



Center for Clinical and Translational Science e-NEWSLETTER

Center News

Dr. Sohail Tavazoie to Join Rockefeller University and CCTS

By Zach Veilleux and Angela Slattery

Dr. Sohail Tavazoie will join The Rockefeller University and the Center for Clinical and Translational Science (CCTS) as an assistant professor, Head of the Laboratory, in January 2009.

Dr. Tavazoie, whose research focuses on the molecular basis of cancer metastasis, will be setting up a new laboratory, the Laboratory of Systems Cancer Biology, upon his arrival. He will also be appointed as an attending physician at The Rockefeller University Hospital and faculty member in the Center for Clinical and Translational Science.

Dr. Tavazoie received his Ph.D. from Harvard University and his M.D. from the Harvard-MIT Division of Health Sciences and Technology. He trained in Internal Medicine at Brigham and Women's Hospital in Boston. For the past two years, Dr. Tavazoie has conducted research as a postdoctoral fellow in Dr. Joan Massagué's laboratory at Memorial Sloan-Kettering Cancer Center. As a physician-scientist, his research is focused on understanding the molecular events that lead to cancer metastasis, when cancerous



cells spread from the site of an original tumor and establish secondary tumors in other organs. His work has led to

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Center for Clinical and Translational Science Awarded a \$150,000 Administrative Supplement

By Dr. Rhonda Kost

On September 30, The Rockefeller University Center for Clinical and Translational Science was awarded a \$150,000 Administrative Supplement to the Clinical and Translational Science Award (CTSA) grant to support the expansion of the Research Participant Perception of Care Survey Project to Develop Outcome Measures in the Conduct of Clinical Research.

The project, led by Dr. Rhonda G. Kost, rose from a collaboration in 2003 by Dr. Barry Collier, Dr. Barbara O'Sullivan, Ms. Cindy Seidman, and Dr. Kost with the Clinical Center at NIH and the hospital survey company, NRC Picker, to develop a measure of the research participant's experience. That pilot survey became the basis for Rockefeller's ongoing performance improvement activities. In 2006, as a CTSA innovation, Rockefeller proposed the current project: a multi-year, multi-institutional project to rigorously

develop a validated clinical research-specific survey instrument to be used to directly measure research participants' perceptions of the clinical research process for the purpose of improving the experience and the conduct of clinical research. The first phase of the project is 75% complete, and involves the conduct of 18 focus groups of research participants and research professionals at eight institutions around the country in order to identify key themes from which to draft the survey questionnaire from participants' own words. The second phase involves the fielding and validation of the survey tool at multiple institutions.

In order to facilitate greater Consortium-wide collaboration and to gain the expertise of other centers, the Supplement was proposed through an application process requiring the endorsement of a CTSA national workgroup and its PI

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Announcements

Data Security Survey Available Now

The Rockefeller University IT Department and Rockefeller University Hospital has jointly released the Hospital Sensitive Data Information Security Survey. The aim of this survey is to identify sensitive electronic data such as identified patient data, social security numbers, credit cards, etc. The information is necessary in order to better protect the Rockefeller University. This survey should be completed by all HOLs affiliated with the Hospital, and it should be completed in a timely manner upon its receipt. Participation will be greatly appreciated.

The survey can be accessed below:

<http://b5.rockefeller.edu/hospital/phpQ/fillsurvey.php?sid=2>

Flu Vaccine Reminder

Please stop by Occupational Health Services in Room 118 of the Hospital between 10:00 am and 4:00 pm to get your flu shot. It will not only prevent you from getting the flu, but also protect you from transmitting the flu to other hospital staff and our patients.

Dr. Sohail Tavazoie to Join Rockefeller University and CCTS (continued from page 1)

the identification of three important microRNAs that regulate key genes active in this process. In addition, he has discovered two target genes for one of these microRNAs. He has also found that the cancers of patients whose tumors are unable to express these microRNAs are more likely to metastasize.

“I am extremely enthusiastic to have

Sohail join the university as our newest junior faculty member,” says Paul Nurse, the university’s president. “His research has the potential to help alleviate suffering associated with humankind’s deadliest diseases, and his approach to the problem of tumor metastasis takes advantage of the interdisciplinary and translational research programs which have long been Rockefeller’s strengths.”

Dr. Barry Collier, Physician-in-Chief and Director of the Center for Clinical and Translational Science, added “Sohail’s pioneering translational research has provided exciting new basic science insights as well as potential new therapeutic targets. We are delighted that he will be joining the CCTS faculty.”

Center for Clinical and Translational Science Awarded a \$200,000 Administrative Supplement (continued from page 1)

liaisons to the Consortium Oversight Committee, before the proposal could advance to independent review by the National Center for Research Resources (NCRR). The CTSA Regulatory Support and Clinical Management Workgroup, its Chairs, and the PI liaisons endorsed this proposal as it went forward.

The Administrative Supplement supports the expansion of the second phase of the project from a previously planned cohort of nine institutions, to 15 by adding six CTSA’s. The award also provides administrative support to the participating institutions for their management of the protocol. In order to obtain 5,100 completed evaluable surveys for validation, over 10,000 surveys will be distributed during the fielding of the survey.

As a proposed innovation in the original Rockefeller University CTSA grant application, the development of the survey affords multiple opportunities for internal and external benchmarking: 1) the provision of data for local performance improvement in clinical research; 2) the ability of centers to benchmark local performance against aggregate results; 3) the ability to use performance data to support applications to organizations accrediting clinical research programs; 4) the opportunity to identify excellent performances and best practices for quality improvement at sites and across the consortium; 5) the ability to pool intellectual resources to identify and address areas in clinical research needing improvement; 6) the ability to assess over time whether

a targeted educational or process intervention achieves its goal in changing an important participant perception of research participation outcome in a single institution, and to assess the relative successes of different interventions at different institutions. The ability to introduce validated data into decisions about managing the clinical process will have a transformative effect on the consortium. Ultimately, the survey could provide opportunities for direct comparison of different interventions using a randomized multi-site structure such as those used in clinical trials, to answer questions about optimal interventions to improve the conduct of clinical research.

Dr. Teresa Evering Named Chair of Infection Control Committee

By Angela Slattery

Dr. Teresa Evering, Clinical Scholar in the laboratory of Dr. Martin Markowitz, has been named the new Chair of the Infection Control Committee. The Infection Control Committee works to formulate and implement infection control policies for the Hospital and campus, as well as educate and disseminate information to faculty and staff.

Dr. Evering will replace the current Chair, Dr. Edgar Charles, in December. Dr. Charles has served with distinction, providing leadership in revising the Hospital’s legionella surveillance policy, developing procedures in case of an avian influenza outbreak in New York,

and, along with Infection Control Committee member Barbara Tiddens, promoting an annual Hospital-wide influenza immunization campaign. Dr. Evering reported that she is “pleased and thrilled to accept this position.” She indicated that leading this effort to prevent hospital-acquired infections is a logical extension of her specialty training and knowledge in infectious diseases.

Dr. Evering joined the Clinical Scholars program in July 2007. She received her MD from Cornell University Medical College, continued her training as a resident in Internal Medicine at Columbia Presbyterian Medical Center, and trained as an Infectious Disease



Fellow at Albert Einstein College of Medicine/Montefiore Medical Center. Her research focuses on characteristics of HIV infection in the gastrointestinal tract.

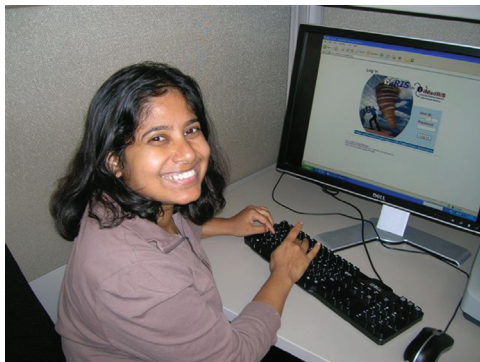
iRIS Implementation is Gathering Momentum

By Jennifer Spada

The Integrated Research Information System (iRIS) now manages over 30 research protocols for Rockefeller University Investigators. Version 8.0.1 is due to be released by iMediRis in November 2008. This version will contain several enhancements and modifications that have been specifically defined by Rockefeller users. Version 8.0.1 is being tested by the Center Informatics department to ensure that the updated software will effectively meet the specialized needs of the Rockefeller University Center for Clinical and Translational Science.

Part of the testing phase has involved the Institutional Review Board (IRB) Submission component of iRIS. IRB members have utilized iRIS in the review process for four active protocols, including one from Clinical Scholar, Dr. Andreas Mauer titled, "Assessment of Bleeding Symptoms in Normal Individuals Using a Comprehensive Bleeding History Phenotyping Instrument." When asked about his experience with iRIS Dr. Mauer commented, "iRIS has the potential to be a very powerful research tool. The integration of all of the various aspects of conducting research will be very valuable." He also stated that, "iRIS's

ability to auto-generate protocol forms, organize patient scheduling, and track patient progress is quite useful."



The Study Management module, which allows users to set target dates for all protocol activities, schedule and view participants' study visits, and create order sheets and nurses' worksheets for the research staff, is also in the process of improvement. The Informatics Department, specifically Ms. Jean Jenkins and Ms. Ummey Johra, have been working diligently to make iRIS more user-friendly. This is being accomplished by tracking commonly made errors and then modifying the software to anticipate such errors in the future.

The Informatics staff is also developing two additional modules within iRIS, Resource Scheduling and Recruitment. The Resource Scheduling module will provide Center staff with the ability to universally schedule such resources as technician rooms, x-ray machine, bionutrition services, and patient wheelchairs for example. This will assist in organizing schedules as well as increasing the utilization of the resources that are available.

The Recruitment Module, which is being developed in close collaboration with the Clinical Research Support Office (CRSO), will serve the purpose of formalizing the recruitment questionnaire and volunteer data collection. This workflow process will help to facilitate the process of directing potential volunteers to the appropriate Study Coordinators, therefore increasing study participation. The Informatics staff and CRSO staff are working together to customize iRIS in order to meet the needs and expectations of the Center.

For more information on iRIS or to become a user, please contact Ms. Ummey Johra at (212) 327-7877 or Ms. Jean Jenkins (212) 327-7861.

Meet the Scholar: Delivette Castor, Ph.D.

By Jennifer Spada



Dr. Delivette Castor joined the Rockefeller University Clinical Scholars Program in December 2006 just after completing her Doctorate in Epidemiology at Columbia University in New York City. At Columbia, Dr. Castor focused her research on the role of drug resistance

on treatment outcomes in individuals with advanced HIV disease. Her current HIV research focuses on the influences of sexual and drug-using behaviors, social networks and social isolation on HIV-1 transmission among men who have sex with men. "It has been established that the level of virus in the blood is extremely high during early HIV infection. There is a growing body of literature that tells us that people periodically engage in higher risk behaviors, and that this behavior pattern could have synergistic effects with the biology of HIV. That is, at the time of infection when they have the highest viral loads, their feeling of social isolation, among other factors, leads them to have more risky events, therefore increasing their chances of transmitting the virus to others."

A self-defined "story of serendipity", she interviewed at other academic institutions as well as pharmaceutical companies looking for the ideal place to continue her research interests of social predictors and biological outcomes. She repeatedly came across Dr. Martin Markowitz's name in the HIV literature and decided to email him. He immediately responded, informing her that he was working on obtaining funding for a study that would focus on the role of social networks on HIV transmission. For her it was the perfect opportunity and so she applied to the Clinical Scholar program, with Dr. Markowitz as her mentor. While the original study was not funded, Dr. Castor was able to create a pilot study titled, "A Pilot Study of the NY HIV

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Clinical Scholars Hone Their Skills in Workshop on Developing and Conducting Clinical Research

By Dr. Rhonda Kost and Angela Slattery

On October 16, the Center for Clinical and Translational Science (CCTS) hosted a Developing and Conducting Clinical Research workshop for the Clinical Scholars. This half-day session focused specifically on the process of developing a clinical research protocol and the resources available to investigators through the CCTS. Dr. Rhonda Kost, Clinical Research Officer and Director of the Clinical Research Support Office and Ms. Donna Brassil, Clinical Research Nurse Facilitator and Director of the Research Facilitation Office co-instructed this seminar.

“Developing a clinical research protocol and conducting a clinical trial is a much different paradigm for our scholars.” Donna Brassil began. “They are experienced physicians who are accustomed to planning and making decisions independently based on their education and experience. Now, as Principal Investigators, creating and conducting clinical research is not intuitive.” The workshop reviewed fundamental principles, such as the definition of human subjects research and human subjects protection training; addressed issues of navigation, such as assessing a study’s feasibility and how to develop and write a protocol and the informed consent document; and finally discussed protocol review and approval by the Institutional Review Board (IRB) and the Rockefeller CCTS Advisory Committee for Clinical and Translational Science (ACCTS).

First year Clinical Scholar, Dr. Rohit Chadwani stated, “I thought the training session was an indispensable primer on the generation of a protocol and navigation through regulatory boards such as the IRB and ACCTS. An investigator equipped with an idea could begin to see their protocol take form as the session progressed.” Clinical Scholar Dr. Allegra Grossman added, “Dr. Kost and Donna Brassil presented a large amount of material in a precise and easily digestible manner. New clinical investigators have to learn and implement many new concepts when developing their first clinical protocol. I believe that every new clinical investigator would greatly benefit from the opportunity of attending a course like this one.”

A follow-up session will be scheduled in early December to address protocol issues and compliance procedures once a research protocol has been approved. This session will focus on how to obtain informed consent, adhere to the approved protocol, document adverse events, and communicate effectively with the IRB and ACCTS committees. “For our new scholars,” Donna Brassil concluded, “education and available resources about clinical research will lead to a more concise, well-planned study design that will foster better outcomes.”

CCTS Reaches Out to the Community

By Dr. Rhonda Kost and Caryne Roey

The Clinical Research Support Office (CRSO) recently participated in two public fairs in order to better educate our community about translational research being conducted at the Rockefeller University Hospital and the clinical research mission of the Center for Clinical and Translational Science (CCTS).

On August 10, the Recruitment staff of the CRSO hosted a table for five hours at the East Sixties Neighborhood Association (ESNA) street fair on East 60th Street between Fifth and Madison Avenues. Nestled between craft booths and the cheese steak table, the Rockefeller table attracted considerable foot traffic; passersby were generally curious and many individuals stopped to learn about translational research at Rockefeller or to take fliers and health-related promotional items. Caryne Roey, Recruitment Specialist in the CRSO led participation in the event, with support from Dr. Rhonda Kost, Clinical Research Officer, and Gregory Siroky, a student helper. The ESNA is a not-for-profit organization created in 1991 with the purpose of improving the community through communication, collaboration and group action. The ESNA boundaries extend from East 60th Street upward to 68th Street, and range from York Avenue to the east side of Third Avenue. Membership is open to residents, commercial businesses, and building owners, as well as anyone else with an interest in the neighborhood. Representatives from ESNA have met in the past with the CCTS Advisory Committee on Community Engagement and Recruitment as part of our efforts to partner with local community organizations.

On September 27, the CRSO team hosted a table for over six hours at The Diabetes Expo, a large health-focused event held at the Javits Convention Center and sponsored by the American Diabetes Association. More than 1,000 promotional items and more than 300 brochures and business cards for the CRSO were distributed to attendees who visited the table. A number of passers-by signed up to become part of the healthy volunteer database, indicating interest in learning about volunteering for future research. The Diabetes Expo is an annual event sponsored by the American Diabetes Association. The purpose of the event is to create awareness about diabetes and diabetes-related illnesses and to promote wellness and healthy living. It attracts hundreds of vendors and thousands of visitors.

The Rockefeller CCTS protocols studying obesity, olfaction, hepatitis, renal insufficiency, and vitamin D were showcased at the fairs. If you would like to participate in the next event, or you would like to have your research project represented at the next event, or for consultation in recruitment and advertising for your studies, please contact Caryne Roey in the Clinical Research Support Office at 212-327-8409

Meet the Scholar: Delivette Castor, Ph.D. (continued from page 3)

Transmission study: Project HITS-NY, Illicit Drug Use and Social Network Effects among at Risk and Recently/Acutely HIV-1 Infected Men who have Sex with Men (MSM)", which she is conducting at the Rockefeller University Hospital Outpatient Research Center. The target sample is 280 MSM enrolled over a three-year period, and 60 individuals have participated so far. She is currently performing an interim analysis of her data.

Dr. Castor's goal in this research is to link sociological and epidemiological information about individuals and their social context with the viral phylogenetic information obtained through sequence analyses to better define HIV transmission patterns and potential points of intervention. "I want to answer the question, who are the core group individuals and what are the pre-existing intangibles that define and connect these core group individuals?" She has been working on organizing the HIV viral sequences that Dr. Markowitz has been collecting since 1995, a cohort that has grown to over 500 recently HIV-1 infected individuals. "With the help of our Hospital's demographic computer program and the Center Information Technology department, I have been able to link the demographic

data to clinical and virologic data. This has allowed me to describe these sample characteristics, clinical and virologic, demographically, geographically and temporally."

The next step for Dr. Castor is to devise a plan to gain access to more minority MSM populations. "Right now about 80% of the participants are caucasian. The volunteers come to the outpatient research center typically by "passive" recruitment, through referrals from their physician, a friend who has been a volunteer in the past, or the health department. The sample is a very select population based on what I would call an information bias - those who know we exist and get here. I hope to create a strategy, based on the success I found in my focus groups, that will identify venues that are frequented by men of color who are also men who have sex with men. These venues would then be the target for recruitment and dissemination of information on the early signs of HIV infection." She feels that the Rockefeller University Center for Clinical and Translational Science is an excellent institution to conduct her research. "This is a great work environment. Being here makes the research feel very possible. There are always hurdles to overcome, but if the

research is going to happen, I believe it will happen here."

Dr. Castor described several benefits to her decision to join the Clinical Scholar Program. "First, the challenge of being a "non-clinician" in a clinical setting has helped me to see other views and consider other possibilities. It has also multiplied my own personal breadth of knowledge. I am always learning about other disciplines outside of my own, while still increasing my skills in my area of expertise. My non-clinical academic track has been a novel experience for the clinical scholars program. Dr. Markowitz has been extremely supportive and creative in mentoring me. And of course Dr. Collier always has at least 10 pieces of wisdom to impart on us at our weekly meetings."

When asked about her long-term goals Dr. Castor replied, "To take translational science from the bench to "the curb" (laughs). I want to continue my research but it must have implications for the community. The research must be meaningful to the population in terms of creating interventions for people before they become patients."

Upcoming Seminars in Clinical Research at the CCTS

Title: Genetics and Pathogenesis of Systemic Lupus: Lessons Learned from a Lupus Prone Mouse Model NZM2328
Speaker: Shu Man Fu, M.D., Ph.D., Professor of Rheumatology, University of Virginia School of Medicine
Date: Wednesday, Nov. 19, 2008
Time: 12:00 pm-1:00 pm
Location: 110B Nurses Residence

Title: NEAT 4 Live: Ending obesity
Speaker: James A. Levine, M.D., Ph.D., Professor of Medicine, Mayo Clinic, Rochester, MN
Date: Wednesday, Dec. 3, 2008
Time: 12:00 pm-1:00 pm
Location: 110B Nurses Residence

Title: Molecular genetics of autosomal dominant polycystic kidney disease (ADPKD)
Speaker: Sandro Rossetti, M.D., Asst. Professor of Medicine Division of Nephrology, Mayo Clinic, Rochester, MN
Date: Wednesday, Dec. 10, 2008
Time: 12:00 pm-1:00 pm
Location: 110B Nurses Residence