



SCIENCE FOR THE BENEFIT OF HUMANITY

Center for Clinical and Translational Science e-NEWSLETTER

Center News

New Certificate Program in Clinical and Translational Science Offered at Rockefeller University

By Angela Slattery

In September 2008, a new Certificate Program in Clinical and Translational Science began at Rockefeller University. This program, sponsored by the Center for Clinical and Translational Science (CCTS), was developed in collaboration with students and postdoctoral fellows to provide trainees with an introduction to the principles and practice of clinical and translational research. PhD students, MD-PhD students, and postdoctoral trainees were all eligible for the program, provided that their participation was supported by their Head of Laboratory. Students and postdoctoral fellows successfully completing the program will receive a Certificate in Clinical and Translational

Science. Eighteen students participated in the inaugural class.

The Certificate Program consists of two courses given over a period of one year. The first course, Introduction to Clinical and Translational Science, was offered in the fall and consisted of two 90-minute lectures per week for eleven weeks. The first lecture of each week described an important element in clinical and translational science (e.g., protection of human subjects, clinical study design). The second lecture was a scientific presentation by a Rockefeller University clinical or translational investigator explaining

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The Rockefeller University Hospital Kicks Off Centennial Celebration

By Angela Slattery

On February 10, 2009, The Rockefeller University Hospital began its centennial celebrations with a ceremony commemorating the sixty-fifth anniversary of the landmark discovery by Drs. Oswald T. Avery, Colin M. MacLeod, and Maclyn McCarty. In 1944, these researchers reported that DNA purified from a virulent strain of pneumococcus could stably transform a non-virulent strain into one that was virulent, thus establishing that DNA is the molecule of heredity. As part of the celebration, a new plaque that describes and honors this research was placed



From left to right: Dr. Barry Collier, Elizabeth McCarty, Bruce McCarty, Marj McCarty, Kathleen McCarty, and Richard McCarty

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Announcements

The Beatrice Renfield Lecture in Research Nursing

Speaker:

Marilyn DeLuca, Ph.D., R.N., C.N.A.
Consultant in Healthcare and Philanthropy

Title:

Professional Nursing in the 21st Century: Challenges & Opportunities

Date: Tuesday, April 28, 2009

Location: Abby Aldrich Rockefeller Hall

Time: 6:00 – 7:00 p.m.

Reception to follow.

RSVP: Admission is complimentary.

Registration is required. If you wish to attend, please email Erika Layfield at elayfield@rockefeller.edu or (212) 327-7434.

This lecture is made possible thanks to the generosity of The Beatrice Renfield Foundation. The program is an initiative of The Hospital's Heilbrunn Family Center for Research Nursing.

Seminars in Clinical Research

Title: Cytotoxic T Cell Therapy for Lymphoma: From Bench to Bedside and Back

Speaker: Catherine Bollard, M.D., Associate Professor of Medicine, Baylor College of Medicine

Date: Wednesday, March 18, 2009

Time: 12:00 p.m.-1:00 p.m.

Location: 110B Nurses Residence

Title: New strategies for Cancer Prevention and Treatment

Speaker: John Cleveland, Ph.D., Professor and Chairman, Cancer Biology, Scripps Institute

Date: Wednesday, March 25, 2009

Time: 12:00 p.m.-1:00 p.m.

Location: 110B Nurses Residence

New Certificate Program in Clinical and Translational Science Offered at Rockefeller University (continued from page 1)

her or his research, emphasizing the element taught at the beginning of the week. The course culminated with each student creating her or his own hypothetical human subjects protocol, including an informed consent form and biostatistical power calculations. The students were also required to critique each others' protocols and the final two classes were a mock ethics review board, where students reviewed and discussed the strengths and areas that needed further explanation of each protocol. The Introduction to Clinical and Translational Science course received excellent evaluations from the students. One student, Dr. Giovanni Ceccarini, a postdoctoral associate in Dr. Jeffrey Friedman's laboratory

stated, "(The course) made me more confident about the steps, aspects, and requirements necessary for conducting clinical research. I don't feel intimidated in submitting my own research protocol at this point." At the end of the course, 100% of the students reported they would recommend this course to other students, 75% of the students stated this course changed their views about clinical and translational research, and 75% of the students stated this course made them more likely to conduct clinical or translational research.

The second course in the program, Scientific Techniques, will begin in March 2009. It will introduce the students to core technical/scientific methods that are

currently employed to address critical problems in human biology. It will also serve to introduce the core resources of the university to the students. A goal of the course will be to both familiarize the students with the techniques as well as personnel available to aid them in applying these cutting edge technologies. The final project will be for the students to return to the protocols that they developed in the Introduction to Clinical and Translational Science course and amend them to include how techniques such as flow cytometry, bioimaging, and genomics can help to test their hypotheses. The students successfully completing the program will receive their certificates on Friday, June 12, 2009.

The Rockefeller University Hospital Kicks Off Centennial Celebration

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in the main entrance of the Hospital. The celebration was attended by Marj McCarty, wife of Dr. Maclyn McCarty, members of the McCarty family, members of the Hospital Committee, Trustees of The Rockefeller University, as well as former and current Hospital faculty and staff.

Rockefeller University President Paul Nurse addressed the audience, explaining that, at its founding in 1910, the Hospital was the first clinical research facility in the United States. The Hospital was viewed as integral to the mission of what was then called The Rockefeller Institute for Medical Research. That mission, as stated in the Institute's charter, was to develop a scientific understanding of "the nature and causes of disease and the methods of its treatment, and to make knowledge relating to these various subjects available for the protection of the health of the public and the improved treatment of disease and injury."

Dr. Nurse stated that "the Hospital is a unique facility where scientific breakthroughs from our laboratories can find their first clinical applications. Today, Rockefeller University Hospital is more committed than ever to

encouraging biomedical inquiry focused on disease-related questions." Researchers in the University's Hospital are now addressing a wide variety of medical conditions. These include addictive disease, cardiovascular disease and metabolic disorders, hepatitis, HIV and AIDS, immune-related diseases and disorders, as well as psoriasis and other skin diseases.



Dr. Barry Collier, Physician-in-Chief of The Rockefeller University Hospital, also addressed the audience. "To properly commemorate this event," he said, "I need to take you back in time to the founding of the Hospital, using the eloquent words of Mac McCarty as written in his book, *The Transforming Principle*." Dr. Collier then quoted Dr. McCarty, who wrote: "At the turn of the century, pneumonia was the leading cause of death, ranking well ahead of

today's principal killers – heart disease and cancer – and it was not limited to the aged and infirm. As the precision of the techniques of bacteriological diagnosis improved, it became evident that most of this devastating pneumonia was caused by a single group of bacteria, referred to most commonly as the pneumococci."

The discovery by Drs. Avery, MacLeod, and McCarty grew out of their studies of patients with pneumonia who were treated in The Rockefeller University Hospital — research that was motivated by the terrible death toll caused by pneumococcal pneumonia. Dr. Collier concluded: "The motivation to understand and better treat disease as an engine of discovery is a recurring theme at Rockefeller, as you will learn from the 100 or more scientific and medical advances we will highlight during our Centennial."

Other events commemorating the Hospital's Centennial will be offered in the upcoming year. These include symposia on past and present clinical and translational science achievements and campus library exhibits devoted to the scientific and clinical advances that have occurred at the Hospital during the past century.

Dr. Rhonda Kost Confirmed as Co-Chair of National CTSA Regulatory Knowledge Key Function Committee

By Dr. Rhonda Kost

In December 2008, Dr. Rhonda G. Kost, Clinical Research Officer, became Co-Chair of the national Clinical and Translational Science Award (CTSA) Regulatory Knowledge Key Function Committee (KFC). Ms. Tesheia Johnson, Chief Operating Officer of the Yale Center for Clinical Investigation, has been the Co-Chair of this committee since October 2007.

The Regulatory Knowledge Key Function Committee is concerned with the efficient conduct of safe, ethical, compliant, high quality clinical investigation, and the provision of appropriate support to research teams to accomplish these goals. The Regulatory Knowledge KFC reports to the CTSA Consortium Steering Committee, comprised of Principal Investigators and NIH staff. In the past year, the Regulatory Knowledge KFC has hosted numerous taskforces, including the Research Subject Advocacy Taskforce. The latter developed the first “Best Practice” endorsed by the CTSA Consortium Steering Committee, a statement of policy adopted in April 2008 to insure participant safety and scientific integrity.

In June 2008, the KFC convened a Clinical Research Management Workshop to identify priorities and develop metrics and best practices to improve IRB review and contract processing efficiencies. The recommendations from that workshop have been adopted by the Strategic Goals Committee of the Steering Committee. The Investigational New Drug/Investigational New Device (IND/IDE) Taskforce surveyed 24 CTSA sites to identify best practices in supporting IND/IDE research, and will provide guidance documents and tools to consortium members to support these initiatives. Finally, the Clinical Research Coordinator Training Taskforce has compiled information from 24 CTSA institutions as a prelude to developing programs and recommendations to standardize and improve the research coordination function across the consortium.

Going forward, the KFC will focus on developing outcome measures in order to make data-driven decisions about best practices. In addition, the KFC is in the process of aligning its taskforce



activities with the new Strategic Goals defined by the Consortium Steering Committee in October 2008. The highest priority for the Regulatory Knowledge KFC is to publish the findings of the work its Taskforces have undertaken in the past year so that they can be reviewed more broadly and then implemented to enhance the efficiency, safety, and quality of research.

iRIS: A Work In Progress

By Donna Brassil



The Integrated Research Information System (iRIS) continues to be implemented in the Rockefeller University Hospital. Version 8.0.1 was released by the vendor, iMedRis, in November 2008. This updated version contained several software enhancements and modifications that were specifically requested by Rockefeller users. This new version has been tested by the Center for Clinical and Translational Science (CCTS) Informatics Department to ensure that the updated software will

effectively meet the specialized needs of the investigators and staff utilizing the Center’s resources.

Since this November 2008 release, there are many more users of the Review Board component of the system. To date, fifteen protocols and forty Adverse Event, IND Safety Reports, and Deviation/ Violation reports have been submitted for Advisory Committee on Clinical and Translational Science (ACCTS) and IRB approval through iRIS. Advantages of the system include electronic signatures of Conflict of Interest forms and the creation of a repository of updated CVs and Human Subject Protection Training Certificates. With the introduction to iRIS technology to more users, we have identified additional opportunities to improve and customize the software and so we appreciate the valuable feedback we are receiving. Each suggestion improves the iRIS system for everyone.

Ms. Jean Jenkins oversees the Review Board Assistant component of iRIS and is available to offer assistance to those who are submitting or reviewing protocols. She recently provided a formal iRIS training session for members of ACCTS and the IRB. Ms. Ummey Johra oversees the study management component of iRIS, including subject scheduling, LIP order sheet and worksheet development, and creation of screening and enrollment logs and research databases. Many of the applications in iRIS can generate customized, secure data reports with restricted access.

As we continue to introduce more users to iRIS, we encourage constructive criticism and suggestions for improvement. Our “wish-list” is getting longer each day! For more information about iRIS or to become a user, please contact Ms. Ummey Johra at ext. 7877 or Ms. Jean Jenkins at ext. 7861.

Meet the Scholar: Neil Renwick, M.D., Ph.D.

By Jennifer Spada

Chief Clinical Scholar, Dr. Neil Renwick received his medical degree from the University of Otago, New Zealand in 1993 and spent the following three years working as a medical officer in Australia, Papua New Guinea, and Thailand. “It might be a New Zealand thing, but OE (overseas experience) is a common rite of passage.” From 1997-2001, he was a PhD candidate in Virology, studying the Kaposi Sarcoma Herpesvirus at the University of Amsterdam, Netherlands. In 2001, he began a combined pathology residency and postdoctoral research position at Columbia University Medical Center. While there, he was awarded the College of American Pathology Foundation Scholars Award and an NBC Fellowship in Biodefense and Emerging Infectious Diseases to work on pathogen detection and discovery techniques.

Sensing the importance of post-transcriptional genetic regulation in disease, he joined the Laboratory of RNA Molecular Biology as a Clinical Scholar to work with Dr. Thomas Tuschl, analyzing the expression of microRNAs in patient tissue and cell samples, and testing if misexpression of microRNAs is linked to disease progression. The discovery that miRNAs are expressed in viruses — in particular, members of the herpesvirus family — also came out of the Tuschl lab, catching Dr. Renwick’s interest as a virologist. Dr. Tuschl has identified numerous components

involved in RNA interference and has elucidated how miRNAs work to regulate gene expression in the cell. Dr. Renwick is working on developing miRNA diagnostic tools to evaluate the contribution of this gene family in disease, and continue to identify new miRNA genes.

Dr. Renwick explained how working in the Tuschl lab has provided a new and exciting research experience. “Dr. Tuschl is a PhD scientist and chemist and I have a clinical background. It has turned out to be an unexpected but amazing combination. The entire lab is very diverse in their expertise. We have a bioinformatician, a cell biologist, biochemists, cell biologists, chemists, as well as medical doctors with different training. This creates an environment of great collaboration and teamwork. What it also allows for is more control over our work. We are not dependent on outside people because the lab can provide all of the elements required.”

When asked about his experience at Rockefeller University Center for Clinical and Translational Science, Dr. Renwick replied, “Rockefeller University is the pinnacle for research. The environment is heads and shoulders above the other institutions I have been at in terms of supporting and encouraging research work. I saw a documentary about Rockefeller



University when I was in New Zealand, so it is quite amazing to me that I am now working here. As a clinical scholar I am receiving individualized training, as well as the opportunity to develop new interests and receive constructive critiques from experts in my field.”

In 2008, Dr. Renwick was selected to receive a pilot project award from the Center for Clinical and Translational Science to help fund his continued studies. In addition, he was appointed to the Chief Clinical Scholar, a position for which he has much enthusiasm. “The Clinical Scholars program is great and being the Chief is brilliant because I can focus on the science that interests me most. (laughs) It’s fascinating to work with such an exciting group!”

Pharmacy Renovation Enhances Its Ability to Serve the Rockefeller University Research Community

By Angela Slattery

Rockefeller University investigators benefit enormously from the ability of the research Pharmacy, under the expert leadership of the research pharmacy manager, Johanne Andersen, to compound custom research medications, including the preparation of placebos for blinded studies. To insure the safety and sterility of research drugs compounded in the Rockefeller University Hospital Pharmacy, the compounding process is conducted in an isolator that maintains a clean air environment. To further increase the safety and



Research pharmacist, Johanne Andersen

sterility of the compounded drugs, the Pharmacy recently underwent a renovation

to separate the room that houses the isolator and to include additional air filtration equipment (HEPA filters). To accomplish this, the flooring was replaced with new seamless vinyl flooring with integral base six inches up the wall and new procedures were introduced for cleaning the room. After the renovation, the air quality was tested and found to meet the standards for a “clean room” as defined by the United States Pharmacopoeia (USP). This upgrade thus insures that the Pharmacy meets the highest standards of safety and sterility in the

Sleep Research Center Opens in Rockefeller University Hospital

By Dr. Neil Kavey and Dr. Barbara O'Sullivan

The Sleep Research Center is a fully equipped sleep research facility located on the third floor of the Rockefeller University Hospital comprised of two study bedrooms and a technicians' room. Each bedroom is equipped with polysomnography hardware and software, audio and visual monitoring equipment, a private bath, new Tempurpedic beds, TV, DVD, and satellite radio.

The Sleep Research Center provides an ideal resource for investigators interested in expanding their research programs to encompass a sleep component. One goal we have for this new center is to stimulate interest in the study of sleep in conditions and disorders already under investigation at Rockefeller University, including:

- Cancer and the impact of sleep on the course of illness, response to treatment and quality of life
- Metabolic disorders including the role of sleep in diabetes, insulin resistance and markers of inflammation
- The effect of sleep and sleep deprivation on weight loss and weight gain
- Immune response and the impact of sleep and sleep deprivation on immunity
- Menopause and sleep
- Parkinson's disease and sleep
- The aging process and sleep
- Sleep patterns in addictive disease and abstinence
- Sleep patterns in coma and other states of altered consciousness

The first sleep research project is already underway. A study of sleep and insomnia in survivors of breast cancer is being conducted by a team of investigators from Memorial Sloan-Kettering Cancer Center and Columbia Presbyterian in collaboration with physicians at Rockefeller University Hospital.

If you are interested in learning more about the Sleep Research Center or want to expand your research to include sleep studies, please contact Barbara O'Sullivan, MD at bos@mail.rockefeller.edu.

Rockefeller University Hospital Sensitive Data Survey Status

By Ed Barbour and Marty Leidner

The leadership of the Center for Clinical and Translational Science has identified data safety and security as an extremely important component of conducting clinical investigation, and so it has developed a new initiative to assess our current practices and provide additional resources to insure that we are meeting the highest standards. As the first step in the effort, an internal survey was recently commissioned to assess how Center and Hospital researchers and staff balance the use, management, and protection of sensitive data. This includes data accessed via newer technologies such as smartphones, PDAs, and USB flash drives.

Once completed, the survey, which was spearheaded by Hospital Informatics Manager, Ed Barbour and Chief Information Security Officer, Marty Leidner, will help to insure that all data are handled at the highest level of security. The survey includes questions about HIPAA guidelines, Hospital policies, protocols for sharing data securely with other researchers and institutions and New York State's laws addressing identity theft and PII (personal identifying information) disclosure. In addition, responders are queried about tracking and auditing data security.

As methods of digital data handling and transmission grow increasingly complex, the Center for Clinical and Translational Science, in partnership with University IT, is absolutely committed to insuring that all investigators have state-of-the-art knowledge, equipment, and access to expertise to insure the security and safety of sensitive data. We urge you to complete the brief questionnaire so that we can target our programs and resources most effectively and efficiently.

The Center for Clinical and Translational Science's sensitive data survey is available online. All relevant personnel at the Hospital are asked to complete the survey by 03/27/2009.