

PROFILE 2005





A student, teacher, and practitioner of American politics, Mark O. Hatfield has devoted himself to improving the human condition through a lifetime of public service. During his long career in Washington, Senator Hatfield provided strong support for biomedical research and the National Institutes of Health. Before he retired, he shepherded through the legislation authorizing construction of the new NIH Clinical Research Center, and he is proud to be associated with it.

“This clinical research facility is so much more than bricks and mortar,” said the senator at the new hospital’s dedication on September 22, 2004.

“Three thousand people will be here on a daily basis, doing translational research. As medical knowledge increases, so does hope. Writer O.S. Marden once said, ‘There is no medicine like hope, and no incentive so great, and no tonic so powerful as the expectation of something.’ The people here will be creating and testing the next generation of treatments and cures, but they also will create something that’s difficult to measure: hope. With this facility, we have created a new community of hope.”

A videocast of the September 22, 2004, dedication is online. Go to “Past Events” at <http://videocast.nih.gov>

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OUR VISION

The NIH Clinical center will serve as the nation's premier research hospital for conducting clinical research. It will serve as a national resource for clinical research by developing new diagnostic and therapeutic interventions, enhancing systems to ensure the safe, efficient, and ethical conduct of clinical research, training future clinical researchers, and responding to the nation's public health needs.

OUR MISSION

As the nation's clinical research center, the NIH Clinical Center provides an outstanding environment for:

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

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

GROWTH AND RENEWAL



2004 has been a historic year for the NIH Clinical Center. Two landmark achievements will greatly improve our ability to support state-of-the-art clinical research: the completion and dedication of our new research hospital, the Mark O. Hatfield Clinical Research Center, and the launching of our new electronic medical and clinical research information system, CRIS. Both are described more fully in the following pages, along with other important achievements. Years of planning, development, and training went into both projects, and the workload increased dramatically throughout the Clinical Center, involving and affecting every employee. But employee morale and enthusiasm remained consistently positive, reflecting a widely shared sense of growth and renewal.

As a research hospital for the nation, the Hatfield Center will provide a new chance at life for people from every state in the union. Many patients with poor prognoses—patients told they had just weeks or months to live—are alive today because of their participation in research studies at the Clinical Center. For many more patients, who will never visit the NIH, the Hatfield Center promises to be the incubator of science that will produce some of tomorrow's greatest advances in medicine. This new facility is a wonderful gift to the American people and to the world, a gift that promises a healthier life for everyone.

Activating a clinical research hospital is an enormous undertaking; we're lucky it happens only once every 50 years! At the same time, we were charged with doing more with less, and did so as our patient census and the intensity of service continued to increase. There were 7.6% more inpatient days and 9.4 % more outpatient visits in 2004 than in 2003. In the same period, admissions increased 2.4% and the average daily census increased 6.4%. The Clinical Center budget increased only 1.9%. While managing limited fiscal resources, clinical and operational departments met the demand for new and increasing levels of specialized services for the support of institute research and improved patient services.


The Clinical Center also underwent organizational changes, including changes in the Clinical Center's governance structure. Based on recommendations from the NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research, the Clinical Center Board of Governors became the new NIH Advisory Board for Clinical Research. The scope of this new advisory body extends beyond the Clinical Center to the entire intramural clinical research program, the idea being to reinvigorate and integrate it.

Let me take this opportunity to recognize and thank each and every Clinical Center employee and patient volunteer. Their commitment, sustained enthusiasm, and consistent efforts to support our clinical research efforts enabled us to successfully achieve many important goals. I have every confidence that our team's efforts and commitment will make 2005 another successful year.


John I. Gallin, MD
Director, NIH Clinical Center

RECENT CLINICAL CENTER ACHIEVEMENTS

In 2004 we:



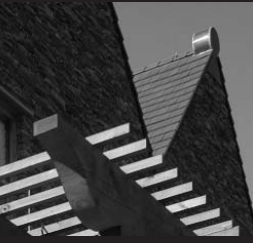
Began moving into our new research hospital. The Mark O. Hatfield Clinical Research Center will continue the Clinical Center's long tradition of being a place for patients who have begun to lose hope—a national home for great minds dedicated to discovering new approaches to preventing and treating disease. The largest hospital in the world dedicated totally to clinical research (research involving patients), the Hatfield Center will provide hope not just for the patients who come to the facility as volunteer partners in research, but for citizens around the world, whose lives are changed when that research advances medical knowledge.



Launched CRIS. Years of planning, development, and training went into the changeover from our 28-year-old medical information system (MIS) to the core medical system at the heart of our new electronic Clinical Research Information System (CRIS). A user-friendly system that links many subsystems, CRIS provides a range of reliable new electronic services. One part of it, ProtoType, can be used to author protocols and will eventually be useful for tracking protocol approvals and changes. A new nutrition system improves access to clinical nutrition services, enabling all patients to order meals “room service” style.

Strengthened training for clinical researchers. Building the infrastructure for training the nation's next generation of clinical researchers helps increase the pool of clinical researchers with expertise in various specialties. NIH's core curriculum in clinical research includes four mandatory courses directed at improving how clinical research is conceived, conducted, and monitored. Matriculation in curriculum courses continued to grow in 2004, and courses were videocast to 24 sites nationally and internationally.


A new Clinical Fellows Committee representing all institutes was established and meets with the Clinical Center director. In 2004, the fellows proposed a new position to bridge the fellow experience and tenure-track positions and developed a survey to assess patient care and the fellows' experiences.



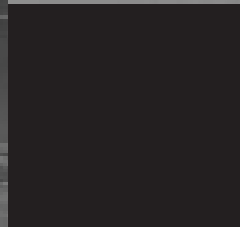
Improved patient services. By improving our services to patients, we make it easier for patients to undertake the extended stays or frequent visits so important for clinical research. New resources for our patients will include a computer at every bedside, giving them access to information on hospital services and amenities and on patients' rights and responsibilities. A business center will give patients additional resources to sustain their regular lives while they participate in research.

Finished building the Safra Family Lodge at NIH. With its 34 guest rooms, the Edmond J. Safra Family Lodge at NIH will provide a comfortable, nurturing home away from home for the families and caregivers of patients who partner with NIH in clinical research.

Improved support for clinical research. Powerful new imaging technology, cutting-edge mass spectrometry technology to assay critical immunosuppressive drugs used by the solid organ transplant program, new techniques for collecting stem cells for bone marrow transplant protocols, and facilities for developing experimental pharmaceutical products unavailable commercially help sustain the Clinical Center's reputation as a world center to support groundbreaking medical advances.



Formed partnerships for disaster planning. In partnership with two neighboring institutions, the National Naval Medical Center and Suburban Hospital, we participated in a joint drill to test the partnership's communications, transportation, and surge capacity, in line with NIH's commitment to being prepared for bioterrorism and other public health emergencies.



THE MARK O. HATFIELD CLINICAL RESEARCH CENTER

“This building is to U.S. medicine what the U.S. Capitol is to government and what the Pentagon is to defense,” said Rep. C.W. Bill Young, chairman of the House Committee on Appropriations, at the hospital’s dedication. **“It is really awesome,”** he said, **“but it is more than a building.”**

The Mark O. Hatfield Clinical Research Center is the NIH’s remarkable new hospital for clinical research. The Hatfield Center is a physical extension of the original red-brick hospital, now known as the Magnuson Center. Together, the Hatfield and Magnuson Centers make up the NIH Clinical Center.

The recently expanded Children’s Inn is right across the street and the new Edmond J. Safra Family Lodge at NIH is a short walk further down Center Drive.

To make it easier for patients when they arrive at NIH, a new gate for patients and visitors is being built at Cedar Lane and West Drive, approaching the main hospital entrance from the north. CC Hospitality staff will greet patients as they pass through routine security checks.



Ample space and natural light

One benefit of the building's long, low silhouette is that all of the rooms are larger, more comfortable, and more open, with plenty of natural light. At the heart of the building a spacious seven-story atrium, the Science Court, serves as a central gathering area, connecting the patient care units that run east and west. Patient wings are separated by and overlook two large, internal courtyards entered through the Science Court.

The patients who toured the hospital the day of the ribbon-cutting and dedication ceremony all agree that the new hospital seems physically brighter, warmer, more cheerful, and more spacious than the old hospital, with courtyards and other gathering places to facilitate getting together between tests and appointments with medical staff.

Being able to meet and socialize with patients with different illnesses, from different walks of life and parts of the country, feels like part of the therapy to many of the patients. Being able to meet each other at the end of a day of being poked, prodded, or treated—being able to sit outside in good weather and to talk about each other's diseases and families, even, in a strange way, to laugh and joke about what's going on—is part of healing. And it feels to most of the patients as if the new hospital will encourage that.

(photo on left) Aerial photo of Mark O. Hatfield Clinical Research Center.

(right) Walkways connecting the new hospital's patient wings are bathed in natural light. Patients and staff seated in conversation areas have a clear view of the central seven-story atrium.



Built for flexibility

Built for flexibility, the seven-story facility can easily adapt to changing research agendas. The hospital will open with 242 inpatient beds and 80 day-hospital stations, but patient rooms are large, and capacity can expand to 400 should the need arise. Patient care units on floors 1, 3, 5, and 7 alternate with floors of “interstitial” (in-between) space on floors 2, 4, and 6, which will permit rapid changes in the use of space and in air-handling systems and other infrastructure, without moving or disturbing the patients. This arrangement allows the hospital to open with 25 rooms with negative airflow (preventing air from exiting, to shield staff and other patients from exposure to highly infectious diseases such as SARS) and 30 rooms with positive airflow (blowing air out, to protect patients with severe immune deficiencies from exposure to infectious diseases).

The day-hospital stations will allow outpatients to participate in research studies—in new therapeutic approaches using gene therapy or stem cell therapy, for instance—without being admitted to an inpatient unit for overnight stays. A special pharmacy will enable the custom manufacture of small quantities of new drugs for initial evaluation in patients.

In the new center, several institutes are planning cross-institute collaboration on programs to address the problem of obesity. The plan is to address the problem at several levels, from molecular to behavioral. The goal: to generate new knowledge about the pathophysiology, prevention, and treatment of obesity and the conditions and diseases with which it is associated—especially type 2 diabetes and its complications.

LINGERING NOSTALGIA



Patient Brienne Schwantes, left, chats with Drs. Harold Varmus and Bernadine Healy (center), former NIH directors, and with Dr. Ruth Kirschstein, senior advisor to the NIH director, at the hospital's dedication. Upper right, Brienne as toddler with Dr. Lynn Gerber, chief of rehabilitation medicine.

Not that there aren't regrets about leaving the

Magnuson Center. “I will always have a warm place in my heart for the old building,” says Brienne Schwantes, a 24-year-old patient with osteogenesis imperfecta (brittle bone disease) who has been coming to the Clinical Center from Wisconsin since she was three months old. Brienne helped the Clinical Center's rehabilitation department pioneer in the use of long-legged braces for children whose bones broke so easily that doctors used to recommend just letting them lie on a pillow, for safety's sake. “That's where I grew up. That's where I made friends, and ran around in the playrooms and learned how to count by the numbers in the elevator. I loved the old building and knew every nook and cranny: where the fastest elevators were, and the cheapest vending machines, where the nicest nurses hung out for coffee breaks.”



And patients will be grouped differently in the new building. “In the old building so many floor units were just bursting with patients,” says Schwantes, “and everyone kind of felt at home in their own specific area. For instance, I am a 9-West girl and couldn't dream of being any place else. Even when they tried to convince me, when I was 24, that I no longer was a child and had to move (gasp!) to 9-East. That's just not home. It will be interesting to see how it is going to work out having all of the genetic kids, AIDS kids, cancer kids, and everyone else all together in one area. I guess time will tell.”

Schwantes does like the openness of the new hospital, “the building and gardens are beautiful, and there seem to be many beautiful places to hang out when you aren't in appointments. The patients and families won't feel so trapped in this new building and are going to really appreciate the open areas.”

“THE BUILDING AND GARDENS ARE BEAUTIFUL.... PATIENTS AND FAMILIES ARE GOING TO REALLY APPRECIATE THE OPEN AREAS.” – patient **Brianne Schwantes**



The new facility will also contain a self-care unit to facilitate clinical trials of new vaccines and to allow containment studies of volunteers receiving live-virus vaccines. This reconfigured space will be designed in such a way that it can be used as a step-down unit for all institutes, when not serving as an isolation unit.

Several patient care units will support long-term studies of patients with behavioral-health diseases such as schizophrenia, depression, alcoholism, and obesity. The study and treatment of these diseases often requires longer patient stays, so these units contain special areas for dining, exercise, interaction, and group therapy—and other resources to help patients leave their homes and communities. The unique combination of special staff and facilities provides a spectacular opportunity for breakthrough observations.

To accommodate the building’s large footprint, horizontal orientation, and long distances, there are 36 elevators, to move people and materials up and down quickly. An extra-wide corridor in the basement runs around the whole building, along which small trucks pulling tugger devices can transport food and other materials.

Patient rooms are spacious enough to accommodate more patients should the need arise. Large windows let natural light flood into rooms.

Small trucks pulling tugger devices transport food and other materials along an extra-wide corridor in the basement.



SPECIAL FEATURES

What's **new** and **different**?

- The Science Court, a grand, airy space—an atrium with many areas in which to meet, sit, and talk with others, and with doors exiting to two landscaped courtyards containing many seating areas.
- A coffee shop, bookstore, and florist on the main floor.
- A nondenominational chapel on the seventh floor for spiritual renewal, prayer, meditation, or respite.
- A business center and kiosks throughout the building, providing additional information sources for patients, families, and visitors.
- Many special rooms: 46 rooms with dialysis capabilities, four lined with lead for patients who have received significant therapeutic doses of radioisotope, 33 with large showers for assisted bathing, nine bathrooms with tubs, and adjustable shower heads for patients for whom the standard shower head simply did not work.



- Plenty of sinks—1500 of them—because frequent hand washing is the secret to reducing the spread of infection.
- Intensive care units with wide doors that fold open so large beds and other equipment can be moved in and out easily. (That ICUs have their own bathrooms and windows, letting in natural light, is one of the improvements most applauded by patients.)
- Lights that turn on and off automatically, and doors that open and shut automatically, as you enter and leave a room.



Photo across top of page: Roof of atrium. Inset photo: Hospitality staff at the main entrance. Center left: There is space for informal gatherings throughout the new facility. Center right: Wide doors in the intensive care unit fold open so that beds and large equipment can pass through easily. Bottom left: Playground outside the pediatric unit.

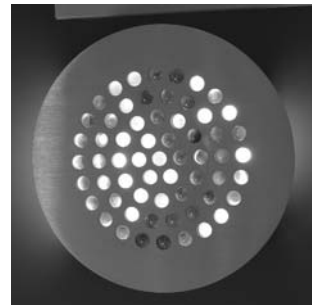


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- Bright colors and cheerful decor in the pediatric units, with patterned lights to help children identify their rooms.
- A computer at every patient's bedside, to provide patient information and education and eventually to allow e-mail communications.
- More conference and meeting spaces, with formal and informal gathering spaces throughout the building, on every floor, including interstitial floors.
- More nurses' stations, closer to more patient rooms, with low tables so that patients in wheelchairs can communicate easily with nurses.
- Plenty of office and other workspace for nurses, at or near the nurses' stations.
- A special steam turbine generator, to reduce building operating costs.
- Special card keys for security, programmed to provide access only to the areas for which the cardholder has been approved.
- Open labs, with up-to-date mechanical equipment and equipment that can carry heavy electrical loads. Adjacent to the labs, special interaction areas connecting patient care providers and the laboratories, to encourage the exchange of observations and ideas.



Top right: A stairway from the patient parking lobby connects to the main hospital level. Above: Decor in pediatric units features cheerful colors with playful light fixtures (right), and child-oriented nurses' stations. Bottom left: Gathering areas encourage interaction between basic and clinical scientists and between staff and patients.



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As the most technologically advanced clinical research facility ever built, the Hatfield Clinical Research Center was designed to provide patient care in the service of facilitating medical advances. Patients will receive their treatment in a hospital designed to deliver the highest quality care in the best environment possible, to ensure that they will complete the full course of research and evaluation. The Clinical Center nurses—among the best educated in the world—say “there is no other hospital like it” because at the Clinical Center, in a clinical research setting, they can practice nursing the way they learned it should be practiced.

THERE IS NO OTHER HOSPITAL LIKE IT.

PATIENT RECRUITMENT AND SUPPORT

HOUSE OF HOPE



Patient Susan Butler and Dr. John Gallin, Clinical Center director, onstage during the dedication ceremony for the new hospital.

Patient Susan Butler salutes the “house of hope.” Diagnosed with simultaneous advanced breast and ovarian cancer in 1995, Susan Butler, at 51, had been told that her odds of surviving more than two years were less than 20%. She had come to the Clinical Center and the National Cancer Institute, she told the audience at the dedication of the Clinical Center’s new hospital, “to see if this ultimate hospital, this place of last, best hope,

might have an answer for me. I remember very clearly how excited I was calling my family and friends, saying, *I’m accepted in the clinical trial!* It was the day that my heart began to lift and a feeling of hope came to me.”

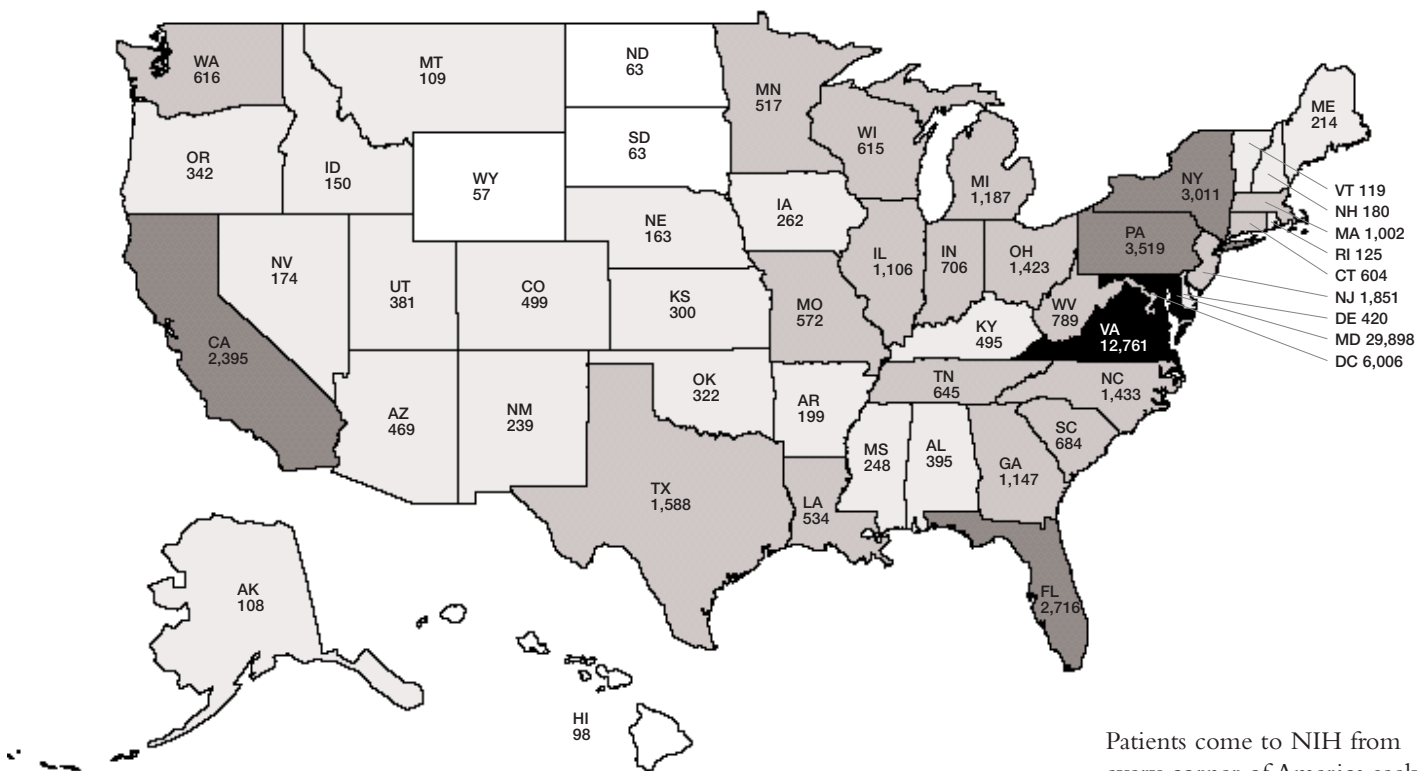
As a volunteer in a complex clinical trial for ovarian cancer, she said, “I became immersed in this sometimes intimidating, enormous hospital and, like many patients, the size and complexity overwhelmed me.” But the people in the building changed that. “One by one, their skill and compassion lifted and supported me through prolonged and arduous treatment. One by one, they cheered me when I was exhausted. And one by one, they took the time to meet my ever-present needs, day and night.”

“Of course, the treatment was not all sweetness and light . . . but because you are treated here, you are sometimes in the company of many people who are far more ill than you are, who clearly will not have an ideal outcome. . . . You see all around you the full panorama of life and death, and with this reality comes, at times, enormous inspiration at the power of the human spirit. . . . It is the family of man here—in all its glory and misery, pain and celebration. It is real life, here in the House of Hope.

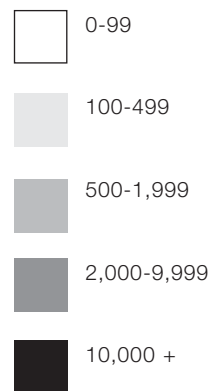
“This magnificent Clinical Center is first and last its people,” said Butler, “with brains and hearts dedicated to saving lives, prolonging lives, improving the quality of lives. . . special people of iron will who get up every day determined to do the best they know how for the sickest of people, those of us who come here, our hearts in our hands, hoping for a miracle. . . . I have had my miracle. I have lived to see my grandchildren, and I am the recipient of the enormous grace and wisdom of the NIH scientists and staff of this wonderful place. So I wish Godspeed to all who are treated and who work here in this house of hope. . . the magical place where science and compassion come together to save our lives.”

Butler made three wishes for the Center’s official birthday: that NIH receive the funding increases needed; that it find creative and meaningful ways to attract and retain the best and the brightest scientists and clinicians; and that every American be informed about the enormous resources available at NIH and the Clinical Center. “Sometimes I think this place is a dangerously well-kept secret. All too often, patients learn too late, or not at all, about the trials and research that take place here.”

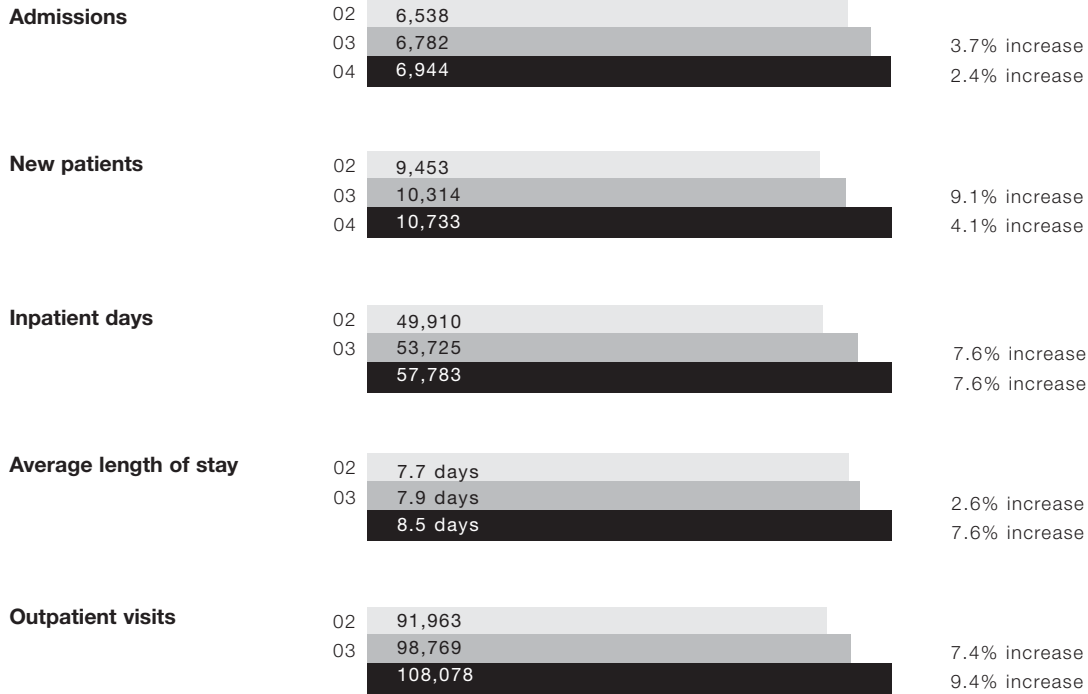
HOME STATES OF ALL ACTIVE CLINICAL CENTER PATIENTS



Patients come to NIH from every corner of America seeking answers to their scientific and medical questions. Finding these answers through leading-edge clinical research is the sole mission of the NIH Clinical Center, guiding all of its activity.

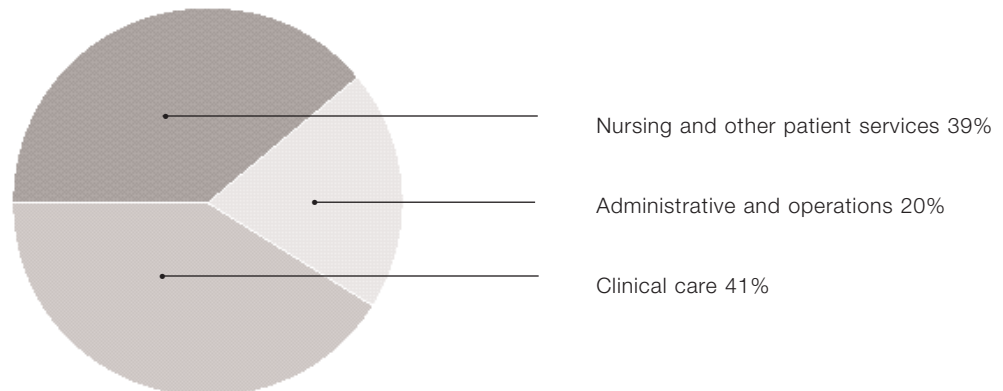


PATIENT ACTIVITY



WORKFORCE DISTRIBUTION

The Clinical Center has a staff of about 2,000. Roughly 80% of the Clinical Center's employees work with patients, as the following exhibit shows. Another 20% work in administration and operations.



Patient Advisory Group

The Patient Advisory Group was established in 1998 when a number of patients were invited to offer their perspectives on the design of the new hospital. At least 20 patients or family members meet quarterly with Dr. Gallin, and the meetings are open to any patients or family members who wish to attend. Efforts are made to represent patients from as many institutes as possible. In FY 2004, the group held several discussions about patient services in the new Clinical Research Center. Many features of the new hospital reflect recommendations patients have made about amenities, signage, security at the dedicated patient entrance, computerized bedside educational resources, business center needs, and patient travel services. Speed bumps in the garage, for example, were eliminated when a cancer patient said they increased nausea in patients undergoing chemotherapy. Flexible showerheads were installed in patient showers in the new hospital to allow patients with intravenous catheters to take showers. The group discussed department- and service-specific functions in the Clinical Center and offered comments on upcoming patient surveys.

Volunteer services

The Clinical Center's volunteer services program accepts and places volunteers in nearly 20 hospital programs. Retirees, spouses of visiting scientists, students from area high schools and colleges, and other volunteers contribute about 75,000 hours of service a year. For example, a cadre of specially trained volunteers in the "Family Friend" program help provide child care for patients who want to participate in clinical trials but don't have the resources for child care. In radiology, in physical therapy, in the library, serving coffee or snacks, welcoming visitors—wherever they work, these volunteers provide a valued helping hand to patients and employees throughout the Clinical Center.

PATIENT ADVISORY GROUP



For their valuable contributions to the patient environment, the Patient Advisory Group received an NIH Director's award in 2004. Shown here, left to right: Dr. Elias Zerhouni, NIH director, Donna J. Decker, Dr. John F. Haughton, Donald J. Cecchi, Michael Harper, Susan L. Butler, Johanna Kool, Jerald S. Sachs, Ellen Berty, Beth Thompson and Mary Priestland (friends of the late Susan E. Greenwald), and Clinical Center Director John I. Gallin. Not shown: John K. Carr, Sue Carroll, Patty Delaney, Leslie L. Flattery, Jon J. Overby, Maureen K. Schultz, and Venlo Wolfsohn.

Interpreters program

The number of Clinical Center patients who speak Spanish or languages other than English has been steadily increasing, says José Luis Rosado-Santiago, one of two full-time Spanish interpreters at the Clinical Center. The other is María Radulovic. Rosado-Santiago and Radulovic are assisted at times by student interns from the Hispanic Association of Colleges and by volunteers from inside and outside of the Clinical Center.

Spanish-speaking patients account for 83% of all non-English speaking patients. There are others, including Haitian Creole, Italian, Greek, French, Mandarin, and Arabic, but none amount to 1%. We need to accommodate people who feel more comfortable speaking another language, says Rosado-Santiago. "It's not that they can't

One of two landscaped internal courtyards that provide natural beauty and secure respite space for patients and staff—as well as a place to linger together and chat between tests and appointments.



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“speak English,” says Rosado-Santiago. “Rather, it’s that we don’t speak their language. When you have what is essentially an international research center and we’re recruiting volunteers from all over the world for various medical studies, we have to accommodate their language needs.”

Two full-time multilingual interpreter positions were created two years ago, and the unit has developed both in-service training (to make staff more aware of language issues) and Spanish-language print materials explaining various services available to patients. One brochure tells patients about their right to an interpreter, explains how to request one, and includes an “I Speak...” card that can be used to identify the patient’s language and inform the staff that this person is requesting an interpreter.

A Spanish-language video, “Bienvenidos!,” adds closed captions for the hard of hearing. Closed captioning may later be made available in other languages.

A training video in English, “The Many Languages of the Clinical Center,” informs staff how best to use an interpreter, how to structure their conversations, and what they can or cannot expect from interpreters. “While some are very experienced and savvy in working with foreign patients, others weren’t as comfortable,” says Rosado-Santiago. Some of the staff didn’t know how to ask for an interpreter, or didn’t know there was such a program. Understanding how to communicate with a patient through an interpreter is central to effective research.

Room service

This year the Nutrition Department improved the room service program it launched in 2002. Under the improved system, a new computer system makes the room service program available to most Clinical Center patients, including those on modified or restricted diets. The food is delivered within 45 minutes.

THE EDMOND J. SAFRA FAMILY LODGE AT NIH



Construction on the Edmond J. Safra Family Lodge at NIH, located near the Clinical Center, was completed in 2004. The Lodge, a major project of the Foundation at NIH, represents the culmination of a dream Clinical Center employees have worked toward for nearly 10 years. With its 34 guest rooms, the Lodge will provide a retreat and sanctuary for the families and caregivers of patients who partner with NIH in clinical research. Guests experiencing the stress and anxiety that accompany the serious illness of a loved one can make the Lodge their

home away from home, knowing that the patient is close by if they are needed.

A \$4.75 million donation from The Edmond J. Safra Philanthropic Foundation helped NIH fund the Family Lodge. Generous contributors include the Merck Company Foundation, the Bristol-Myers Squibb Foundation, GlaxoSmithKline, and many more corporations, foundations, and individuals.

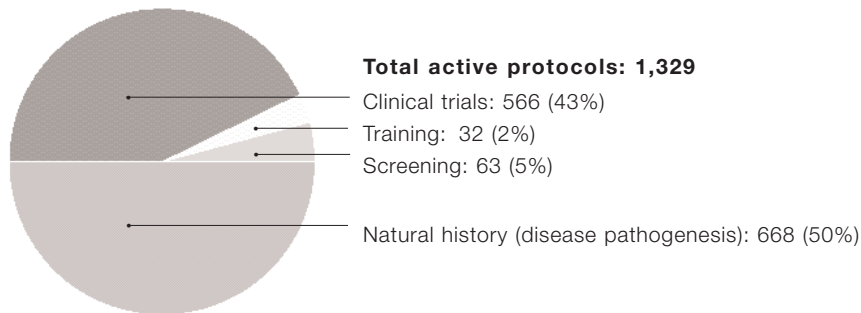
For more information,
contact Jan Weymouth,
Executive Director
301-496-2925
jweymouth@cc.nih.gov

*Funding for the Lodge is sought
through the Foundation for the
National Institutes of Health.*

ADVANCING CLINICAL RESEARCH

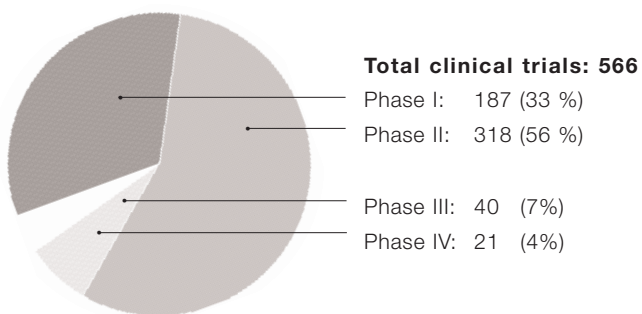
PROTOCOLS BY RESEARCH TYPE

(onsite intramural protocols, fiscal year 2004)



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

Breakdown of clinical trials



Clinical trials proceed through four phases

- Phase I:** Researchers test a new drug or treatment for the first time in a small group (20–80) of people 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 (100–300) of people 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.



Labs (above) and patient care units (right) are bright and airy.



ACTIVATING CRIS



Dr. Stephen Rosenfeld, left, the Clinical Center's new chief information officer, relaxes with Dr. Cliff Lane, NIAID clinical director. Rosenfeld led the team that developed NIH's new clinical research information system (CRIS) and Lane headed the project's steering committee. "There was a strong feeling of NIH community during the time leading up to the launch," says Lane.

During a year of major transitions, one of the chief milestones—and one of the most complex—was the changeover from MIS, the hospital's original Medical Information System, to CRIS, the hospital's powerful new Clinical Research Information System. With the active involvement of clinical leaders from the institutes, the core medical information system at the heart of CRIS went live on August 23, replacing patient-care functions that for 28 years had been handled by MIS. The culmination of the first phase of a \$60-million effort, the project was within budget and was delayed only three weeks from the scheduled activation date.

In 2002 the Clinical Center accepted bids for development of a clinical research information system to replace MIS. Dr. Stephen Rosenfeld led the development team and Dr. Cliff Lane, clinical director of NIAID, headed the steering committee. "

A hospital information system is essentially a tool kit for building a model of how your hospital should operate," says Dr. Rosenfeld. "These systems don't come with a starter set. You have to design almost everything from scratch, from where orders go and what orders look like to how things are used." CRIS will serve as a national model for how to build such systems.

There was a strong feeling of NIH community during the time leading up to the launch, says Dr. Lane. "I think everyone bonded as an NIH community, because everyone knew how important this is, particularly to the safety and the care of the patients."

CRIS represents the next generation of medical information technology. The second phase of the CRIS project includes a data warehouse, capable of storing and merging clinical and research information. The data warehouse will collect longitudinal patient data for use in research (while protecting patient privacy and confidentiality).

In 2004 the Clinical Center inaugurated a new tool called ProtoType, to help author and manage protocols. Two institutes, NHLBI and NEI, were the first to require use of Prototype in their intramural clinical research programs. The ProtoType system was also installed at Rockefeller University in the fall of 2004 as part of a reciprocal effort to build new tools to facilitate clinical research.

ROSENFELD NAMED CHIEF INFORMATION OFFICER

Dr. Stephen Rosenfeld was named chief information officer of the Clinical Center and associate director for Clinical Research Information Systems. He has been chief of the Department of Clinical Research Informatics since the department was established in 2001. In that capacity he was responsible for development of the Clinical Research Information System (CRIS), a system designed to replace the 28-year-old Medical Information System. In this new position, Dr. Rosenfeld will direct the Department of Networks and Applications and the Department of Clinical Research Informatics.

STRENGTHENING CLINICAL CARE

Patient safety

In 2004, the Clinical Center developed new approaches to ensuring a robust patient safety program. Features of this program include:

- An emphasis on nonpunitive, voluntary, real-time electronic reporting of actual or potential events that may affect the quality of patient care and patient safety, using an electronic occurrence reporting system.
- Analysis of the occurrence reporting system data to identify clusters or trends of similar types of events, so interventions may be designed to eliminate them. This highly successful program has been presented at national meetings of the National Quality Forum, the National Patient Safety Foundation, and the Society for Healthcare Epidemiology in America.
- Survey of nursing staff to assess their perception of the organization's "culture of patient safety."
- Patient education about the care patients receive and their rights and responsibilities. "Speak up for your safety," a brochure published in 2003, stresses the patient's vital role in ensuring safety. Printed in both English and Spanish, the booklet is given to all new patients on admission.
- A study of the feasibility of using electronic patient identification devices (biometrics) to identify patients.

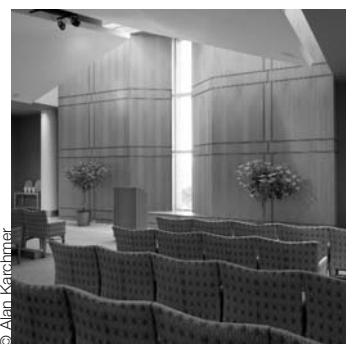
Pain and palliative care

In 2004, the Clinical Center Pain and Palliative Care Service became one of only nine palliative care fellowship training programs in the United States to be accredited by the American Board of Hospice and Palliative Medicine (ABHPM). Accreditation is giving credibility to a new and growing field—palliative care—in this country. Getting the accreditation was more than a mere formality. The requirements led many of the staff through training they'd never before received. Fellows in training care for patients in inpatient settings, community settings (including Medicare-certified hospices), and ambulatory care settings, and are exposed to consultation services, longitudinal care, and bereavement support. They learn how to provide physical, psychosocial, and spiritual treatment for a patient and family experiencing a chronic, life-threatening illness. They learn to work in interdisciplinary teams and to value the contributions of other disciplines

In its fourth year, the service saw an average 25 to 30 inpatients a day (7,500 a year) and 30 outpatients in two weekly outpatient clinics. Under the leadership of Dr. Ann Berger, the core team has grown—adding three nurses and 2.5 physicians (including a half-time anesthesiologist). The larger team, which meets weekly, includes the patient representative and members of several disciplines, including nutrition, spiritual ministry, recreation therapy, and social work.



Above, Dr. Ann Berger, chief of Pain and Palliative Care. Below, the chapel on the 7th floor.



Tannia Cartledge, shown here with Dr. Elias A. Zerhouni, NIH director, and Dr. John I. Gallin, director of the Clinical Center.

MENTOR HONORED

Tannia Cartledge, chief of Adult, Pediatrics and Behavioral Health in Nursing and Patient Care Services, received the NIH Mentoring Award for "her superb approach to mentoring that has benefited so many nurses at NIH and in the community at large." Not only is Nursing Care committed to mentoring, said Cartledge, but it is an important value at NIH generally.



TONY STATON, MAKING A DIFFERENCE



“This is a very easy job to get up for. I know I make a difference,” says Tony Staton.

“It’s a joy to get up in the morning to come and do this,” says Tony Staton of his job on the Clinical Center’s hospitality staff. A 25-year employee, Tony moved from Housekeeping to Hospitality a year ago. His job now is to help patients and visitors by giving them directions or other information, escorting them when they need help getting places, and helping out in ways that change daily.

“I know I make a difference because I see the smiles on people’s faces. Last week an elderly lady and her husband came up, but her husband had to turn around and go right back home, so she was here by herself for about a week. I went upstairs a couple times to take her out for a little air, give her a tour of the new building, to take her to the gift shop, and she told me, ‘You know, that was better than medicine.’ If they can just leave with a smile and stop thinking about what they’re here for, we’ve done our job. When her husband came back he came and thanked me personally, and I’m not even the doctor here!

“It makes me feel good, that I made somebody happy for whatever small amount of time I came in contact with them. I can leave here knowing I made a little difference today, and then just look for it again tomorrow.

“This is a very easy job to get up for.”

NIH DIRECTOR’S AWARD FOR BONE MARROW TRANSPLANT UNIT



Shown receiving an NIH Director’s Award from Dr. Elias Zerhouni are, left to right, clinical research nurses Leslie Wehren and Virginia (Ginnie) Warren; Dr. Renee Stubbs, lead recreational therapist; nurse manager Priscilla Rivera; clinical research nurse Eleftheria (Libby) Kozanas; clinical social workers Patricia Prince and Katherine Cone; Dr. Lawrence Friedman, assistant director for Ethics and Clinical Research, NHLBI; Dr. John Barrett, chief of the Stem Cell Allotransplantation Section, NHLBI; Dr. Richard Childs, senior investigator, Hematology Branch, NHLBI; and clinical nurse specialists Margaret Bevens and Nonniekaye Shelburne.

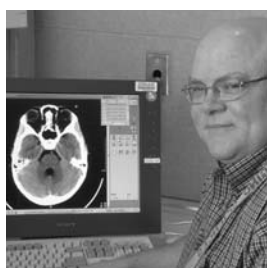
Staff from the Clinical Center and the National Heart, Lung, and Blood Institute were recognized with an NIH Director’s Award for their “commitment to enhance patient care and service at the Clinical Center” and “the team’s outstanding clinical research contributions in the advances of the practice of stem cell transplantation.” Dr. Elias Zerhouni, NIH director, presented the award.

“This program has been not just a team effort from the combined work of a group of doctors, nurses, research nurses, pharmacists, social workers and other healthcare professionals directly involved in patient care,” said Dr. John Barrett, the unit chief, “but it reflects dedicated and enthusiastic effort from the entire Clinical Center. It is not an exaggeration to say that the transplant program has only been possible in the unique environment of NIH, where we have enjoyed state-of-the art expertise.”

“We are rewarded each day as we are given the opportunity to make a difference in the lives of our stem cell transplant patients,” noted Nonniekaye Shelburne, a clinical nurse specialist in stem cell transplants. “Having the BMT team recognized with the NIH Director’s Award energizes our passion to continue working in this intense and ever-changing area of medical research.”

Margaret Bevens was also awarded the Josh Gottheil Memorial Bone Marrow Transplant Career Development Award, sponsored by the Oncology Nursing Society Foundation, for meritorious practice in bone marrow transplant nursing. Bevens has been a part of the Bone Marrow Transplant program since it began in 1993.

Clinical Center departments facilitate the biomedical research of their colleagues in institute or center intramural programs. They also continue to be recognized for their own scientific accomplishments.



James Vucich is project manager for PACS.

Imaging sciences
With implementation in 2004 of the upgraded PACS (Picture Archival and Communication System) web system, clinical investigators can now access imaging data from the past 5 years, 24 hours a day, 7 days a week,

using computers connected to the Clinical Center intranet. PACSweb software allows investigators to control the display of images, compare imaging studies performed at different times, access dictated reports, review patient data, and then use the images for research and teaching purposes.

Renovations in the radiology department's waiting room and ultrasound area were completed in 2004 and it is hoped that renovations in general radiology and most of the renovations in interventional radiology will be completed in early 2005. In 2006 most of the renovations for the new magnetic resonance imaging suites and for the new reading rooms and digital film library are also scheduled for completion.

A new high-resolution research tomograph (HRRT) PET scanner was installed, which permits high-resolution PET brain studies. The number of radiochemistry hot cells will be expanded, making it possible to increase the variety of radiopharmaceuticals used for PET studies in clinical research protocols.



Laboratory medicine

The Department of Laboratory Medicine is developing a Biosafety Level 3 laboratory in microbiology to ensure preparedness for dealing with emerging highly contagious infectious agents (such as SARS) and with agents of bioterrorism. DLM has also implemented a new cutting-edge mass spectrometry technology to assay sirolimus and tacrolimus, critical immunosuppressive drugs used by the solid organ transplant program.



Transfusion medicine

In the Department of Transfusion Medicine, Drs. Susan Leitman and Charles Bolan conducted clinical trials to establish safer and more effective ways of collecting (by apheresis) blood progenitor cells in support of patients needing bone marrow transplants. Dr. Bolan, a visiting scientist from the Office of the U.S. Army Surgeon General, has worked in DTM for six years. The procedure Drs. Leitman and Bolan developed is safer and also collects twice the number of hematopoietic stem cells from donors for bone marrow transplant protocols. The procedure—adopted by the National Marrow Donor Program (NMDP)—has decreased the number of visits a patient requires, increased the efficiency of scheduling, reduced costs, and improved service.

Pharmacy

The pharmaceutical development section of the pharmacy department formulated a preservative-free steroid injection for the eye. A commercially available product (Kenalog) contains preservatives that produce undesirable side effects, and community ophthalmologists have nothing else to use. The pharmaceutical development staff worked with the National Eye Institute to formulate a preservative-free injection.

Dr. Patrick Murray, chief of the Clinical Microbiology Laboratories, led development of the Biosafety Level 3 laboratory, so that the Department of Laboratory Medicine could safely process specimens from patients with highly infectious diseases.

Healthy volunteer Richard Haddon donating blood progenitor cells by apheresis, in support of an unrelated patient who needs a stem cell transplant. Through the NIH Marrow and Apheresis Donor Center (part of DTM), Haddon is participating in the National Marrow Donor Program.

AWARD FOR HEMOCHROMATOSIS WORK



Making a difference.

Dr. Susan Leitman (left) receives the Making a Difference Award from Randy Alexander, chairman of the Iron Disorder Institute. With them are Dr. Charles Bolan (in uniform) and Glorice Mason, team leader of the Donor Room Staff. Leitman, Bolan, and Mason are all members of the Hemochromatosis Protocol Team in the Department of Transfusion Medicine.

Dr. Susan Leitman, chief of Blood Services in the Department of Transfusion Medicine, received the Iron Disorders Institute's prestigious annual "Making a Difference" Award in August. She received the award for her work improving care for patients with too much iron in their blood—a disorder that can lead to early death if not treated by regular blood drawing.

Randy Alexander, chairman of the board of trustees of the patient advocacy organization making the award, has hereditary hemochromatosis. He is one of 200 participants in DTM's hereditary hemochromatosis donor protocol. The

condition, dubbed the "Celtic Curse" by some, is more commonly known today as hereditary hemochromatosis (HH). Its effects can be devastating: arthritis, fatigue, heart palpitations, nonspecific stomach pain, impotence, loss of menstruation, and infertility. In advanced stages, the skin can take on a gray or bronze hue, and serious problems—such as cirrhosis of the liver, liver cancer, diabetes, heart and joint disease, severe fatigue, cardiac arrhythmia, and congestive heart failure—may develop, resulting in disability or death.

A common genetic disorder in people of northern European Caucasian descent, it affects one in 200 people in this risk group. "Many people don't even know they have it, although it affects them from early childhood," says Leitman. She believes it should be tested for at infancy or in childhood. Under Dr. Leitman's auspices, said Alexander, NIH has demonstrated "tremendous forward thinking in designing an outstanding program yielding significant data and publicizing HH." Leitman finds it highly rewarding to be able to improve the quality of care in this group of patients, who are so highly informed about their condition. Ironically, "blood donations by people with HH constitute 15 percent of all the blood units collected in DTM and transfused to Clinical Center patients." By participating in the DTM protocol, those with HH "not only get the best, most expert and informed care, but they help save other lives while being treated. That is the paradigm that IDI was honoring with this award."

HONOR FOR DR. EZEKIEL EMANUEL



Dr. Ezekiel Emanuel

On October 18, Dr. Ezekiel Emanuel, Department of Clinical Bioethics, became the latest Clinical Center physician to be elected to the prestigious Institute of Medicine (IOM), joining Dr. Harvey Alter and Dr. John Gallin in this honor. Emanuel was elected to the Institute in recognition of his work in bioethics.

A breast cancer specialist, Emanuel was appointed chair of the Clinical Center's Department of Clinical Bioethics in 1998. He received his MD from Harvard Medical School and his PhD in political philosophy from Harvard University. His doctoral dissertation received the Toppan Award for the finest dissertation in political science of the year. Emanuel was a fellow in the program in ethics and the professions at the Kennedy School of Government and Harvard.

After completing an internship and residency in internal medicine at Boston's Beth Israel Hospital and an oncology fellowship at the Dana-Farber Cancer Institute, Emanuel joined the faculty at the Dana-Farber Cancer Institute. He was also associate professor at Harvard Medical School. Emanuel served on the ethics section of President Clinton's health care task force and on the National Bioethics Advisory Commission. He has published widely in medical journals on the ethics of clinical research, advance care directives, end-of-life care issues, euthanasia, the ethics of managed care, and the physician-patient relationship. His book on medical ethics, *The Ends of Human Life*, received honorable mention for the Rosenhaupt Memorial Book Award by the Woodrow Wilson Foundation. He received the AMA-Burroughs Wellcome Leadership Award and a Fulbright scholarship (which he declined).

Improving outpatient services

A major initiative in 2004 has been the redesigning of outpatient services.

Outpatient clinics. Based on current usage and scheduling practices, there are not enough exam rooms to meet the increasing demand for clinic space. When the Hatfield Center begins taking patients, some of the current occupants of the Ambulatory Care Research Facility will relocate to the new hospital. Freeing up that space in the ACRF provides a good opportunity to analyze current scheduling practices, the use and configuration of space, and patient flow in the clinics. As clinic space is reorganized and reallocated, the Clinical Center and the institutes have a unique opportunity to evaluate the way outpatient care is provided. A proposal for realignment of the outpatient clinics has been proposed. Next step: Develop an implementation plan in 2005.

Renovation of outpatient surgery.

The current Clinical Center surgical suite was designed before outpatient surgery became standard practice. In 2004 a study was done to determine if it was feasible to renovate the area and provide modern services to help accommodate the growing number of outpatient operations. If possible, design for a new outpatient surgery facility will begin in 2005.

To complement the growing outpatient surgery program and to improve inpatient surgery, a new pre-anesthesia clinic (PAC) opened in the Department of Anesthesia and Surgical Services in 2004.

AWARD FOR DR. HARVEY ALTER



Dr. Harvey Alter

In April, Dr. Harvey Alter received the American College of Physicians Award for Outstanding Work in Science as Related to Medicine. Only 47 scientists nationwide have received the award. Other NIH scientists to do so were Nobel Prize winners Marshall W. Nirenberg and Michael S. Brown, former NIH Directors Donald S. Fredrickson and Harold E. Varmus, and current researchers J. Michael Bishop, Thomas A. Waldmann and Francis S. Collins. In December Dr. Alter received the First International Prize of Inserm (the French equivalent of NIH).

In 2003, Dr. Alter became the first Clinical Center scientist elected to both the National Academy of Sciences and the Institute of Medicine. In 2000, he was awarded the prestigious Albert Lasker Medical Research Award, and in 2002 he received The International Society of Blood Transfusion Presidential Award.

Dr. Alter, who came to the NIH Clinical Center as a senior investigator in 1969, is chief of the infectious diseases section and associate director of research in the Department of Transfusion Medicine. As a young research fellow, he co-discovered (with Baruch Blumberg, a geneticist with Arthritis and Metabolic Diseases) the Australian antigen, a key to detecting the hepatitis B virus. Later, he spearheaded a Clinical Center project to create a storehouse of blood samples used to uncover the causes and reduce the risk of transfusion-associated hepatitis. Because of such work, the United States instituted blood and donor screening programs that reduced the risk of transfusion-associated hepatitis from 30 percent in 1970 to nearly 0.

In collaboration with Bob Purcell and Stephen Feinstone (NIAID), Dr. Alter used this repository of clinically linked blood samples to solve another puzzling clinical problem. Most transfusion-related hepatitis was attributed to a virus different from the two then-known hepatitis agents. Calling this new form “non-A, non-B hepatitis,” the researchers subsequently proved through transmission studies in chimpanzees that it was transmitted through a new agent—which led eventually to discovery of the hepatitis C virus.

DISASTER PLANNING AND EMERGENCY PREPAREDNESS



Preparing for emergencies.

As part of an emergency response drill conducted jointly by three local partners, some participants—portraying seriously injured patients—were transferred from the National Naval Medical Center across the NIH campus to Suburban Hospital. So that Suburban could accept the influx of “patients” from the Naval Center, participants portraying stable patients were transferred from Suburban to the Clinical Center.

Emergency preparedness is increasingly important in health care. In line with the NIH commitment to preparedness for, and effective responses to, bioterrorism and other public health emergencies, in 2004 the Clinical Center revised its emergency preparedness plan and developed a streamlined response template. It also formed a partnership with the National Naval Medical Center and Suburban Hospital, focusing on the relative and complementary expertise and resources of the three neighboring institutions. Dr. Gallin leads the NIH in this partnership between two government agencies and a private-sector hospital.

On October 21, the Clinical Center participated in a joint drill with its two partners, to test the partnership’s communications, transportation, and surge capacity. As part of the exercise, some participants—portraying seriously injured patients, replete with makeup for mock injuries—were transferred from NNMC across the NIH campus to Suburban Hospital, which lies just west of NIH across Old Georgetown Road. So that Suburban could accept the influx of “patients” from NNMC, participants portraying stable patients were transferred from Suburban to the Clinical Center. A fleet of fire emergency vehicles from NIH; NNMC; Montgomery County; Naval Surface Warfare Center, Carderock; Walter Reed Army Medical Center; and Naval District Washington took part, as obstacles such as simulated car accidents were cleared and emergency vehicles navigated the necessary routes of access. To launch the event, more than 40 distinguished guests from the Department of State, Department of Health and Human Services, Department of Homeland Security, and other local, state and federal emergency management agencies attended a press conference.

The Department of Health and Human Services (DHHS) supports this partnership. The Office of the Secretary provided support by contributing a contingency hospital with the supplies and infrastructure needed to provide surge capacity for up to 250 patients in the event of a natural or man-made disaster. These efforts capitalize on the complementary strengths that are essential to an effective regional response to man-made or

natural disasters in the Washington metropolitan area. Dr. Gallin represents the NIH in emergency preparedness planning for the Department of Health and Human Services.

Supporting disaster relief in Florida

Dr. Gallin also coordinated NIH’s staff mobilization for disaster relief during the 2004 Florida hurricane season. Hurricane Frances came ashore near Stuart, Florida, on Saturday, September 4, followed soon by hurricanes Ivan and Jeanne, disrupting lives and inflicting massive damage. Surgeon General Richard H. Carmona activated the Commissioned Corps of the Public Health Service in what might have been the “largest disaster response ever.” Teams from different agencies and commands, who had not worked together before, came together from all over the country to provide disaster relief and services. PHS officers worked with Red Cross volunteers and with staff from the HHS Secretary’s Emergency Response Team (SERT), Homeland Security, DOD, FEMA, Veterans Affairs, the Public Health Service, and the USDA Forest Service.

PHS officers working with FEMA trained thousands of volunteers to help out in Florida, Mississippi, Georgia, Alabama, and North Carolina, and many NIH nurses, research nurses, and nurse practitioners traveled south to help out.

“As a civilian in wartime, the best thing you can hear is, ‘We are the Marines, and we are here to help,’ ” said Dr. Andrew Daigle, one of the senior emergency room physicians at Pensacola’s Sacred Heart Hospital. “Now I have learned that after a disaster the best thing you can hear is, ‘We’re the United States Public Health Service, and we’re here to help.’ ”

TRAINING THE NEXT GENERATION

It is a top Clinical Center priority to train clinical researchers in the responsibilities involved in planning and conducting clinical research and to increase the pool of clinical researchers with expertise in various specialties. By building an infrastructure for clinical research training on NIH's main campus, the Clinical Center has helped address the nationwide shortage of training opportunities for physicians, fellows, medical and dental students, nurses, and allied health professionals interested in clinical research.

The Office of Clinical Research Training and Medical Education, established in the Clinical Center in May 2003, is responsible for developing, administering, and evaluating clinical research training and medical education initiatives that aid the professional growth and development of NIH clinician-scientists and other health care professionals. Through distance teaching classrooms, the NIH Clinical Center can now export its clinical research training programs throughout the United States and the world.

In 2004 the **curriculum in clinical research** was formalized and a certificate program implemented to acknowledge completion of and outstanding performance in all of the curriculum's core components. The first certificate was conferred on Dr. Linda Griffith (photo upper right), who satisfied all of the certificate requirements with commendation. The curriculum program was described in an article about clinical research training in *Clinical Trials Administrator* (February 2004, Vol. 2, No. 2, pp. 21-22) and in the *NIH Catalyst* (March/April 2004, p. 13). An intranet site describing the target audience and the curriculum was launched in May 2004: <http://intranet.cc.nih.gov/clinicalresearchtraining/curriculumcert.shtml>. The curriculum includes the following four courses directed at improving how clinical research is conceived, monitored, and conducted. These courses may be taken as part, or independent, of the clinical research curriculum.

Introduction to the principles and practice of clinical research. This course, established in 1995, provides formal training on how to effectively



design a clinical trial and implement clinical protocols. To date, 4,138 students have registered for the program, and 1,325 certificates have been awarded. The 2004-2005 course has 721 registrants (274 on NIH's Bethesda campus and 447 participating at 14 remote sites by "live" video-conference). The archived content is provided to Seoul National University College of Medicine in North Korea, the National Cancer Center in Singapore, and the University of Bergen in Norway. A second edition of the course textbook, published by Academic Press in 2002, is being planned.

Principles of clinical pharmacology.

Designed to meet the needs of researchers who have an interest in the clinical pharmacological aspects of contemporary drug development and utilization, this course is entering its seventh year. Of the 1,962 enrollees since the course began in 1998, 448 students registered for the 2004-2005 program, and 520 certificates of participation have been awarded. A second edition of a companion textbook published by Academic Press in 2001 is being developed.

Ethical and regulatory aspects of clinical research.

More than 2,000 students have enrolled in this program (415 in fall 2004), which was implemented in 1999 to offer formal education and training in research ethics and to expose students to a broad range of issues important to the ethical conduct of clinical research. Individual sessions and group institutional review board (IRB) reviews are presented by leading experts in various areas of clinical research ethics. The course was broadcast by satellite and the Internet to participants at the Western IRB in Olympia, Washington.

Left: Dr. Linda Griffith, medical officer, Division of Allergy, Immunology and Transplantation, of extramural NIAID, receives the clinical research curriculum certificate from Dr. Frederick Ognibene (left), director, Office of Clinical Research Training and Medical Education, Clinical Center, and Dr. John Gallin, director, Clinical Center.

A textbook, *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, was published by Johns Hopkins University Press.

Clinical research training. Developed in 2000, this course addresses the NIH Training and Education Standard for conducting clinical research in the intramural research program. All NIH clinical investigators must take the course and pass an exam before receiving approval to conduct new clinical protocols. All clinical principal investigators with a protocol approved through the Clinical Center have done so. To date, 3,302 people from the United States and elsewhere have successfully completed the course, through live classroom sessions and via the Internet. The course was made available via the World Wide Web in January 2001 and has been accessed from sites in the United States, Europe, Central America, Asia, and the Caribbean. The course is available online at <<http://www.cc.nih.gov/researchers/training/crt.shtml>>. The curriculum in clinical research also includes a computer-based training course for NIH Institutional Review Board (IRB) members and an IRB experience.

Two masters programs in clinical research

The Clinical Center's training portfolio has grown to include local and long-distance partnerships. Two different collaborative programs lead to graduate degrees in clinical research.

to physicians and dentists who successfully complete a distance-learning partnership program between the Clinical Center and the Duke University School of Medicine. This program, offered by videoconference, provides formal courses in research design, research management, and statistical analysis. Sixteen new NIH students enrolled in the 2004-2005 program. A total of 105 students, representing a cross-section of NIH institutes and centers have been admitted to the program; 34 have received their degrees.

NIH-University of Pittsburgh. A master's degree in clinical research is available to those successfully fulfilling the requirements in a Clinical Center-University of Pittsburgh School of Medicine program. Initiated in 2001, this program expands training options for PhDs and allied health professionals. Students who matriculate can receive a Master of Science in Clinical Research or a Certificate in Clinical Research from the University of Pittsburgh School of Medicine. The curriculum, available by videoconference, includes courses in biostatistics, clinical research methods, measurement, clinical trials, ethics, and grantsmanship. Julie Hvizda, a research nurse specialist in the Clinical Center's diagnostic radiology department, graduated from the program in 2004.

Clinical Investigator Student Trainee Forum.

This academic forum was launched to emphasize the importance of translational and clinical research and to encourage the training of the next generation of clinician-scientists to conduct that research. Established investigators from the NIH and other academic medical centers comprise the forum faculty, and in lectures, workshops, and interactive panels the student attendees learn about contemporary biomedical advances as well as academic careers in clinical research. Participants include Howard Hughes Medical Institute scholars (Cloister) and fellows (non-Cloister); Doris Duke Clinical Research Program medical students; National Center for Research Resources/GRC students in year-long research programs; Sarnoff Endowment for Cardiovascular Science fellows; and NIH

Below: Students in the Clinical Investigator Student Trainee (CIST) Forum program, taking a break. Left to right: Julie Rosenthal, Samer Jaber, Arash Koochek, Robert Allison, Sinae Park, Chris Keh, and Rebecca Hommer visit with Dr. Frederick Ognibene (far right), director of the CC's Office of Clinical Research Training and Medical Education. The November forum drew over 250 students.



NIH-Duke masters program. Under this program, introduced in 1998, a master of health sciences degree in clinical research is awarded

Clinical Research Training Program for Medical and Dental Students fellows. The first forum was held in October 2003; the second, November 2004. The November 2004 forum attracted over 250 medical students to the Clinical Center for a two-day event, which featured lectures on recent biomedical advances, a career development panel, a panel devoted to bioethical controversies in medicine, tours of the new Clinical Research Center, and keynote addresses by Dr. Elias Zerhouni (director, NIH) and Dr. Anthony S. Fauci (director, NIAID). This forum is supported with public and private funds from the Howard Hughes Medical Institute, the Doris Duke Charitable Foundation, the Sarnoff Endowment for Cardiovascular Science, and the National Institutes of Health.

Departmental training programs. The NIH Dietetic Internship, fully accredited by the American Dietetic Association, was established in 1993 as a national program for training dietetic interns for careers in nutrition research. The program provides experiences that meet all competencies for entry-level dietitians, but emphasizes clinical and research skills. This highly competitive program has successfully recruited and trained 44 students, over half of whom have continued with their education and enrolled in graduate degree programs. Three former interns have attended medical school and are now practicing physicians. On July 1, 2004, three interns graduated from the program.

The nursing department's well-known clinical research training program draws nationally from students, new graduates, and senior clinicians who qualify based on their school achievements and interest in clinical research. In the summer of 2004, the department hosted eight summer students and one PHS Junior COSTEP (Commissioned Officer Student Training and Extern Program), all from minority backgrounds. Several were returning because of a positive earlier experience. The neuroscience internship program, jointly sponsored with NINDS, drew six highly qualified interns, and the oncology fellowship program, jointly sponsored with NCI, drew 10 fellows. Both of these programs target

new graduate nurses with an interest in the clinical specialty and in clinical research. Graduates from these programs occupy current positions of leadership at the NIH and in the outside community. The nursing department jointly sponsored a postdoctoral fellowship with the National Association of Hispanic Nurses. The first fellow completed the program in 2004, and joined the department's health disparities research program. A second fellowship will be offered in summer 2005, this time through the National Coalition of Minority Nursing Associations. The nursing department also implemented a pilot program for a predoctoral clinical fellowship for internal NIH nurses who have demonstrated success early in a doctoral program, have identified a career interest in clinical research, and have a dissertation topic aligned with programs at the Clinical Center. Two fellows were selected for support, which includes release time for dissertation-driven research activities. Their areas of interest: hematology/oncology and transplants.

The Clinical Center pharmacy department offers three specialized postgraduate training programs. American Society of Health System Pharmacists-accredited residencies have been offered since the mid-1970s and currently specialized Society of Health System Pharmacists programs are available in Oncology Pharmacy Practice and Primary Care Pharmacy Practice. A two-year research fellowship in Pharmacokinetics/Pharmacogenetics, the newest entry, was begun in June of 2004. These programs have graduated over 100 pharmacists since their inception.

Clinical Fellows Committee

In 2004 Dr. Gallin created the Clinical Fellows Committee. Clinical fellows representing all institutes propose topics for discussion, which have included a proposed new position to bridge the fellow experience and tenure-track positions, the proposed development of a survey to assess the quality of clinical services, and the impact on fellows of proposed conflict of interest policies.





Areas for informal gatherings and meetings are found throughout the Hatfield Center.

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ATKINSON AWARDED FOR OUTSTANDING SERVICE



Arthur Atkinson

Dr. Arthur J. Atkinson, senior advisor in Clinical Pharmacology to the Clinical Center Director, was awarded the 2004 Henry W. Elliot Distinguished Service Award. Sponsored by the American Society for Clinical Pharmacology and Therapeutics, the award recognizes individuals who have made significant contributions to the organization. Dr. Atkinson directs NIH's ClinPRAT post-doctoral training program, the NIH Clinical Center course on Principles of Clinical Pharmacology, and an NIH computer workshop on Principles of Pharmacokinetic Data Analysis: Modeling and Simulation.

He has been a member of the American Society for Clinical Pharmacology and Therapeutics for more than 25 years, serving as president for 1995-1996. He was also a member of the board of directors, chairman of the Committee on Coordination of Scientific Sections, and associate editor of the organization's journal, *Clinical Pharmacology & Therapeutics*.

Atkinson received his A.B. degree in chemistry from Harvard College and graduated from Cornell University Medical College in 1963. He served as a clinical associate in the Laboratory of Clinical Investigation, NIAID, and received postdoctoral training in clinical pharmacology at the University of Cincinnati. In 1970, Dr. Atkinson started a clinical pharmacology center at Northwestern University Medical School, where he served in the departments of medicine and pharmacology for 24 years before accepting a position at the Upjohn Company as corporate vice president of clinical development and medical affairs. Following the merger of Upjohn with Pharmacia, he returned to the NIH Clinical Center where he began his research career.

DOING MORE WITH LESS

It is possible to make operations more efficient—to do more and better with less—only if the people who do all the work remain committed to excellence. Clinical Center employees are doing the best job possible despite increasing demands and limited resources.

Operations in 2004 were particularly challenging, as the Clinical Center continued its efforts to decrease its use of full-time-equivalents (FTEs, or slots for full-time federal employees) from 1,947 (in FY2003) to 1,852 (in FY2004). The result was a 4.9% reduction (95 FTEs). FTEs were reduced through a targeted hiring freeze. During the same period, the patient census increased significantly: Inpatient days were up 7.6%, outpatient visits were up 9.4%, and the average daily census was up 6.4%.

Clinical Center employees are learning to do a better job by conscientiously becoming more aware of patients' wants and needs and of their fellow employees' need for recognition when hard work is done. Under a customer service initiative launched in 2001, most Clinical Center employees participated in customer service training over an 18-month period. Many departments implemented quality improvement projects that improved patient care and satisfaction.

LECTURE PAYS TRIBUTE TO FORMER DIRECTOR



John Laws Decker

The first annual Dr. John Laws Decker Memorial Lecture was given June 2 in Lipsett Amphitheater. The lecture recognizes an outstanding clinical teacher at the Clinical Center. The lecture, sponsored by the Clinical Center and the Foundation for the NIH, honors the contribution of former Clinical Center Director Dr. John Laws Decker, who died of a heart arrhythmia in July 2000. Dr. Decker served as director of the Clinical Center and as NIH associate director for clinical care from 1983 until his retirement in 1990.

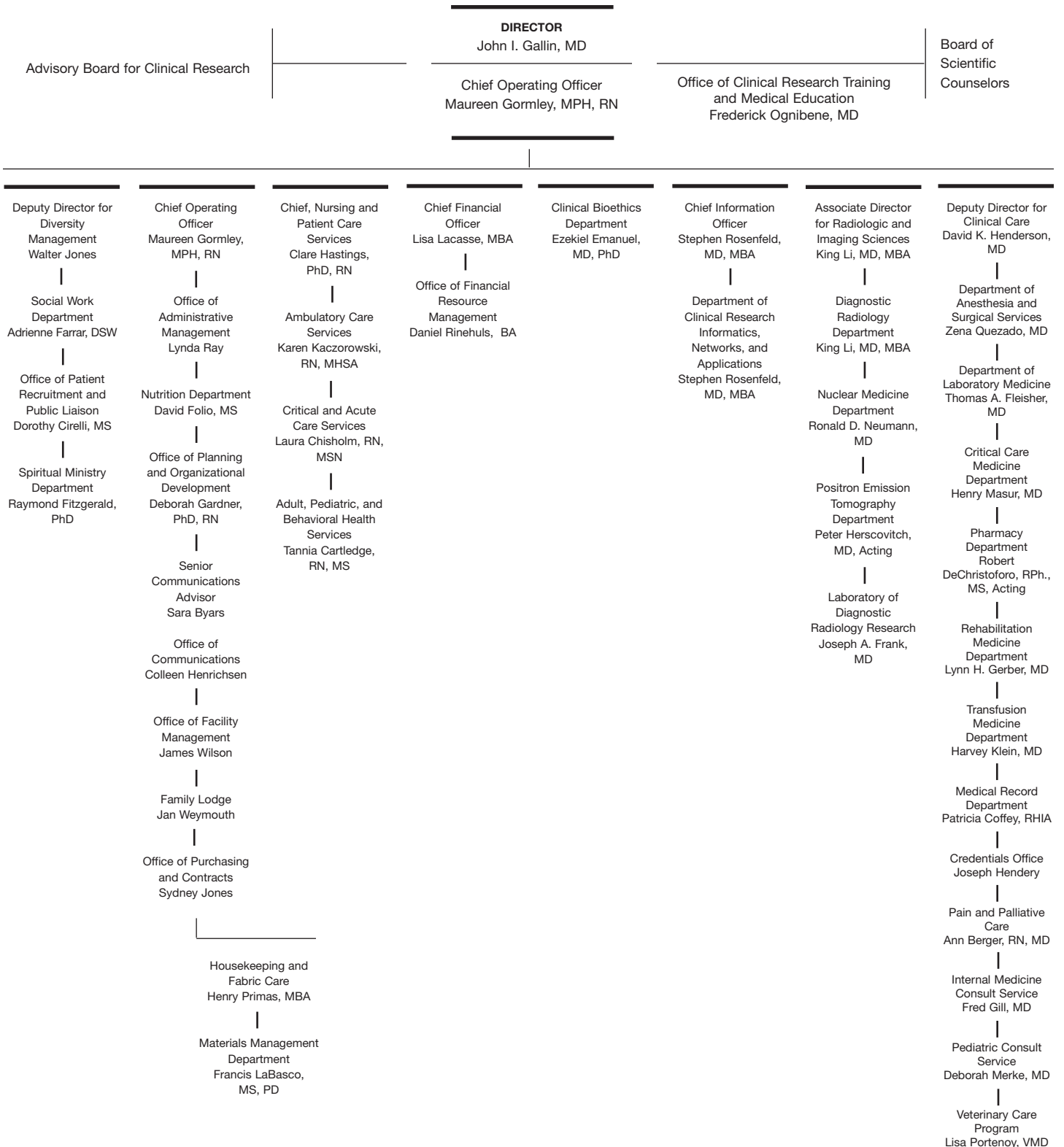
2004 lecturers were Drs. Steve Holland and Michael Bishop. Dr. Holland, chief of the immunopathogenesis section of NIAID's Laboratory of Host Defenses, discussed "The Human Genetics of Mycobacterial Susceptibility." Dr. Bishop, investigator and clinical head of NCI's Experimental Transplantation and Immunology Branch discussed "Allogeneic T Cells as Adoptive Immunotherapy for Metastatic Breast Cancer."

Dr. Decker came to NIH in 1965 as chief of the Arthritis and Rheumatism Branch in what is now the National Institute of Arthritis and Musculoskeletal and Skin Diseases, serving as clinical director from 1976–1980 and scientist emeritus following his retirement in 1990. A native of New York and the son of missionary parents, he grew up in China and returned to the United States for his education. A World War II Navy veteran, Dr. Decker served in the Pacific and received the Purple Heart.

His studies in rheumatic diseases, including systemic lupus erythematosus, earned him international recognition and many distinguished awards. In retirement, he remained active at the Clinical Center, serving as author and contributing editor of *Protomechanics, A Guide to Preparing and Conducting a Clinical Research Study*.

NIH CLINICAL CENTER

Organizational Chart



ADVISORY BOARD FOR CLINICAL RESEARCH
NATIONAL INSTITUTES OF HEALTH

A broader role for governance

Clinical Center governance changed in FY 2004, as part of an effort to promote the NIH intramural program as a model for interdisciplinary research. As recommended by the NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research, the former Clinical Center Board of Governors assumed a new and larger identity, becoming the NIH Advisory Board for Clinical Research. The Board will oversee all intramural clinical research, while continuing its oversight of Clinical Center resources, planning, and operations. It will play a key role in guiding the development of trans-NIH strategic planning and priority setting for intramural clinical research through the integration of Institute/Center strategic visions and agendas. The Board's responsibilities extend only to the intramural clinical research program, but it will also be open to new opportunities for clinical research, including high-risk, high-impact research, research in rare diseases, and interactions between intramural and extramural clinical research programs.

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Clinical Sciences
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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.

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Office of the Director, NIH

Laura M. Lee, RN (Executive Secretary)
NIH Clinical Center

*Dr. Merchant represents the NIH Fellows Committee.

NATIONAL INSTITUTES OF HEALTH

(the institutes, in alphabetical order)

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)
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)

(the centers, in alphabetical order)

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







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