broadcast the lectures, so in addition to 291 students enrolled at NIH, 11 students participated at remote sites. The number of students enrolled at NIH grew steadily—to 419 in 2006/07—and the growth in distance learning grew even faster. This year, a total of 942 students enrolled in the course, with 523 from 16 remote sites, ranging from Harbor UCLA Medical Center (in southern California) and Morehouse School of Medicine (in Georgia) to the Universidad Peruana Cayento Heredia and the U.S. Naval Medical Research Center Detachment (both in Lima, Peru). Since 1997, a total of 5,880 students have registered for this course, and 1,981 have received certificates. From 1997 to 2005, the course was teleconferenced to 22 domestic and five international locations.

Students in a convenient time zone can participate in real time through live teleconferencing. But many students participate through archived content—available through a Webcast or a DVD—from as far away as Singapore, Seoul (South Korea), Bergen (Norway), and Rabat (Morocco). Sometimes a group of students watches the course together; sometimes students go through the material on their own.

The course *Ethical and Regulatory Aspects of Clinical Research* is administered by the CC Department of Clinical Bioethics. To date, 2,723 students have enrolled. A textbook, *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, was published by Johns Hopkins Press.

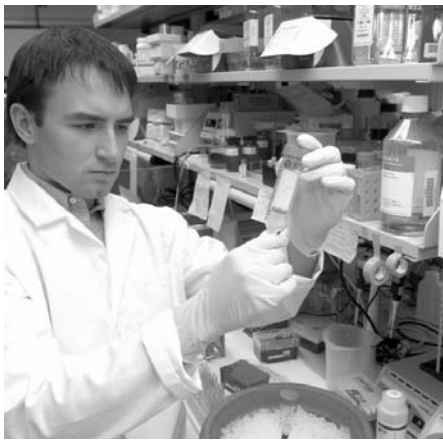
Clinical Research Training, required of all intramural NIH principal investigators, is an active component of the Clinical Center training portfolio. All NIH principal clinical investigators must take the course and pass an exam before receiving approval to conduct new clinical protocols. The course was developed in 2000 to address the NIH Training and Education Standard for conducting intramural clinical research. To date, 8,516 people worldwide have successfully completed the course, which is available online at http://www.cc.nih.gov/researchers/training/crt.shtml.

Now in its ninth year, the course *Principles of Clinical Pharmacology* started with 11 intramural students in two institutes in 1997/98. The 2006-07 program, serving 620 students, is being teleconferenced live to 10 sites. To date 3,398 students have enrolled.

NIH is not a degree-granting institution, but physicians, dentists, and allied health-care professionals who successfully complete the three mandatory components of the training (the first three courses listed above), plus an IRB experience can receive a Clinical Research Curriculum Certificate from the Clinical Center.

Clearly, clinical research is no longer the mythical scientist working alone in a laboratory but a team activity involving both laboratories and patient care facilities, with all the support that requires. Medical fellows take the courses, but so do the pre- and post-PhD researchers with whom they may collaborate. Also enrolled are many other health care professionals, including pharmacists, nurses, respiratory and other therapists, and even a few lay people.

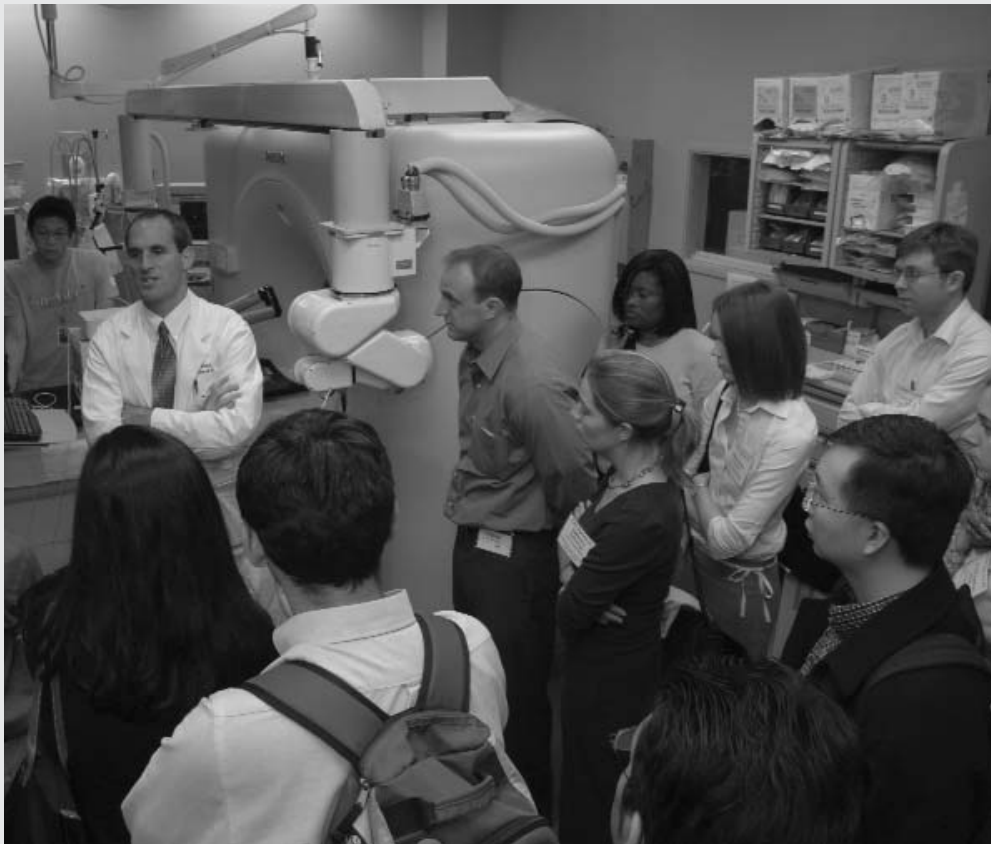
Another distance-learning program designed to strengthen training opportunities in clinical research is a collaboration between the NIH Clinical Center and Duke University. Participants complete coursework mainly through videoconferences with faculty at Duke. NIH staff teach other courses as Duke adjunct faculty. The Duke University School of Medicine awards a Master of Health Sciences in Clinical Research for successful completion. Eight students are enrolled in the current session. Fifty students have earned the degree since the program began in 1998.



KEEPING THE PASSION FOR CLINICAL RESEARCH ALIVE

The medical and dental students who came to NIH from across the country to attend the fourth annual Clinical Investigator Student Trainee (CIST) forum were told they had come at a pivotal time in their careers and in medicine, which is changing in important ways.

"Three *p's* will characterize medicine in the future," said Dr. Michael M. Gottesman, deputy director for intramural research at NIH, citing Dr. Elias A. Zerhouni, NIH director. "It will become more personalized, predictive, and pre-emptive. Each patient will have more molecular and cellular analyses of their specific disease so the medical community can predict what's going to happen with the disease and pre-empt, as much as possible, the development of serious disease."



Dr. Brad Wood (in white coat), who is acting head of CC research programs in imaging sciences, leads a tour for CIST participants.

HHMI fellow Gregory Nelson solicits the opinions of panelists during the session, "How to Succeed as a Physician-Scientist."

"You really are the shock troops for this transformation," Gottesman told the students. "You are the people in the next generation who are going to work in the labs, work in the clinics, and figure out how to change the face of medicine. Therefore this program is extremely important to the NIH."

The two-day CIST forum is designed for students participating in clinical and research fellowships at NIH and academic medical centers. Roughly 250 students attended.

"The speakers are so encouraging. They keep telling us 'You are the future of biomedicine,'" said Kristin Weeks. She was the first student from the University of Kentucky College of Medicine to be a fellow with the Clinical Research Training Program (CRTP) at NIH.

The students were encouraged to find the right mentor and to connect with the other students at the forum. "You'll be meeting for the first time some people who will undoubtedly influence your careers," said CC Director Dr. John I. Gallin. "Don't underestimate the role of your peers in your career development as you move forward."

"It's invigorating to imagine what's ahead," said Gregory Nelson, a fellow with the Howard Hughes Medical Institute (HHMI) from Yale University School of Medicine. He said the physician-scientists at the forum encouraged the students to find their niche and not to decide prematurely that the road was too hard.

"For me, the most interesting thing has been talking to other students, hearing about how they approach scientific problems," said Eric Buras, an HHMI fellow from Baylor College of Medicine. Buras had already decided to become an endocrinologist and a physician-scientist, but he liked learning about new fields and the career directions other students are taking.

Alexander Diaz de Villavilla, a Yale medical student and HHMI fellow who was concerned that he had too many interests and no focus, said, "The forum was helpful in that I got exposure to what top researchers are doing and I realized many are multidisciplinary. I wasn't expecting that, so it was encouraging to me."

Dr. Frederick P. Ognibene, director of clinical research training and one of the forum organizers, says the number of physicians going into academic or research careers is falling somewhat, so the forum was about much more than learning. "It also was an attempt to continue to keep the passion they have in clinical research an active passion—to let them know this is an interesting, exciting, and viable career," says Ognibene.

Participants included Howard Hughes Medical Institute Scholars (Cloister) and Fellows (non-Cloister); Doris Duke Clinical Research Program Medical Students; National Center for Research Resources/GRC Students in

year-long research programs; Sarnoff Cardiovascular Research Foundation fellows; Fogarty International Center/Ellison Foundation Overseas Fellowship fellows; and NIH Clinical Research Training Program for Medical and Dental Students fellows. The first forum was held in October 2003. It is supported with public and private funds from the Howard Hughes Medical Institute, the Doris Duke Charitable Foundation, the Sarnoff Cardiovascular Research Foundation, the Fogarty International Center/Ellison Foundation, and the National Institutes of Health.

WELCOME RECEPTION FOR NEW FELLOWS

After a week working in their new jobs at the Clinical Center, July's incoming NIH clinical fellows enjoyed a welcome reception, which has become an annual tradition. Dr. Katherine Calvo (right), co-chair of FelCom, the NIH fellows committee, talks with a group of new fellows.

Also in 2006, 30 high school seniors from Brooklyn's Arthur Ashe Health Sciences Academy (below) visited the CC and learned from staff about opportunities for careers in allied health and research. The Clinical Center hosted a one-day orientation to the NIH for Howard University undergraduate science and mathematics students enrolled in the university's Reach Back Program.

STUDENTS LEARN ABOUT CAREERS IN SCIENCE

April was a busy month for student visitors to the Clinical Center. Eighth graders from the Landon School in Bethesda (top) listened to lectures on infectious diseases by experts from Critical Care Medicine and Laboratory Medicine and watched as one of their classmates was sent through the PET scanner under the supervision of Dr. Ron Neuman, chief of Nuclear Medicine. Hundreds of youngsters visited the CC on Take Your Child to Work Day (bottom). Among the things some learned: how to draw blood, record their movements in the state-of-the-art clinical movement analysis laboratory, perform CPR on the mannequin "Mr. Simmons," and touch everything from a pig's lung to a microscope. The annual event introduces children to the world of biomedical research and to the wide array of skills and services needed to support it.

2006
DISTINGUISHED TEACHER

NCI's Dr. Elaine Jaffe (center) received the 2006 Distinguished Clinical Teacher's Award, the highest honor bestowed on an NIH senior clinician, staff clinician, or tenure track clinical investigator by the NIH Clinical Fellows. Recipients of the award, given annually since 1985, are recognized for their excellence as a mentor and teacher and their contributions to clinical research. Dr. NaYoung Kim, NIAID fellow, chaired this year's award committee and read a few comments from fellows as she introduced Jaffe. "Fellows are in awe of her amazing clinical skills, and there is often a sense that we are in the presence of greatness as she teaches the intricacies of diagnosis while signing out clinical cases at the microscope," was one. Another tribute: "Whenever clinicians have questions or want to discuss issues surrounding patient care, Dr. Jaffe stops whatever she is doing and devotes her undivided attention to the clinical team to help manage difficult clinical issues." Jaffe joined the NCI as a resident in anatomic pathology and has been a senior investigator since 1974. Her current area of expertise is the molecular basis of lymphoma and the use of targeted inhibitors to develop more effective treatments for cancer. As the 2006 DCTA award recipient, Jaffe will deliver the Fourth Annual John Laws Decker Memorial Lecture during a NIH Clinical Center Grand Rounds in June 2007.

CC hosts young scientists in Discovery Channel Challenge

"People have two kinds of reaction to virtual colonoscopies," says Dr. Ron Summers, staff radiologist and senior investigator in the Clinical Center. "Either they're fascinated or they're grossed out."

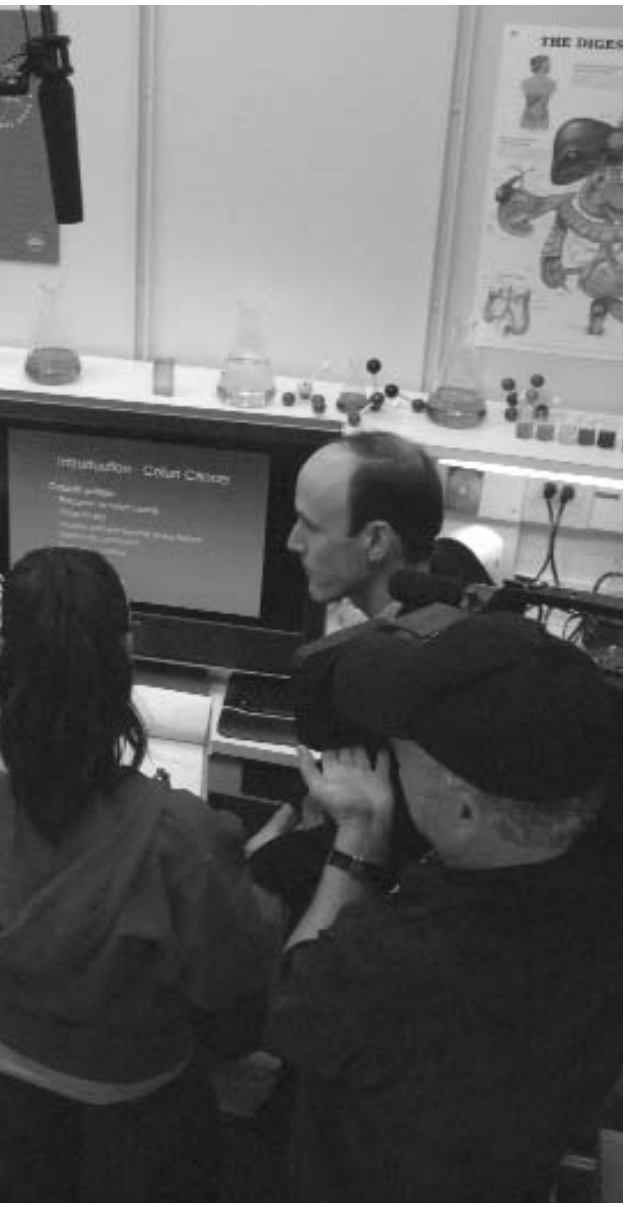
The forty middle school students who competed in the Discovery Channel Young Scientist Challenge (DCYSC) in late October were not grossed out. Navigating their way through a virtual colon looked a little like playing a videogame: Spot the polyps! Working in eight teams of five students each, they listened to Summers' mini-lecture, got a hands-on experience detecting polyps with computer software, played around with a colonoscopy simulator, and finally produced a kid-to-kid video explaining the nature and benefit of a colonoscopy—all in 90 minutes.

In the movies, young science buffs rarely have social skills. Hollywood might have a problem stereotyping this group, which seemed as comfortable working in groups and appearing on camera as it did looking at zebrafish embryos under a microscope (a nearby challenge).

The adult talent looked equally at ease, especially after guiding eight teams in a row through the same challenge, thanks to the remarkable adeptness at people-moving displayed by the Discovery team. This was the first time NIH hosted the event, and NIH employees were amazed at how quickly—in two fairly last-minute days—the Discovery team transformed a few somewhat drab NHGRI labs on the 10th floor of building 10 into brightly decorated stage-set laboratories.

"It was indeed a challenge to turn the empty lab into a television-friendly learning arena," said Steve Jacobs, or Judge Jake, science educator and creator of the Discovery program, "Jake's Attic." Jacobs develops and administers the challenges. "I tip my hat to the creative ability of the Discovery production team. However, I fall to my knees in praise of the volunteers from the NIH staff. It is not difficult to make television shine when working with such jewels. The people at NIH are truly amazing. Just amazing. I stood in awe of their scientific expertise, and even more, their ability to communicate an excitement for their work. They are just the inspiration we needed for motivating young people to consider careers in science and medicine."

The Young Scientist Challenge is a national science contest for students in grades 5 through 8. Discovery Communications, Inc., launched the competition in partnership with Science Service to nurture the next generation of U.S. scientists at that critical age when interest in science begins to decline. To enter the contest, students must first compete in a local or regional science fair affiliated with Science Service. The 40 finalists



who competed in the Clinical Center on October 24-25 were selected from the top 400 national semifinalists, based on the scientific merit of their original science project and their ability to communicate its goals. The semifinalists had been chosen from among over 1,900 entrants representing 273 affiliated science fairs from 47 states, the District of Columbia, Puerto Rico, and the Virgin Islands. For two days the Final 40 competed in complex, team-based, hands-on challenges. They competed as teams but were judged individually on their performance in challenges, understanding of the science process, teamwork, and ability to communicate about science, including their original science project. It always comes down to finalists who "possess the ability to inspire and inform others of the delights of scientific discovery," says Judge Jake.

Disease detectives

This year's theme, "Disease Detectives," featured a series of challenges in which the finalists investigated the causes and impact of global health concerns, from avian flu to obesity. NIH collaborated with DCYSC in the final round of the 2006 challenge and hosted this year's program. The scientists leading the challenges worked with Steve Jacobs to formulate and design the experiments, built around current health issues. The finalists were given eight fairly formidable tasks to accomplish, in small teams, in segments of 90 minutes or less.

"The opportunities are greater now than they were when I was a kid," says Summers, who in seventh grade learned about physics and science through the "discovery" approach to learning science provided in the Intermediate Science Curriculum Study (ISCS). Instead of yawning through the old "chalk-and-talk" approaches, in which often-bored students memorized facts delivered through lectures and textbooks, students in discovery-science classes spend far more time engaged in inquiry-oriented activities that require interpreting data, suggesting hypotheses, conducting experiments, working on projects, and sharing results.

The Discovery Channel's show about the Discovery Challenge will air in February 2007. Read more about the winners, the science projects of the Final 40, a dozen or more additional awards (including a "dream science trip"), and the Challenge itself at http://school.discovery.com/sciencefaircentral/dysc/

NEVELSON WORK NOW OFFICIALLY PART OF NIH

Susan Whitehead (center), daughter of the late Edwin C. Whitehead, was at the Clinical Center in October for a ceremony marking her family's gift of the Sky Horizon sculpture to NIH. She is flanked by John Burklow (left), NIH associate director for communications, and CC Director Dr. John I. Gallin. The steel work by artist Louise Nevelson was dedicated in 1988 and displayed here since then courtesy of the Whitehead family. Originally located at the Clinical Center's front entrance on Center Drive, the piece was relocated to its present site at the end of West Drive during construction of the Mark O. Hatfield Clinical Research Center. Sky Horizon was selected in the mid-1980s when Dr. James B. Wyngaarden, then NIH director, established a committee to advise him on selection of a sculpture that would "stand as a reminder of the accomplishments of NIH to the health of mankind and a salute to those who made those accomplishments possible" to mark NIH's 1987 centennial celebration. It was purchased by Edwin Whitehead, founder of the Whitehead Institute for Biomedical Research and the Technicon Corp. In his later years, he was a founder and chairman of the board of Research! America. "My father was enormously proud the sculpture was at NIH," said Susan Whitehead. "It's a privilege for me and my family to make this gift."

American College of Physicians honors Gallin, Young

Two NIHers were honored during the annual convocation of the American College of Physicians. In April, Dr. John I. Gallin, CC director, received a prestigious Rosenthal Award for his "contribution to the advancement of clinical research, to the teaching structure, to the principles of patient care and to the overall productivity of hospital programs." Dr. Neal S. Young, chief of the hematology branch in NHLBI's intramural program, was cited for his election as a Master of the American College of Physicians, which recognizes outstanding career accomplishments and contributions.

CC staff receive NIH directors awards

Leadership requires heart, spine, and brains, said Dr. Elias A. Zerhouni, NIH director, offering an anatomy lesson in remarks opening his 2006 awards ceremony in July. Heart because we're "the National Institutes of Hope to millions," and spine because it's important "to stand up for what you believe in, believe in what you say, and say what you believe…stay true to your principles and core values."

Staff in the Office of the CC Director honored with individual awards were Patricia Piringer, for outstanding management and oversight of the bench-to-bedside program; Laura Lee, for leadership in emergency preparedness planning and creation of an emergency preparedness partnership; and Hillary Fitilis, for exemplary leadership and guidance in improving performance management here. Dr. Robert Danner, in Critical Care Medicine, received an individual award for creating a multi-user genomics facility, yielding substantive insights into the physiology of sepsis. A mentoring award went to Dr. Mark Gladwin, Critical Care Medicine and NHLBI, for his contributions to understanding the role of nitric oxide in the regulation of sickle cell anemia.

Transisitons

New CIO a veteran in advances here Dr. Jon McKeeby was named the Clinical Center's chief information officer in July. Acting CIO since January, McKeeby, who has been at the CC since 1991, will also oversee the Department of Clinical Research Informatics. McKeeby led the development and implementation of interfaces between MIS (the CC's original medical information system), CRIS (NIH's current clinical research information system), and other key information systems, including radiology, hospital statistics, nutrition, and surgery. He earned a BS degree in computer science from Hope College in Michigan and an MS in computer science from Bowling Green State University. McKeeby succeeds Dr. Stephen Rosenfeld, who had served as CIO since 2004 and was leader of the CRIS development team. Rosenfeld left the CC to become CIO for MainHealth in Portland.

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Lertora heads clinical pharmacology program The CC office of clinical research training welcomed Dr. Juan Lertora as the new director of the CC clinical pharmacology program in July.

As program director, Lertora will teach and oversee the Principles of Clinical Pharmacology course and will be involved in issues related to training clinical investigators. Before accepting the job at the Clinical Center, Lertora worked as a professor and head of the section of clinical pharmacology at Tulane University's Departments of Medicine and Pharmacology in New Orleans. In addition to his academic positions at Tulane, he was a staff physician at Tulane Medical Center Hospital and Clinic, Charity Hospital, and the Veterans Administration Medical Center—all in New Orleans. He was also a principal investigator in the Tulane-Louisiana State University Adult AIDS Clinical Trials Unit (funded by NIAID) and program director of the General Clinical Research Center (funded by NCRR).

When Hurricane Katrina hit in August 2005, Lertora evacuated the city—his home for more than 20 years—with thousands of others, ultimately ending his journey in Houston. So when he became aware early in 2006 that the CC position was still open, he was ready to consider the opportunity. Dr. Arthur Atkinson, who served in the role until October 2005, was a friend and mentor. "I remember congratulating Art when he retired from his position as director of the clinical pharmacology program last year. At the time, I had no idea I would be looking for a new opportunity," Lertora says.

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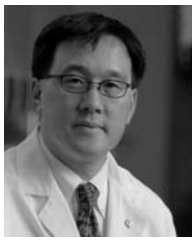

Chan named chief of rehabilitation medicine Dr. Leighton Chan of the University of Washington will be the new chief of CC's Rehabilitation Medicine Department. He was chosen from a highly competitive field of candidates after an extensive national search. His appointment is effective in January 2007.

Dr. Chan will oversee the Clinical Center's rehabilitation medicine programs, including patient care, research, training, and support. On the rehabilitation medicine faculty at the University of Washington in Seattle since 1994, he has been recognized as an outstanding teacher and a strong clinical researcher and collaborator. He served as co-director of the university medical center's pulmonary rehabilitation program, assistant medical director for the rehabilitation clinic, and consultant to the lung transplant committee.

Of special note is his work as a regional medical epidemiologist for the Centers for Medicare and Medicaid Services. He and colleagues used large databases to evaluate the quality of rehabilitation care, work that resulted in sweeping changes in reimbursements and payments.

Dr. Chan earned his undergraduate degree at Dartmouth, completed pre-medical work at Bryn Mawr College, and earned his MD at the UCLA School of Medicine. He also holds master of science and master of public health degrees from the University of Washington. After residency training in the Department of Rehabilitation Medicine there, Dr. Chan completed a Robert Wood Johnson Fellowship.

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Dr. King Li, associate director for radiology and imaging services and chief of the diagnostic radiology department since 2001, left the Clinical Center in October to join the Cornell Methodist Hospital in Houston.

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Tom Reed, former director of the CC Office of Human Resources Management, retired in April after 34 years of federal service. While at the CC, Reed was able to influence much-needed reform in a key civil service law that would allow the hospital to improve nurses' salaries (and later those of allied health staff) using the authority of the Veterans Administration (Title 38). In 2001, further human resource gains were made using Title 42 (the Public Health Service Act) to pay and appoint clinical research support staff engaged in direct or indirect services related to clinical patient care.

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Known for bringing relaxation to CC patients, **Dr. George Patrick,** chief of recreational therapy, has opted to start some relaxing of his own—he retired in June. Patrick began his NIH career in 1988. "The available treatments were different back then," he said. "At the time, our department compiled a list of what patients were doing—

things like tai chi and other relaxation techniques—and we also looked at what patients were asking for." With that information, Patrick and others began forming discussion groups to determine what new offerings they could bring to the CC. Today patients can take advantage of a host of options, including acupuncture, biofeedback, massage, meditation, and music therapy. Patrick is the author of 41 publications, covering such topics as complementary and alternative medicine, novice wheelchair athletics, developmental psychology and geropsychiatric recreation, and day camping for developmentally disabled children.

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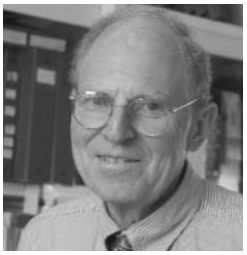

Dr. Paul Plotz stepped down as chair of the acclaimed CC Grand Rounds Great Teachers lecture series in May. Plotz originally conceived the idea for the series when he was chair of the NIH/FAES continuing medical education committee. Charged with enhancing education programs on campus, Plotz and the committee surveyed NIH physicians to find out what clinical topics would be of interest to them. With the survey results in hand, the committee invited physicians from the United States and abroad who were best suited to address a particular topic, based on their reputations as outstanding clinicians and great teachers. Since its inception in 2001, the successful Great Teachers series has fueled enthusiasm among clinical physicians and has delivered practical medical advice. Comprising ten lectures annually, the series is part of the weekly Clinical Center Grand Rounds. Dr. Jeffrey Cohen, National Institute of Allergy and Infectious Diseases, is current chair.

JAN WEYMOUTH, SAFRA FAMILY LODGE DIRECTOR, RETIRES

After 35 years employment with NIH, Jan Weymouth retired from her position as executive director of the Safra Family Lodge. "It's been amazing," says Weymouth. "It's almost like a family, there's so little turnover and everyone is so dedicated. Everyone feels compelled to push forth the mission of improving the health of the nation. It's been a privilege to work in some small capacity to do that."

She began working at NIH in 1970, straight out of college. In 1977 she moved to the Division of Space Management, in the NIH Office of the Director, at a time of unprecedented growth at NIH. After the Ambulatory Care Research facility was built, the Clinical Center created a new position just to manage the CC's growing space and facilities. So much new construction happened over the next 35 years that moving people and things became an important skill. The work was interesting, but required the mindset of a politician, with so many institutes seeing patients and vying for space in the Clinical Center.

In 1999 she helped launch the CC's hospitality services program, at the suggestion of the Patient Advisory Group. Existing staff were retrained and redeployed to welcome patients and give them guidance. After 9/11, security was tightened, and patients had so much trouble getting on campus that they were turning around and going home. In 2001, Weymouth helped develop and set up the extended-visitor pass program, which allowed patients and other visitors to be screened, identified, photographed, and given a pass that allowed them to come and go with the same ease as employees. She issued the first passes to the Patient Advisory Group.

In 1999, approval was given to begin program and design work on what would become the Safra Family Lodge, with an early enough start that when funding for the lodge became available, construction could begin without delay. From 2004 on, she worked full-time on the Family Lodge, on everything from construction to staffing.

"Jan is the kind of person who knows how to get things done," says Maureen Gormley, CC's chief operating officer. "Jan knows the 'art of the possible.' Not only did she make sure the Family Lodge would be comfortable and supportive of guests' needs, she gave the place a heart."

"JAN IS THE KIND OF PERSON WHO KNOWS HOW TO GET THINGS DONE."

Dr. Robert Warwick Miller, scientist emeritus at NCI and founder of the Astute Clinician Lecture series, died on February 23, 2006. He was 84 years old. Throughout a distinguished career spanning 45 years at NCI, Miller stressed the importance of alert clinical observations in providing initial clues to the causes of cancer, birth defects, and other diseases, as well as the value of interdisciplinary approaches that integrate the epidemiologic, clinical, and basic sciences.

As an extension of his research interests, Miller founded the Astute Clinician Lectureship, which is part of the NIH Director's Wednesday Afternoon Lecture series, coordinated by the Clinical Center. The series specifically honors the path-breaking work of clinical scientists. Now in its ninth year, it was established through a gift from Miller and his wife, Haruko "Holly" Miller.

"Dr. Miller recognized that insightful clinical observations often lead to innovative research and medical breakthroughs," said Dr. John I. Gallin, CC director. "Because of the generous gift he and his wife made to NIH, scientists who exemplify this path to discovery give lectures here annually as a celebration of clinical research."

Miller is survived by Haruko "Holly" Miller, his wife of 51 years, who served as a research chemistry technician in NCI's Laboratory of Molecular Carcinogenesis.

DOTTIE CIRELLI, DIRECTOR OF PATIENT RECRUITMENT, SAYS GOODBYE

Dottie Cirelli, who retired as director of patient recruitment, is a case study in how to build a career at NIH.

Cirelli served for 9 years as a substance abuse counselor for the Arlington County Department of Human Resources. Most of her clients came to her through court orders. "One of my dreams was to work at the NIH, which was the premier place to be for research and medicine," she says. In 1980, she landed a job as a research psychologist with the National Institute on Alcohol Abuse and Alcoholism. She moved to the Clinical Center in the mid-1980s as a hospital administrative officer, responsible for patient care unit budgets and administrative and facility issues. "It was never boring," says Cirelli. "Something always needed attention. I liked interacting with the patients, the nurses, and other patient care staff. I felt I was part of the heartbeat of the organization."

In 1997, a subgroup of the Medical Executive Committee decided that more active patient recruitment was needed to fill intramural clinical trials. Dottie soon took on her most challenging career post, actively managing a centralized patient recruitment service.

With a staff of three, she was asked to develop a proposal to increase recruitment for the Clinical Center, with a special mandate to recruit more minority patients. "The four of us literally worked night and day, not only conducting recruitment but initially answering all of the calls, developing our own database, and creating forms to collect data," she says.

By opening a call center, attending health fairs and national conferences, sending mailings to doctors, advertising, and getting media attention, the department went from 125 patient enrollments (out of about 9,000 calls) in fiscal 1997 to 3,041 patient enrollments out of 46,796 calls and 12,492 referrals to protocols in fiscal 2006.

"The mission of this organization is wonderful and the people who work here really care. I am proud to have been a part of it."

NIH CLINICAL CENTER

Organization Chart

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Adrienne Farrar, DSW

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Dinora Domingues, BS, RN (acting)

Spiritual Ministry Department
Walter Jones, MS, (acting)

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Sara Byars

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Leighton Chan, MD

Transfusion Medicine Department
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Credentials Office
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Fred Gill, MD

Pediatric Consult Service
Deborah Merke, MD

Veterinary Care Program
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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 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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Head of Laboratory of Blood and Vascular Biology
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NIH Clinical Center

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Office of the Director, NIH

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(the institutes, in alphabetical order)

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National Human Genome Research Institute (NHGRI)
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National Institute of Nursing Research (NINR)
National Library of Medicine (NLM)

(the centers, in alphabetical order)

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National Center for Minority Health and Health Disparities
National Center for Research Resources (NCRR)
NIH Clinical Center (CC)
Mark O. Hatfield Clinical Research Center
Warren Grant Magnuson Clinical Center

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