THE ROCKEFELLER UNIVERSITY HOSPITAL

UPDATE

FALL • 2006

Rockefeller University Receives "Outstanding" Priority Score for Clinical and Translational Science Award Application

by Dr. Barry S. Coller and Dr. James G. Krueger

On March 24, 2006, The Rockefeller University Clinical and Translational Science Award (CTSA) grant proposal was submitted to the National Center for Research Resources (NCRR) of the National Institutes of Health (NIH). The proposal was the culmination of the efforts of dozens of investigators and staff members who worked tirelessly for more than four months. Dr. Barry Coller is the Principal Investigator of the grant, and Dr. James Krueger is the Co-Principal Investigator.

The CTSA program is a new initiative from the Director of the NIH, Dr. Elias Zerhouni, as part of his "roadmap" plan to re-engineer the clinical research enterprise. The current plan is to phase out the General Clinical Research Center (GCRC) program, which has provided partial support of The Rockefeller University Hospital since the program's inception in 1963, and to offer current GCRC grant recipients the opportunity to apply for a CTSA grant. The Rockefeller University GCRC grant received a very favorable priority score when it was last reviewed in 2004, and the grant funding is secure until December 2009. Thus, although The Rockefeller University had the option to wait until 2008 to apply for a CTSA grant, we made the strategic decision to apply for the first round of funding now.

The CTSA program differs from the GCRC program in a number of ways, some of which are listed in the table on page 10. Dr. Zerhouni's stated goal is to encourage academic medical centers to transform their administrative structures to ensure that there is a "home" for clinical investigation in a Center, Institute, or Department of Clinical and Translational Science. Here at The Rockefeller University, The Rockefeller University Hospital has been the home for clinical and translational science continuously since 1910. A new Rockefeller University Center for Clinical and Translational Science is proposed in the CTSA grant, along with a new CTSA Advisory Committee with broad representation and an external advisory committee. A new K-12 educational program, which is very similar to the current Clinical Scholars program, is also proposed, leading to either a master's or a Ph.D. degree in Clinical and Translational Science. Dr. Sarah Schlesinger will take an active role in the K-12 educational program as its Co-Director.

The core of The Rockefeller University proposal is outlined in the figure on page 10, which emphasizes

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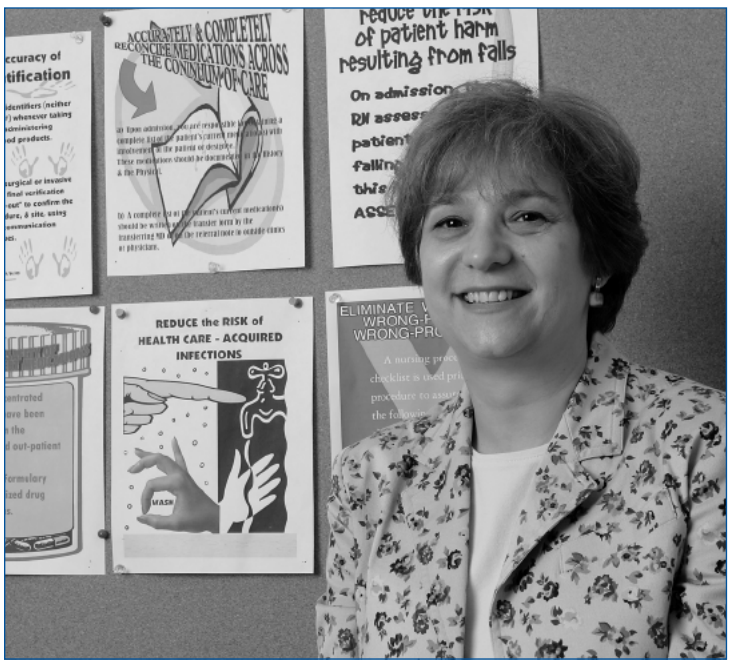
At approximately 8:30 p.m. on Friday March 24 the Clinical and Translational Science Award (CTSA) Grant Proposal was loaded onto a FedEx truck for transport to Bethesda, MD.

Patient Safety Is a Top Priority at The Rockefeller University Hospital

by Cynthia Seidman



Cynthia Seidman

It has been five years since the Institute of Medicine (IOM) published its report on medical errors, *To Err Is Human: Building a Safer Health System*. The report, citing as many as 98,000 deaths per year due to medical errors, led to a public and professional examination of patient safety in the United States. The report suggested that better systems could make many, if not most, of these injuries or even deaths preventable.

At The Rockefeller University Hospital, the report had a profound effect on how we consider every medical error, even those that do not seem serious. Thus, every medical error or even a "near miss" is considered a red flag causing us to examine our systems and implement safer procedures.

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The Humoral Response to Hepatitis C Infection

by Edgar Charles, M.D.
Laboratory of Virology and Infectious Diseases
Dr. Charles Rice, Head

During my infectious diseases fellowship, I witnessed firsthand a transformation in the treatment of HIV-infected individuals. Medicines became available that allowed HIV to be treated as a chronic illness. As individuals infected with HIV began to survive longer, previously unrecognized and/or underappreciated co-morbidities started to become apparent. This fact was forcefully brought home to me when, over the course of several months, three of my patients whose HIV infection was well controlled on medicines suddenly decompensated and died of hepatitis C virus (HCV)-induced liver failure. I had some previous research experience working with Dr. Frederick Valentine of NYU on developing monoclonal antibodies against the HIV gp120 molecule, and I was interested in pursuing a patient-oriented scientific career. Thus, when I learned about the Clinical Scholars Program at The Rockefeller University Hospital, and the opportunity to study HCV infection at the basic science level in Dr. Rice's lab, I jumped at the opportunity.

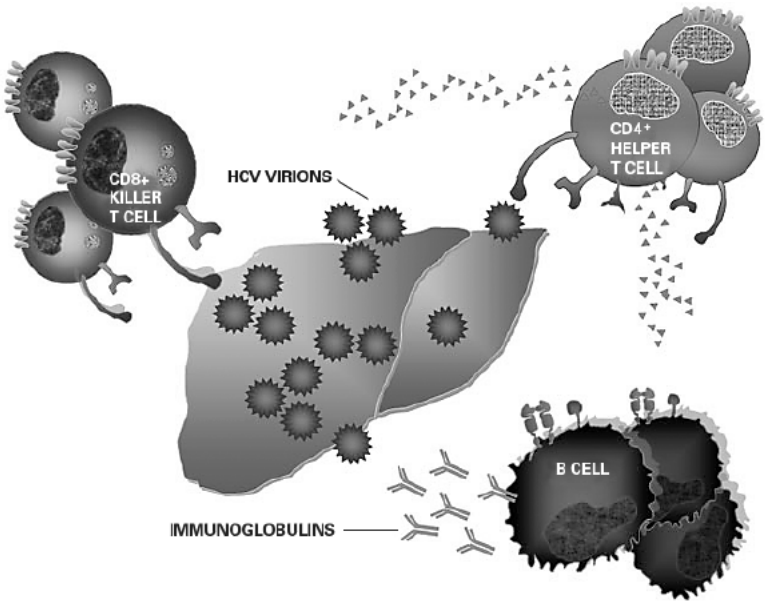
Edgar Charles, M.D.

I am investigating patients' antibody (humoral) control of HCV infection. HCV is a leading cause of chronic liver disease, infecting approximately five million persons in the United States and 170 million persons worldwide. Currently there is no vaccine for HCV, and treatment, which has numerous side effects, is effective only 25-75 percent of the time. A significant proportion of HCV-infected individuals suffer from "extrahepatic" manifestations of HCV, such as vasculitis from mixed cryoglobulinemia and non-Hodgkin lymphoma (NHL). Mixed cryoglobulinemia is a condition in which antibodies have a tendency to precipitate out of the serum in areas of the body that are cool (such as legs and arms), causing a painful inflammation of blood vessels (vasculitis) that sometimes results in ulceration of the fingers or toes. Some of these antibodies may also deposit in the filtering membrane of the kidney, and others may react to self-antigens in the skin, muscles, or joints. HCV has also been associated with an increased risk of NHL. The best evidence supporting a causal link between these illnesses is that in one study, seven of nine patients with both illnesses achieved remissions of their NHL when HCV was eradicated with interferon treatment.

It is currently unknown why certain individuals develop these abnormal extrahepatic manifestations. It is paradoxical that during the course of normal infection, an individual's antibody response to HCV takes an unusually long time to develop (about six weeks), is not sufficient to clear the virus, and does not protect the individual from contracting another HCV infection. One hypothesis to explain these findings is that HCV itself stimulates B cells to produce antibodies that bind to HCV as well as self-antigens. Perhaps the majority of these B cells are rendered functionally ineffective (anergized) or killed by the body in an effort to protect itself from potentially damaging autoreactive antibodies.

To test this hypothesis, I am studying the immune responses of HCV-positive and -negative volunteers. I examine them in The Rockefeller University Hospital Outpatient Clinical Research Center and perform routine tests to measure the magnitude of their HCV infection, as well as their liver function. I also determine whether they are producing auto-antibodies such as rheumatoid factor and isolate peripheral blood mononuclear cells (PBMCs) from their blood using a density-gradient separation. After extracting the DNA from some of these PBMCs, I perform a polymerase chain reaction (PCR) specific for the hypervariable immunoglobulin region CDR3. This region of the antibody molecule is coded for by DNA that has undergone V/D/J segment recombination and, in most circumstances, somatic hypermutation of nucleotides. These events are responsible for generating the extraordinary breadth and specificity of an individual's antibody response.

It has already been shown by others that certain persons with HCV infection, particularly those with symptoms of autoimmune disease, are predisposed to developing monoclonal expansions of B cells, that is, a proliferation of B cell clones that react specifically with particular antigens. To explore the underlying mechanisms, I am immunophenotyping B cells from HCV-infected individuals. I stain the PBMCs with a variety of cell surface molecule-specific antibodies that have been conjugated to fluorochromes, and I analyze them using the sophisticated instruments available to me in Rockefeller's Flow Cytometry Resource Center. So far I have analyzed the B cells from approximately 50 individuals, and I am homing in on the type of B cells that are responsible for these monoclonal expansions. I am now sorting the B cells from these individuals and cloning their immunoglobulins, with the goal of expressing them in vitro and testing their reactivity against a panel of HCV and self antigens. If the hepatitis C virus infection drives autoreactive B cell expansion, it would be an example of microbial-generated autoimmunity and could have important implications for the diagnosis and treatment of rheumatologic diseases. Information gleaned from these studies could also prove useful in the design of a preventative HCV vaccine, in that HCV proteins capable of inducing an autoimmune response should be excluded from a potential candidate vaccine.



B cells recognizing hepatitis C virus (HCV) that has been released from infected hepatocytes.

Image courtesy of: Laboratory of Virology and Infectious Disease

Dr. Edgar Charles grew up in Birmingham, Alabama; completed his undergraduate education at The University of Chicago; returned to Birmingham for medical school; and performed his residency in internal medicine and his fellowship in infectious diseases at New York University (NYU).

Improving The Treatment of HIV Infection in Lesotho

by Andrea Low, M.D.
Aaron Diamond AIDS Research Center
Dr. David Ho, Head

Lesotho has frequently been in the news lately. A tiny country of two million citizens located within South Africa, it has gained notice due to an HIV prevalence that is the third highest in the world. In 2003, 50 percent of all deaths in Lesotho were attributable to HIV and AIDS. This year, I was able to volunteer there as part of the Clinton Foundation's pilot program to bring medication to treat HIV in rural areas. Since its inception, the Clinton Foundation has had the mandate to improve access to life-saving antiretroviral medications drugs for HIV in resource-limited settings. The Foundation is currently working in many countries in Africa and Asia and has started a mentorship program through which health care workers with experience in using antiretroviral medications train those who are now just beginning to be able to use them.

I am an Infectious Disease Physician now working with drug-resistant HIV at the Aaron Diamond AIDS Research Center. I was placed in a small but well-run clinic in the mountains in southern Lesotho. The doctors with whom I worked are a married couple recruited from the Democratic Republic of Congo. Other volunteers worked in clinics staffed by nurse clinicians; in all clinics the volume of patients seen was enormous and often overwhelming.

The Clinton Foundation regularly delivered the antiretroviral medications to each of the rural clinics, and, later on, the Foundation brought pediatric formulations. Management of pediatric drug dosing is difficult because as a child gains weight, the dose must change accordingly. In addition, the medication must be administered by droppers to the smaller children. However, the staff was very eager to learn, as were the parents. Patients were initially very reluctant to be tested for HIV, but as word spread in the community that potentially life-saving treatment was available, more came forward. Sadly, those who presented with evidence of advanced AIDS were often the most reluctant to be tested because of the social stigma that continues to plague those with HIV/AIDS. Over a period of six weeks, we tested 125 people for HIV, and over 50 were positive. Of these, 15 met the WHO criteria to initiate antiretroviral therapy.

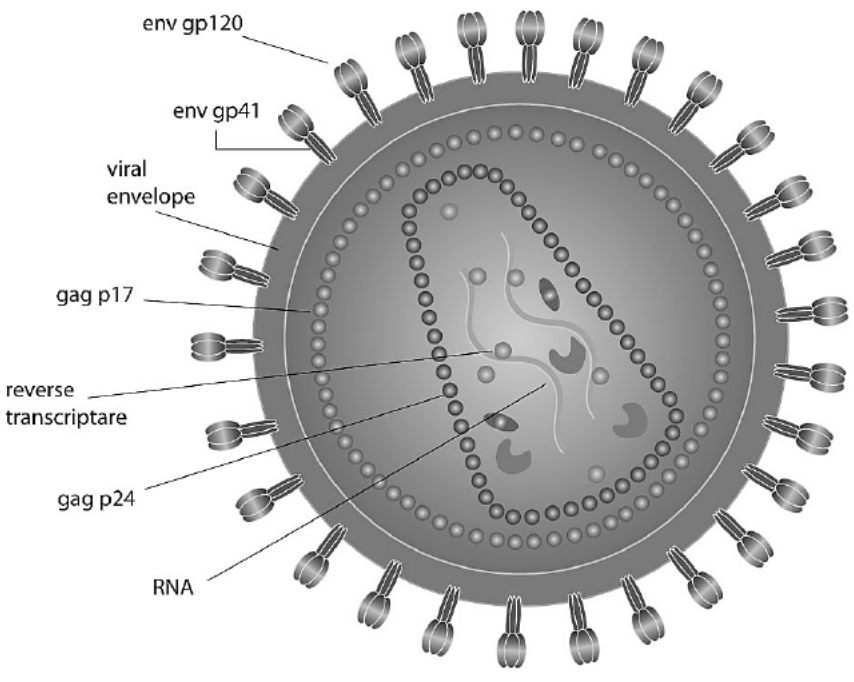
Our first patient to start antiretroviral therapy had already completed two months of his six-month antituberculosis therapy and stated that he felt "fresh" after two weeks of antiretrovirals. A young mother with an infected three-year-old son returned diligently each week until we had the pediatric supply, and then they started the medication together. When they both returned for their initial follow-up, she seemed happy and relieved, as her son had started to eat more and had gained weight, and she was already feeling stronger. Another 45-year-old man complained only of persistent hunger at his first visit. This underscores the importance of adequate nutrition for those with AIDS, which can be very difficult to address in a country as poor as Lesotho. Thankfully, UNAIDS and USAID are donating food to those with a "chronic infection," a category that includes people with tuberculosis or cancer, but that is particularly geared for people with HIV.

Since my visit, the Clinton Foundation has employed many more volunteer preceptors and has assisted in placing health care workers in many different

Andrea Low, M.D.

clinics. According to the Lesotho Ministry of Health, there are now over 11,000 patients on antiretroviral medication. One clinic that had six patients on HIV medication prior to a six-week visit by a Canadian nurse mentor now has over 60. Of course, such a very rapid scale-up in treatment is not easy to achieve. There is still no easy access to evaluation or treatment for many of the opportunistic infections that kill people with AIDS, and these can become life-threatening when someone first starts antiretroviral therapy. Tests for viral load are not readily available, which means that the physicians will not know whether their patients are responding to their treatment and they are then at risk of developing resistance to their medications. Most basic laboratory tests are difficult to obtain, increasing the risk that side effects will not be identified before causing symptoms. However, most people are expected to respond to the treatment, and the Clinton Foundation and other NGOs are working daily to improve all aspects of care. Thus, although the health campaign in Lesotho is far from perfect, it is having an enormous impact on these small rural communities. Having witnessed the dramatic change that medication can make here in the United States, I feel immense hope that this small country will be able to make HIV a manageable chronic disease and patients will be afforded the opportunity to live a full and productive life.

Andrea Low received her Bachelor of Science in Marine Biology from the University of British Columbia. She then worked as a Field Biologist for the National Marine Fisheries Service in Alaska. She attended medical school at McGill University in Montreal, Canada, where she pursued research into malnutrition in Haiti. She completed a residency in Internal Medicine at Saint Vincent's Hospital, Manhattan and a Fellowship in Infectious Diseases at New York University (NYU), and performed research on the vertical transmission of HIV infection with an NYU lab in Mombasa, Kenya. She joined the Clinical Scholars Program at Rockefeller University in 2005 and is working with Dr. Martin Markowitz in studying the integrase gene of HIV-1 at the Aaron Diamond AIDS Research Center.



The anatomy of the HIV virus.

Image courtesy of: Wendy Chen,
Aaron Diamond AIDS Research Center

New Program of IND-Assistance Proposed for Sponsor-Investigators at The Rockefeller University

by Dr. Rhonda G. Kost

Research involving investigational new drugs, existing drugs used for investigational purposes, or new medical devices falls under the jurisdiction of the Food and Drug Administration (FDA), a branch of the Department of Health and Human Services. Permission to conduct such a study is granted by the FDA through a scientific, medical, and administrative review process that is initiated by submitting an Investigational New Drug/Investigational Device Exemption (IND/IDE) application. Preparation of an IND/IDE application, responding to the FDA's stipulations, and complying with the mandated responsibilities during study conduct require considerable regulatory knowledge and time, and can be daunting.

Every IND/IDE application has a sponsor—a researcher, company, or institution—who is ultimately responsible for assuring the safe conduct of the research and compliance with FDA reporting requirements. Investigators are required to report important information to the sponsor. The relevant statutory code of federal regulations is found in the Code of Federal Regulations at 21 CFR. The related set of study conduct standards is referred to as Good Clinical Practice. If the IND includes the actual production of the test article—vaccine, drug, testing agent, reagent used in a treatment preparation process—then additional standards describing production quality assurance and quality control oversight and reporting may apply, such as those of Good Manufacturing Practice (GMP), Good Tissue Practices (GTP), and Good Laboratory Practice (GLP). Sponsorship involves a significant amount of oversight and reporting responsibility. In investigator-initiated research involving an IND, the sponsor may be the investigator, thus placing the dual responsibilities and burdens of study conduct and study oversight on a single individual, the Sponsor-Investigator (SI).

In response to investigator requests for assistance in navigating the regulatory and administrative requirements of IND sponsorship, the Clinical Research Office is creating a new Program of IND-Assistance for Investigator-Sponsors at Rockefeller. This program also addresses The Rockefeller University Hospital's stated goals of providing comprehensive oversight of the IND process, centralizing the coordination of regulatory documentation, and achieving transparency in reporting. The program is modeled after one created three years ago at the University of Minnesota, reported recently by Arbit and Paller in *Academic Medicine*.

The main functions of the program include providing infrastructure and education to support the sponsor-investigator in the form of the following services to investigators:

- Overview of investigational new drug (IND) and investigational device exemption (IDE) regulations;
- Explanation of obligations and responsibilities as an IND/IDE sponsor and investigator;
- Determination and documentation regarding the need to file an IND/IDE application;
- Information regarding the contents of the IND/IDE application and assistance in its preparation;
- Templates for the initial IND/IDE application, clinical monitoring activities, adverse event reporting, annual report submissions, product disposition log, study protocol, and case report forms;
- Assistance drafting the clinical protocol to comply with Good Clinical Practices guidelines;
- Written procedure for clinical trial monitoring;
- Assistance preparing forms and communications to the FDA regarding protocol amendments, additional co-investigators, process changes, and adverse event reports;
- Reminders when annual progress reports and other obligations are due;
- Review of IND/IDE documentation to assure compliance with FDA regulations and university policy;
- Assistance during FDA inspections;
- Registration of study with ClinicalTrials.gov; and
- News items relevant to investigator-initiated research

Dr. Rhonda G. Kost

Educational information and ongoing resources will be provided through a Program of IND-Assistance (PIA) website with links to relevant federal sites, regulations, guidance documents, Standard Operating Procedures (SOPs), as well as IRB, GAC, hospital, and university policies. A full-time IND-Assistance Monitor is currently being recruited by the Clinical Research Office to work with Dr. Rhonda Kost in implementing the website and SOPs, and determining the assistance and services desired by each investigator-sponsor at the hospital. The IND-Assistance Monitor will also develop educational sessions in Good Clinical Practices and IND management to supplement the web-based resources.

The initiative for the Program of IND-Assistance emerged during the CTSA grant writing period as senior staff sought strategic and integrative ways to better support the clinical research investigator at The Rockefeller University. A GCRC Scientific Advisory Committee subcommittee, formulated to address Clinical Research Regulatory Knowledge and Support issues in the hospital, will be acting in an advisory capacity as the plans for the Program of IND-Assistance are advanced. For questions, comments, or suggestions about the proposed plan, or for assistance with your IND, please contact Dr. Kost (x8408, kostr@rockefeller.edu).

New Enhanced Patient Interpreter Services

by Dr. Rhonda Kost and Dr. Barbara O'Sullivan

Nearly one million New Yorkers speak a language other than English and over 140 different languages are spoken in the city. Research has shown that lack of sensitivity and responsiveness to the linguistic needs and health beliefs of different cultures impacts quality of care, patient safety, and patient satisfaction.

Meeting the needs of our increasingly diverse population is an ongoing challenge for health care providers. The Joint Commission on Accreditation of Heathcare Organizations (JCAHO) has several standards that support the provision of care, treatment, and services in a manner that is responsive to the cultural and language needs of individuals and has established an obligation to provide culturally and linguistically appropriate services. With respect to clinical research, the U.S. Department of Human and Health Services Office for Civil Rights (OCR) issued policy guidelines in 2004 stating that it may be a violation of the Civil Rights Act to "require, encourage, or request" a volunteer to use friends, family members, or minors to translate. Family members and friends may translate only if an offer for a skilled interpreter is made and declined. Therefore, there is an obligation to have available interpreter services for all volunteers who need them.

As an institution in which investigators perform research on human subjects, we at The Rockefeller University Hospital have an added obligation to support the IRB and investigators in the goal of increasing the participation of minorities in research studies. To achieve this, The Hospital has a responsibility to create an environment that facilitates and supports the equitable selection of research participants.

The inclusion of broad ethnic representation in clinical studies is important both to ensure that all groups receive an appropriate share of the benefits of research and that no one group bear a disproportionate burden. Under-representation of any group denies the individuals in that group the opportunity to benefit from research.

In addressing these many obligations, and serving investigators and research volunteers alike, the Hospital offers assistance to investigators in the recruitment of volunteers for whom English is not their primary language through the Program of Recruitment and Outreach (PROP) http://clinfo.rockefeller.edu/irb/ptrecr.html. The Clinical Research Office provides guidance as to the appropriate use of interpreters and translations. It also offers assistance in the correct selection of traditional IRB-approved written translated Informed Consent, or the correct "Short Form" process for obtaining informed consent, through an interpreter.

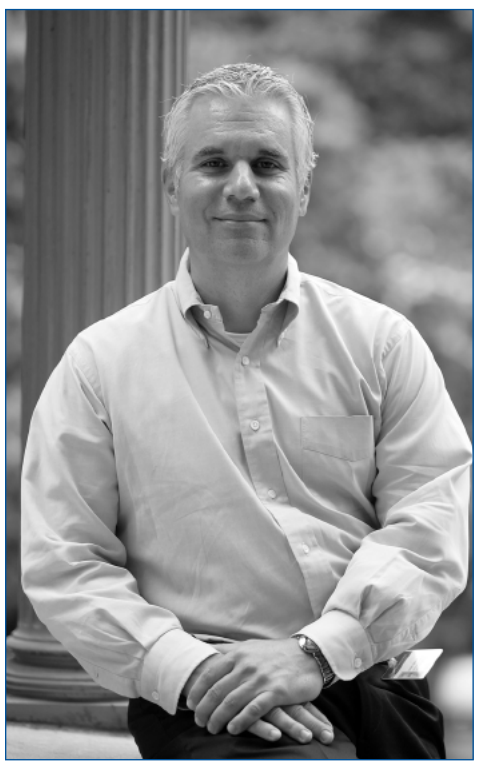
The staff of the Clinical Research Office is available to help when the non-English language in question has not been anticipated by the research team. To simplify matters, the Office's link on the Hospital internal webpage (http://www.rucares.org/nurses/nurses.php) is designated "If Subject is not fluent in English, Click here" and will also provide links to appropriate forms in English and "Short Forms" in a wide variety of languages. Links to The Rockefeller University IRB policies and procedures are also provided. In addition, you can receive step-by-step guidance and CME credit for training on this topic using the "CITI" Program of web-based training modules, "IRB Policies on the Use of Interpreters and Translations," at www.CITIprogram.org, or through the Clinical Research Office weblink.

The Hospital has a new contract for comprehensive telephonic interpreter services with Pacific Interpreters, Inc. This service is available 24 hours a day, 365 days a year, and offers translation in over 180 languages. There is usually a delay of less than one minute to reach an operator who speaks the appropriate language. The company has provided translation services at New York-Presbyterian Hospital for over five years and is highly regarded. It offers a broad range of languages, and its interpreters are experienced in medical interpretation and fully trained in the issues of confidentiality relating to patient care and regulatory requirements.

As the Hospital continues to enhance its interpreter services, we encourage everyone to let us know how best to meet the needs of the research participants, the staff, and the investigators.

Bioinformatics Department Adds New Software for IRB and Study Management and Scientific Pathway Analysis

by Edward Barbour



Edward Barbour

This is a very exciting time for the Hospital Informatics Core! The reason: the acquisition of new software in both of the principal areas that comprise our mission—medical informatics and bioinformatics. Medical informatics consists of, but is not limited to, such activities as protocol development, informed consent, pre-study feasibility, population identification, IRB submission, patient recruitment, capture of clinical research data, storage and archival of clinical data, IRB reporting, adverse event reporting, safety monitoring, and GCRC reporting requirements. Our medical informatics mission is to improve and advance medical informatics to enhance the safety and security of our patients, as well as to improve the efficiency of investigators and staff. To accomplish this mission, we are installing new state-of-the-art software for the purpose of IRB and Study Management.

Over the first quarter of this calendar year, we completed a comprehensive evaluation of three of the leading competitive IRB and Study Management software products on the market. These products facilitate the creation, workflow, review, and approval of study protocols for both the GAC and IRB.

The "winner" from this evaluation process is a product called iRIS from a California-based company named iMedRIS Data Corporation. As of this writing, this product is being installed at our facility to begin the process of examining and defining our workflows, documents, and processes associated with IRB and Study Management. As you can imagine, this setup, training, and delivery will not be an overnight solution to improving our medical informatics systems, but when fully implemented, iRIS will provide much more complete and predictable handling of documents and communications, all for the betterment of our patients, researchers, and staff.

The second component of our mission is providing and supporting bioinformatics software solutions for our researchers. While our involvement in this area is nascent, we are now frequently being called upon to provide bioinformatics solutions to fill the voids in currently available bioinformatics software.

While bioinformatics software consists of numerous categories, including molecular modeling, pathways analysis, natural language processing, sequence alignment, protein identification, sequence analysis, microarray analysis, etc., based upon demand from our researchers we have focused on pathways analysis as our first supported category.

The first two products in this category are Ingenuity Pathways Analysis and PathwaysStudio, from Ingenuity Systems and Adriene Genomics Inc., respectively. Both of these products were tested in a head-to-head comparison at The Rockefeller University Hospital and found to be valuable when applied to "early stage" discovery. Both are currently considered leaders in the field and yet take different approaches to the display and analysis of biological interaction pathways.

Stay tuned for more exciting advances in the area of bioinformatics software as we increase our involvement and product offerings in this area. We are eager for your input and feedback, so please contact me with your comments and suggestions to improve our services.

New Members of the Rockefeller University Hospital Team

by Melissa Offenhartz




MAUREEN POLLINA, R.N.

The nursing staff of the Heilbrun Outpatient Research Center welcomed new member Maureen Pollina in April of this year. In the few months that she has been at The Rockefeller University Hospital, Maureen has become an integral member of the outpatient staff. Her engaging, compassionate, and insightful approach to patient care has earned her the respect of patients and colleagues alike, and her insatiable curiosity about all aspects of the clinical research environment has facilitated her transition into her new role as Clinical Research Nurse.

Maureen brings over 20 years of nursing experience to Rockefeller, having worked in oncologic, critical care, psychiatric, dermatologic, and substance abuse nursing. Prior to joining The Rockefeller University Hospital, she worked at the Adolescent Methadone Clinic of the New York-Presbyterian Hospital (NYPH)/Weill Cornell Medical Center as a Senior Staff Nurse and Nurse Supervisor. Maureen has extensive clinical and managerial experience, and was awarded the Nurse Excellence Award in Psychiatric Nursing from the Payne Whitney Clinic at NYPH in 1995. In 2004, Maureen was credentialed as a Certified Addiction Registered Nurse.

Maureen received her B.S. in nursing from the Hunter College-Bellevue School of Nursing. She is currently enrolled in a Legal Nurse Consultant Certification course at Marymount Manhattan College.

Maureen lives in Queens with her husband and two daughters, and enjoys spending time at her country cottage in Litchfield County, Connecticut.

BRENDA RAY, F.N.P.

Brenda Ray joined the laboratory of Dr. Mary Jeanne Kreek (Laboratory of the Biology of Addictive Diseases) in June 2005 as a Clinical Research Nurse Practitioner. In this role, Brenda conducts the initial screening of research volunteers, administers structured clinical psychological interviews, provides medical management of inpatient research protocols, and oversees the clinical implementation of established protocols.

Brenda brings a rich and diverse set of skills to Rockefeller. She has 30 years of nursing experience in a variety of settings spanning the continuum of care from acute inpatient environments, to ambulatory settings, to home care. Working with chemically dependent patients, patients with asthma and tuberculosis, infants, adolescents, and adults, Brenda has worn many professional hats: staff nurse, educator, community outreach coordinator, infection control practitioner, director of operations, nurse practitioner, and clinical coordinator. She was responsible for the development and successful implementation of a number of innovative educational, compliance, and care provision models at Columbia Presbyterian Medical Center-Babies Hospital, Alliance Home Services, Inc. and Cooperative Home Care Associates, Inc., Harlem Hospital Center, Columbia University (the Harlem Center for Health Promotion and Disease Prevention), Saint Barnabas Hospital in the Bronx, and Beth Israel Medical Center. Brenda's extensive urban nursing experience is evident, and she proudly points out that she is "a true New Yorker—born, raised, and completely educated in New York."

Brenda received her B.S. in nursing from the City College of the City University of New York. She proceeded to Columbia University where she received both a Master of Public Health degree and an M.S. in nursing (family nurse practitioner) with a focus on HIV/AIDS. She maintains her affiliation with Columbia University, where she has an appointment as a clinical instructor and preceptor for nurse practitioner students, providing structured learning experiences for them in a clinical environment.

Brenda lives in Queens with her two miniature Pinschers.

EDWARD BARBOUR, M.S.

The new manager of the Hospital Informatics Core, Ed Barbour joined The Rockefeller University Hospital staff in November 2005. Ed's background consists of extensive commercial software development and bioinformatics research laboratory experience. His particular area of expertise is relational database technology. While working as a Database Administrator for a Fortune 500 company, Ed was the principal architect of an industry-leading relational database management product. He has 15 years of management experience and has managed technically diverse teams developing software on all major platforms including Web-based development.

Ed received his undergraduate degree in computer science from Oakland University in Rochester, Michigan, and his master's in bioinformatics from the University of Michigan. In addition, Ed has laboratory experience in both microarray data analysis of gene expression data for angiogenic studies of animal pancreatic tissue and the analysis of tandem mass spectrometry proteomic data for the Michigan Proteome Consortium.

Ed's considerable talent in the area of software development is matched only by his musical and athletic abilities. In his free time, Ed plays the keyboard in a rock band, golfs, and plays tennis.

REBECCA LATTER, B.A.

Becky Latter is a familiar presence at The Rockefeller University, having worked at the Laboratory Animal Research Center (LARC) and at The Rockefeller University Hospital part time while attending college. We are now pleased to welcome her as the new Medical Staff Services Coordinator/QA, where she will be working closely with Cindy Seidman, Director of Regulatory Affairs. Becky's experience as a Regulatory Affairs Assistant will serve her in good stead in her new role, as will her experiences in customer service and cataloging archival library materials.

Becky graduated magna cum laude from Hunter College in 2005 with a B.A. in religion and a minor in economics. She spent part of the following year living in Ireland. We are delighted that she has landed back on The Rockefeller University soil as a full-time member of the Hospital staff.

New employees (left to right): Maureen Pollina, R.N.; Brenda Ray, F.N.P.; Edward Barbour, M.S.; Rebecca Latter, B.A.; Susan Schienberg, B.S.; Suzanne Magnotta, M.S., R.D.; Ummey Johra, M.S.; Kathy Bell, R.N.




SUSAN SCHIENBERG, B.S.

We are pleased to welcome Susan Schienberg to The Rockefeller University Hospital staff as the new Administrative Assistant for Hospital Administration. Susan has been a member of The Rockefeller University community since November 2000, when she was hired as the Assistant to the Associate Vice President and CIO of Information Technology. She remained in that role until January 2006, when she joined the Hospital staff. Her familiarity with personnel and systems within the University has prepared her well for her current role working closely with Dr. Barbara O'Sullivan, Hospitalist and CEO of the Hospital.

Susan received a B.S. in business administration, with a concentration in management, from Northeastern University. She has been certified since 2004 by the American Management Association. Among her favorite activities is tap dancing. Susan has been dancing for 15 years in shows in Connecticut that benefit the American Cancer Society.

SUZANNE MAGNOTTA, M.S., R.D.

The Bionutrition Department welcomed a new director, Suzanne Magnotta, M.S., R.D., in July 2005. Suzanne brings a wealth of experience, including a stint as a Nutrition Research Assistant at The Rockefeller University Hospital from 1995 to 1997. "I'm happy to be back at the Rock!" she says. That sentiment is echoed by all who knew Suzanne from her previous tour here, as well as those just getting to know her. After receiving her M.S. in clinical nutrition from New York University, Suzanne participated in a dietetic internship at the National Institutes of Health, where she completed a certificate course in clinical research. This internship was followed by an appointment at the NIH Clinical Center as a Clinical Research Dietician, where she specialized in the care of patients on pediatric units.

Suzanne has spent the past five years broadening her clinical nutrition background through her work with adolescents and adults, giving her expertise in nutrition through all phases of the lifespan. At Greenwich Hospital-Yale New Haven Health Systems, Suzanne served as Manager of Nutrition Services. She then went on to work as a Clinical Dietician at the Healthy Living Center of Greenwich Hospital, providing nutrition assessment and counseling to cardiac and pulmonary rehabilitation patients, as well as employees of the hospital. While expanding her clinical experience, Suzanne has continued her affiliation with NYU, serving as an Adjunct Faculty Instructor for its graduate Pediatric Nutrition course. Suzanne is also a much sought-after consultant and speaker in the area of clinical pediatric and adolescent nutrition counseling. She recently was accepted into the Doctoral Program in Clinical Nutrition at the University of Medicine and Dentistry of New Jersey (UMDNJ) and will begin the part-time program in September.

Suzanne lives in Connecticut with her husband Michael and son Jackson.

UMMEY JOHRA, M.S.

During the past year, The Rockefeller University Hospital Information Technology (IT) Department has had the good fortune to engage the consulting services of Ummey Johra. On June 1, 2006, Ummey joined the IT Department full time as a Java Programmer. She now maintains all of the Hospital's Perl and Java applications, and is working on enhancements to these applications.

Before becoming a programmer, Ummey taught mathematics at community colleges in California. She has two M.S. degrees from California State University, East Bay—one in computer science and one in applied mathematics.

"I believe Rockefeller University is a great place to work. I enjoy working as a programmer and am glad to be part of the Hospital Informatics team," says Ummey. The IT Department and the entire Hospital community look forward to working closely with Ummey as the Hospital undertakes its many new IT initiatives.

KATHY BELL, R.N.

Kathy Bell joined the outpatient unit as a Clinical Research Nurse in July 2005. She has been a presence in The Rockefeller University Hospital since 1999, when she first came to The Rockefeller University as a Research Nurse in Dr. Mary Jeanne Kreek's Laboratory of the Biology of Addictive Diseases. Kathy has many years of experience working with chemically dependent patients. In addition to serving as the Assistant Head Nurse of an inpatient detox unit, she was also a Clinical Nursing Care Coordinator at the largest methadone program in New York City. Additionally, Kathy has extensive experience caring for patients with renal disease undergoing hemodialysis. She has worked as a Clinical Nursing Instructor at an upstate New York community college and has been a Supervisor in a nursing home.

No one who knows Kathy would be surprised to learn that her nursing career has taken her to some interesting places. In addition to having lived and worked in New York; Wrightsville Beach, North Carolina; and Far Rockaway, Queens, Kathy was a member of the Peace Corps. She served in Jamaica, West Indies, where she practiced and taught community health nursing.

Kathy was born and raised in upstate New York. She received a nursing diploma from the Charles S. Wilson Memorial Hospital School of Nursing in Johnson City, New York, and a BSN from the State University of New York Institute of Technology at Utica/Rome. Among her favorite things are "my family, my sweet dog, Manhattan, Rockefeller, cooking, and laughing real loud!" Her current goal is to learn to speak Spanish.

Nurses' Day Celebration Attracts Nurses From Near and Far

by Maureen Pollina, R.N. and Kathy Bell, R.N.

National Nurses Week begins each year on May 6 and runs through May 12, Florence Nightingale's birthday. Since many consider Florence Nightingale the founder of modern nursing, this week not only recognizes the contributions of contemporary nurses but commemorates her birth as well. The history of Nurses Week began in 1953 when Dorothy Sutherland of the U.S. Department of Health, Education and Welfare sent a proposal to President Eisenhower. In 1974, President Nixon proclaimed a "National Nurses Week" and, on May 3, 2004, the New York State Assembly and Senate approved the resolution declaring May 6-12 Nurses Week in New York State.

The Rockefeller University's Clinical Research Nursing Day Celebration began early this year with our own research nurses highlighted in the April 27 issue of *Nursing Spectrum*, a widely distributed periodical throughout the New York City metropolitan area. Jeanne Walker, N.P., and Mayu Frank, N.P., were featured in the full-page photo on the cover. An article written by Kelly McClary, R.N., and Melissa Offenhartz, R.N., appeared inside this journal describing the unique role of the Clinical Research Nurse at The Rockefeller University Hospital.

This year, for the first time, we invited our nursing colleagues in the New York City area and beyond to join us for our celebration on May 10. Approximately 80 nurses attended, representing The Rockefeller University Hospital, NewYork-Presbyterian Hospital/Weill Cornell Medical Center, the Irving Center GCRC at Columbia-Presbyterian Medical Center, Mount Sinai Medical Center, St. Luke's-Roosevelt Hospital Center, Lenox Hill Hospital, New York University School of Medicine GCRC, Bellevue Hospital Center, and the Feinstein Institute for Medical Research of the North Shore-Long Island Jewish Health System. Leaders in clinical research nursing spoke on the developing role of the clinical research nurse. Madelene Ottosen, R.N., and Glenna Scott, R.N., from the University of Texas, Houston, discussed "The Emerging Role of the Clinical Research Nurse" and "Developing the Association of Clinical Research Nurses," while Mary Sullivan, N.P. from Massachusetts General Hospital in Boston spoke on "The Integration of the Nurse Practitioner into Clinical Research."

The celebration provided an opportunity for The Rockefeller University nurses to meet colleagues in the area and to begin to develop collaborations to exchange ideas, devise standards of practice, and discuss ethical issues. Considerable discussions ensued focusing on the development of a national certification in the field of Clinical Research Nursing. During the sumptuous reception that followed, nurses expressed their desire and commitment to the creation of a local Association for Clinical Research Nurses, which would sponsor talks and lectures, encourage members to develop standards of best practice, and foster collaborations between institutions.

The nurses were inspired by the enthusiastic support and encouragement expressed by the research community (nurses, nurse practitioners, physicians, and scientists), which demonstrated its recognition of the valuable contributions nurses make during the implementation of clinical research by their attendance at various events throughout the day. The Rockefeller University community also showed its support by participating in a humorous and thoughtful Nurses' Day video produced by Karen Zaremba, Coordinator for The Rockefeller University Hospital Recreation Department.

All the nurses at The Rockefeller University Hospital sincerely thank our community, investigators, and patients alike for their continued thoughtfulness and professional respect.

(Top row left to right)

Mary Sullivan-Whalen, N.P.; Suzanne Rivera B.S.;
Kathy Bell R.N.

Jeanne Walker, N.P.; Mayu Okawa-Frank, N.P.;
Celeste Nelson, N.P.

Madelene Ottosen, R.N.; Glenna Scott, R.N.;
Gail Glenn, R.N.

Ellen Martin, R.N.

(Middle row left to right)

Leann Zaar, R.N.; Melissa Offenhartz, R.N.; Carlton Niven, R.N.;
Tina Dardac, R.N.; Crystal Peltz, R.N.

Wei Yue, R.N.

Mary Sullivan, N.P.; Glenna Scott, R.N.; Atallah Kappas, M.D.;
Kelly McClary, R.N.; Madelene Ottosen, R.N.

(Bottom row)

Vistors from Mount Sinai GCRC: Margaret Garrett Herry R.N.;
Beth Robinson, R.N.; Christian Malatesta, F.N.P.;
Sheila Walsh, R.N.; Betty Chen, F.N.P.

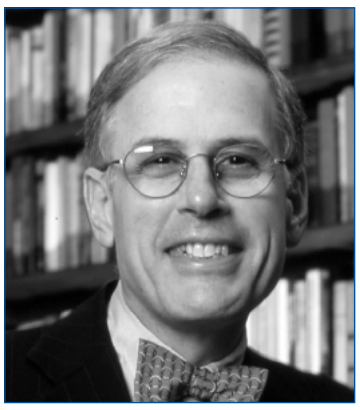
Clinical/Translational Science continued from Page 1

how the individual elements will be integrated for the purpose of facilitating both the development of research protocols and the conduct of the research. Much emphasis will be placed on information technology to help achieve Good Clinical Practice (GCP), a very high standard set by the FDA for performance in clinical investigation. Specific initiatives in research nursing, research pharmacy, protection of human subjects, and management of investigational new drugs (INDs) are also included in the proposal. Additionally, a series of novel technologies that are crucial for the conduct of the research projects at Rockefeller are detailed in the proposal, including genomics, vaccine development, assessment of metabolic disorders, immune response monitoring, and dendritic cell therapy. A new initiative to assess participants' and staff's perceptions of the clinical research process (using data obtained from a validated questionnaire as outcome measurements to judge the effectiveness of training in the protection of human subjects) is also proposed. Finally, a national program to organize clinical and laboratory information obtained as part of the clinical investigation process into formal ontologies using a standardized medical language is proposed as well.

The NIH has informed us that the scientific review panel voted our application a priority score of 149, which is in the "outstanding" category. Funding decisions are expected shortly, after additional administrative reviews and assessment of financial resources. Start dates for funded grants will be in September.

We want to take this occasion to thank everyone who worked so hard to prepare our CTSA proposal. Although it was a challenging and intense experience, developing the proposal helped us strengthen our programs and to think creatively about new initiatives.

Dr. James G. Krueger



Dr. Barry S. Coller

Comparison of the General Clinical Research Center (GCRC) and Clinical and Translational Science Award (CTSA) Programs

	GCRC	CTSA
ADMINISTRATIVE STRUCTURE	Grant (M0-1)	Cooperative Agreement
ELEMENTS	Patient Care Bionutrition Program Leadership Bioinformatics Biostatistics Research Subjects Advocate (Clinical Research Officer)	Infrastructure a) all current GCRC elements b) expanded regulatory support (including enhanced support by study coordinators) c) enhanced informatics and statistics Education a) Training of translational investigators b) K-12 Career Development Program c) Enhanced access of graduate students to translational course work
BUDGET	Based on defined budgets for each element	Combination of funding for each existing element (e.g., GCRC, K-12 Program) plus either $4 million or $6 million more in total costs per year
EDUCATIONAL REQUIREMENTS	None	K-12 program leading to a master's or a Ph.D. degree
REVIEW PROCESS	Site visit	No site visit
GRANT PROPOSAL	Focus on both infrastructure and scientific projects	Focus on clinical research infrastructure, novel technologies, and novel initiatives to enhance clinical research. No specific scientific review.
GOVERNANCE	Principal Investigator, Program Director, GCRC Advisory Committee	Principal Investigator, Center/Institute/Department of Clinical and Translational Science, External Advisory Committee
NATIONAL COMMITMENTS	Participation in annual GCRC meeting	Participation in national CTSA steering committee and adoption of best practices in IT and other areas

The Rockefeller University Joins the Clinical Research Forum

by Dr. Barry S. Coller

The Rockefeller University Hospital joined the Clinical Research Forum this year, with Dr. Barry Coller, Kelly McClary, and Ed Barbour participating in the Forum's meeting in April. The Forum was first organized in 1996 by Dr. William Crowley, Jr. of Massachusetts General Hospital to provide an opportunity for investigators performing patient-oriented research to share best practices and to advocate for increased funding for clinical research. Currently approximately 50 different institutions—comprising some of the nation's most prestigious and acclaimed academic health centers— are members of the Forum.

This year's meeting included detailed discussions on a wide range of topics related to clinical research. Ms. McClary participated in informal discussions about the importance of research nursing and was invited by the Forum's Chief Executive Officer John Courtney, Ph.D., to present a proposal for developing standards for research nursing and to advocate for the recognition of research nursing as a specialty. Mr. Barbour participated in the extensive information technology and bioinformatics program and brought back new insights into national strategic planning in this area. The Forum is particularly focused on developing national information technology strategies and tools to support clinical investigation.

Dr. Coller participated in discussions about the success of different NIH career development programs in preparing trainees for careers in clinical research, as well as discussions about the future goals of the Forum. We anticipate that the Forum will become increasingly effective in helping institutions and individual investigators achieve their goals of improving clinical research. If you would like to know more about the Forum and its activities and resources, please visit its website at www.clinicalresearchforum.org.

Patient Safety continued from Page 1

Also in response to this report, our accreditation agency, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), implemented the National Patient Safety Goals (NPSG) initiative to address critically important safety topics. These safety goals are designed to remedy issues identified by JCAHO as problematic in the health care setting.

The 2006 National Patient Safety Goals include: 1) improving the accuracy of patient identification; 2) improving the effectiveness of communication among caregivers; 3) improving the safety of high-alert medications; 4) reducing the risk of health care-acquired infections; 5) accurately and completely reconciling medications across the continuum of care; and 6) reducing the risk of patient harm resulting from falls.

The Rockefeller University Hospital leadership has taken many actions in response to these safety goals. According to Kelly McClary, R.N., Director of Nursing and Patient Care Services, "Ensuring compliance with the National Patient Safety Goals takes hard work and a team approach. For example, each week at Interdisciplinary Rounds, we select one safety goal to discuss with our frontline staff members. It is an ideal opportunity to engage in conversations about patient safety issues and proper procedures that are specific to our hospital."

Dr. Lauren Golden, past Chair of the Medical Record Review Committee, adds, "Our current initiative involves improvement in documentation legibility and reduction in the use of easily misconstrued abbreviations. A list of 'Do Not Use' abbreviations has been created and the staff has been educated regarding its contents. Medical records are scrutinized quarterly and staff members using easily misconstrued abbreviations or writing illegibly are asked to use approved abbreviations and write more clearly." In fact, the use of potentially ambiguous abbreviations in the medical record that could result in medical errors decreased from 20 percent in 2004 to less than 2 percent in 2006. Equally important, the legibility of handwritten orders improved from 78 percent in May 2005 to 100 percent in 2006.

The Rockefeller University Hospital also measures compliance with hand hygiene guidelines. Washing or disinfecting one's hands between patient contacts has been demonstrated to be the single most important method to decrease hospital-acquired infections. Yet according to recent research, even with this heightened awareness, hospital staff wash or disinfect their hands less than 50 percent of the time.

The Rockefeller University Hospital has an active program to educate staff about proper hand hygiene. "Staff members take turns going undercover to observe whether other members of the staff comply with the handwashing and disinfecting recommendations. These 'Deep Throats' have helped us identify activities where staff are most likely to forget to wash or disinfect their hands, and that is where we concentrate our education," states Barbara Tiddens, Infection Control Nurse. Ms. Tiddens notes that "compliance at The Rockefeller University Hospital has always been well above the national average and continues to improve."

GOOD NEWS

Dr. Christian Münz

Dr. Jan Breslow

Dr. Madhav Dhodapkar

Dr. Kavita Dhodapkar

Clinical Scholars and Fellows Honors and Awards

Faculty Honors and Awards

Dr. Christian Münz received a 2006 Investigators in Pathogenesis of Infectious Disease Award from the Burroughs Wellcome Fund.

Dr. Jan Breslow received the 2005 NYC Mayor's Award for Excellence in Biological and Medical Sciences, and a Medical Sciences 2006 American Heart Association Distinguished Scientist Award.

Dr. Madhav Dhodapkar was elected to the American Society for Clinical Investigation.

Dr. Kavita Dhodapkar received the Alexandrine and Alexander Sinsheimer Scholar Award for her work on monoclonal antibodies in cancer.

Dr. Barry S. Coller was elected to the American Academy of Arts and Sciences.

Dr. David Ho received an Honorary Doctorate of Science from Bates College and an Honorary Doctorate from Tsinghua University.

National Recognition of Hospital Staff Members

Dr. Rhonda Kost served as President of the National Society of Research Subject Advocates of the GCRCs from 2005-2006.

Kelly McClary, R.N. is President-Elect of the National Association of GCRC Nurse Managers for 2006-2007.

Diane Meehan, R.D. is Secretary/Treasurer of the National Association of GCRC Bionutritionists for 2006-2007.

THE ROCKEFELLER UNIVERSITY HOSPITAL

UPDATE

The *Update* newsletter is produced by the Rockefeller University Hospital

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The Rockefeller University Hospital Gets a Facelift!

by Bryan Whitefield

The facade of The Rockefeller University Hospital building has been cleaned and renovated. The scaffolding and shroud that enabled the workers to complete the project and keep the community protected has been removed on the north and south sides of the building with complete removal expected by the end of August. The Planning and Construction Department is working with architects to create a warm and inviting landscape for the front of the building and entrance to the Heilbrunn Outpatient Research Center. The scope of this project includes resurfacing the entrance pathway, installing aesthetically pleasing lighting, and creating seating and container gardens.

Renovation Work in Progress

Work continues on the exterior of the Nurses Residence facing the East River. The existing porch has been completely removed and replaced with a wrought iron fire escape designed to provide an outdoor egress that will further increase the fire safety aspects of this building. Completion of this work and removal of the scaffolding is anticipated by the end of August.

Work also continues on the bridge connecting the hospital to the Nurses Residence. After careful analysis, a plan for providing greater support for the bridge was developed and is now being put into place. The roof covering the bridge has been completely replaced.

We want to thank the Planning and Construction Department and the contractors, Nicholson & Galloway, for all of the extra efforts they have made to ensure the safety of the occupants of the hospital during this massive project. We also thank all users of the hospital, and our patients and volunteers, for their patience and understanding. We are delighted that the final result is a safe, sound, and beautiful building that has aged gracefully as it approaches its 100th birthday in 2010!