



SCIENCE FOR THE BENEFIT OF HUMANITY

Center for Clinical and Translational Science e-NEWSLETTER

Center News

Information Technology Update

The Integrated Research Information System, better known at the Center as iRIS, is nearing a milestone at the Rockefeller University Hospital. Over the past year, the Informatics Core of the Hospital has been working closely with potential users of this software to customize the application for use in the Center for Clinical and Translational Science.

This month, we will be moving the first component of iRIS onto production servers for use by the Center's staff. The component being launched is in the area of Study Management. Following this launch, study personnel will be able to: 1) schedule patients with the assistance of a generated calendar for each patient that includes target dates and windows for each study visit, 2) have an overview of which visits and procedures were

completed and when, and 3) automatically know when the next visit will be scheduled and which procedures are scheduled for that visit. In addition, the system will make it possible for nurses to produce order sheets electronically and to generate and print daily worksheets.

Edward Barbour,
CCTS Informatics Manager

Investigational New Drug (IND) Assistance Program Launched

The Clinical Research Support Office announces the debut of the new Program of IND Assistance website as part of its Program of IND/IDE Assistance (PIA). You can view this website at <http://www.rockefeller.edu/pia/>. The website provides guidance, information, and key hyperlinks for investigators and investigator-sponsors related to Investigational New Drug (IND) applications. Sample topics include: when an IND is required, how to file an IND, and investigator-sponsor obligations, as well as links to applicable forms and frequently asked questions. The website also lists an IND, and services and assistance available to investigators from the IND Specialist in the Clinical Research Support Office. New services provided include assistance with and review of submissions, clinical trial monitoring, and annual progress report reminders. Contact Kim Bazylewicz kbazylewicz@rockefeller.edu (x 7408) for more information.

Kim Bazylewicz,
IND Specialist and Monitor

Seminars in Clinical Research

Seminars in Clinical Research returns on Wednesday, September 5, 2007.

Seminars are held in the Nurses' Residence Bldg., Room 110B on Wednesdays at 12 noon. The first seminar in this year's Seminars in Clinical Research was delivered by Paul Pentel, MD Prof. of Medicine and Pharmacology, U. of Minnesota Director, Division of Clinical Pharmacology, Hennepin County Medical Center on the fascinating topic of 'Vaccines for Nicotine Addiction: Targeting the Drug Instead of the Brain'.

The current schedule of future Seminars can be accessed by visiting http://appserver2.rockefeller.edu/calendar/e_show_events?ccolname=type_id&ccolvalue=15&csignin=%3E=.

Announcements

Center Studies Currently Recruiting Participants

Investigators at The Rockefeller University are trying to understand the effect of frequency of meals on metabolism. This is a six week inpatient study at The Rockefeller University Hospital located in NYC. All meals are provided to participants and they are compensated for their time. For more detailed information please visit <http://cctsnews.rockefeller.edu/assets/Healthy%20Research%20Volunteers%20Needed%20grossman.pdf>

September 10, 2007

Dates of Upcoming ACCTS and IRB meetings

The next ACCTS meeting will be held on Oct 31st, 2007, in NR 110B at 2:30 PM. The IRB will meet on Nov 1st, 2007, in NR 110B, at 9:30 AM.

Submissions for both the Oct. and Nov. meetings are due by Oct. 23rd, 2007 at 9AM.

July 05, 2007

New Funding Opportunities!

Year-long Mentored Medical Student Positions: Applications are due on Oct. 1st, 2007

June 14, 2007

Rockefeller University NIH CTSA K-12 Clinical Scholars Program is Accepting Applications

The CTSA-supported K-12 Clinical Scholars Program is a three-year Master's degree program with fully protected time designed to provide an optimal environment for physician-scientists starting a career in patient-oriented research.

Go to <http://scholarapplication.rockefeller.edu> to view the online application.

New Clinical Scholars Join Program

Since July, 2007, six new Clinical Scholars have joined the program, including Dr. Teresa Evering, Dr. Igor Kravets, Dr. Kristine Nograles, Dr. Swaroop Pendyala, Dr. Manish Ponda, and Dr. Neil Renwick. Below are biographical sketches on these new Scholars and the other Scholars currently in the program.

Clinical Scholars Program 2007-2008

Dr. Edgar Charles - charlee@rockefeller.edu

Mentors - Drs. Charles Rice & Lynn Dustin Chief Clinical Scholar

Dr. Charles is currently working with two mentors, Charles Rice, Ph.D. and Lynn Dustin, Ph.D., to investigate the autoimmune manifestations of chronic hepatitis C virus (HCV) infection. They have identified specific B cell subsets that are clonally expanded in HCV-infected patients who have the syndrome of mixed cryoglobulinemia. They ultimately hope to apply their findings toward the diagnosis and treatment of HCV-related autoimmune disorders.

Dr. Marina Caskey - mcaskey@rockefeller.edu

Mentor - Dr. Ralph Steinman

Dr. Caskey trained in Infectious Diseases at Weill Cornell Medical Center and after completing fellowship she joined Dr. Ralph Steinman's laboratory. She is now studying the immune responses elicited by DEC-205 monoclonal antibody targeted HIV-1 vaccine. She is also working to bring this novel candidate HIV vaccine into Phase I clinical development at The Rockefeller University Center for Clinical and Translational Science.

Dr. Delivette Castor - dcastor@adarc.org

Mentor - Dr. Martin Markowitz

Dr. Castor is trained as an epidemiologist with a focus on infectious disease epidemiology, analysis of longitudinal data and other clustered data. She is currently working in the lab of Dr. Martin Markowitz. Her research focuses on broadly exploring the effects of social factors and other population-level factors on health outcomes. Her current study is examining the effects of sexual and drug social networks on HIV transmission and transmission of drug resistant HIV among men who have sex with men in New York City.

Dr. Teresa Evering - tevering@adarc.org

Mentor - Dr. Martin Markowitz

Dr. Evering received her Medical Degree at the Weill Cornell Medical College, after which she completed residency training in Internal Medicine at the Columbia-Presbyterian Medical Center. She later completed training and obtained board certification during a research fellowship in Infectious Diseases at the Albert Einstein College of Medicine. Dr. Evering is currently working at the Aaron Diamond AIDS Research Center in the laboratory of Dr. Martin Markowitz, where she is examining the immunologic and virologic effects of the intensification of highly active antiretroviral therapy (HAART).

Nursing Staff Develops Creative Ways to Advance Patient Safety

As anyone who was a fan of Schoolhouse Rock on Saturday morning knows, putting facts related to grammar, science, or history to music can be a fun and effective way to learn and memorize. At the Rockefeller University Hospital, we have put this concept to the test to help educate staff members about one of the National Patient Safety Goals (NPSG) set by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). The NPSG compels hospitals to identify and review medications used by the organization that either look alike or sound alike (LASA), and thus might be interchanged and lead to patient harm.

To help staff members remember the LASA medications that we have identified, members of the nursing department engaged their colleagues in a sing-a-long to the tune of "Let's Call the Whole Thing Off."

You say "alprazolam" and I hear "lorazepam"

You say "clonidine" and I hear "clonazepam"

Alprazolam, Lorazepam, Clonidine, Clonazepam

Let's call the whole thing off

You say "Claritin", I hear "Clarinex"

You say "Citracal", I hear "Citrucel"

Claritin, Clarinex, Citracal, Citrucel

Let's call the whole thing off

But, oh, if we call the whole thing off

Then we might give the wrong drug and oh

If we gave the wrong drug, then that would really break our hearts

So you say "Alupent" and I hear "Atrovent"

I'm not gonna give the wrong drug just 'cause it sounds the same

You say "Retrovir", I hear "Ritonavir"

Alupent, Atrovent, Retrovir, Ritonavir

Oh, let's call the whole thing off

Let's not have a problem

Oh, for we need to work together

We'd better call the calling off off

And pay attention

To the LASA meds

So don't be surprised if the patient care areas of the Hospital are alive with the sounds of music. It's just one way we help keep our research study participants safe.

Melissa Offenhartz,
Director of Nursing and Patient Care Services

New Clinical Scholars Join Program (continued from page 2)

Dr. Allegra Grossman - agrossman@rockefeller.edu

Mentor - Dr. Markus Stoffel

Dr. Grossman's research focuses on the nature, diagnosis and treatment of obesity and diabetes. One of her clinical studies looks at whether the frequency of eating, not the total number of calories consumed, has an effect on fat and glucose metabolism. A second study looks at the expression of a protein called *foxa2* in human fat cells. This protein in the fat cells of obese mice helps fat to take up and break down sugar from the blood. *Foxa2* also prevents the generation of more fat cells. *Foxa2* is only present in the fat stores of obese mice and absent from the fat stores of lean animals. Insulin can stimulate the production of *Foxa2* in fat cells. Furthermore, the levels of *Foxa2* protein correlate with the degree of blood insulin levels. Dr. Grossman's study is a follow-up study to the studies that have been conducted in mice to answer the question of whether *Foxa2* is also produced in the fat cells of humans and if these levels correlate with the degree of obesity, blood insulin levels, and insulin resistance.

Dr. Andrea Low - alow@adarc.org

Mentors - Dr. Martin Markowitz

Dr. Low is currently working at the Aaron Diamond AIDS Research Center in the labs of Dr. Markowitz and Dr. Muesing. She is examining the integrase gene of HIV for natural resistance to integrase inhibitors. She received her medical degree at McGill University in Montreal, with a residency in Internal Medicine at St. Vincent's Hospital. She later trained at NYU in Infectious Diseases.

Dr. Lisa Neff - lneff@rockefeller.edu

Mentor - Dr. Jan Breslow

Dr. Neff is trained and board-certified in internal medicine, endocrinology, and clinical nutrition. Her current clinical research studies include a controlled feeding study investigating the metabolic effects of different weight loss diets in individuals with the metabolic syndrome and a longitudinal study examining biologic, environmental, and behavioral predictors of long-term success with conventional weight loss treatments.

Dr. Igor Kravets

Mentor - Dr. Mary Jeanne Kreek

Dr. Kravets obtained his bachelors degree cum laude from Queens College, and his medical degree from the SUNY Upstate Medical University in Syracuse, NY. He completed a residency in Internal Medicine at the Thomas Jefferson University Hospital in Philadelphia, PA. After working as a hospitalist at the Yale- New Haven Hospital for a year, he completed a fellowship in Endocrinology and Metabolism at the Stony Brook University Medical Center. He recently joined the laboratory of Biology of Addictive Diseases to study neuroendocrine mechanisms responsible for the development and perpetuation of drug abuse.

Dr. Kristine Nograles - knograles@rockefeller.edu

Mentor - Dr. James Krueger

Dr. Nograles completed her undergraduate studies with honors at the University of the Philippines where she obtained a Bachelor of Science degree in Molecular Biology and Biotechnology. She attended medical school at the same institution and then specialized in Dermatology and Dermatologic Surgery at the Skin and Cancer Foundation, Manila, Philippines. Her strong interest in immunology led her to pursue a post-doctoral fellowship at the National Cancer Institute, NIH, working with mouse models of autoimmunity and tolerance with Dr. Stephen I. Katz as her mentor. She recently joined the Laboratory of Investigative Dermatology as a Clinical Scholar to further study skin immunology with particular focus on the mechanisms that lead to the full disease expression of psoriasis.

Dr. Swaroop Pendyala - spendyala@rockefeller.edu

Mentors: Drs. Peter Holt & Jan Breslow.

Dr. Pendyala received his medical degree from Christian Medical College, India in 2002 and completed his residency in Internal Medicine at St. Luke's Roosevelt Hospital, New York in 2007. Dr. Pendyala is investigating the presence of chronic inflammation in the colorectal epithelium in obesity. He will study the effects of weight loss by calorie restriction on colorectal inflammation in obesity.

Dr. Manish Ponda - mponda@rockefeller.edu

Mentors: Dr. Jan L. Breslow

Dr. Ponda is board-certified in Internal Medicine and has completed a fellowship in Nephrology. He joined Dr. Breslow's Laboratory of Biochemical Genetics and Metabolism to investigate mechanisms of accelerated atherosclerosis in patients with chronic kidney disease. His work focuses on endotoxemia and associated metabolic changes in this population.

Dr. Neil Renwick - nrenwick@rockefeller.edu

Mentor - Dr. Thomas Tuschl

Dr. Renwick received his medical degree from the University of Otago, New Zealand in 1993 and spent the following 3 years working as a medical officer in Australia, Papua New Guinea, and Thailand. From 1997-2001, he was a PhD candidate in Virology (KSHV) at the University of Amsterdam, The Netherlands. In 2001 he began a combined pathology residency and postdoctoral research position at Columbia University Medical Center and was awarded the College of American Pathology (CAP) Foundation Scholars Award and an NBC Fellowship in Biodefense and Emerging Infectious Diseases to work on pathogen detection and discovery techniques. Realizing the importance of moving beyond disease association studies, he joined the Laboratory of RNA Molecular Biology as a Clinical Scholar to work with Dr. Thomas Tuschl to analyze the expression of microRNAs in patient tissue and cell samples and test if misexpression of microRNAs is linked to disease progression.

Administration Provides Streamlined Procedures for Industrial Sponsorship of Clinical and Translational Projects

In order to facilitate the review and approval of commercial sponsorship of basic research projects and clinical research studies, Rockefeller University has developed a streamlined procedure in which the investigator and sponsor work with a senior administrative official. In the case of basic research projects, that person is Kathleen Denis, Associate Vice President, Technology Transfer at 327-7688 (denisk@rockefeller.edu) for assistance. In the case of clinical research studies, contact Terry Solomon, Assistant Counsel, Office of General Counsel at 327-7598 (solomot@rockefeller.edu) for assistance. Since the process commonly requires several months to complete, please contact Kathleen Denis or Terry Solomon now if you expect in the next 12 months to have either a laboratory or clinical research project sponsored by a commercial sponsor.

All industry-sponsored basic and clinical research programs at the University are governed by the University's Intellectual Property (IP) Policy and Sponsored Research Policy. The text of both of these policies is available on the RU Office of Technology Transfer (OTT) website at: <http://www.rockefeller.edu/techtransfer/resources.php>

For your convenience, a summary of the IP and Sponsored Research Policies are provided below:

Summary – INTELLECTUAL PROPERTY POLICY

- All employees and others authorized to use University facilities are required to sign the Agreement Concerning Intellectual Property.
- All inventions that are conceived or reduced to practice using the facilities, equipment or funds of the University by employees of the University or by others authorized to use the facilities, equipment or funds of the University are owned by the University.
- The copyright in scholarly works and works created outside of the University are owned by the author. All other copyrightable works are owned by the University.
- Cash proceeds from licensing transactions, after the University recovers its costs for intellectual property protection, licensing, and management and disposition of equity, are shared between the inventors or authors (one-third) and the University (two-thirds).
- Any equity or other securities derived from a license transaction is held by the University, and managed by the University's Office of Technology Transfer ("OTT") or its designee. The equity is liquidated as soon as reasonably practicable, with cash proceeds distributed as described above.
- Should any inventor receive equity, or other class of securities, from an entity that is or becomes involved in a license transaction with the University (regardless of whether the University also receives equity, or other class of securities), the University's Technology Transfer Committee may decide to mandate an alternate distribution of cash proceeds with such inventor.
- Any licensing transactions involving equity will be governed by the Equity Guidelines in Appendix B.

Summary - POLICY ON INDUSTRIAL SPONSORSHIP OF RESEARCH

- Any agreement for industrial sponsorship of research on campus must emphasize the University's basic mission and the traditions related to it.
- Investigator-initiated projects should represent areas in which the sponsor's objectives converge with the University's independent priorities.
- Full traditional freedom to publish and present promptly all results of research should be included in any agreements. Reasonable delays, not to exceed 90 days, in the publication of research results will be accommodated for consideration of filing patent applications.
- The budget will encompass all direct operating costs plus the University's full indirect costs at not less than the rate approved by Federal auditors. Payments will be made quarterly in advance.
- The Principal Investigator will have the authority to continue to obtain diverse complementary support for the laboratory from public and private (not-for-profit) sources.
- The sponsor may send representatives to discuss preliminary results of research in progress and details of the investigative techniques at mutually agreed upon times.
- The Principal Investigator (and others, as appropriate) may serve as a consultant to the sponsor under a separate agreement that is consistent with University's policy on consulting.
- The agreement may give the sponsor the right of first refusal on exclusive, royalty-bearing licenses for a certain period of time.
- The University greatly values open interactions between scientists and the research community. Accordingly, the sponsor is expected to minimize the amount of any proprietary or confidential information associated with the sponsored research.
- Any public statement or announcement about the contract, either by the University or the sponsor, will be made only after written approval by both parties.
- Procedure - The Director of the Office of Sponsored Programs coordinates administrative and budgetary reviews of all elements of formal proposals and awards. The Associate Vice President, Technology Transfer, in conjunction with the Office of the General Counsel, reviews proposed contracts and carries out the negotiations designed to assure compliance with prevailing law and University policies. The Vice President for Finance assures financial controls and prepares budgetary reports to corporate sponsors. The Vice President for Medical Affairs reviews the medical aspects of the contracts.

The University supports the principles enunciated in the White Paper "In the Public Interest: Nine Points to Consider in Licensing University Technology" prepared by the Association of American Medical Colleges and eleven academic medical centers and research institutes with regard to insuring that licensed technology is available to patients throughout the world. You can view the White Paper at <http://cctnews.rockefeller.edu/assets/White%20Paper%20-%20Licensing%20University%20Technology.pdf>