

# PROFILE 2011

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Other Hospital  
Like It



NIH CLINICAL CENTER • DIRECTOR'S ANNUAL REPORT





Mark O. Hatfield  
Clinical Research Center

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## MESSAGE FROM THE DIRECTOR

### HISTORIC OPPORTUNITIES



The Clinical Center underwent unprecedented scrutiny in 2010 as part of a thorough review of NIH's intramural program by the Scientific Management Review Board. The Board was authorized by the NIH Reform Act of 2006 to advise the NIH Director, HHS officials, and Congress. Recommendations made by the Board at the end of 2010 included expanding the Clinical Center's role as a resource for the external clinical research communities; streamlining its governance structure; and defining a more stable mechanism for funding that is responsive to evolving priorities. These recommendations still face further discussion across NIH and HHS prior to a final decision, which will be reported to Congress.

The Clinical Center has made strides in opening its doors to extramural researchers in recent years. The Bench-to-Bedside program has included research collaborations involving extramural investigators since 2006. A pilot partnership with the Damon Runyon Cancer Research Foundation, announced late in 2010, is a promising new avenue for external collaborations with early-career investigators. Training in clinical research and its management has long been an important cornerstone of the Clinical Center's mission. Since 1995, more than 21,000 students world-wide have participated in the NIH Curriculum in Clinical Research. In 2010, the innovative sabbatical in clinical research management attracted its first participants. The sabbatical provides a learning environment that is totally flexible and responsive to student needs.

The Clinical Center provides an unparalleled environment for all aspects of clinical research. The coming months and years offer remarkable opportunities for the Clinical Center to contribute to medical discovery in important new ways.

John I. Gallin, MD  
*Director, NIH Clinical Center*



**OUR VISION** As America's research hospital, we will lead the global effort in training today's investigators and discovering tomorrow's cures.

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

- investigating the pathogenesis of disease;
- conducting first-in-human clinical trials with an emphasis on rare diseases and diseases of high public health impact;
- developing state-of-the-art diagnostic, preventive, and therapeutic interventions;
- training the current and next generations of clinical researchers; and,
- ensuring that clinical research is ethical, efficient, and of high scientific quality.

There's No Other Hospital Like It



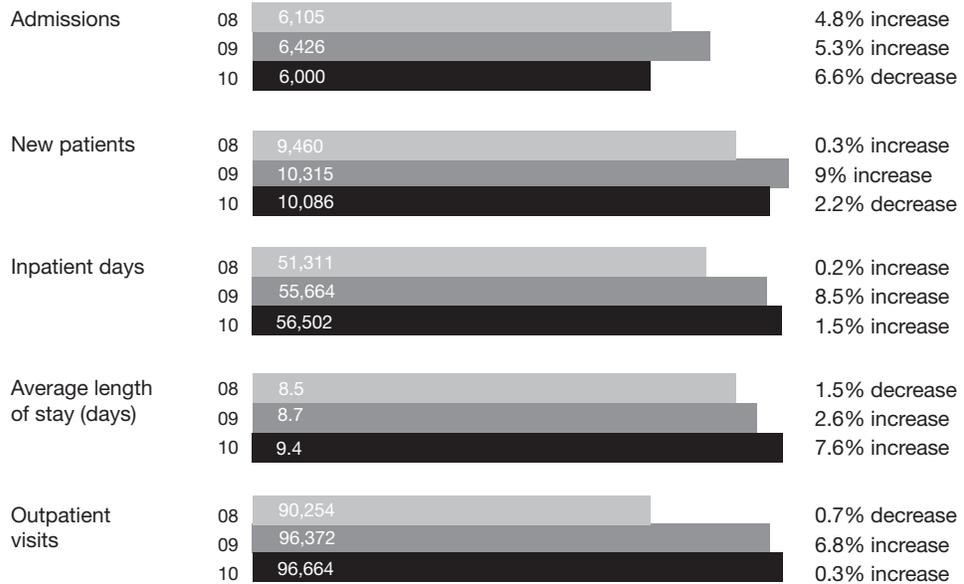
## RECENT CLINICAL CENTER ACHIEVEMENTS

IN 2010 WE:

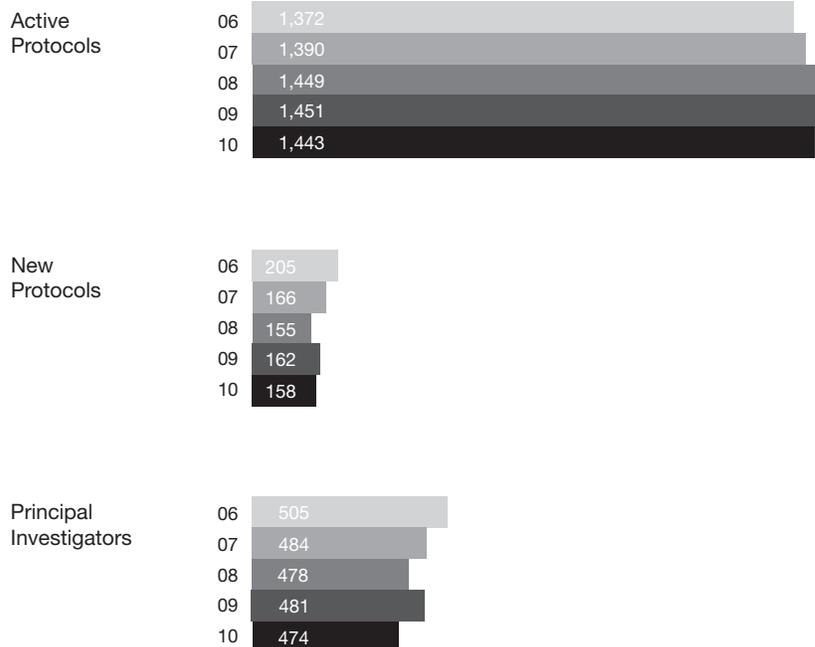
- **Expanded the international reach of clinical research training programs.**
- **Initiated a sabbatical in clinical research management.**
- **Began a pilot partnership with the National Cancer Institute's Center for Cancer Research and the Damon Runyon Cancer Research Foundation, offering some of the Clinical Center's capabilities and expertise to an external group of clinical investigators in cancer research.**
- **Defined the nursing subspecialty in clinical research nursing.**
- **Opened a new pharmaceutical development facility to formulate candidate drugs and a Special Clinical Studies Unit offering state-of-the-art isolation and extended-stay capabilities.**
- **Partnered with Project SEARCH to launch an internship program for young adults with disabilities.**
- **Underwent review as part of the Scientific Management Review Board's focus on NIH intramural research. The Board, established by the NIH Reform Act of 2006, advises the NIH Director and HHS officials on certain organizational authorities.**
- **Celebrated the fifth anniversary of the Edmond J. Safra Family Lodge.**
- **Continued collaborations in the Undiagnosed Disease Program. Nearly 400 patients have been accepted since the program began in 2008.**
- **Improved communications with referring physicians.**
- **Enhanced patient safety through expanded bar-coding capabilities.**



## PATIENT ACTIVITY 2008-2010



## ONSITE CLINICAL ACTIVITY FOR 2006-2010



## PATIENT ART ON DISPLAY



A new display in the NIH Visitor Center and Nobel Laureate Exhibit Hall in the Natcher Building spotlights Clinical Center partners in research—the patients. Tiles from “The Art of Healing” art therapy project out of the CC Rehabilitation Medicine Department Recreation Therapy Section and the CC Art Program were installed in late February. The project was conducted in the summer of 2008 and invited patients and their family members to decorate tiles to express their experiences through illness and treatment using mixed media like copper cut-out shapes, game pieces with letters, paint, and a texturized modeling paste. Many of the tiles are presented in

the “Hope Flows from One to Another” display on the Hatfield Building’s seventh floor. Next to the wall of NIH Nobel Prize laureates, the patient artwork completes a representation of translational research.

“We so appreciate the addition of this patient-focused exhibit. It adds a wonderful dimension and balance to the other displays in the exhibit hall that focus on the importance of researchers as mentors,” said Visitor Center and Nobel Laureate Exhibit Hall director Jennifer Gorman (at right in photo with coworker Tara Mowery). “The patient tiles bring the human story of research to the audience. They literally jump off the wall and say to the viewer that research and discovery is about life.”

The art selection and arrangement of the work, with identifiable themes at eye-level, particularly appeals to middle-school age groups who participate in programs at the NIH, Gorman said, though any kid at heart should be drawn to the tiles.

The Visitor Center plans to continue enhancing the Nobel Laureate Hall’s aesthetic with interactive consoles where visitors can hear stories of discoveries from the researchers who made them and experience virtual tours and science that highlight the NIH.

## FORMER PATIENT CELEBRATES LIFE AFTER BEATING CANCER AT THE NIH



Robert Longo celebrated an anniversary in June 2010. Given a 20 percent chance of living two years, Longo has survived 35 years after a bone cancer diagnosis at age 15.

He was diagnosed on June 10, 1975. Living in Rockville at the time, Longo learned of an NIH protocol for the cancer that would take his left leg above the knee. Others in the study were also teenagers and together they did two legged races down the hall and played in wheelchair basketball games organized by the nurses.

His experience as a research volunteer inspired his project to earn “life rank” in the Boy Scouts of America: a blood drive at the NIH Blood Bank. More than 100 people donated 92 pints of blood. Longo continues to organize NIH blood drives.

## VOLUNTEER INTERPRETERS HELP STAFF AND PATIENTS BRIDGE LANGUAGE BARRIERS



Eileen DeSantillana (right) is one of more than 70 language interpreter volunteers who help patients like Jaime Sanchez of Oaxaca, Mexico, navigate the sometimes complicated journey of clinical research. To assure that all patients have a full understanding of their involvement in clinical research, and, conversely, to assure that staff have a full understanding of what the patient is experiencing, the CC relies on a dedicated staff of language interpreters.

The program also comprises three staff members to handle the average of 25 (though as high as 40) interpreter requests that come in a day. From Amharic (spoken in Ethiopia) to Yiddish, the program offers interpreters in more than 40 languages. Volunteers come in the form of former and current NIH staff, local retirees of such international entities as the World Bank and the Pan American Health Organization, and medical students or those who wish to soon be such. “Our volunteers are selfless people who serve with devotion and humanity,” said coordinator Brenda Robles. “They value their experience and show respect to the patients. We admire them and highly value them.”

All volunteers are vetted and tested to assure that their capabilities match the CC needs, particularly knowledge of medical and legal jargon, Robles said. No matter their background, applicants take a written and an oral test then, if they pass, shadow an interpreter to learn the CC process.

Nurse Eleftheria (Libby) Koklanaris of the National Heart, Lung, and Blood Institute uses the service almost daily to interpret for procedures and consents and to communicate and correspond with patients and their doctors in their country of origin.

“Without the Language Interpreter Program and their services, it would be challenging to advocate for the patient’s needs, which does not do justice for the patients,” Koklanaris said. “They offer many services and their endless efforts of advocacy and professionalism are what make them desired by many.”

## ARTIST'S EYES



Chevy Chase artist Jean Meisel made a generous donation to the Clinical Center in 2010—13 large works, half of which hang in the Magnuson’s Building new main corridor. Her artist’s statement explains her work: “Every day of our lives we are astounded by the glorious and mysterious objects and events in the natural world. In my paintings I isolate shapes and colors and simplify what I see—rocks, leaves, skies, shells—in the hope that the viewer, like the painter, can apprehend these miracles with new eyes.”

## EDMOND J. SAFRA FAMILY LODGE MARKS FIFTH ANNIVERSARY



The Edmond J. Safra Family Lodge has housed close to 74,000 caregivers of Clinical Center patients since it opened on June 1, 2005. It offers convenience and community to the loved ones of our partners in research.

A haven for caregivers of Clinical Center patients—the Edmond J. Safra Family Lodge—welcomed its first guests on June 1, 2005.

Since then, about 74,000 family caregivers from around the world have stayed at the Family Lodge. “The lodge was first conceived by Clinical Center nurses, and having a resource like the Family Lodge was a goal of mine for many years,” said Dr. John I. Gallin, CC director. “Patient volunteers make clinical research and medical discovery possible. The lodge makes it possible for their loved ones to stay close and be comfortable during what can be a very stressful time.”

Just steps away from the CC, the 34-room guest house is an extension of the patient experience, said Denise Ford, chief of CC Hospitality Services.

“We know how much our patients need the support of their loved ones while they are inpatients. It gives them peace of mind to know that family is close by and well cared for by our wonderful staff at the lodge,” Ford said.

### **Getting here**

The CC initiated the NIH Guest House program in 1996 in Building 20, the former staff Apartment House. Building 20 was torn down in 1998 to make way for the Hatfield Building. The six-unit Guest House moved to a nearby

apartment building on Battery Lane in Bethesda then to six rooms in a local hotel. These pilot programs demonstrated the need for housing. The CC approached the Foundation for the NIH, asking that the foundation’s board spearhead a campaign to solicit support from private sector partners to build the Family Lodge. As the project closely reflects its mission—supporting NIH’s efforts to improve health through scientific discovery—the foundation board made fundraising for the much-needed lodge its highest priority.

On April 17, 2002, a ceremony marking the naming of the facility as the Edmond J. Safra Family Lodge was held at the Russell Senate Office Building in Washington, DC.

Massachusetts Sen. Ted Kennedy was a keynote speaker in support of the lodge. Contributors of the \$9 million raised to build the lodge, besides the main benefactor, the Edmond J. Safra Philanthropic Foundation, included the Merck Company Foundation; the Bristol-Myers Squibb Foundation; GlaxoSmithKline; the Harry and Jeanette Weinberg Foundation; and many other corporations, foundations, and individuals.

Considered by many to have been the twentieth century’s greatest private banker, Safra quietly carried out many philanthropic activities. The Edmond J. Safra Philanthropic Foundation carries forth Safra’s lifetime commitment to medical



### Special garden setting

Through an additional special gift to the Foundation for the NIH made by Lily Safra, landscaping around the Family Lodge offers visitors a myriad of garden experiences, including the more private Claudio and Evelyne Cohen Garden. A peaceful, tranquil venue provides guests with a place of rest and refuge from their day-to-day concerns in an English park-like setting reminiscent of the lodge's architecture. A path meanders along the perimeter of the lodge's property, and a number of smaller pathways lead to more intimate seating areas. Each is distinctively treated with plantings and a water feature. Benches offer guests multiple areas for conversation and reflection. The gardens were designed by Madison Cox Design Inc.

research and humanitarian causes. His namesake organization gave millions to the Foundation for the NIH. Safra's wife, Lily, serves on the foundation's board of directors.

A groundbreaking ceremony on October 29, 2002, marked the beginning of construction of the Family Lodge. It was designed by Amy Weinstein of Weinstein Studio in conjunction with the architectural firm Louviere, Stratton and Yokel. Designed in the unique style of an early 1900s English Manor House, the lodge offers a retreat to the families and caregivers who make it their temporary home.

Lily Safra, on making her gift for the building of the Family Lodge, said, "We know that when illness afflicts one person, an entire family can suffer. The mission of the Edmond J. Safra Family Lodge is to give those families a place to remain resilient together."

On May 26, 2005, the six-year planning and construction project officially came to an end as the Family Lodge was formally dedicated and opened. When Lily Safra saw the completed building for the first time, she smiled and simply stated, "Beautiful."

### How it works

Guests are offered a room at the Family Lodge based on a priority system. Caregivers of patients

in the intensive care unit are given first priority, followed by those with loved ones in palliative or end-of-life care. Close to 70 percent of guests are from the third priority group: those accompanying a patient having inpatient surgery or admitted for more than one week.

The remaining priorities are for discharged inpatients (and their guests) transitioning home and outpatients (and their guests).

The Family Lodge is located at the corner of Convent and Center Drives, across the street from the CC. "The proximity of the lodge to the Clinical Center offers ease of access," Ford said. "It gives them one less thing to worry about and lets them focus on caring for their loved one."

"Staff are customer service-oriented, but respect the guests' privacy," said Edmond J. Safra Family Lodge Executive Director Lawrence Eldridge. Many want to reflect or relax alone, while some guests may care to engage with others, frequently in the lodge's shared kitchen.

National Symphony Orchestra conductor Marvin Hamlisch and violinist Marissa Regni presented a holiday concert at the Edmond J. Safra Family Lodge in December. It was the renowned musician's fifth holiday concert here.



## SURGERY SPACES RENOVATED TO IMPROVE PROCESS FOR PATIENTS AND VISITORS



A new space for the Department of Perioperative Medicine's family waiting and outpatient arrival area offers separate enclaves for privacy and comfort.

Surgery is a multi-step process for patients and for their loved ones, too. Recognition of the stakeholders and the several stages involved in preparing for an invasive procedure led to a recently completed renovation of some areas of the Clinical Center Department of Perioperative Medicine.

The pre-anesthesia clinic now includes three interview and exam areas, along with a separate waiting area, which allows for more privacy and a more relaxed setting. At the clinic, patients scheduled for surgery review the planned procedure and the risks of anesthesia with staff and have the opportunity to bring up any questions or discuss concerns.

On the day of their surgery, outpatients report to the new waiting area, where loved ones of all surgical patients can wait to

team. Closer to the procedure areas and recovery room than its predecessor, the new waiting area features isolated areas where family members and friends can gather separate from other patients' visitors.

An appreciated addition to the new space is a private room for sensitive conversations. A volunteer services representative is present to answer questions and assist the arriving outpatients and the waiting family and friends. A bright, new holding area lets the surgical team take proper preparation steps—such as documentation and site marking—efficiently and privately.

### CRACKING A SMILE

Clowns from the Ringling Bros and Barnum & Bailey Circus visited Clinical Center patients—including Vienna Mariela Martinez Fuentes—in March.





The new “elegant” Clinical Center patient menu features fresher ingredients and new offerings from the Nutrition Department.

## FRESHER, MORE SEASONAL

More fresh foods, more variety, redesigned layout. The Clinical Center Nutrition Department rolled out its revised patient menu in mid-2010.

The new menu replaces some frozen foods with fresh versions. For example, fresh spinach replaces frozen spinach on the dinner sides menu. The

Fall/Winter seasonal menu also offers more variety, adding shrimp, pork chops, beef stew, baked sweet potatoes, and a variety of new soups, including a soup of the day. The menu is without added trans fat.

“The Clinical Center strives to be ahead of the curve when it comes to our room service program,” said Jennifer Widger, Food Service Section chief, comparing the new menu to the options offered at other hospitals. “We provide a ‘build-your-own’ concept for many of our items, such as a salad bar and pasta bar, so patients can combine whichever ingredients they would like.”

The recipes are developed by the department’s certified executive chef, Robert Hedetniemi. Every new menu item is then thoroughly reviewed by clinical dietitians who determine if the item complies with more than 150 diets.

Nutrition Department food preparation staff and phone operators receive training on new recipes and participate in a taste test, so they can answer questions about items. Lee Unangst, dietitian informaticist and manager of the department’s complex computer system, ensures ingredients and nutrition information is accurate and correct.

With a diverse patient population, the CC must work to feed a variety of diets.

“Because we serve patients from all over the world, there are, of course, different food preferences,” explained Widger, describing how her group found a source of halal-certified meat for a Muslim patient who came to the CC for a lengthy stay. “When we get a patient request, we honor it.”

## CELEBRATING PATIENT SIBLINGS

Brothers and sisters of Clinical Center patients were honored during the Third Annual Sibling Day at the Clinical Center on July 13, 2010. “It is truly important that there is a time . . . they can be a proud, contributing member of their family,” said Dr. Lori Wiener, event organizer and coordinator of NCI’s Pediatric Psychosocial Support Program. The program is conducted in conjunction with the Clinical Center Rehabilitation Medicine Department Recreation Therapy Section and The Children’s Inn. Participants visited the Department of Laboratory Medicine, the Department of Perioperative Medicine, and a mock scanner in the National Institute of Mental Health Behavioral Health Clinic. Chief of the Recreation Therapy Section Donna Gregory facilitated therapeutic activities encouraging the siblings to talk about their experiences with a sick brother or sister and starting a conversation on what they face and how they cope with it.



In an operating room, siblings learned how staff sterilize the environment and got a chance to practice surgery in a mock belly. Nurse Shayna Herbert showed patient siblings Katalina Khoury (left) and Cassidy Koch some of the tools surgeons use.

## HOSPITAL RECOGNIZES COMMUNITY OF CAREGIVERS WITH DAY OF ACTIVITY

In recognition of the support provided by family and loved ones to patients participating in clinical research, the Clinical Center celebrated National Family Caregiver Month with Family Caregiver Day on November 1, 2010.

Research shows that family caregivers are at increased risk for health, emotional, financial, and work-related problems. In addition, family caregivers often find themselves in positions that make it difficult to maintain their own health.

“Caregivers report a lot of disruption in their sleep, high levels of physical and emotional fatigue, and high levels of distress that might even suggest that they need clinical intervention,” said Dr. Margaret Bevans, clinical nurse scientist in Nursing and Patient Care Services. According to Bevans, research in the chronic care setting shows that individuals who provide informal care to loved ones exhibit not only an increase in morbidity, but may also have an increased risk of mortality.

The agenda for Family Caregiver Day included a presentation from guest speaker Dr. Richard Schulz, a nationally recognized expert in the field of caregiver research. Schulz is the director of the University Center for Social and Urban Research at the University of Pittsburgh. His talk—“Reflections on Three Decades of Research on Caregiving”—described some of the psychosocial and general health issues encountered by family caregivers, along with intervention research and implications for policy.

Dr. Richard Schulz, a nationally recognized expert in the field of caregiver research, was guest speaker.



As a caregiver for her husband, Nancy Bradfield of Harrisonburg, Va., understands how hard it can be. “For people who are just coming into a situation where their loved one has been diagnosed with a serious illness, it can be quite a challenge,” she said. “I think that if you can tell yourself that you need to stay as optimistic as possible, it helps a lot. And try to communicate as well as you can with the patient.”

Events included an information fair and expo; an interactive art project; sessions with mental health and social work workers; and fitness, yoga, and massage demonstrations.

“We are already caring for a unique population, so we need to think of our caregivers as having to deal with unique challenges. They are managing not just the clinical needs of their loved ones, but they also need to understand and interpret the needs associated with the clinical trial their loved one is enrolled in. This is an added complexity,” said Bevans.

She is currently investigating the effectiveness of problem-solving education in caregivers and patients who are receiving stem cell transplantation. “We are trying to determine if caregivers who are supporting individuals undergoing a stem cell transplant also report levels of emotional distress or symptoms that will put them at risk for health issues in the future,” she said.

Ideally, Bevans would like to see caregivers maximize the resources and education available to them while at the CC, giving them the knowledge and resources necessary to stay healthy when they return home.

“If you think about the role of the caregiver—the commitment to their family, their employer, their own health—one can easily recognize the scope of the caregiving experience. It’s much broader than what we see when they are with us,” she said.



Asyky Maris works a paper cutout of a hand to add to the “Collage of Helping Hands” interactive art project offered by the Rehabilitation Medicine Department Recreation Therapy Section.

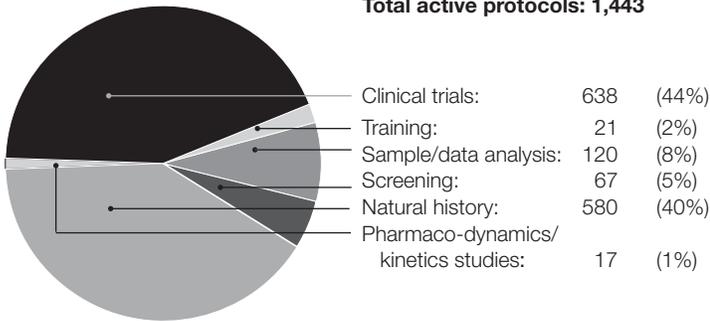
## TEEN RETREAT



Members of The Children’s Inn band—including staff members Alex Florez (left) and Joe Hage—serenaded participants in the Fourth Annual Teen Retreat in June 2010. The Clinical Center Rehabilitation Medicine Department’s Recreation Therapy Section—in collaboration with The Children’s Inn—coordinates the event, which offered two days of programs aimed at balancing therapeutic activities with team-building exercises.

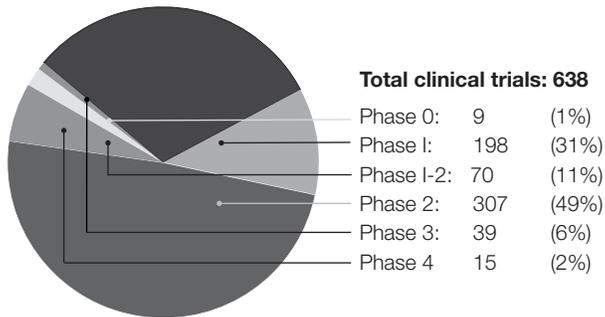
# Advancing Clinical Research

## PROTOCOLS BY RESEARCH TYPE (ONSITE INTRAMURAL PROTOCOLS, FISCAL YEAR 2010)



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

### Breakdown of clinical trials



### Clinical trials phases

- Phase 0:** An initial first-in-human study (20–30 participants) under an exploratory IND (investigational new drug) for early identification of biologic and molecular markers in new clinical agents. There is very little agent exposure with no therapeutic or diagnostic intent.
- Phase I:** Researchers test a new drug or treatment for the first time in a small group of people (20–80) to evaluate its safety, determine a safe dosage range, and identify side effects.
- Phase II:** The study drug or treatment is given to a larger group of people (100–300) to see if it is effective and to further evaluate its safety.
- Phase III:** The study drug or treatment is given to large groups of people (3,000 or more) to confirm its effectiveness, monitor side effects, compare it with commonly used treatments, and collect information that will ensure safe usage.
- Phase IV:** These studies are done after the drug or treatment has been marketed. Researchers continue to collect information about the effect of the drug or treatment in various populations and to determine any side effects from long-term use.

## THE ROAD AHEAD FOR CLINICAL RESEARCH NURSING

Clinical research nurses from more than 20 states and four countries discussed the “Road Ahead” during the Second Annual International Association of Clinical Research Nurses (IACRN) Conference co-hosted by Clinical Center Nursing and Patient Care in November 2010.

Dr. Christine Grady, acting chief of the CC Bioethics Department, delivered the conference’s keynote, “Clinical Research Nursing: Ethical Foundations and Challenges on the Road Ahead.” Grady described some of the central ethical tensions experienced by nurses in a clinical research setting and encouraged nurses to be active, vocal members of the research team.

“Each of the diverse nursing roles has its own absolute critical function in the conduct of clinical research, and all of us are committed to quality research practices, high ethical standards, regulatory compliance, and human subjects protection,” she said. “In order to accomplish those goals, we need to be familiar with the ethical challenges that we face—the principles, regulations, and other guidance for the ethical conduct of clinical research.”

According to Grady, clinical research nurses or research nurse coordinators often find themselves in a position where they are advocates for three competing components of research: the individual as patient, the individual as study participant, and the research.

“All of us, I think, can recognize times when there is a tension between a data point that needs to be taken care of and a patient who might be upset or asleep,” she said. “We wake them up, we calm them down, but the tension that we feel in that process is real. There are struggles between what we believe is important for the comfort and interest of the patient, and the need to collect and report accurate data.”



CC Chief Nursing Officer Dr. Clare Hastings (left) accepted the IACRN Distinguished Clinical Research Nurse Award from the association’s past-president Margaret McCabe (center) and current president Nicole Mullen (right).

## DEFINING CLINICAL RESEARCH NURSING

Discover a better nursing career for a better world. So said a video played at the beginning of the Clinical Research Nursing 2010: Nursing Practice at America’s Research Hospital pre-conference November 17, 2010.

Clinical Center Nursing and Patient Care Services hosted the event, which was held the day before the International Association of Clinical Research Nurses conference. The pre-conference reviewed the department’s four-year initiative to define the specialty. “Clinical research nursing encompasses the care that is required because of the condition the patient has and any work that is necessary for the clinical research study,” said Dr. Clare Hastings, chief nurse officer. “If the person has diabetes, a clinical research nurse takes care of the diabetes. There is also serial sampling, blood draws, and other procedures that are part of the protocol.”

The CRN2010 initiative was launched in 2007 following a review that encouraged nursing to share the specialized nature of its practice. A team of nurses worked to define the domain of practice through interviews, review of



Acting chief of the CC Bioethics Department Dr. Christine Grady delivered the IACRN conference keynote on ethical foundations and challenges of clinical research nursing.

A panel of representatives of different clinical research nursing positions gave their perspectives on their roles in research. Participating were (from left) Leslie Wehrlen, nurse specialist in research; Dirk Darnell, clinical research nurse; and Carol Levinson, senior clinical research nurse.



clinical research nurse job descriptions, and review of relevant literature. They narrowed their findings to five dimensions that represent the specialty. “CRN2010 was the basis for our strategic plan, and we feel very good that we accomplished what we set out to do,” Hastings said.

Clinical Research Nursing 2010 took this definition to the level of detail and consensus required to create a certification process for nurses practicing in clinical research. This nursing specialty focuses on the care of research participants. In addition to providing and coordinating clinical care, clinical research nurses have a central role in assuring participant safety, ongoing maintenance of informed consent, integrity of protocol implementation, accuracy of data collection, data recording, and follow up.

Hastings also explained the role of nurses at the CC and demonstrated the value of the profession in the research process. “If you want precision data collection and patient care as specified in the protocol, you can’t be understaffed,” she said.

Pre-conference attendees, who came from academic institutions across the country, heard from LCDR Dr. Margaret Bevans on the results of a role delineation study—differences between a research nurse coordinator and a clinical research nurse—and the need for further analysis.

Representatives from different roles gave their perspectives on nursing roles in research, and nurses attended round table discussions on innovative approaches to a particular challenge in clinical research nursing. The afternoon also held an opportunity for tours of the Clinical Center and discussion of research in particular patient care settings.

Bertha Robbins, clinical research nurse coordinator, is one of a small research staff at Middlesex Hospital Cancer Center in Middletown, Conn. She traveled to the Clinical Research Nursing 2010 pre-conference to learn from and share with others in her field. “I think the initiative is a great idea,” Robbins said. “This is the only way to move the profession forward.”

## DECKER LECTURE COMBATS MYTHS AROUND HOSPITAL-ACQUIRED INFECTIONS

The seventh in a series honoring NIH leaders in clinical teaching, the 2010 John Laws Decker Memorial Lecture in June, highlighted the work of Dr. Tara Palmore, deputy hospital epidemiologist at the Clinical Center and staff clinician at the National Institute of Allergy and Infectious Diseases. Palmore is the recipient of the NIH Fellows Committee's 2009 Distinguished Clinical Teacher Award.

Palmore's lecture, "Hospital Infections: Rumors and Reality," addressed common misconceptions about hospital-acquired infections, an area of interest of the NIH community evidenced by the crowd at Lipsett Amphitheater.

Hospital-acquired infections—which affect nearly 2 million people a year and kill an estimated 99,000—come at a serious cost, economically, and socially, Palmore said.

"An intangible but extremely important consequence of hospital infections is a loss of public confidence in the health-care system, which allows these infections to occur in a place where people go to get well," she said.

Palmore refuted the misconception that "hospital infections are bound to happen" and explained ways health-care professionals can prevent and treat infections. Palmore discussed the CC policy of mandatory flu vaccination for patient-care staff.

"The reality is that flu vaccination of health-care workers saves patient lives," she said.

Palmore discussed strategies to prevent or terminate the transmission of infection and encouraged lecture attendees to always consider the possibility of an outbreak until proven otherwise and to avoid viewing single infections as isolated incidents or coincidences.

"Hospital infections should not be accepted as a normal part of patient care," she said. "We aren't going to get certificates for having clean hands, but preventing infections is really its own reward."

Palmore came to the NIH in 2001 as an infectious disease fellow after completing her medical degree at the University of Virginia School of Medicine and residency at New York-Presbyterian/Weill Cornell Medical Center. She joined the NIH staff in 2005 and became deputy hospital epidemiologist in 2007. Palmore directs development, organization, and implementation of the CC infection control program.

The annual lecture is presented in memory of former CC Director Dr. John Laws Decker, who died in 2000. He served as director of the CC and as NIH associate director for clinical care from 1983 until 1990, after which he was named scientist emeritus.



Dr. Tara Palmore presented the 2010 John Laws Decker Memorial Lecture.

### Doppman imaging lecture presents "The Evolution of PET"

Radiology and Imaging Sciences hosted the 10th annual John Doppman Memorial Lecture for Imaging Sciences on October 27, 2010.

Dr. Carolyn Cidis Meltzer, William P. Timmie Professor and Chair of Radiology, as well as associate dean for research at Emory University School of Medicine, was the speaker. She is also director of the Emory Center for Systems Imaging.

Meltzer spoke on "The Evolution of PET: Images of Progress." The Doppman lecture is held in honor of the late chief of the CC's former Diagnostic Radiology Department.



Dr. David Bluemke, director of CC Radiology and Imaging Sciences, with Carolyn Cidis Meltzer, who presented the 10th John Doppman Memorial Lecture for Imaging Sciences.

## Recovery Act funds go to Clinical Center projects

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

- Instrument to provide automated assessment of the white blood cell differential, identifying the fraction of white cells that are neutrophils, monocytes, lymphocytes, eosinophils, and basophils.
- Hardware and software upgrades for the Clinical Research Information System (CRIS), the electronic patient record application.
- Upgrade to existing information technology system to integrate the new perioperative information system and extend the infectious diseases and health-care epidemiology surveillance platform to outpatients.
- New capability for centralized patient scheduling that integrates into the Clinical Research Information System.
- Hi-resolution display monitors so clinicians have greater access for review of images from the Electronic Picture Archiving Communications Systems that enable filmless radiology operations.
- Portable computers to enhance quality care and patient safety by facilitating documentation at the point of care.
- Expansion of the perioperative information system, which enables procedures scheduling and nursing/physician/anesthesia documentation. Information will be integrated to the Clinical Research Information System.
- System to automate the process of nucleic acid extraction from samples, which increases the efficiency of molecular diagnostic services.
- Freezers to replace old and outdated equipment for use with clinical blood products, reagents, and clinical specimens.
- Freezers to replace equipment used to store cellular therapy products, rare red blood cells, and human leukocyte antigen (HLA) specimens for clinical use.
- Equipment used during surgeries when excessive blood loss occurs. Such pumps can be life-saving by rapidly infusing large volumes of blood and blood products.
- Replacement endoscopes that are used during surgical procedures to visualize the respiratory and gastrointestinal tracts.
- Equipment to support ultrasounds, oxygen-dependent patients, and patients in impending respiratory failure.
- New server that will allow storage of complex data for electronic data-capture projects involving movement analysis studies in rehabilitation medicine.
- Hardware and software to provide authentication to all clinical and administrative information systems following *Homeland Security Presidential Directive 12* regulations using the Government Smart Card.
- Equipment to automate the process of isolating specific cell types, based on surface antigens using monoclonal antibodies.
- Equipment to enhance support for the hospital standard for intravenous medication safety infusion.
- Software that enables extracting data from the CRIS and ancillary systems to the Data Transformation Initiative System used for financial and activity reporting by protocol.
- Hardware and software to enable patient and health-care provider access to patient records and facilitate communications with the NIH care and research teams.
- New PET/CT (positron emission tomography) scanner to strengthen and expand support for clinical research, patient care.
- Equipment to improve the quality of peripheral blood and bone marrow smears used in laboratory tests.
- Patient lifts to ensure staff safety and patient-care efficiency.
- Support to accelerate efforts to transition to and maintain electronic medical records for patients.
- Upgrades for processing servers and Tesla acceleration systems to facilitate more rapid generation of higher-quality patient images.

## ASTUTE CLINICIAN EXAMINES GENES' ROLE IN LIVER AND HEART DISEASE

The 13th annual Astute Clinician Lecture brought a crowd to Masur Auditorium on November 17, 2010, with a popular topic—"Genes Versus Fast Foods: Eat, Drink & Be Wary."

Dr. Helen H. Hobbs delivered the lecture established through a gift from the late Dr. Robert W. Miller and his wife Haruko. The Astute Clinician Lecture honors a US scientist who has observed an unusual occurrence and, by investigating it, has opened an important new avenue of research.

Hobbs is a Howard Hughes Medical Institute investigator, director of the Eugene McDermott Center for Human Growth and Development, and professor of internal medicine and molecular genetics at the University of Texas Southwestern Medical Center. For the past 10 years she has spearheaded the Dallas Heart Study, a large population-based study of Dallas County.

In her lecture—part of the NIH Director's Wednesday Afternoon Lecture Series—Hobbs presented the case study of Morgan Spurlock, the star of the documentary "Supersize Me" that chronicled his

experience with a McDonald's-only diet. Spurlock's elevated liver function tests and cholesterol levels after only 12 days of his experiment is indicative of the effect such diet has on many Americans, albeit at a slower rate, Hobbs said.

The elevated liver function tests are most likely due to the development of fatty liver disease, which is associated with both obesity and insulin resistance. However, some diabetics and obese people do not have fatty liver disease, Hobbs said.

"The question that we wanted to address was 'Are there genetic factors that are responsible for individuals contributing to the propensity to deposit triglyceride in the liver?'" she said.

Hobbs' team also used genetics to examine the relationship between plasma levels of cholesterol and heart disease. Researchers know that high plasma levels of cholesterol promote atherosclerosis (plaque buildup in the arteries), Hobbs said. She presented evidence that low plasma levels of cholesterol, if maintained over a lifetime, provide protection from heart disease.



Dr. Helen Hobbs of University of Texas Southwestern Medical Center presented the 13th annual Astute Clinician Lecture. With her is Dr. William Gahl, NHGRI clinical director.

## MEETING SUPPORTS ADVANCEMENT IN CRITICAL CARE TRIALS

Clinical Center staff joined other NIH representatives and researchers from around the nation to encourage the best science and exchange ideas on clinical trials in critical care medicine in November 2010.

Approximately 100 researchers attended the third meeting of the US Critical Illness and Injury Trials Group, which vets study ideas, offers networking opportunities, and facilitates large, multi-center trials. This year's meeting at Natcher Conference Center focused on neurologic emergencies. Attendees discussed the key role played by emergency room and ICU staff in treating strokes and other neurologic emergencies, when quick response matters most.

"Meetings like this improve the efficiency of studies," said Dr. Anthony Suffredini, associate chief of the CC Critical Care Medicine Department and member of the meeting organizing committee. "There was a lot of synergy between different groups in the multi-disciplinary critical care community who might not otherwise have the opportunity to communicate or collaborate."

## SYMPOSIUM PRESENTS CHALLENGES AND TRIUMPHS OF TRANSFUSION MEDICINE



CC Department of Transfusion Medicine Chief Dr. Harvey Klein (left) presented the 2010 Richard J. Davey Award to Dr. Walter Dzik of Massachusetts General Hospital for his dedication to research and education in transfusion medicine.

The Clinical Center Department of Transfusion Medicine hosted the 29th annual Immunohematology & Blood Transfusion Symposium, co-sponsored by the American Red Cross, in Masur Auditorium on September 16, 2010. The program provides practical information about recent developments, current practices, controversies, and laboratory management issues relative to transfusion medicine.

The Richard J. Davey Award—given annually to an individual whose contributions have significantly advanced the field of transfusion medicine—was presented to Dr. Walter Dzik, co-director of the Blood Transfusion Service at Massachusetts General Hospital and associate professor of pathology at Harvard Medical School. He was a fellow in transfusion medicine here from 1981 to 1983.

During the symposium, Dzik presented on cerebral malaria and cytoadherence. Infected red blood cells attach to blood vessels by binding protein pfEMP-1 to the CD-36 antigen. CD-36 is found on platelets, which bond to endothelium (layer of cells in blood vessels), and endothelium itself.

The clusters of red blood cells, platelets, and endothelium make blood delivery difficult and can be lethal. Complicating the connection, CD-36 is also present on monocytes, which swallow red blood cells thereby protecting from dangerous adhesions to endothelium.

After a few unsuccessful attempts, Dzik's group found a way to code for CD-36 on monocytes versus platelets to examine expression in relation to cerebral malaria and outpatient malaria. They are doing so in a clinical study in Uganda. "There are a lot of obstacles in trying to get to the heart of that matter," Dzik said. "You just have to accept that and keep working toward your intent."

Dr. Susan Stramer, executive scientific officer at the American Red Cross, presented "Plagues in the Blood Supply? Emerging Infectious Disease Agents du Jour" and listed causes of infectious disease risk, including failure of donor selection, insensitive tests, mutant/variant organisms, and emerging/reemerging agents. Other presentations during the day-long symposium focused on infectious diseases, blood and drug evaluation, blood usage and monitoring, and application of red blood cell molecular testing.

### International field physician draws a crowd in Lipsett

Reflecting on the lessons learned and challenges faced in the field with international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF), Dr. Jean-Herve Bradol spoke to a packed Lipsett Auditorium on April 16, 2010.

Director of research at the MSF Center for Reflection on Humanitarian Action & Knowledge, Bradol has extensive field experience with MSF including in refugee camps in Thailand and in Rwanda during the early 1990s. He also served as president of MSF-France for eight years and is a former board member of MSF-USA. Bradol discussed his experience with Burmese refugees in Thailand suffering from advanced malaria. A patient told him that he had resorted to smuggled drugs from China because the MSF drugs were not working. Bradol's team obtained the other pharmaceuticals and started investigating their safety and efficacy.

"But setting up trials in those environments is not that easy," Bradol said. The refugee community was not initially receptive to using a Chinese drug not registered in their country, and ethical concerns were rampant in conducting research with such a patient population. "How can a refugee give consent when the question is asked by the very organization that provides their basic survival? The person is not really in a position to say no," Bradol said. He reported that with advance treatments and preventive measures such as mosquito nets, malaria is no longer a major public health issue in that area.

His lecture coincided with the release of the MSF collection *Medical Innovation in Humanitarian Situations: The Work of Médecins Sans Frontières*, which illustrates 10 examples of the complexities of introducing medical innovations in the midst of difficult humanitarian crises.

## PHARMACEUTICAL DEVELOPMENT SECTION UPGRADES TO NEW, TAILOR-MADE SPACE

The unique and groundbreaking work of the Clinical Center calls for clinical trial drugs not always available from a study sponsor, so we make our own.

The CC Pharmacy Department Pharmaceutical Development Section (PDS) was established in 1956 and has operated in several areas over the last half-century. Evolving good manufacturing practices, as mandated by the Food and Drug Administration, presented an opportunity to upgrade the PDS environment and equipment in a new space created especially for the section.

PDS formulates and analyzes vaccines and medications not able to be purchased from manufacturers. These products account for one-third of the 1,000 separate drugs (including placebos and varying strengths) that the CC uses in its research protocols, said PDS Chief George Grimes, Jr. An example is a topical, sterile gel of resiniferatoxin, which PDS is developing for research into its utility as a pain treatment in an upcoming National Institute of Dental and Craniofacial Research protocol from Dr. Mike Iadarola, chief of the NIDCR Integrative Neurobiology and Neuronal Gene Expression Unit, and Dr. Andrew Mannes, staff clinician in the CC Department of Perioperative Medicine.

The section also registers and packages all drugs obtained from outside pharmaceutical companies for use in CC clinical trials. “We handle all investigational drugs,” Grimes said. “In the double-blind studies in particular, all the drugs look alike, so we have to be really good about record-keeping and procedures.”

In the new facility, there’s a different room for seemingly every step of their process, allowing for better air and overall quality control, Grimes said. Where staffers work with HIV-infected blood in the Clinical Pharmacokinetic Research Laboratory, for example, negative air flow (pulling more air in than is pumped out) and the use of a biological safety cabinet decreases the risk of contamination outside the confines of the laboratory.



Pharmaceutical Development Section Chief George Grimes, Jr., does the honors at a ribbon-cutting on January 8, 2010. With him are CC Director Dr. John I. Gallin (left) and Pharmacy Chief Robert DeChristoforo.

PDS staff (from left) Kumi Ishida, Scott Hotaling, and Ram Agarwal adjust the new automatic capsule machine in their section’s updated area.

Clinical Pharmacokinetic Research Laboratory staff characterize how drugs are excreted and metabolized, another function of the PDS.

## 2010 BENCH-TO-BEDSIDE AWARDS



The Bench-to-Bedside (B2B) Program was launched in 1999, and 176 projects totaling about \$40 million have been funded to date. The program expanded in 2006 to include extramural collaborators with 68 grants supplemented so far. Over the past five cycles, extramural interest in the program has greatly increased; in the current 2011 application cycle, investigators from 114 extramural institutions were listed as collaborators or principal investigators on the 143 Letters of Intent.

### AIDS CATEGORY: PROJECTS FUNDED BY OFFICE OF AIDS RESEARCH

PROJECT	INVESTIGATORS INSTITUTE(S)/INSTITUTION
New Bioinformatic Approach to Determine HIV Incidence	<b>NCI:</b> F. Maldarelli; M. Kearney; W. Shao; <b>NIAID:</b> R. Dewar; <b>Johns Hopkins University, Bloomberg School of Public Health:</b> J. Margolick; <b>Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center; (LA BioMed):</b> E. Daar
Role of Gut-Associated Lymphoid Tissue in HIV-1 Persistence	<b>NCI:</b> F. Maldarelli; M. Kearney; <b>University of Pittsburgh:</b> D. McMahon; <b>National Naval Medical Center:</b> A. Ganesan
Multiplex Microarray Chip-based Diagnosis of Respiratory Infections in HIV	<b>CC:</b> J. Kovacs; A. Suffredini; P. Murray; <b>NIAID:</b> S. Holland; J. Cuellar-Rodríguez; <b>NCI:</b> J. Gea-Banacloche; R. Lempicki; <b>Washington Hospital Center:</b> M. Smith

### BEHAVIORAL & SOCIAL SCIENCES CATEGORY: PROJECT FUNDED BY OFFICE OF BEHAVIORAL & SOCIAL SCIENCES RESEARCH

Antibody Identification and IVIG Treatment of PANDAS	<b>NIMH:</b> S. Swedo; <b>Yale University:</b> J. Leckman; <b>Oklahoma University Health Sciences Center:</b> M. Cunningham
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### WOMEN'S HEALTH: PROJECTS FUNDED BY OFFICE OF RESEARCH ON WOMEN'S HEALTH

Adrenal Hyperplasia Among Adolescent Patients With Polycystic Ovarian Syndrome	<b>NICHD:</b> C. Stratakis; <b>SUNY:</b> S. Ten
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### MINORITY HEALTH CATEGORY: PROJECTS CO-FUNDED BY NATIONAL CENTER FOR MINORITY HEALTH & HEALTH DISPARITIES AND INSTITUTES/CENTERS

Control of XMRV Replication in PBMCs and Prostate Carcinomas	<b>NCI:</b> V. Pathak; A. Rein; W. S. Hu; F. Maldarelli; <b>University of California, Davis:</b> R. deVere White; H.J. Kung
In vitro Fucosylation to Augment Cord Blood Stem Cell Engraftment	<b>NHLBI:</b> R. Childs; J. Pantin; <b>CC (Transfusion Medicine):</b> D. Stroncek
Biochemical Mechanisms of the Etiology of Sickle Cell Pain	<b>NIDDK:</b> A. Schechter; <b>NINR:</b> R. Dionne; <b>CC (Transfusion Medicine):</b> D. Stroncek; W. Smith <b>Beth Israel Medical Center:</b> R. Portenoy; R. Cruciani

### GENERAL CATEGORY: PROJECTS CO-FUNDED BY NATIONAL CENTER FOR RESEARCH RESOURCES AND INSTITUTES/CENTERS

Optical Guidance for Improved Prostate Cancer Surgery	<b>CC (Radiology and Imaging Sciences):</b> B. Wood; M. Dreher; A. Kapoor; <b>NCI:</b> P. Pinto; W. Linehan; <b>Massachusetts General Hospital:</b> U. Mahmood
Imaging CXCR4-Expressing Cancer Using 64CuAMD	<b>NIAID:</b> J. Farber; I. Weiss; <b>NIBIB:</b> X. Chen; O. Jacobson; <b>NCI:</b> P. Choyke; <b>Georgetown University:</b> C. Isaacs

### PHARMACOGENOMICS CATEGORY: PROJECT FUNDED BY FOOD & DRUG ADMINISTRATION (FDA)

Mechanism of Response to Anti-TNF Therapy in Inflammatory Bowel Disease	<b>NIAID:</b> M. Yao; W. Strober; I. Fuss; <b>University of MD:</b> R. Cross; M. Flasar
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**RARE DISEASES CATEGORY: PROJECTS CO-FUNDED BY OFFICE OF RARE DISEASES RESEARCH AND INSTITUTES/CENTERS**

<b>PROJECT</b>	<b>INVESTIGATORS INSTITUTE(S)/INSTITUTION</b>
Targeting Antigen-Antibody Responses in Systemic Capillary Leak Syndrome	<b>NIAID:</b> K. Druey; T. Myers; S. Porcella; <b>NCI:</b> O. Landgren; <b>NIBIB:</b> A. Gorbach; <b>University of Minnesota:</b> A. Dudek; <b>Mayo College of Medicine:</b> P. Greipp
Sympathetic Innervation & Myocardial Injury in Acute Stress Cardiomyopathy	<b>CC (Radiology and Imaging Sciences):</b> C. Sibley; D. Bluemke; <b>NINDS:</b> D. Goldstein; <b>NHLBI:</b> D. Rosing; <b>Johns Hopkins:</b> I. Wittstein; F. Bengel; J. Mudd; J. Lima
Preclinical Testing of Targeted Agents for Clinical Development in NF1	<b>NCI:</b> A. Kim; B. Widemann; E. Dombi; <b>Children's Hospital Medical Center:</b> N. Ratner; J. Wu
The DICER1-related Pleuropulmonary Blastoma Cancer Predisposition Syndrome	<b>NCI:</b> C. Kratz; B. Alter; P. Rosenberg; <b>National Children's Medical Center:</b> A. Hill; <b>Children's Hospital &amp; Clinics of MN:</b> Y. Messinger; K. Schulz
Brain Development in Children with Williams Syndrome and the LIMK1 Gene	<b>NIMH:</b> K. Berman; J. Kleinman; <b>University of Louisville:</b> C. Mervis
The Role of EGFR in Endolymphatic Sac Tumors	<b>NCI:</b> P. Dennis; <b>Yale University:</b> A. Vortmeyer

**RARE DISEASES DRUG DEVELOPMENT: PROJECTS CO-FUNDED BY THERAPEUTICS FOR RARE AND NEGLECTED DISEASES PROGRAM AND INSTITUTES/CENTERS**

A Novel Therapy to Treat Acid Lipase-Deficiency by LCAT Inhibition	<b>NHLBI:</b> A. Remaley; K. Vickers; R. Shamburek; <b>Cincinnati Children's Hospital Medical Center - Research Foundation:</b> G. Grabowski; H. Du
Development of Combination Therapy for Niemann-Pick Disease, Type C	<b>NICHD:</b> F. Porter; A. Yergey; S. Bianconi; <b>NHGRI:</b> W. Pavan; <b>Washington University:</b> D. Ory
Gene Therapy Clinical Trial for LAD-1 Using a Foamy Viral Vector	<b>NCI:</b> D. Hickstein; <b>University of Washington Medical Center:</b> D. Russell; <b>Cincinnati Children's Hospital Medical Center:</b> P. Malik
BH3 Mimetics for the Treatment of Autoimmune Lymphoproliferative Syndrome	<b>CC (Laboratory Medicine):</b> J. Oliveira Filho; T. Fleisher; <b>NIAID:</b> V. Rao; K. Dowdell; <b>NIDDK:</b> D. Appella
Preventing Aortic Dilation in Women with Turner Syndrome	<b>NICHD:</b> C. Bondy; V. Bakalov; J. Zhou; <b>NHLBI:</b> A. Araj; D. Rosing; M. Boehm; V. Sachdev; <b>Johns Hopkins University:</b> J. Van Eyk; Q. Fu
Immunogenicity and Leishmania Vaccine Potential of Sandfly Saliva in Humans	<b>NIAID:</b> J. Valenzuela; S. Kamhawi; <b>Uniformed Services University of the Health Sciences/Walter Reed Army Medical Center:</b> N. Aronson; <b>George Washington University:</b> M. Bottazzi

**PROJECT FUNDED BY THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

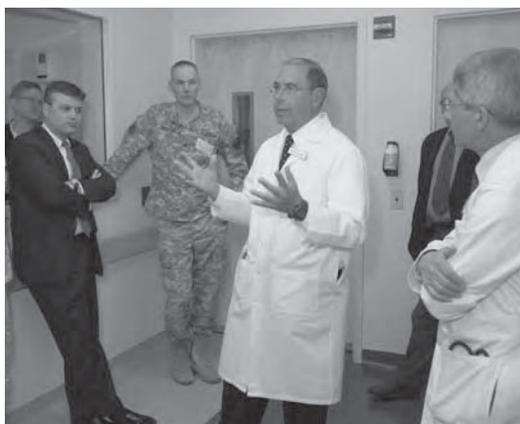
The Role of BDNF in Autism Spectrum Disorder and Cognitive Function	<b>NICHD:</b> J. Han; C. Pierpaoli; <b>NIMH:</b> K. Martinowich; D. Weinberger; C. Golden Williams; S. Swedo; A. Thurm; <b>NCI:</b> L. Tessarollo; <b>Uniformed Services University of the Health Sciences/Walter Reed Army Medical Center:</b> S. Sharp; <b>GlaxoSmithKline Pharmaceuticals:</b> B. Lu
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## NEW UNIT PROVIDES UNIQUE SUPPORT FOR CLINICAL RESEARCH



(Above) Dr. H. Clifford Lane, NIAID clinical director, was among speakers at the unit's opening.

(Right) Doing the honors at a ribbon-cutting for the new Special Clinical Studies Unit were (from left) Stewart Simonson, former HHS assistant secretary for public health emergency preparedness; Dr. (Col. US Army) Mark Kortepeter, deputy director of the Infectious Diseases Clinical Research Program at the Uniformed Services University of the Health Sciences; CC Director Dr. John I. Gallin; and NIAID Director Dr. Anthony Fauci.



A ribbon-cutting for NIAID's new Special Clinical Studies Unit at the Clinical Center was held on April 14, 2010. The new seven-bed unit, which is in the 5NE-S corridor of the Hatfield Building, affords state-of-the-art isolation capabilities.

"This new unit is another example of the Clinical Center's ability to adapt to emergency situations," said CC Director Dr. John I. Gallin at the ceremony.

During the event, NIAID Director Dr. Anthony Fauci presented a special award to Stewart Simonson, former HHS assistant secretary for public health emergency preparedness, who was instrumental in the creation and development of the unit. "He promised it would happen, and here it is,"

Fauci said. Simonson applauded NIH staff for the ability to "use their imagination, try to anticipate problems, and create solutions before they happen." Inpatient healthy volunteers and low-acuity patients in clinical trials will typically spend extended periods of time on the unit. The facility, designed as a mini-apartment to make the time spent more comfortable, includes one single room (with an anteroom), three double inpatient rooms, a common area for dining, a kitchenette, an exercise area, and laundry space.

The entire unit is also capable of functioning as an isolation suite of rooms and can be used to house patients with known or suspected infections with especially virulent infectious agents. It will be available for use by investigators whose patients are suspected of having a highly contagious condition. When patient isolation is needed, all four patient rooms and their connecting corridor will be kept under negative pressure at a high rate of air exchange and with HEPA-filtered exhaust. When isolation is mandated, access to the unit will be restricted to the unit staff with state-of-the-art infection control procedures in place. Point-of-care laboratory testing and telemetry monitoring are additional capabilities of the unit.

Staffing the access-protected Special Clinical Studies Unit requires a new process, too, said Ann Marie Matlock, nurse manager. While new to the CC, all 10 nurses hired to staff the unit came with clinical experience and a professional interest in infectious diseases. Specific training was developed and implemented to deal with infectious pathogens staff could potentially encounter despite the expected rarity of these types of occupational exposures or exotic infections, Matlock said.

## DC PARTNERSHIP FOR HIV/AIDS PROGRESS SEES ACCELERATED ACTION, OPENS FOURTH CLINIC

The DC Partnership for HIV/AIDS Progress, announced in January 2010, has seen substantial acceleration in progress for the four original pillars of the program, said Dr. Henry Masur, chief of the Clinical Center Critical Care Medicine Department.

In addition to directing the overall project in collaboration with Dr. Carl Dieffenbach, director of the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS, Masur leads one of the four pillars—enhanced care. The others—surveillance, prevention, and test and treat—complete the base of the initiative. The initial investment in this long-term program, \$26.4 million over the first two years, supports clinical research to help address the District’s HIV/AIDS epidemic, where roughly 3 percent of the population is infected with HIV—among the highest HIV/AIDS rates in the nation. The project is a collaboration among several NIH institutes and centers and the NIH Office of AIDS Research.

One of the most exciting programs in the initiative is the DC Cohort, which will link electronic records from the 12 largest HIV providers in DC to a database that can be used for research and for quality improvement studies. These 12 clinical partner sites see 85 to 90 percent of the District’s HIV patients. The collected information will provide important data for epidemiologic and clinical investigations. “We think we will have an unparalleled opportunity to look at an urban cohort,” said Masur.

The four clinics where NIH specialists are embedded to improve HIV subspecialty care for the underinsured—directed by Dr. Dawn Fishbein and within Masur’s pillar of enhanced care—have seen approximately 200 patients with HIV and hepatitis C infections. Three initial clinics opened in June 2009 in connection with existing programs at Family & Medical Counseling Service, Inc., in Southeast Washington; Unity Health Care’s Walker Jones Health Center in Northeast Washington; and Whitman-Walker Clinic in Northwest. The fourth clinic based at Unity’s D.C. General Health Center opened in the fall of 2010.

In each clinic, NIH staff work directly with patients to provide care and treatment. As the clinics expand, NIH is adding more experts. Dr. Anu Osinusi, an HIV-hepatitis co-infection specialist from the University of Maryland School of Medicine in Baltimore, joined the Clinical Center to work with patients at the new Unity Health Care’s D.C. General site and at the Unity’s Walker Jones facility. Additionally, Dr. Suad Kapetanovic, a psychiatrist with extensive HIV clinical and research experience at the University of Southern California, has been recruited by the National Institute of Mental Health to develop HIV-related mental health research initiatives in connection with the DC Partnership.

“This is a chance for NIH to do something good for the city and to expand our intramural research agenda into more areas that will contribute to reducing the impact of HIV/AIDS in urban America,” said Masur.

The clinics serve as study sites for a currently enrolling safety and tolerability clinical research study examining an experimental, orally administered drug in combination with injectable interferon and ribavirin to treat hepatitis C in patients with HIV/AIDS. The oral drug has been proven safe and effective to treat parasitic infections, and is currently being studied in research volunteers with hepatitis C mono-infection. The new study will involve as many as 35 research volunteers with HIV and hepatitis C who did not respond to prior standard treatment regimens.

New oral medicines potentially could replace injectable interferon-based regimens that are associated with adverse effects. “The patients are excited about the opportunities they will have to be enrolled in clinical trials, especially for hepatitis C, which is so hard to treat,” added Osinusi.

In addition to the new treatment study, the sites are participating in a study that is retrospectively examining progression of liver disease in African-American patients with HIV/AIDS and hepatitis C to evaluate the theory that this population remains in early stage liver disease longer than other populations with the same co-infections.

“We think we will have an unparalleled opportunity to look at an urban cohort.”

## LEARNING ABOUT RESEARCH AND HEALTHY EATING ON THE NATIONAL MALL

Get kids fired up about scientific research. Demonstrate that healthy food can be tasty and affordable. To accomplish these goals, Clinical Center staff joined thousands of children, teachers, parents, and scientists on the National Mall in Washington on October 23 and 24, 2010, for the inaugural USA Science and Engineering Festival. More than half a million people attended the event, where hundreds of NIH employees staffed booths and answered questions alongside business leaders and representatives from other government agencies.

Nearly 900 kids participated in an activity at the Clinical Center's booth, *Pack a Lunch with Punch for Kids in Research*, that demonstrated the scientific research process.

Selecting a favorite food from a menu of options, children learned to form a hypothesis, collect and analyze data, and report results. A colorful take-away—a lunch box featuring the CC website—reinforced messages about healthy eating.

“This was a unique opportunity to educate the community about our research hospital,” said Kelli Carrington of the Office of Communications, Patient Recruitment, and Public Liaison. “It was exciting to see so many young faces eager to select their favorite food for the demo study.” Results of the demonstration are posted on the CC website ([clinicalcenter.nih.gov](http://clinicalcenter.nih.gov)) for further use by teachers and parents educating children about the scientific method.

Also representing at the USA Science Festival, CC Executive Chef Robert Hedetniemi headlined a cooking demonstration with Pete Thomas from the second season of NBC's “The Biggest Loser.” “Learning how to eat is fundamental,” said Thomas, who lost 185 pounds over nine months. “And contrary to popular belief, healthy eating can be both very tasty and economical.”



In front of the crowd, Hedetniemi prepared three healthy meals as part of a daily menu: a pomegranate and fig breakfast parfait, an apple-encrusted autumn lunch salad, and a vegetable pasta dinner dish.

The USA Science and Engineering Festival aims to invigorate the interest of the nation's youth in science, technology, engineering, and math.

Britt Ehrhardt, Office of Communications, Patient Recruitment and Public Liaison, looks on as a science festival attendee spins the prize wheel, completing the *Pack a Lunch with Punch* science demonstration.



Omar Echegoyén, from the Office of Communications, Patient Recruitment, and Public Liaison, chats with young science enthusiasts at the Clinical Center booth at the USA Science and Engineering Festival.

CC executive chef Robert Hedetniemi prepared three healthy meals as part of a daily menu during his demonstration at the USA Science and Engineering Festival while Pete Thomas of “The Biggest Loser” discussed his weight loss with the crowd.



## RESEARCH DAY EXPOSES DIETITIANS TO CLINICAL RESEARCH

The Clinical Center Nutrition Department welcomed 85 attendees from around the country to an NIH Research Day on March 18, 2010.

National Cancer Institute/CC Nutrition and Cancer Prevention Research Practicum participants and local dietetic interns heard a morning of presentations from staff before touring the hospital and the Metabolic Clinical Research Unit to get a glimpse of the work of clinical research dietitians

Attendees heard a welcome and introduction to the CC from dietetic internship director LCDR Merel Kozlosky, before learning about the role of dietitians in research from Nancy Sebring. In an acute care hospital, clinical dietitians spend about 80 percent of their time on clinical patient care, with the rest devoted to hospital and department support. Clinical research dietitians, on the other hand, Sebring said, split their time between those responsibilities and research support, though the breakdown varies by staff member.

Sebring presented some types of nutrition-focused research. “For example, in one of our studies looking at obesity we’re interested in patients’ taste preferences—do certain people taste sweet or sour differently than others?” Sebring said.

In the “Parade of Protocols” presentations, CC clinical research dietitians spoke on their roles in various NIH studies. Beth Moylan found it impor-

tant to evaluate the existing low iodine diet, which is used in conjunction with the treatment for thyroid cancer patients, due to food manufacturing changes and an international patient population consuming foods grown in different soil compositions. LCDR Jennifer Graf explained balancing types of protein for those with methylmalonic acidemia who need enough protein for normal anabolic function but not too much of particular amino acids they cannot properly break down. LT Rachel Drabot recounted helping a cancer research patient who experienced a multitude of treatment side effects by providing her with liquid nutrition supplements, individualized nutrition counseling, meal plans, and support.

Dr. Amber Courville, metabolic research dietitian, presented the Metabolic Clinical Research Unit, where more than a dozen obesity-related studies are being carried out, such as one examining how genes and the environment interact to determine body weight. The unit continues to grow and several more protocols with nutrition components are currently under development.

Dr. Amy Subar, nutritionist from the National Cancer Institute, spoke on new methods of dietary assessment, including using cell phone photos to track what someone eats. Marnie Dobbin, CC clinical research dietitian, presented an overview of botanical and “other” dietary supplements and resources available to guide safe supplement use.

### **BTRIS—the Biomedical Translational Research Information System**

—was launched in 2009 and is available to the NIH intramural community, bringing together clinical research data from the CC and other institutes and centers.

“BTRIS is designed to bring together clinical research data from all the institutes and centers to give investigators one place to get all their data and allow other users to ask new questions of the old data,” said Dr. Jim Cimino, chief of the Clinical Center Laboratory for Informatics Development.

BTRIS provides clinical investigators with access to identifiable data for the subjects on their own active protocols, while providing all NIH investigators with access to de-identified data across all protocols. The advanced search, filtering, and aggregation methods to create data sets support ongoing studies and stimulate ideas for new research.



Dr. Jim Cimino demonstrated the sorting capabilities of BTRIS to a group of NINDS intramural researchers in June 2010

## NURSES PRESENT ON TRIBAL COMMUNITY'S ROLE IN RESEARCH DEVELOPMENT



Presenting at the 2010 Nurse Leaders in Native Care Conference in July on their experience with community-based participatory research were (from left) Desiree Goodman, director of nursing, Fort Belknap Service Unit; Teresa N. Brockie, Clinical Center research nurse specialist; and Kathleen Adams, manager of public health nursing, Fort Belknap Community Council.

Clinical Center Nursing and Patient Care Services and nurse leaders from the Indian Health Service (IHS) organized a symposium and workshop on the use of the principles of community-based participatory research on the Fort Belknap Indian Reservation in 2009. In 2010 NIH, IHS, and Fort Belknap representatives presented outcomes from those events.

At the 2010 Nurse Leaders in Native Care Conference held in DC in July, Kathleen Adams, manager of public health nursing, Fort Belknap Tribal Health, and Desiree Goodman, director of nursing, Fort Belknap Service Unit, presented a poster and led a discussion on “Utilizing Community Based Participatory Research Principles as a Mechanism for Delivery of EBP in Tribal Communities: Fort Belknap Research Symposium and Evidence-Based Practice Workshop.”

Community-based participatory research is a collaborative approach that involves tribal communities in knowledge generation, intervention research, and policy change. Evidence-based practice is a problem-solving approach to the delivery of health care that integrates the best evidence from research with a clinician’s expertise and a patient’s or a community’s preferences and values.

The research symposium informed practitioners of significant research findings related to community-identified health topics of concern (community and family violence, methamphetamine abuse, mental health, and suicide). The interactive workshop facilitated and encouraged the implementation of evidence into practice.

The presentation at the July conference provided the process of collaboration—from initiation to the culmination of the research symposium and workshop—using a community-based participatory research model for Native American community engagement.

Through continued collaboration with the CC, Fort Belknap nursing is using the process to develop a project focused on adolescent alcohol use, with an implementation date of mid-2011.

## MOVEMENT ANALYSIS LAB STEPS INTO RENOVATED SPACE WITH LATEST EQUIPMENT

More tools make for better research in the Clinical Movement Analysis Lab in the Clinical Center Rehabilitation Medicine Department Functional & Applied Biomechanics Section. Recently renovated space brings the latest in motion capture and analysis equipment to the study of how patient populations move. The lab uses a combination of tools—cameras, electrodes, force plates, and a new body weight support system—to give a comprehensive view of how

patients with debilitating disorders such as cerebral palsy and osteogenesis imperfecta move. While the focus is on walking, any type of movement in any part of the body can be measured. “Combining all those data gives a full quantitative analysis,” said Lindsey Bellini, a section engineer. The goal is to develop new strategies to improve movement and to test those strategies already in place, said Chris Stanley, senior research engineer.

The primary piece of the puzzle involves ten new cameras that measure motion—replacing seven older cameras—by recording the changing positions of reflective markers on specific locations of the patient’s body. A bone model created from the reflective markers calculates joint angles, for example how much the knee bends when walking. The new motion-capture system features real-time capability, where the software processes the motion as it occurs, rather than after the motion is completed. This allows for more advanced studies and lets researchers check that the capture technology is set correctly and adjust if necessary. Tiny, wireless electromyography electrodes are time-synchronized with the system and measure muscle activity, such as when they fire to propel the person.

“Plus it’s really cool to show people, ‘this is what you’re doing right now,’” Bellini said of the technology, which is also used in sports performance analysis and motion picture technology.

A color pattern on the floor camouflages plates that measure three dimensional forces and moments in each patient’s step. With a lot of pediatric visitors, the colors are also “just more fun for the kids,” Stanley said.

A bigger, better treadmill also holds force plates. The treadmill is split, right and left, to measure and compare forces on each side. The treadmill will be used with a new virtual reality system that will be tested first in patients with Parkinson’s disease or traumatic brain injury, the engineers said. This type of system can ‘trick’ the person to step over obstacles or navigate through a narrow hallway or busy store, to more realistically assess how they function in everyday life.

The last piece to be installed was a body weight support system with a track extended over the force plates and treadmill. The patient wears a harness that is connected to the system, allowing the team to provide support to enable weak or heavy patients to practice walking when they would not be able to on their own. Additionally, the support system can help patients safely practice more difficult tasks, such as running or deep squats, without a fear of falling. The support is dynamic, that is

the same tension is held through the entire exercise, both when pulling away and when moving closer through the natural gait pattern.

“This allows us to start rehabilitation sooner and accelerate people more quickly. When they’re not supporting their entire body weight, they can challenge themselves,” said Bellini.

Data from all the lab’s tools are combined to form a more complete picture for both patients with motor disabilities and healthy volunteers. The lab measures the effects of interventions—everything from surgery to medications, a brace to an exercise regime—to see if the patient makes and retains progress. For example, the movement of a young child with a brain injury would be captured and analyzed before, during, and after completing an exercise program on the elliptical machine to see if greater practice of making reciprocal arm and leg movements would translate to faster and better walking.

The renovations were funded by the phenotyping core of the Center for Neuroscience and Regenerative Medicine. Ongoing research involves the categorization and study of pathogenesis in traumatic brain injuries.



The Clinical Movement Analysis Lab captures the gaits of patients with markers and cameras and displays the movement in real-time on a screen in the room.



**First full genome sequence completed on NIH patient**

The first NIH patient to have his whole genome sequenced calls the experience “fabulous” and “eye-opening.”

Rick Del Sontro was first to have researchers complete a detailed description of the order of the chemical building blocks, or bases, in his DNA. As part of the National Human Genome Research Institute’s ClinSeq™ study, this milestone is an advance toward personalized medicine and a better understanding of how patients may react to their genetic information.

“Ultimately what personal genomics is all about is finding out what your risks are and modifying your behavior accordingly to maximize staying healthy,” NIH Director Dr. Francis S. Collins told science reporters in May 2010.

The ClinSeq™ study is a trans-NIH effort to understand the genetic roots of disease susceptibility and the challenges of using genome (the entire set of genetic instructions found in a cell) sequencing tools in a clinical research setting. It is also the first study to return individual genetic sequencing results to research subjects from a large-scale sequencing effort. Coronary heart disease is a good place to start because of its high association with genetic risk factors and the numerous interventions available, reported the research team.

While most ClinSeq™ participants were initially sequenced for about 300 genes known or suspected to be associated with heart disease, Del Sontro was the first chosen for whole genome sequencing. In this process, a person’s three billion base pairs are sequenced to identify the million or so variants that make everyone unique and hopefully link some of those to risk of disease. Patients want to know, “What’s wrong with me? What caused it? What can we do?” said ClinSeq™ principal investigator Dr. Leslie Biesecker, chief of the NHGRI Genetic Disease Research Branch. “We want to use these genomic technologies to answer those embarrassingly simple, but difficult, questions.”

Del Sontro enrolled through a referral from

the NIH Heart Center at Suburban Hospital in Bethesda, Md. With a family history of heart problems, he forced himself on a cardiologist, even though he appeared in good health with an Ironman triathlon to his record. His doctors found “off-the-charts calcification,” of his coronary arteries, Del Sontro said, and, after treatment, recommended him to the ClinSeq™ study for further investigation of an underlying cause.

Launched in 2007, the research protocol invites participants to the Clinical Center for a half-day clinical work-up that includes visits to phlebotomy and the EKG heart station. A partner in the study, the National Heart, Lung, and Blood Institute, performs an echocardiogram and a computerized axial tomography, or CAT, scan of the heart on each ClinSeq™ patient volunteer.

“We get a snapshot of the current state of that person’s heart health,” Biesecker said. “We can use that as the starting point, but only as the starting point, to begin to dissect their long-term risk of having heart disease.”

The blood participants donate is screened for markers like cholesterol and glucose levels, and some is sent to the NIH Intramural Sequencing Center where the 300 candidate genes or, in Del Sontro’s case, the whole genome is sequenced.

He was selected for the more comprehensive sequencing because of the unusual presentation of plaque buildup in his arteries but no history of high cholesterol, said genetic counselor and ClinSeq™ researcher Flavia Facio. Del Sontro shares this unique health history with generations of his family and his seven brothers and sisters. Many of them have joined the ClinSeq™ study. While the initial analysis of Del Sontro’s genome has not yet revealed the genetic mutation that causes his hereditary heart disease, it did show that he has inherited a condition called hereditary neuropathy with liability to pressure palsies, which causes numbness in his extremities.

Though there is no cure, he said he is glad to have an explanation for the trait. Such knowledge could be comforting after symptoms have arisen, but it

is still unclear if patients want to know about their odds of future disease. Another goal of the Clin-Seq™ study is to assess how patients feel about genome analysis, which might reveal risk for serious conditions.

“We want to know what patients want; what patients think; what they’ll do with the data,” Facio said.

She discusses with study participants the possible outcomes and what results they would like to be notified of. Her anecdotal experience is that most want to know what their tests and gene analysis reports, but Facio is careful to note that her study population is self-selected and not generalizable.

She reports that another patient has been selected for whole genome sequencing and that others are undergoing exome sequencing (just the portions of genes that code for proteins, thought to contain most mutations that have a major effect on the cause or predisposition to diseases).

“We are intrigued about insights we are gaining from the study so far,” Biesecker said. “I think the research will be driven by collaboration and what we find in the sequencing.”

### **Researchers link gene mutations to stuttering**

A trans-NIH study has identified three genes responsible for stuttering in its patient sample, a discovery that opens the door to new potential treatments for the speech disorder.

Led by the National Institute on Deafness and Other Communication Disorders with Clinical Center and National Human Genome Research Institute contributors, the study found that stuttering may be the result of a glitch in the process by which cellular components in key regions of the brain are broken down and recycled.

“For hundreds of years, the cause of stuttering has remained a mystery for researchers and practitioners alike,” said Dr. James F. Battey, Jr., NIDCD director. “This is the first study to pinpoint specific gene mutations as the potential cause of stuttering,

a disorder that affects three million Americans, and by doing so, could dramatically expand our options for treatment.”

Stuttering is a speech disorder in which a person repeats or prolongs sounds, syllables, or words, disrupting the normal flow of speech. The condition tends to run in families, and researchers have long suspected a genetic component.

The NIDCD study grew from previous research by Dr. Dennis Drayna, a geneticist with the institute, which indicated a place on chromosome 12 that was likely to harbor a gene variant that caused stuttering in a group of families from Pakistan. Drayna and his team then refined the location of interest on chromosome 12 and identified mutations in a gene known as GNPTAB, which helps encode an enzyme that assists in breaking down and recycling cellular components, a process that takes place inside a cell structure called the lysosome.

GNPTAB encodes its enzyme with the help of another gene called GNPTG. In addition, a second enzyme, called NAGPA, acts at the next step in this process and together, these enzymes make up the signaling mechanism that cells use to steer a variety of enzymes to the lysosome to do their work. Because of the close relationship among the three genes in this process, the GNPTG and NAGPA genes were the next logical place for the researchers to look for possible mutations in people who stutter. Indeed, when they examined these two genes, they found mutations in individuals who stutter, but not in control groups.

The new study involved patients from Pakistan, the United States, and England. Dr. Penelope Friedman of the CC Internal Medicine Consult Service and Dr. Donna Krasnewich, assistant clinical director of the NHGRI, went through a medical history and physical examination with each patient seen in the CC to investigate if stuttering occurs in tandem with other abnormalities classically associated with severe mutations in these genes. They did not find evidence of such symptoms in the individuals who stutter. Their initial work is a fundamental step in identifying where to look in a

“We want to know what patients want; what patients think; what they’ll do with the data.”



patient's DNA and in maintaining the validity of the research, Friedman said.

The findings open new doors into possible treatments for stuttering. "Stuttering has been thought of as a behavioral problem," Friedman said. Current therapies have focused reducing anxiety and regulating breathing and rate of speech. Drayna is interested in bringing the study and treatment of this condition into the world of medicine. An exciting future possibility may be offering enzyme replacement therapy as a potential treatment, as is used for some lysosomal storage disorders.

The researchers estimate that roughly 9 percent of people who stutter possess mutations in one of the three genes—a lot for such a complex disorder, Friedman said. Among the next steps, Drayna and his team are conducting a worldwide epidemiological study to better determine the percentage of people who carry one or more of these mutations. They are also conducting biochemical studies to determine specifically how the mutations affect the enzymes. A long-term goal is to use these findings to determine how this metabolic defect affects structures within the brain that are essential for fluent speech.

In addition to the NIH partners, researchers at the University of Punjab, Lahore, Pakistan and the Hollins Communications Research Institute, Roanoke, Va., contributed to this work.

#### **Team tackles a debilitating bone disorder**

Big things come in small packages. Just ask Erin Jones. The 14-year-old from the state of Washington had a pea-sized tumor to thank for two broken femurs, among multiple other bone fractures. Jones suffered from tumor-induced osteomalacia, a disorder caused by a benign tumor that produces the hormone FGF23, which affects the metabolism of phosphorus and vitamin D and ultimately bone strength. A small tumor resting on her tibia was removed by an NIH team in August 2010, and Jones is on her way to a full recovery. Almost as impressive as the condition is the fact that doctors were able to find the tumor.

"This was the most challenging and therefore most satisfying case of this disorder we've seen," said Dr. Michael T. Collins, head of the Skeletal Clinical Studies Section of the National Institute of Dental and Craniofacial Research.

Jones first came to the Clinical Center in mid-2010. She had broken one leg at age 11 in a simple bike accident. Her physicians sensed there was something more complex going on, since her accident wouldn't usually cause such an injury. A few months later, her dog jumped into her lap and the chair she was sitting in collapsed. Jones broke her other leg.

"I got out of one cast, got the flu, then got into another cast," she said, remembering that difficult year. In addition to the big breaks, Jones had a dozen small fractures through her body, from her ribs to her feet.

Doctors suspected an underlying skeletal disorder, and when her blood phosphorus level came back low, they thought of tumor-induced osteomalacia.

The disorder is very rare—there are fewer than 200 cases in the medical literature, Collins said—and even more uncommon in children. Complicating the search for a cure for Jones was the nature of the tumors. They are typically very small and can appear anywhere from head to toe, in soft tissue or bone.

Her physicians in Seattle did a positron emission tomography (PET) scan and an octreoscan, which looks for tumors, but couldn't find anything. These tests are very sensitive, and in a patient like Jones with multiple fractures they can "light up like a Christmas tree," Collins said. Deciding which marks on the scan could be the culprit is the difficult part.

While these tumors are always hard to find, Jones's was proving to be a particularly difficult one. Still, Collins agreed to try to help her. His team did more scans when Jones came to the NIH, and through the process of elimination—ruling out symmetrical marks and corroborating the marks with CT and MRI—narrowed the

possible trouble spots to only a few. Dr. Clara Chen, deputy chief of the nuclear medicine section in Radiology and Imaging Sciences, was instrumental in deciphering which marks had potential and which were misleading, Collins said.

With an idea of where the tumor may be, next to Jones' right tibia, Dr. Richard Chang, chief of the endocrine and venous services section, threaded a catheter down a vein in Jones' leg and took blood samples at different points to test presence of FGF23. The numbers spiked around the tumor.

Jones was at her grandmother's house when Collins called with the news. When she heard they'd found the tumor, she gave her grandmother a thumbs up. "She started screaming, she was so happy," Jones remembered.

Dr. Felasfa Wodajo, medical director of Inova Health System's Musculoskeletal Tumor Program and a consultant to the National Cancer Institute, removed the tumor in August. Recurrence is rare, especially when a large margin of surrounding tissue is removed, as was done with Jones.

She is back in Washington, returning to life as a healthy teen. "I'm back on my swim team, which I really love," she said. "I can walk in the hall without being worried about knocking into something."

The end result wasn't due to fancy science, Collins said, just the meticulous, rigorous teamwork that occurs at the CC. "How often in medicine do you get a chance to really cure someone? That was fantastic."

### **Study could improve care for rare immune disease**

NIH investigators have observed that the survival rate of people with a rare immunodeficiency disease called chronic granulomatous disease (CGD) is greatly improved when even very low levels of microbe-killing molecules are present. Because production of these molecules, made by an enzyme called NADPH oxidase, can be predicted from genetic analysis, a patient's risk for severe

CGD could be assessed very early in life, allowing for more personalized treatment, say the researchers.

The study was conducted at the Clinical Center and led by researchers from the National Institute of Allergy and Infectious Diseases and their associated labs at SAIC-Frederick Inc. The study is available online in the *New England Journal of Medicine*.

"Advances in treatment of CGD have made it possible for people with this once-fatal disease of early childhood to survive into adulthood; however, the disease remains difficult to manage," said NIAID Director Dr. Anthony S. Fauci. "Having a marker to help predict disease prognosis will enable physicians to recommend treatment options that are more tailored to the needs of individual patients."

People with CGD have increased susceptibility to infections caused by certain bacteria and fungi. They can have abscesses in the lungs, liver, spleen, bones, or skin. Those with severe disease also can have tissue masses, called granulomas, that can obstruct the bowel or urinary tract. CGD affects an estimated 1,200 people in the United States and approximately 25,000 people worldwide.

The disease is caused by inherited mutations in any one of five different genes required by immune cells to make the NADPH oxidase enzyme, which in turn makes superoxide, an oxygen-derived molecule that immune cells use to destroy harmful bacteria and fungi. All CGD patients have impaired superoxide production, but some make a little superoxide, while others make none. The research team found that the level of superoxide production was linked to the type of mutation in the NADPH oxidase gene, and that the more superoxide a patient with CGD can make, the better the life expectancy.

Until now, the severity of CGD has been linked only to how people inherit the NADPH oxidase gene mutation. If people inherit the mutation as an autosomal recessive trait, meaning that two copies of the abnormal gene, one from each parent, are present, the disease has generally been less severe than in those who inherit the mutation as

an X-linked trait, meaning that the abnormal gene is located on the female sex chromosome. The majority of people with CGD inherit the mutation as an X-linked trait.

For their study, the NIH team tested the level of superoxide production by immune cells isolated from blood samples taken from 287 people with CGD, aged 1 to 64 years old, compared with superoxide production in healthy people. Some tests dated back to 1993, though patients and families affected by CGD have come to the CC for treatment since the 1970s.

The NIH researchers used methods that could detect even trace amounts of superoxide, and grouped people with CGD based on the amount of superoxide made by the immune cells. The patients who produced the highest levels of superoxide had the highest survival rates, whereas those who produced the lowest levels of superoxide had the lowest survival rates.

“By precisely measuring superoxide production, we observed that even tiny residual amounts, at levels below what doctors paid attention to in the past, had a significant impact on patient survival,” said CC Director Dr. John I Gallin, chief of the Pathophysiology Section of the NIAID Laboratory of Host Defenses, and senior author on the paper.

Treatment of CGD consists of lifelong antibiotics and antifungal medications. Some people also receive injections with interferon-gamma, a protein that can stimulate the immune cells to fight infections. For people with the most severe forms of CGD, bone marrow transplantation is a treatment option, but it carries potential complications that can make patients and their families reluctant to elect this therapy.

Based on the research team’s observations, doctors should be able to use DNA gene-typing results to help identify those patients who are candidates for more aggressive treatments, including possible bone marrow transplantation. In addition, therapies designed to promote NADPH oxidase function might reduce CGD severity.

“This study is a great example of the special strengths of the Clinical Center,” commented Gallin. “We have worked for over three decades with patients with CGD, which at one time was almost entirely fatal, and have seen vast improvements in care and treatment. This work now gives us another tool to help individuals fight this disease.”

Additional support for this research was provided by the National Institute of Diabetes and Digestive and Kidney Diseases and the National Cancer Institute.

### **Finding the new ‘normal’ after allogeneic stem cell transplantation**

As any survivor knows, life doesn’t snap back to the way it was as soon as one hears that coveted “r” word—remission. Nurse researchers at the Clinical Center are leading a study to examine function, adjustment, quality of life, and symptoms (FAQS) in long-term survivors who have undergone an allogeneic (from a donor) hematopoietic (blood) stem cell transplant (HSCT).

Dr. Margaret Bevans and Dr. Sandra Mitchell of Nursing and Patient Care Services and their multi-institute study team collect survey data once a year from participants to characterize the pattern of recovery after this intense treatment regimen. Understanding the factors that influence variation in these recovery patterns can help patients know what to expect over the long term and help clinicians improve services to aid in patients’ recovery. “Together with other intramural researchers conducting survivorship studies here on campus, we are contributing to the evidence base to guide assessment and tailor interventions in transplant survivors,” Mitchell said.

Mitchell and Bevans began their work in 2005, noting gaps in the understanding of the recovery experience for several specific groups of transplant survivors. As the researchers noted in their summary of the study, most previous research had been cross-sectional (giving a snapshot rather than a timeline) and had sampled a small number of survivors with limited diversity.” In the FAQS study, Bevans and Mitchell are examining the extent to

which a patient's condition improves, remains the same, or deteriorates with the passage of time after HSCT in a large sample of transplant survivors with clinical and demographic diversity. The National Heart, Lung, and Blood Institute performed its first allogeneic HSCT in 1993.

Mitchell and Bevans' FAQS study proceeds in tandem with other intramural NIH research examining late effects of this intense, often curative treatment for cancer or a serious bone marrow disorder. These late effects may include chronic graft-versus-host disease, osteoporosis, endocrine complications, and secondary cancers.

"All typical problems seen in cancer survivors are multiplied after allogeneic HSCT. Therefore the treatment presents a unique opportunity for researchers to develop strategies to address late effects of cancer therapy," said Dr. Steven Z. Pavletic, head of the Graft-Versus-Host and Autoimmunity Unit in the National Cancer Institute Experimental Transplantation and Immunology Branch.

As nurse scientists, Bevans and Mitchell are particularly interested in the impact these late effects may have on how patients feel and function as they resume usual activities and roles in their daily lives.

In the early period of recovery after an allogeneic HSCT, patients and families are often focused on aspects of physical recovery from an aggressive treatment regimen. As they proceed into the survivorship phase, other dimensions of well-being including mood, relationships, and symptoms such as fatigue and impaired sleep problems come to the forefront. The opportunity to complete the study questionnaires may help to validate the importance of these issues, and "may empower survivors to be their own advocates and raise such concerns with the doctors, nurses, and social workers on their transplant team," Bevans said.

Study results to date suggest that a number of these dimensions are affected in transplant survivors. For example, the team has found that approximately 45 percent of study participants had insomnia, and that those with more physical

and psychological symptom distress reported more problems with sleep. Survivors experiencing difficulties with psychosocial adjustment reported the greatest concerns with immediate and extended family issues, sexual relationships, and emotional distress. Ultimately, Bevans and Mitchell believe that a better understanding of the factors associated with variability in recovery can be applied to develop ways to help patients return to a fulfilling and productive life.

"The FAQS study is making major progress in this direction, but it only addresses the first step—describing the scope of the problem. The big next challenge is to decide what to do about the problem," Pavletic said. "Survivors face a number of challenges affecting their health and well-being. Much work remains to be done in this arena, and the NIH can be a major contributor."

#### **Endometriosis survey data gives insight on co-occurring disease, incites research**

A study in *Fertility and Sterility* co-authored by NIH clinician-scientists reported new findings on endometriosis. The paper, "Cancers, infections, and endocrine diseases in women with endometriosis," has ramifications for care of this patient population and the advancement of related research, said co-author Dr. Ninet Sinaï of the Biostatistics and Clinical Epidemiology Service in the Clinical Center Office of the Deputy Director for Clinical Care.

Sinaï began analysis of an Endometriosis Association survey during her doctorate work with the National Institute of Child Health and Human Development and continued her series of papers when she transferred to the Clinical Center in 2006. The 1998 survey covered an array of topics to capture the broad scope of living with endometriosis, a condition where tissue that usually grows inside the uterus shows up elsewhere like the surface of organs in the pelvis or abdomen. Scientists believe the number of women living with endometriosis—said to be between 10 to 15 percent of reproductive-age females—may be underestimated, Sinaï said.

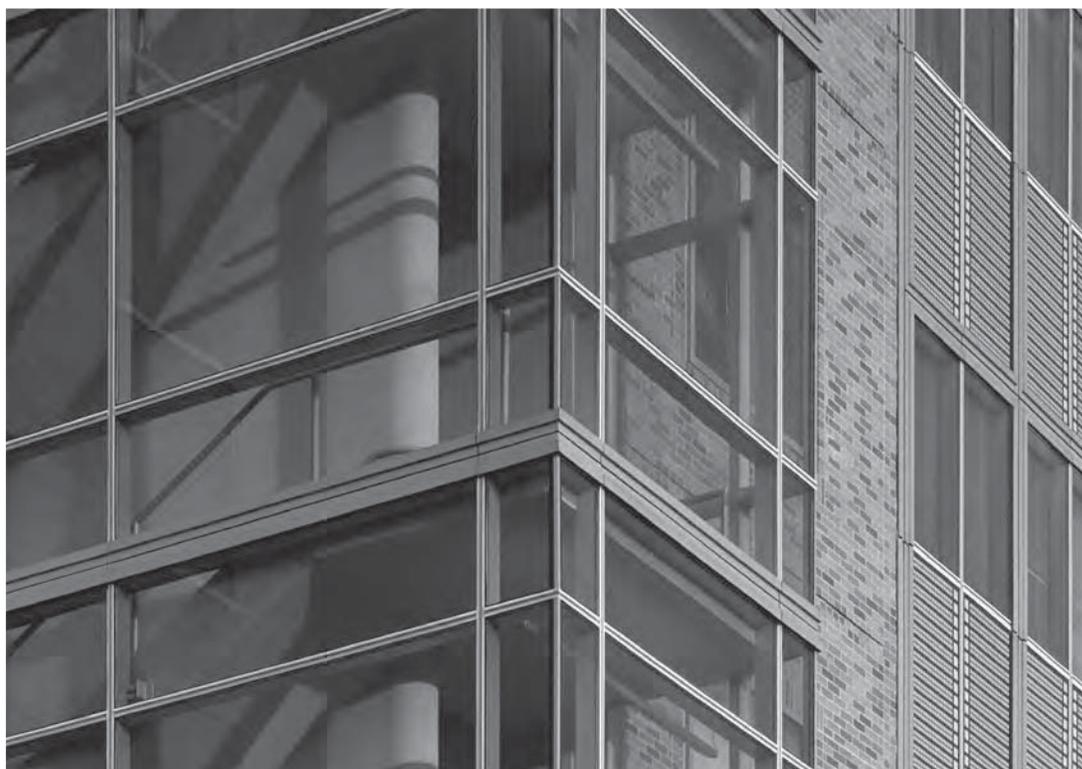
In addition to the symptoms of long-lasting chronic pain and high rates of infertility directly attributed to endometriosis, sufferers also have to deal with commonly co-occurring afflictions, the Endometriosis Association survey showed.

“Overall, 2,859 (66.0%) women self-reporting surgical diagnosis of endometriosis also reported physician diagnosis of at least one other condition,” the authors of the *Fertility and Sterility* paper wrote. Most common among responders were infectious diseases—recurrent upper respiratory infections and recurrent vaginal infections—but melanoma and ovarian cancers were also noted as “more common in the study population than in similarly aged women in the general population.”

“It’s kind of like a chicken-and-the-egg situation,” Sinaii said. “While we believe that women with endometriosis may have an altered immune system, we don’t know if a compromised immune system causes endometriosis or if endometriosis causes a compromised immune system.”

The survey results will inform physicians and patients of possible coexisting conditions after diagnosis of endometriosis, Sinaii said. The findings may also stimulate further studies into the experience of the disease.

“This survey data related to other clinical observations is what helps shape translational research,” said Dr. Pamela Stratton, chief of the Gynecology Consult Service in the NICHD Program in Reproductive and Adult Endocrinology and second author on the *Fertility and Sterility* paper. While there is no cure for endometriosis, research into better treatments and strategies to prevent reoccurrence of symptoms and disease is strong. Stratton is examining the after effects of endometriosis, such as chronic fatigue and heightened sensitivity to pain, and exploring promising recent research involving endometrial stem cells for its possible link to the central nervous system.



## Training the Next Generation

### TRAINING TODAY'S INVESTIGATORS TO FIND TOMORROW'S CURES

The Clinical Center continues to be a primary resource for training in clinical research, and the demand for such training has never been higher. The Office of Clinical Research Training and Medical Education develops, administers, and evaluates clinical research training initiatives for nearly every level of career development. With a summer internship program for high school,

college and graduate students, a year-long clinical and translational research enrichment program for medical and dental students, and even a sabbatical program for experienced researchers, the Clinical Center has something for everyone. The CC also manages a curriculum of three courses in clinical research and graduate medical education opportunities for clinical fellows.

### CURRICULUM IN CLINICAL RESEARCH

Thanks to the latest technology, the CC is able to broadcast its popular courses, *Introduction to the Principles and Practice of Clinical Research (IPPCR)*, *Principles of Clinical Pharmacology (PCP)*, and *Ethical and Regulatory Aspects of Clinical Research*, to remote sites domestically and around the world.

Thirty-two remote sites with more than 1,100 students participated in the 2010-11 IPPCR course, including ten international locations such as the Asan Medical Center Clinical Research Center in Seoul, Korea, and the Walter Sisulu University in Eastern Cape Province, South Africa. The CC makes content available for students using live stream and archived content on the web for the sites without a live broadcast.

A record number (1,563) of students enrolled in IPPCR in 2010-11, demonstrating the strong and sustained interest in the subject matter and the positive reputation of the course. And the word keeps spreading. In May 2010, course faculty

including CC Director Dr. John I. Gallin, conducted a five-day version of the IPPCR course in-person at the University of Ibadan in Nigeria. Local faculty then continued to work with students on the full syllabus.

Designed to meet the needs of researchers who have an interest in the clinical pharmacologic aspects of contemporary drug development and utilization, the *Principles of Pharmacology* course has entered its twelfth year. The course has also reached students far away from NIH's Bethesda campus. Twenty-three remote sites, including seven international, and a record 1,200 students participated in the 2010-11 course.

Even the newest course, *Ethical and Regulatory Aspects of Clinical Research*, saw growth for the 2010-11 year. More than 475 students enrolled at both NIH and at 12 remotes sites, including six international, which represents a 40% increase from 2009.



Student participation for 2010-11 IPPCR and PCP

## GRADUATE MEDICAL EDUCATION BROADENS

The Clinical Center, as the Accreditation Council for Graduate Medical Education (ACGME) accredited sponsor of graduate medical education at NIH, made strides to expand the scope of Graduate Medical Education (GME) training offered to residents and clinical fellows at the NIH. In 2010, the NINDS-based Neurological Surgery program officially received accreditation from the ACGME, bringing the NIH's total to 18 accredited programs. The Neurological Surgery program represents the first ACGME accredited surgical specialty program at the NIH and is the first collaborative training partnership to be established between the NIH Clinical Center and the University of Virginia Medical Center.

This seven-year training program, which provides clinical exposure to a large spectrum of patients with diseases of the brain and spinal cord at both institutions and in-depth exposure to translational research at the NIH, allows trainees to develop the skills necessary to become highly competent, board-certified academic neurosurgeons.

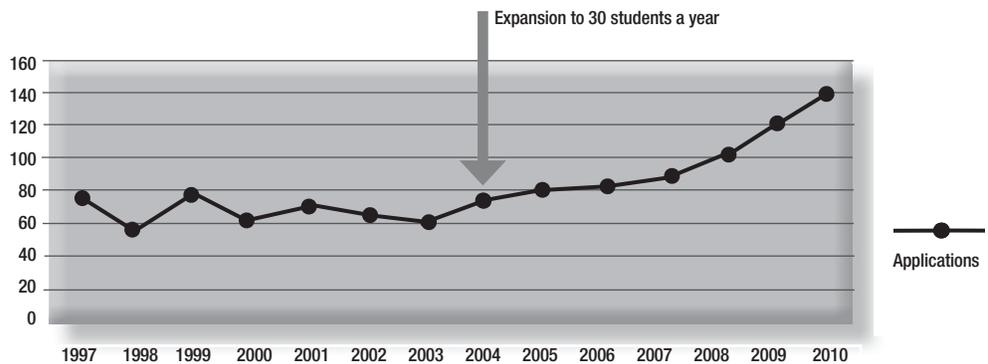
Expansion of GME programs furthers the Clinical Center's mission to educate the next generation of clinician-scientists. With more GME programs available at the NIH in more specialty fields, researchers are better able to address the broader needs of patients.

## MEDICAL AND DENTAL STUDENTS SEEK OPPORTUNITIES IN RESEARCH

The Clinical Research Training Program (CRTP) has always been a popular program at the NIH. The level of enthusiasm has reached new heights this year. Established in 1997, the program offers unique opportunities for medical and dental students to add one year of school to learn the principles of and to perform clinical and

translational research at the NIH. The number of students who apply for the CRTP has grown steadily over the last seven years, and the CC received a record number of applications for the 2010-2011 class. The growth in applications to the CRTP is depicted in the graph below.

This public-private partnership is supported by the NIH and the Foundation for the National Institutes of Health through a generous grant from Pfizer Inc.



## FELLOWS PROGRAM ATTRACTS NEW TALENT

New clinical fellows from medical institutions across the country mingled at a reception in July 2010 with leaders from the different NIH institutes and centers. National Institute of Mental Health Intramural Research Program Scientific Director Dr. Richard Nakamura (left) and Clinical Director Dr. Maryland Pao (right) welcomed their institute's fellows: (from left) Patricia Bauza from the Mayo Clinic, Rishi Kakar from Georgetown University School of Medicine, and Jose Franco-Chavez from the University of Puerto Rico School of Medicine.



## CTSA VISITORS SEE LATEST FROM THE CLINICAL CENTER

The Clinical Movement Analysis Lab in the Rehabilitation Medicine Department Functional & Applied Biomechanics Section was one stop for a group of visiting fellows from the Clinical and Translational Science Award (CTSA) consortium on April 7, 2010. The CTSA program—funded by the NIH National Center for Research Resources—creates academic homes for clinical and translational science at research institutions across the country.

In the Washington, DC, area for the 2010 Clinical and Translational Research and Education Meeting, sponsored by the Association for Clinical Research Training and the Society for Clinical and Translational Science, about 75 CTSA representatives from academia around the country—such as Morehouse School of Medicine, Washington University in St. Louis, and Weill Cornell Medical

College—toured the CC after an overview of the hospital from CC Deputy Director for Educational Affairs and Strategic Partnerships Dr. Frederick Ognibene.

Engineers Christopher Stanley (in front) and Lindsey Bellini demonstrated the capabilities of the newly updated Clinical Movement Analysis Lab. CTSA fellows also visited the new CC Pharmacy Department Pharmaceutical Development Section facility and the National Heart, Lung, and Blood Institute Vascular Biology research area.



### Staying in touch with alumni

By connecting with alumni of our training programs, the Clinical Center is able to answer the questions, “Where are they now, and what are they doing?” This reveals success stories of alumni, as well as whether our training programs are setting students up for a career in clinical and translational research as they

aim to do. The CC’s OCRTME already has data collection mechanisms in place for the Clinical Research Training Program (CRTP) and Graduate Medical Education (GME) and is working on expanding to all of our training programs. In addition, OCRTME uses Facebook and Twitter to stay in touch with alumni.

For example, the CRTP alumni group on Facebook has 66 members who can converse with each other, as well as read news about the CRTP posted by OCRTME staff. And the alumni e-newsletter launched in December 2010, with plans to distribute quarterly, allows the CC to provide detailed updates to alumni.

## FACULTY BRING CLINICAL RESEARCH COURSE TO NIGERIA



Dr. Charles Natanson, head of the anesthesia section in the CC Critical Care Medicine Department, lectured during the IPPCR course in Nigeria in May 2010.

The course *Introduction to the Principles and Practices of Clinical Research* (IPPCR) was presented at the University of Ibadan, Nigeria, in May 2010. Co-sponsors were the Clinical Center, the NIH Fogarty International Center, and the University of Chicago Global Health Initiative. “This was the first time an adaptation of this course, which was developed by the Clinical Center, has been taught in sub-Saharan Africa,” noted Dr. John I. Gallin, CC director and lead of the NIH faculty.

Faculty members traveled to the most populous nation in sub-Saharan Africa for four days of classes and conversations. They touched on highlights of the course that is offered annually at the CC and videocast to locations around the world. Dr. Olufunmilayo (Funmi) Olopade, Walter L. Palmer Distinguished Service Professor in Medicine and Human Genetics and director of the Center for Clinical Cancer Genetics at The University of Chicago, learned of IPPCR while on the NIH Advisory Board for Clinical Research.

After hearing that the CC brought IPPCR to China in 2008, Olopade asked, “Why not Nigeria?” (her native country), recalled professor Dr. Laura Lee Johnson, statistician in the Office of Clinical and Regulatory Affairs at the National Center for Complementary and Alternative Medicine.

About 90 people attended the course in Nigeria, ranging from heads of departments to fellows. Highlights of IPPCR—data safety monitoring, epidemiological design, ethical issues, community engagement—brought a new perspective to the students.

Nigerian investigators were interested in “all-over-the-map research,” Johnson said. From nutritional choices to encourage fertility to eye disorders, pregnancy-related issues to parasitic diseases, the students asked about a variety of studies, Johnson reported.

To continue the education of Nigerian researchers, the local coordination group helped assemble a sustainability team of participants who were young Ibadan faculty. The team will keep the training going for other cohorts, “so it’s not just a single shot, and we walk away,” Johnson said.

NIH and HHS faculty who went to Nigeria were Gallin; Johnson; Dr. Charles Natanson, CC Critical Care Medicine Department; and Dr. Jerry A. Menikoff, director, Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services. They were accompanied by Dr. Letitia Robinson of the NIH Fogarty International Center. Also teaching were Dr. Oladosu A. Ojengbade, University College Hospital, Ibadan, Nigeria; Dr. Christopher ‘Sola’ Olopade, University of Chicago; and Dr. Olufunmilayo (Funmi) I. Olopade.

## COLLABORATION OFFERS CLINICAL CENTER RESOURCES TO EXTERNAL INVESTIGATORS

A new pilot partnership between the Clinical Center, the National Cancer Institute's Center for Cancer Research, and the Damon Runyon Cancer Research Foundation will offer some of the capabilities and expertise of America's research hospital to an external group of clinical investigators in cancer research. The special talent and resources of the NIH will allow Damon Runyon-funded investigators to undertake studies and collaborations that will advance understanding of the prevention, diagnosis, and treatment of cancer.

Damon Runyon Clinical Investigators (DRCIs) are early career physician-scientists whose focus is on the translation of basic science discoveries into practical therapies. Since 1946, the Damon Runyon Cancer Research Foundation has invested more than \$230 million in early career cancer researchers who have the energy, drive, and creativity to become leading innovators in their fields.

"Thanks to the new three-component partnership, these young investigators can apply to use certain equipment, facilities, and patient cohorts at the Clinical Center in research collaborations with

NIH clinician-scientists," said Dr. John I. Gallin, Clinical Center director.

An approved research proposal could also provide access to select research materials, services, or products that may not be available or possible at their home institutions—such as products from the Pharmacy Department's Pharmaceutical Development Facility—through arrangements with the Clinical Center but without a formal research collaboration with a specific institute. If the pilot proves successful, the NIH and the Clinical Center may pursue similar partnerships with other NIH institutes and centers and external organizations.

"This is a first step toward opening the doors of the Clinical Center to a new group of clinician-scientists, further supporting the NIH mission to enhance health and reduce the burden of disease," said Gallin. The partnership allows DRCIs to partner with an NIH-tenured or tenure-track investigator on a research project. If the NIH research partner is not identified independently, the DRCI can submit a research proposal to NCI and the



Dr. Jeffrey Baron (left) received the 2010 Distinguished Clinical Teacher Award. With him is Dr. Joo Song, chair of the CC Clinical Fellows Committee.

### **NICHD endocrinologist named 2010 Distinguished Clinical Teacher**

The 2010 Distinguished Clinical Teacher Award went to an investigator with a "logical and thorough" teaching style, according to the fellows who work with him. Dr. Jeffrey Baron, chief of the Section on Growth and Development at the National Institute for Child Health and Human Development, received the award in September 2010.

The Distinguished Clinical Teacher Award has been presented each year since 1985 to an NIH faculty member who demonstrates excellence in mentoring health-care professionals and has made outstanding contributions to the advancement of clinical research. The recipient is chosen by the Clinical Center Clinical Fellow's Committee and delivers the annual John Laws Decker Memorial Lecture the following spring.

Also nominated this year were Dr. Alan Decherney (NICHD), Dr. Theo Heller (NIDDK), Dr. Steven Warach (NINDS), Dr. Juan Gea-Banacloche (NCI), and Dr. Susumu Sato (NINDS).

Clinical Center for assistance in identifying a suitable collaborator. A scientist applying for a Damon Runyon Cancer Research Foundation Clinical Investigator Award could apply with a mentor from NCI or another NIH institute or center. The application would identify the research to be done and the resources used at the Clinical Center.

“We are thrilled to offer these opportunities and resources to the clinical investigators we fund,” said Lorraine Egan, executive director of the Damon Runyon Cancer Research Foundation. To facilitate these partnerships, the Clinical Center and NCI’s Center for Cancer Research will create an

annually updated portfolio of ongoing research and of the research interests of NIH investigators.

In addition to scientific collaborations, this pilot partnership will provide interested DRCIs opportunities to participate in the Clinical Center’s clinical research training curriculum. Courses are *Introduction to the Principles and Practice of Clinical Research*, *Principles of Clinical Pharmacology*, and *Ethical and Regulatory Aspects of Clinical Research*. Damon Runyon Clinical Investigators also are invited to apply to the Clinical Center Sabbatical in Clinical Research Management.



### **Clinical Research Training Program gathers best from across the United States**

The 2010-2011 Clinical Research Training Program class of fellows represents universities from coast to coast, pulling medical students from Boston University School of Medicine; Louisiana State University School of Medicine; and the David Geffen School of Medicine at the University of California, Los Angeles, to name a few.

The program—directed by the Clinical Center Office of Clinical Research Training and Medical Education—brings medical and dental students to the NIH campus for 12 months of mentored clinical or translational research in an area that matches the fellows’ personal research interests and career goals.

## CLINICAL CENTER OFFERS SABBATICAL IN CLINICAL RESEARCH MANAGEMENT

The Clinical Center's Sabbatical in Clinical Research Management program provides wide access to the knowledge, expertise, and experience of leaders at the NIH.

The program started accepting applications in 2009 from a limited number of those who are experienced in the world of clinical research but want to learn more about management of a clinical research enterprise. The four participants in the pilot phase of the sabbatical program chose an individualized set of electives and received one-on-one attention from managers, executives, and clinician-scientists. The elective leaders are mainly from the CC, but other educational partners include other NIH institutes and centers, the US Food and Drug Administration (FDA), the HHS Office for Human Research Protections, and the Foundation for the NIH.

Dr. Roman Ivanov traveled from Russia to participate in the Sabbatical in Clinical Research Management for three months in 2010. As a researcher at both a biotechnology company and an academic medical center, Ivanov was curious to learn about protocol writing and tracking and patient recruitment, as well as the regulatory aspects of clinical research. Spending a month full-time at the FDA and two months at the NIH developing

an ongoing project allowed him to meet his educational goals.

"The program provided me with a unique opportunity to get a better understanding of the infrastructure required for investigator-associated clinical trials and regulatory issues associated with them. I will do my best to share this knowledge with my colleagues and I hope that this will contribute to development of medical science in Russia," Ivanov said.

This is a major goal of the sabbatical program: giving participants hands-on experience in clinical research management so that they may apply what they learn at their home institutions. Opening the CC's doors allows individuals to learn from the science, the management and operations, and the unique circumstances under which we conduct clinical and translational research conducted here.

"This program provides management training to help ensure that medical research programs are safe, ethical, and efficient," said CC Director Dr. John I. Gallin. "The sabbatical will help demystify the complexities of governmental regulatory agencies while providing an opportunity to achieve excellence in clinical research management."



## TRAINEE FORUM INTRODUCES FUTURE COLLABORATORS

Despite the presence of NIH institute and center directors, distinguished researchers, and even NIH Director Dr. Francis S. Collins, some of the most important people young clinician-scientists met at a forum in November were those sitting next to them in the auditorium seats.

The Eighth annual Clinical Investigator Student Trainee (CIST) Forum—developed and hosted by the Clinical Center Office of Clinical Research Training and Medical Education—convened more than 260 medical, dental, and veterinary students in year-long enrichment programs at academic medical centers and at the NIH for two days of panels, tours, and networking.

“You are what we call, in epidemiology, a cohort,” said NIH Deputy Director for Intramural Research Dr. Michael Gottesman. “Look to your left and your right. These are the people who will be your collaborators. These are the people who will be reviewing your grant applications.”

In addition to the opportunity to talk shop with their peers, the CIST Forum presented fellows and scholars access to possible mentors and leaders in their fields of interest. Leaders of the CC, the National Institute of Biomedical Imaging and Bioengineering, the Fogarty International Center, and the National Institute on Drug Abuse spoke on the latest from their groups. Forum attendees could speak with investigators from their intended research areas at networking luncheons, and a panel on genomics and genetics elicited much interest from the students.

Another popular panel was the group of alumni from the same programs as CIST Forum attendees. Dr. Eric Adler, assistant professor of cardiology and

medicine at Oregon Health Sciences University and a former Sarnoff Fellow, kept the crowd laughing, as he referred to content from NIDA Director Dr. Nora Volkow’s presentation.

“I was addicted to science,” he said. “Find something you’re addicted to, but not something destructive like methamphetamines.”

Panelist Dr. Adam M. Zanation, assistant professor in the Department of Otolaryngology at University of North Carolina School of Medicine and former Doris Duke Charitable Foundation fellow, reflected, “Being a successful researcher is about commitment, effort, and having good ideas.”

The other two panelists were Dr. Karen E. Hoffman, assistant professor in the Department of Radiation Oncology at the University of Texas MD Anderson Cancer Center and former CC Clinical Research Training Program (CRTP) fellow, and Dr. Jayanta Debnath, assistant professor in the Department of Pathology at the University of California, San Francisco Medical Center and former Howard Hughes Medical Institute-NIH research scholar. [Read about Hoffman’s journey from CRTP to clinical research at a premier academic medical institute on page 47]

For the second year, CIST Forum organizers used social media to appeal to their millennium generation audience. Students asked questions and staff provided helpful links through tweets marked with the hashtag #CIST8, which were displayed on the Masur Auditorium screen during question-and-answer sessions and breaks. Additionally, online networking linked attendees and organizers before the conference—getting them need-to-know information and letting them coordinate travel.

Tours of CC units allowed forum attendees to see first-hand the cutting-edge facilities that allow the groundbreaking work of the NIH intramural program.

Lauren Stossel, a Doris Duke Charitable Foundation fellow from the Mount Sinai School of Medicine, visited the new Pharmacy Department’s Pharmaceutical Development Section and

A panel of alumni of the research training programs that CIST Forum attendees are in shared their journeys and gave advice to the current trainees.



Rehabilitation Medicine Department's Clinical Movement Analysis Laboratory. "I thought it was really interesting," she said. "They demonstrated the different technologies and showed us the clinical correlates."

The keynote speaker of the forum—NIH Director Collins—addressed the importance of translating basic science discoveries into new and better treatments and how the NIH is putting science to work for the benefit for health care reform. Collins also discussed what the NIH is doing to encourage innovation and empower young researchers like CIST Forum attendees.

"As the director of the NIH, one of the things that I enjoy most is the opportunity to brainstorm, particularly with people that are going to lead our field in the future, and that is all of you, about the directions that science is taking that are going to be particularly transformative," he said.

Collins closed his speech with a musical performance on his double helix-inlayed guitar: a self-penned update about DNA to the tune of Del Shannon's 1960's hit "Runaway."

"Dr. Collins was amazing. He's like the superman of scientists," said CRTP fellow Hari Trivedi from the Medical College of Georgia. Above all, for many of the forum attendees, though, was the chance to walk away with new contacts.

"These are going to be my future colleagues, future collaborators, and people who I'll be seeing over and over again. So getting to know them now, at this early stage, is going to be beneficial for fostering those relationships," said Shah Ali of the Stanford University School of Medicine, a Howard Hughes Medical Institute fellow.



NIH Director Dr. Francis S. Collins serenaded CIST Forum attendees with a personalized version of "Runaway" after his keynote speech.

### Former CRTP fellow reflects on influence of program

The NIH Clinical Research Training Program (CRTP) aims to prepare the next generation of clinician-scientists through a year of immersion in the NIH intramural program. One alumna of the program recently returned to speak on her experience and to inspire her successors.

Karen Hoffman, assistant professor in the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center, spoke on a panel of graduates of the year-long research programs represented at the Clinical Investigator Student Trainee Forum, which was held in the Clinical Center in November. She was part of the CRTP class of 2001-2002. The CRTP competitively selects participants, known as fellows, to spend a year engaged in a mentored clinical or translational research project in an area that matches their clinical research interests and goals.

Hoffman did her undergraduate work at the University of Virginia and earned her medical degree from Duke University. She also holds a Master of Public Health from the Harvard School

of Public Health and Master of Health Science in Clinical Research from Duke University. While in the CRTP, Hoffman researched the late effects of treatment in long term survivors of pediatric sarcoma with Dr. Patrick Mansky, formerly of the National Center for Complementary and Alternative Medicine, and genetic and hormonal regulation of osteosarcoma metastasis with Drs. Lee Helman and Chand Khanna of the National Cancer Institute Center for Cancer Research.

"My experience here in the CRTP helped launch my career," she said. "It really helped me develop the thought process to formulate research questions and provided the skills to pursue my independent work."

At MD Anderson, Hoffman conducts prostate and breast cancer clinical research. Her time is split with 75 percent devoted to clinical practice and 25 percent to research. She enjoys the interaction with patients this balance allows her, Hoffman said.



Dr. Karen Hoffman, part of the 2001-2002 Clinical Research Training Program class, is now assistant professor in the Department of Radiation Oncology at the University of Texas MD Anderson Cancer Center.

## Organizational Improvement/Teamwork

### WEEK CELEBRATES VOLUNTEERS' TIME AND TALENTS



The CC volunteer squad includes (back, from left) Janet Logan, Victor Canino, Vickie Campbell, and (front, from left) Kristopher Yoon, Louise Gorman, and Jeanette Ferris.

Volunteers Mark and Michelle Cohen (from left) with program coordinator Courtney Duncan.

Volunteers contribute about 30,000 hours a year to the Clinical Center and the CC honored them during National Volunteer Week in April 2010. “Volunteers add a tremendous amount of support to the Clinical Center,” said Courtney Duncan, Volunteer Services coordinator. “They bring excitement, genuine interest, and willingness to learn.”

The 17th annual CC volunteer appreciation event on April 22 included presentation of special recognition awards to nine volunteers based on consistency, reliability, hours spent, or “general overall wonderfulness,” as Duncan said. Honored were: Mark and Michelle Cohen, animal-assisted therapy program; Eileen De Santillana and Monica Sullivan, language interpreters program; Joanne Hill, Armen Thomasian, and Cynthia Kim, patient ambassador program; Saroja Kanesa-Thanan, Red Cross; and Janet Logan, volunteering in Outpatient Clinic 12 for 14 years.

#### Tools of the trade

Bandages, needles, sterile equipment, and isolation carts are necessary items in any hospital, and the Clinical Center is no different. The group that assures such specialized items are provided is Central Hospital Supply (CHS).

“We are the hub of this Clinical Center. The doctors and nurses couldn’t do their job without supplies,” said medical supply technician Kerry Bruton.

To use the system, clinical staff log on to the station and press a take or return button on the bin of their selected item. This crucial step links to the CHS inventory to alert staff when they need to replenish the machine’s supply. Completing this step rather than simply taking an item or putting one back without registering the action is crucial to help CHS equip the units with what they need.

“CHS, in a team effort, achieves excellence in customer service by providing safe medical-surgical supplies in a cost-effective and timely manner for clinical care and protocol support,” said Paula Wrenn, chief of CHS.



Some volunteers use their contribution as a way to try out an area of interest. Tiffany Murray (at right, with her supervisor Justine Harris) worked as a pharmacy technician in a retail setting, but wondered if she would prefer work in a hospital setting. Murray offered some advice to those looking to get the most out of their volunteer opportunity: “Be dependable and committed ... Grasp everything. Ask questions.”



## MORE ABOUT VOLUNTEERS

To learn about volunteer openings and to apply, visit <http://clinicalcenter.nih.gov/volunteers>.

Post-baccalaureate Intramural Training Research Award fellows (post-bac IRTAs to NIH insiders) spend a year or two at NIH between their undergraduate studies and pursuit of an advanced degree. For those with plans to apply to medical school, the CC Volunteer Program offers patient-care experience. Volunteering in patient-care areas supplements IRTAs’ laboratory or administrative assignments to humanize translational research and develop skills not found in a textbook. “I think one of the most important parts of being a doctor, no matter your specialty, is knowing how to communicate,” said Nizar Dowla (at right with microphone), a fellow with the CC Rehabilitation Medicine Department who plans to pursue a career in pediatrics. Dowla spent two hours a week in the department’s main playroom, interacting with kids.



## SWEET TREATS WIN SMILES

The Seventh Annual Clinical Center Gingerbread House Contest made a sweet appearance again in 2010. Entries were displayed in the Hatfield Building atrium through the December holiday season. Patients, staff, and visitors cast ballots for their favorite. This year’s competition drew 28 entries and more than 2,500 ballots cast. First place went to the 3NE Disney firehouse, with the 3SE North Toy Story 3 in second, and 7SE Alice in Wonderland taking third. WJLA featured the Clinical Center’s gingerbread house competition in a “Good Morning, Washington!” segment with Dr. Clare Hastings, chief nursing officer, leading the welcoming cheer.



## EMERGENCY PREPAREDNESS PARTNERSHIP PUT TO THE TEST IN DRILL

Mary Beth Price (right) from Nursing and Patient Care Services welcomed mock patient Lynne Spivack to the Clinical Center as Adam Russell of Hospitality Services took her to the triage area.

Jacqueline Reid (far right), CC director's office, managed the flow of electronic patient data through the medical information transfer system at the drill.



Clinical Center staff prepared for the worst on October 14, 2010, with the sixth-annual multi-agency Emergency Preparedness Exercise. The drill is a simulation of how area medical facilities would handle a catastrophic event. The CC practiced managing an overflow of patients from DC hospitals that were “full” after a fictional event caused a large volume of casualties.

The Bethesda Hospitals’ Emergency Preparedness Partnership—consisting of the National Naval Medical Center, Suburban Hospital Health Care System, the CC, the National Library of Medicine, and the NIH Fire Department and Hazardous Response Units—was formed in 2004 to stand ready to provide a rapid and sustained medical

response to the community during a catastrophic event in the National Capital Region.

For the first time CC employees simulated triaging and admitting stable patients from both the National Naval Medical Center and Suburban Hospital Health Care System. In prior years, mock patients were transported only from Suburban Hospital.

Command centers communicated clearly and efficiently through a variety of avenues, from radio communication compliments of the NIH Radio Amateur Club to videophones that allowed callers to speak “face-to-face” on small screens in each command center.

### Team NIH races



Members of the NIH community—staff from across institutes and centers and their families—banded to form Team NIH at the Susan G. Komen Global Race for the Cure on the National Mall in Washington, DC, on June 5, 2010.

## HOSPITAL WELCOMES PROJECT SEARCH INTERNS

Twelve new interns arrived at the Clinical Center in September 2010 through a partnership with Project SEARCH, an international organization, for a 30-week unpaid internship.

Project SEARCH works with hospitals and businesses in the United States, the United Kingdom, and Australia to provide opportunities for young adults with disabilities to learn employability skills and gain work experience.

The CC launched this intern program as a pilot under the management of Denise Ford, chief of the Office of Hospitality Services, and as part of the CC Volunteer Program.

“This will help people see beyond the disability and understand the interns as contributing members of our workforce,” Ford said. “It’s a win all the way around.”

The ultimate aim for young people in the Project SEARCH program is competitive employment.



Chief of the Office of Hospitality Services Denise Ford led a tour in July 2010 for some of the 12 interns who now work at the Clinical Center through a partnership with Project SEARCH. From left are Van Berg, Aamer Khan, Ricky Day, Crystal Battle, Ashton Bell, Amethyst Thornton, and Justin Haynes.

## NURSES WEEK 2010 CELEBRATES CREATING A CLINICAL RESEARCH SPECIALTY

At the opening ceremony of 2010 Nurses Week, Clinical Center Chief Nurse Officer Dr. Clare Hastings referenced the influence the CC has in the network of Clinical Translational Science Awards consortium institutions and NIH-funded centers across the country that perform clinical research. “We represent the flagship that people look to for leadership in this whole structure,” she said.

Hastings thanked the nurses for their development of the domain of practice for the specialty of clinical research nursing as part of the Clinical Research Nursing 2010 initiative. Depending on their role—for example, clinical research nurse, research nursing coordinator—nurses balance their days among the different dimensions, Hastings said. The five foci of the specialty of clinical research nursing are clinical practice, study management, human subjects protection, contributing to the science, and care coordination and continuity.



## PATIENT CARE PERSEVERES THROUGH SNOWPOCALYPSE



Patient care and research continued at the Clinical Center through the twin blizzards of February 2010. CRTP fellow Zachary Dezman snapped this as he skied to the hospital.

It may have seemed that the Washington, DC, metropolitan area shut down for a week in early February as two snowstorms rendered roads impassable and left hundreds of thousands without power. The needs of Clinical Center patients remained constant, though, even as the weather patterns of the mid-Atlantic did not.

CC staff banded together to provide round-the-clock care for more than 170 patients over the federal government closure from noon Friday, February 5, through Thursday, February 11. This area has faced storms before that have complicated operations, but the twin blizzards of 2010 posed a greater challenge. “It was worse for two reasons,” said Dr. John I. Gallin, CC director. “One, the duration and severity of the storm. And two, we had more patients in the hospital than we’ve had in the past.”

Staff stayed overnight and worked double shifts to keep patients safe and on track with their treatments. The CC provided beds for 304 employees, and The Children’s Inn lent their few vacancies. More than 54 staff with four-wheel drive vehicles volunteered to transport those without between their homes and the hospital.

“I was just astounded by the level of energy, the commitment, and the cooperation. Even with a blizzard outside, there wasn’t anything going on inside that would indicate people were doing anything but focusing on patients,” said Maureen Gormley, chief operating officer



### Fantastic voyage

The Clinical Center hosted multiple events on Take Your Child to Work Day on April 22, 2010, including an inside look at imaging, veterinary services, and anesthesia. Department of Laboratory Medicine staffer Tor Moore (right) led “Fantastic Voyage Through the DLM” where visitors dressed up like medical technologists; performed laboratory tests; used microscopes to view microorganisms, parasites, and blood cells; learned how to collect specimens; and practiced using different laboratory equipment.

## CLINICAL CENTER RUNNERS SPEED THROUGH THE NIH RELAY



Six Clinical Center teams participated in the 27th NIH Relay in September 2010. The best time from a CC team came from Rehab Medicine's *Push(1)ng our Gluteus to the Maximus*, one of the department's three teams in the competition. They came in 10th overall by finishing in 15:47. The CC Cheetahs entered for the first year with runners from across Clinical Center.

(Left) Cells R Us from the Department of Transfusion Medicine Cell Processing Section entered (from left) Luciano Castiello, Angela Pickett, Jean Gildner, Hugo Luizaga Diaz, and Thai Truong.



The Drug Runners from the Clinical Center Pharmacy Department included (from left) Schaun Norman, Thomas Dorworth, Sara Abshari, Jordan Petit, and Rose Pauline.

## NEW CORRIDOR STREAMLINES BUILDING TRANSITION

After more than a year of detours and construction, a new main corridor from the Clinical Center south entrance to the Hatfield Building makes navigating the hospital easier. Additionally, the updated Phlebotomy and EKG Heart Station units (two of the Clinical Center's most frequented patient-care areas) now enjoy a larger, brighter waiting area.





## Noteworthy

### Maryland governor visits

Governor Martin O'Malley (right) met with NIH leaders and toured the Clinical Center before addressing the Federal Facilities Advisory Board on November 18, 2010. The governor appointed the board last year to develop a comprehensive assessment of how Maryland can best support and leverage the vast potential of its more than 50 federal facilities and help connect Maryland companies with federal opportunities to create jobs. Greeting him were (from left) CC Director Dr. John I. Gallin; Dr. Griffin P. Rodgers, director of the National Institute of Diabetes and Digestive and Kidney Diseases; and Dr. Francis S. Collins, NIH director.



### 2010 NIH director's awards

Receiving 2010 NIH Director's Awards were:  
The CC Blizzard Response Team, for extensive efforts behind the scenes that kept the hospital operational during winter 2010 blizzards. Team members were Tannia P. Cartledge, Sean D. Dancy, Beverly Farrington, Monique Harrison, Rodney Higginbotham, Ronald Jones, Karen Kaczorowski, Travis Palmer, James Rowe, Michael Sandifer, and Yvonne O. Scypion.

As part of the Traumatic Brain Injury Team honored for effective collaboration in early implementation of the Congressionally established research initiative in traumatic brain injury, Dr. David A. Bluemke, director of Radiology and Imaging Sciences, and Dr. Leighton Chan, chief of the Rehabilitation Medicine Department, were given director's awards.

Patricia Coffey, director of the Medical Record Department, was honored for shepherding the CC toward an electronic patient record.

A Ruth L. Kirschstein Mentoring Award went to Dr. Juan Lertora, director of the Clinical Pharmacology Program, for exemplary performance while demonstrating significant leadership, skill, and ability as a mentor.

Dinora Dominguez and Frinny Rocio Polanco were among those noted for participation in the Volunteer Program for English Proficiency that creates an opportunity for NIH non-professional/non-scientific staff to improve their communication skills.

The Long-Term Administrative Services Contract Team honored for contributions to the goal of reducing the need for multiple individual contracts included Lynda Ray.

### Marincola leads international society



Dr. Francesco Marincola

Dr. Francesco Marincola, chief of the Infectious Disease and Immunogenetics Section in the Department of Transfusion Medicine, is serving as vice president of the International Society for Biological Therapies for Cancer (iSBTc) and will become president in 2012. He has been a member of iSBTc since

2000 and sat on the board of directors from 2004 to 2007. During his tenure, he hopes to support the continued advancement of immunotherapies for malignancies and to increase participation from members outside the United States.

“It’s a year where things are really happening in the field,” Marincola said. “Being president, you have an ability to influence.”

Marincola’s research focuses on at what makes some people respond to immunotherapies, such as interleukin-2, while others do not. Only about 10 percent of patients see an advanced positive response to such treatment, Marincola said. The iSBTc held the Symposium on Immunology-Oncology Biomarkers, 2010 and Beyond: Perspectives from the iSBTc Biomarker Task Force in Masur Auditorium on September 30, 2010.

### Informatics staff recognized

The Clinical Center Department of Clinical Research Informatics received a 2010 Circle of Excellence Award from health-care company Allscripts for achievements in using advanced technology to improve patient-care quality. The department responded to the CC goal of improving the percentage of doctors who signed their orders within 72 hours of entry from 50 to 90 percent. In mid-2010, the department deployed a medication logic module within the Clinical Research Information System. The new module presents the signature manager screen to physicians with unsigned orders at login. Countersignature compliance almost immediately rose to 90 percent

and has remained there since implementation. This capability improved regulatory compliance and patient safety by ensuring that orders are promptly reviewed by the appropriate provider. The Circle of Excellence Award recognizes health-care organizations for demonstrating significant achievements in the areas of process improvement, clinical adoption, and collaboration. Additionally, Lincoln Farnum, CC developer and clinical analyst, was recognized for his participation in the Allscripts ClientConnect program and advisory group.

### “Chefs Move to Schools” campaign

There are two ways to get kids to eat healthy food, says Robert Hedetniemi, certified executive chef for the Clinical Center’s Nutrition Department—you can trick them or you can teach them.

“It’s tough to get kids to eat stuff they aren’t accustomed to. The way I see it, you can either hide it in things that they like, or you can get them involved in the cooking process,” he said.

Hedetniemi has recently joined the ranks of individuals and organizations supporting First Lady Michelle Obama’s Lets Move! campaign to solve the childhood obesity epidemic within a generation. He is one of hundreds of chefs from across the country who have signed up to be part of the “Chefs Move to Schools” initiative, a program that pairs chefs with community schools to help teach young people about nutrition.

Run through the US Department of Agriculture, “Chefs Move to Schools” asks culinary professionals to create healthy meals that meet the schools’ dietary guidelines and budgets. The chefs and schools—kindergarten through grade 12—will also work together to teach young people about nutrition and making balanced and healthy choices.



CC executive chef Robert Hedetniemi turns up the heat in a demonstration for Nutrition Department staff members Janet Hoey (left) and Christina Johnson.

In her opening remarks at the kickoff rally, First Lady Michelle Obama explained the severity of the problems associated with childhood obesity. “You all know the statistics when it comes to the health of our kids—and they’re staggering, every time we talk about it—how nearly one-third of children in this country are now overweight or obese. That’s one in three. Just think about that. That means that these kids are at greater risk of obesity-related diseases—you name them, cancer, heart disease, stroke,” she said.

Hedetniemi agrees. “If we don’t do something about it now, we are going to have a generation of kids with extreme health problems who are going to grow up into adults with extreme health problems,” he said. “We have an opportunity now to intervene, and from my little role I think I can expose some kids to some really cool products to help them get excited about nutrition.”

**Murray receives microbiology award**



Dr. Patrick R. Murray

Dr. Patrick R. Murray, chief of the Clinical Microbiology Service in the Clinical Center Department of Laboratory Medicine, and an American Society of Microbiology (ASM) member since 1974, was chosen to receive the ASM Founders Distinguished

Service Award. Murray has been an active ASM volunteer since 1981 and is honored for his years of service to multiple programs. He was editor-in-chief of four consecutive editions of the *Manual of Clinical Microbiology* and served for 15 years on the editorial board and as an editor of the *Journal of Clinical Microbiology*.

**Henderson gives SHEA lecture**



Dr. David Henderson

Clinical Center Deputy Director for Clinical Care Dr. David Henderson gave the Society for Healthcare Epidemiology of America (SHEA) Lecture on March 20, 2010, at the Fifth Decennial International Conference on Healthcare-Associated Outcomes. A member of SHEA for the last two

decades, Henderson was chosen by the society’s board of trustees. The SHEA Lectureship recognizes the career contributions of one senior investigator in infection prevention and control and health-care epidemiology each year. Henderson’s presentation “Opportunists and Opportunities” reviewed his 30 years as a hospital epidemiologist at the CC and commented on options for and barriers to the society’s success.

Former recipients of the SHEA Annual Lectureship include such distinguished hospital epidemiologists as Dr. Robert Weinstein of Rush Medical

**Lasker Foundation directors tour unique space**

The Albert and Mary Lasker Foundation—dedicated to the support of biomedical research toward conquering disease, improving human health, and extending life—held its board of directors meeting at the NIH on April 20, 2010. Clinical Center Director Dr. John I. Gallin (in lab coat) gave the visitors a tour of the hospital, including its interstitial space between floors. This unique feature of the CC allows for adjustments and repairs to be made to settings such as air flow and water supply without disrupting clinical care and research.



College; Dr. Dennis Maki of the University of Wisconsin; Dr. Didier Pittet from Geneva, Switzerland; Dr. Richard Wenzel of the Medical College of Virginia; and Dr. Glen Mayhall from the University of Texas.

In addition to his lecture, Henderson gave three platform presentations at the conference, including an opening plenary talk titled “Charting the Course for the Future of Science in Healthcare Epidemiology” and a symposium presentation about managing providers infected with blood-borne pathogens. He also conducted a workshop on occupational health. Conference co-sponsors were SHEA; the Centers for Disease Control and Prevention; the Association for Professionals in Infection Control and Epidemiology, Inc.; and the Infectious Diseases Society of America.

**Ognibene honored**

Dr. Frederick P. Ognibene (below right), deputy director for educational affairs and strategic partnerships, received the Society of Critical Care Medicine (SCCM) 2009 Distinguished Service Award for exceptional leadership contributions to the society. Dr. Mitchell Levy, 2009 SCCM president, presented the award. Ognibene was president of the SCCM in 2007 and served nine years on its governing council and executive committee. In 2010, Ognibene was one of 59 individuals elected to the Association of American Physicians. The goals of the association include the pursuit of medical knowledge and the advancement through experimentation and discovery of basic and clinical science and their application to clinical medicine. Each year, individuals having attained excellence in achieving these goals are recognized by nomination for membership by the council of the association.



**Patient Advisory Group member Susan Lowell Butler remembered**

The Clinical Center lost a longtime friend when Susan Lowell Butler died on December 18, 2010. Active with the CC since she sought treatment here for a simultaneous diagnosis of breast and ovarian cancer in 1995, Butler was an original member of the Patient Advisory Group and the consumer representative on the NIH Advisory Board for Clinical Research.

She received the 2004 CC Director’s Award for commitment to enhancing patient care. Butler was a keynote speaker at the dedication ceremonies for the new Mark O. Hatfield Clinical Research Center in 2004 and was selected to be the patient greeter of President Barack Obama during his 2009 visit. She served as a faculty lecturer for the CC course *Introduction to the Principles and Practices of Clinical Research* and contributed the only patient-written chapter to the course’s textbook.

“Susan gave her time, her energy, and her love to the Clinical Center and to all of us,” said CC Director Dr. John I. Gallin. “Her words at the dedication of the new Hatfield Building included the phrase ‘the house of hope’— words repeated many times since. Her courage and strength touched and inspired all who knew her and we will miss her terribly.”

One of the first faces President Barack Obama saw upon entering the Clinical Center on September 30, 2009, was that of longtime patient advisory group member Susan Lowell Butler.

## Organization and Governance

### ADVISORY BOARD FOR CLINICAL RESEARCH NATIONAL INSTITUTES OF HEALTH (2010)\*

#### Governance

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

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

#### **CHAIR: Michael J. Klag, MD, MPH**

Dean  
Johns Hopkins Bloomberg  
School of Public Health

#### **VICE-CHAIR: Martin Blaser, MD**

Chairman, New York University  
Medical Center Department of Medicine  
Frederick H. King Professor of Internal Medicine

#### **Josephine Briggs, MD**

Director, National Center for Complementary  
and Alternative Medicine

#### **Elizabeth B. Concordia, BA, MAS**

Executive Vice President  
University of Pittsburgh Medical Center  
President  
Hospital and Community Services Division

#### **Michael Rutledge DeBaun, MD, MPH**

Professor of Pediatrics  
Vice Chair for Clinical Affairs  
Director for Vanderbilt-Meharry Center of  
Excellence in Sickle Cell Disease  
Vanderbilt Children's Hospital

#### **Joe G. N. "Skip" Garcia, MD**

Vice Chancellor for Research  
Professor of Medicine  
University of Illinois at Chicago

#### **Daniel L. Kastner, MD, PhD**

Scientific Director  
National Human Genome Research  
Institute

#### **Stephen I. Katz, MD, PhD**

Director  
National Institute of Arthritis and  
Musculoskeletal and Skin Diseases

#### **Crystal Mackall, MD**

Chief, Pediatric Oncology Branch  
Head, Immunology Section  
National Cancer Institute

#### **Peter Markell**

Vice President of Finance  
Partners HealthCare System, Inc.

#### **Sharon O'Keefe, RN, MSN**

President  
Loyola University Hospital

#### **Maryland Pao, MD**

Clinical Director  
National Institute of Mental Health

#### **L. Reuven Pasternak, MD, MPH, MBA**

CEO, Inova Fairfax Hospital Campus  
Executive Vice President, Academic Affairs  
Inova Health System

#### **Steven A. Rosenberg, MD, PhD**

Chief, Surgery Branch  
National Cancer Institute

#### **Neal S. Young, MD**

Chief, Clinical Hematology Branch  
National Heart, Lung, and Blood Institute

#### *Ex Officio Members*

#### **John I. Gallin, MD**

Director  
Clinical Center  
National Institutes of Health

#### **Michael M. Gottesman, MD**

Deputy Director for Intramural Research  
National Institutes of Health

#### **H. Clifford Lane, MD**

Chair  
Medical Executive Committee  
Clinical Director  
National Institute of Allergy and Infectious Diseases

#### *Executive Secretary*

#### **Maureen E. Gormley, RN, MPH**

Chief Operating Officer  
Clinical Center  
National Institutes of Health

#### *Senior Staff Support*

#### **Richard G. Wyatt, MD**

Executive Director  
Office of Intramural Research  
National Institutes of Health

\*As of December 31, 2010  
There are two pending vacancies

## MEDICAL EXECUTIVE COMMITTEE MEMBERS (2010)\*

### NIH Clinical Center

*The Medical Executive Committee is made up of clinical directors of the NIH intramural clinical research programs and other senior medical and administrative staff.*

**H. Clifford Lane, MD**  
(Chair) National Institute of  
Allergy and Infectious Diseases

**Maryland Pao, MD**  
(Vice Chair)  
National Institute of Mental Health

**James E. Balow, MD**  
National Institute of Diabetes and  
Digestive and Kidney Diseases

**Richard O. Cannon, III, MD**  
National Heart, Lung, and Blood Institute

**Carlo Contoreggi, MD**  
National Institute on Drug Abuse

**William L. Dahut, MD**  
National Cancer Institute

**Josephine M. Egan, MD**  
National Institute on Aging (Acting)

**Frederick L. Ferris, III, MD**  
National Eye Institute

**Mary Kay Floeter, MD**  
National Institute of Neurological  
Disorders and Stroke (Acting)

**William A. Gahl, MD, PhD**  
National Human Genome Research Institute

**Clare E. Hastings, PhD, RN, FAAN**  
NIH Clinical Center

**Markus Heilig, MD, PhD**  
National Institute on Alcohol Abuse  
and Alcoholism

**David K. Henderson, MD**  
NIH Clinical Center

**Henry Masur, MD**  
NIH Clinical Center

**James E. Melvin, DDS, PhD**  
National Institute of Dental and  
Craniofacial Research

**Deborah P. Merke, MD, MS**  
NIH Clinical Center

**Robert Nussenblatt, MD**  
National Center for Complementary  
and Alternative Medicine (Acting)

**Forbes D. Porter, MD**  
National Institute of Child Health  
and Human Development (Acting)

**Steven A. Rosenberg, MD**  
National Cancer Institute

**Leorey Saligan, PhD, RN, CRNP**  
National Institute of Nursing Research

**Richard M. Siegel, MD, PhD**  
National Institute of Arthritis and  
Musculoskeletal and Skin Diseases (Acting)

**Elad Sharon, MD, MPH**  
Clinical Fellow  
National Cancer Institute

**Carter Van Waes, MD, PhD**  
National Institute on Deafness and  
Other Communication Disorders

**Darryl C. Zeldin, MD**  
National Institute of Environmental  
Health Sciences (Acting)

*Ex Officio Members*  
**John I. Gallin, MD**  
NIH Clinical Center

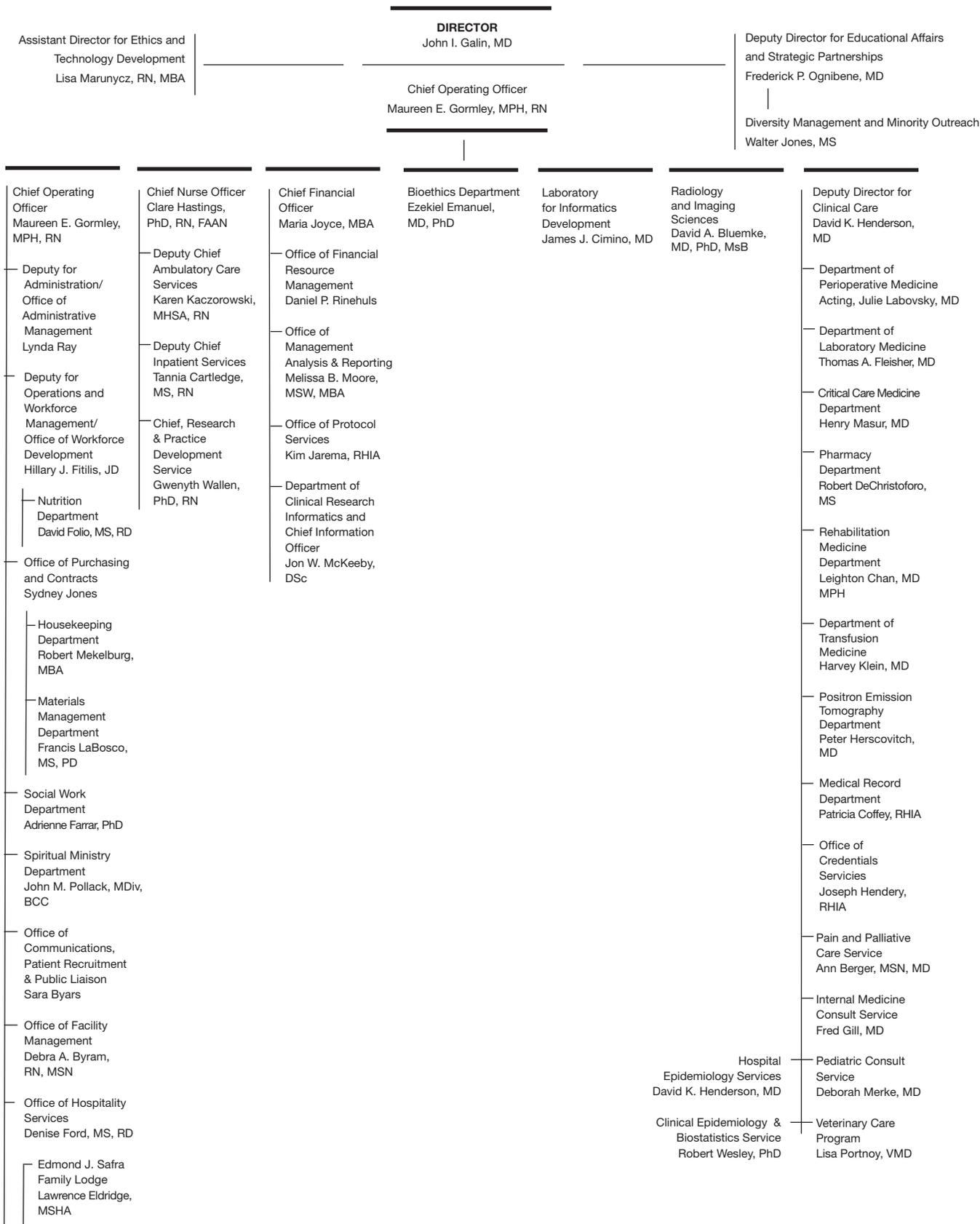
**Daniel L. Kastner, MD, PhD**  
Deputy Director for Intramural Clinical Research

**Patricia A. Kvochak, JD**  
Deputy NIH Legal Advisor

**Richard G. Wyatt, MD**  
Office of Intramural Research, NIH

**Laura M. Lee, RN**  
NIH Clinical Center

\*As of December 31, 2010



# NATIONAL INSTITUTES OF HEALTH

National Cancer Institute (NCI)  
National Eye Institute (NEI)  
National Heart, Lung, and Blood Institute (NHLBI)  
National Human Genome Research Institute (NHGRI)  
National Institute on Aging (NIA)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
National Institute of Biomedical Imaging and Bioengineering (NIBIB)  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
National Institute of Dental and Craniofacial Research (NIDCR)  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute on Drug Abuse (NIDA)  
National Institute of Environmental Health Sciences (NIEHS)  
National Institute of General Medical Sciences (NIGMS)  
National Institute of Mental Health (NIMH)  
National Institute of Neurological Disorders and Stroke (NINDS)  
National Institute of Nursing Research (NINR)  
National Library of Medicine (NLM)  
Center for Information Technology (CIT)  
Center for Scientific Review (CSR)  
John E. Fogarty International Center (FIC)  
National Center for Complementary and Alternative Medicine (NCCAM)  
National Center for Minority Health and Health Disparities (NCMHD)  
National Center for Research Resources (NCRR)  
NIH Clinical Center (CC)

