



Center for Clinical and Translational Science e-NEWSLETTER

Center News

Rockefeller University Hospital Opens New Sleep Research Center

By Talley Henning Brown

A good night's sleep is good for your health, but the details have long been sketchy. Now, after decades of study into the relationship between sleep patterns and health in general, science is pointing to the often overlooked role of sleep in particular diseases — from cancer to diabetes to Parkinson's. But most researchers don't think about it and most laboratories are not equipped to study it.

At The Rockefeller University Hospital, that's changing. The hospital has established a new Sleep Research Center equipped to conduct clinical

investigations of normal sleep patterns as well as sleep disorders that occur in conjunction with disease states under investigation at the hospital. The center, which consists of two patient rooms and a technician's room, was opened with start-up equipment provided by partners at Columbia University College of Physicians and Surgeons.

The Sleep Research Center is equipped with electroencephalography to study brain waves, instruments to examine muscle tone and movements, eye movements and respiratory and

cardiac function. Video cameras and microphones also record the subjects' activities in sleep. Subjects' rooms are also outfitted with state-of-the-art mattresses and bedding to obviate the factor of discomfort from study results.

"Many of our investigators, especially those who are already conducting clinical studies, can benefit from the opportunities the new center affords," says Barbara O'Sullivan, Medical Director of The Rockefeller University Hospital. "So many disorders, including obesity and diabetes, cancer, immune

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Recruitment Outreach and Support Service Hitting Its Stride

By Caryne Roey and Rhonda Kost, M.D.



From left to right: Suzanne Ouyang, Angela Campbell, Anne Tam, and Patricia Gilleadeau

In a light misting rain the morning of Sunday, May 3, 2009, Pat Gilleadeau, NP, a nurse practitioner with Dr. James Krueger's research team, and five members of the Center for Clinical and Translational Science (CCTS) Recruitment and Outreach Support Service attended the National Psoriasis Walk for Awareness at the New York Botanical Garden in the Bronx. The Rockefeller team joined over 450 volunteers to walk among the azaleas and raise money for the cause, while educating patients and their families about clinical translational research and psoriasis research at the Rockefeller University Hospital. More than 130

volunteers and patients stopped at the Rockefeller booth to hear about studies, and receive Rockefeller promotional items and literature; a subset filled out comment cards asking to be contacted regarding information about research studies.

The Walk for Awareness event, organized by the National Psoriasis Foundation and co-sponsored by Rockefeller University Hospital, was one of many new initiatives undertaken by the recruitment team to raise visibility for the CCTS, educate the public about research at Rockefeller, and enhance participation in clinical studies. In

the past year, the Recruitment team has participated in health, community, and street fairs across the city, such as the East Sixties Neighborhood Association street fair, the Diabetes Expo held at the Javits Center, the Isaacs Beacon community fair, and the Hunter College health fair.

Since the Clinical and Translational Science Award (CTSA), the resources and expertise provided to researchers by the Recruitment and Outreach Support Service have been significantly enhanced, including centralization of professional services that have dramatically increased the speed and success of enrolling participants into studies. The greatest impact derives from: 1) early involvement of the recruitment team during protocol design to assess recruitment feasibility and develop a protocol-specific strategy; 2) professional graphic design and advertisement placement to better reach target populations; 3) centralized incoming-call management through 1-800-RUCARES to capture demographics and database enrollment,

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Funds Pledged to Endow the Heilbrunn Family Center for Research Nursing at The Rockefeller University Hospital

By Angela Slattery and Melissa Offenhartz

The Rockefeller University received a generous pledge from Helaine Lerner and Joan Rechnitz, daughters of the late Robert and Harriet Heilbrunn, for the creation of the new Heilbrunn Family Center for Research Nursing at The Rockefeller University Hospital. The Center will establish a home for the profession of clinical research nursing. While the specialty of clinical research nursing is still emerging, this dedicated center and its funding will help to more fully develop resources, educational materials, training, and disseminating of expertise for the professional role of clinical research nurses.

“This wonderful gift is so appropriate for Rockefeller University,” stated Melissa Offenhartz, Director of Nursing and Patient Care Services at the Rockefeller University Hospital, “because in many ways the field of clinical research nursing was born at Rockefeller University. The Hospital was staffed with expert and caring research nurses from the very beginning. The research nurse has to focus on both patient care and conducting scientific research at the highest standard. This new Center will continue Rockefeller’s tradition of innovation in clinical research nursing.”

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Photo credit: Star Black

Marilyn A. Deluca, Ph.D., R.N., guest speaker at the second Beatrice Renfield Lectureship in Research Nursing titled ‘Nursing in the 21st Century: Challenges & Opportunities’, addresses an audience of over one hundred nurses from the greater New York area.

2008-09 Bridges to Better Medicine Addresses Advances in Translational Science

By Philip DiMauro

On Friday morning, May 1, the *Bridges to Better Medicine* Initiative held its third breakfast forum of the 2008-09 academic year, entitled “New Targets for Antibiotic Drugs: Manipulating the Biology of Cells.” The spring breakfast forum featured Dr. C. Erec Stebbins, Associate Professor and Head of the Laboratory of Structural Microbiology, and Dr. Steven Projan, Vice President and Global Head of Infectious Diseases at the Novartis Institutes for BioMedical Research. More than 90 guests attended the forum, which focused on the challenges of antibiotic resistance and the pursuit of more effective antibacterial drugs.

The *Bridges to Better Medicine* Initiative was launched by the University’s Development Office in 2004 to foster the advancement of translational science by encouraging a robust intellectual exchange between academia and industry. *Bridges* participants are leaders in biotechnology and pharmaceuticals, the venture capital sector, and the life sciences investment community. Rockefeller scientists and representatives

of the University’s Office of Technology Transfer also attend *Bridges* forums, which provide a venue in which members of these varied scientific communities can interact with peers, while keeping abreast of the latest in developments from academic research.

Participants gather at fall, winter, and spring breakfast forums each year to learn about science from world-class researchers on the front lines of biomedicine. Presentations are made from the unique perspectives of Rockefeller scientists conducting basic research and industry executives working on clinical applications of the latest discoveries. Networking and discussion sessions offer participants the opportunity to exchange ideas.

The *Bridges* breakfast forums are moderated by Dr. Barry Collier, Director of the University’s Center for Clinical and Translational Science, Vice President for Medical Affairs, and Head of the Allen and Frances Adler Laboratory of Blood and Vascular Biology. Hosting the events are Rockefeller University trustees Robin

Chemers Neustein and Dr. Anthony Evnin, who are also co-founders and co-chairs of *Bridges to Better Medicine*.

The winter breakfast forum, which took place on Wednesday, February 18, featured Dr. Sohail Tavazoie, Assistant Professor and Head of the Laboratory of Systems Cancer Biology, and Dr. Dalia Cohen, Chief Scientific Officer, Rosetta Genomics. The forum addressed the remarkable success and potential of microRNAs as research tools, diagnostic markers, and therapeutic targets for cancer. This past fall, *Bridges* members heard from Rockefeller scientist Dr. Nathaniel Heintz, Professor and Head of the Laboratory of Molecular Biology, and Brad Margus, founder and Chairman of Envoy Therapeutics, who discussed a new platform for central nervous system drug discovery.

For more information on the *Bridges to Better Medicine* program, visit bridges.rockefeller.edu or call Cliff Wasser, Director of Bridges, at (212) 327-8910.

Meet the Scholar: Manish Ponda, M.D.

By Jennifer Spada

Dr. Manish Ponda received his first real exposure to medical research while he was an undergrad at Harvard University, working in a molecular biology laboratory at the Massachusetts General Hospital. He enjoyed the work so much that he graduated early to continue in the lab full-time for a year prior to entering medical school. He obtained his medical degree from SUNY Downstate, “which has a legacy in nephrology”. He completed his residency in internal medicine at New York University (NYU) and then went on to a fellowship in nephrology at Albert Einstein Medical College.



During his first year of fellowship Dr. Ponda began to contemplate what his next step would be. His mentor at NYU, Dr. Ed Skolnik, directed him to the Clinical Scholars program at Rockefeller University. Dr. Ponda was introduced to Dr. Barry Collier and through their discussions he decided that the Clinical Scholars program would be a great fit.

He was delighted when he was accepted into Dr. Jan Breslow’s Laboratory of Biochemical Genetics and Metabolism to investigate mechanisms of accelerated atherosclerosis in patients with chronic kidney disease. “Similar to the general population, cardiovascular disease is the leading causes of death in people with kidney disease, except that it happens at an accelerated rate. However, we do not yet fully understand the underlying mechanisms related to kidney disease. Even when you control for comorbid conditions, such as diabetes and hypertension, kidney disease is still an independent risk factor.”

The importance of this research seems magnified by the statistics. “There are a half million people in the United States who are on dialysis and over 10 million with significant kidney disease who are not on dialysis. The majority of these patients will die of cardiovascular disease at rates 10-20 times higher than the general population.”

Dr. Ponda is currently working on two studies. The first, which was funded by two CTSA pilot project awards, is a clinical study looking at the effect of vitamin D3 repletion on endotoxemia and biomarkers of accelerated atherosclerosis in subjects with moderate chronic kidney disease. This project will compare blood endotoxin levels and other biomarkers in twelve vitamin D-deficient subjects with chronic kidney disease before and after the repletion of vitamin D3. “This is the first study of its kind in patients with kidney disease. The news media has been

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Integrated Research Information System (iRIS) Update

By Donna Brassil

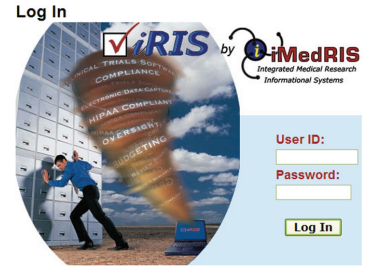
To date, 32 studies have been submitted to the Advisory Committee on Clinical and Translational Science (ACCTS) and Institutional Review

Board (IRB) through iRIS, and 43 studies are using the system for study and subject management. The system has three components, namely, the electronic review board assistant, study management, and subject management. The advantages of the IRB/ACCTS Submission component are that protocols are written so that they are GCP compliant and include standardized language. Annual progress reports are electronically generated, including adverse events, protocol deviations, and gender, race, and ethnicity data, saving an enormous amount of time for investigators and coordinators. Investigators’ CVs and human subjects training certificates are stored in a repository in the system so that investigators and staff who are participating in multiple studies only have to submit these documents once. Members of both the ACCTS and IRB are now reviewing protocols in iRIS, allowing them to begin their reviews as soon as the protocols are logged into the system. Investigators benefit by being able to print IRB-approved documents during or prior to subject visits.

Study management includes an electronic inclusion/exclusion checklist and a schedule of events for easy viewing by the investigator, coordinator, and nursing staff. This program also generates order sheets and worksheets. The system can also create visit time “windows” that notify the investigator when a subject does not complete a visit within the prespecified “window” dates. Adverse events logs and protocol deviation logs are stored in a convenient and searchable electronic format, ending the need to maintain paper logs.

Subject management helps the investigator track subjects’ progress during a study. Subject enrollment, randomization, and visits completed are all easily checked. Data on the number of subjects who were screened and enrolled, as well as the number who withdrew and the number who completed the study are readily available. Thus, instead of having to maintain a paper log in the regulatory binder, any authorized member of the investigation team can log into iRIS and immediately view these documents.

If you would like to learn more about using iRIS to organize your studies, using one or more components of iRIS, or if you need coordinator, data entry, or Navigation assistance, please contact Donna Brassil, MA, RN, CCRC (dbrassil@rockefeller.edu or ext -7886).



The Clinical Research Support Office Post-Approval Audit Program: Scientific Integrity, Participant Welfare, and Good Clinical Practices – Part I

By Angela Campbell and Rhonda Kost, M.D.

Every investigator's pulse inevitably quickens at the prospect of an audit, yet for those investigators who have completed audits with any of the Clinical Research Support Office's (CRSO) three auditors and implemented a Corrective Plan of Action, it is clear that the goals of the program are educational and non-punitive, aiming to make sure that coordinators and investigators have the skills, tools, and knowledge they need to accurately and safely conduct their protocols. The CRSO audit program is an initiative of the University's NIH-supported Clinical and Translational Science Award (CTSA). The audits are conducted according to written Standard Operating Procedures (SOPs), and based on the applicable regulations and practices of the National Institutes of Health (NIH), Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), Good Clinical Practice (GCP), and the Rockefeller Institutional Review Board (IRB). Audits follow a standard set of practices that are specified in the SOPs and outlined in the audit notification letter sent to the Principal Investigator (PI).

Most audits are selected randomly, prioritized so as to insure that the protocols with greatest risk to human subjects receive the highest priority. The experience of the PI is another factor considered in prioritizing audits. Routine audits are considered 'not for cause' meaning that they are conducted as part of quality assurance of our research program and not due to any specific concern. The results of 'not for cause' audits are not routinely reported to the IRB, but may be reported if the audit findings merit IRB review in the opinion of the Clinical Research Officer.

Most protocol deviations identified during audits are addressed rapidly by correction action plans are thus do not need to be reported to the IRB. "For Cause" audits are also conducted, and may be requested by the IRB or the PI, or prompted by a concern brought to the attention of the Clinical Research Officer, such as irregularities in the informed consent forms, research or medical records, or concerns voiced by staff. "For Cause" audits are reported to the IRB Chair for review. The CRSO does not report its audits to OHRP, the FDA, or other entities. Such reporting actions occur only through the SOPs and mechanisms of the IRB. Data obtained by CRSO audits are used to guide the Center's educational programs for the entire staff, insuring that everyone benefits from the information obtained.

The CRSO has conducted 36 audits since the inception of the program. Of the 27 investigators and coordinators filling out post-audit satisfaction surveys, 85% of respondents expressed either positive or highly positive comments about the program. Investigators who attend the educational training programs sponsored by CRSO have fewer findings during their audits, indicating the value of these programs. These seminars review standards for study conduct and provide an explanation of the audit process. The CRSO and audit staff are available to answer questions about study conduct or audits at any time.

When a protocol is chosen for an audit, the Auditor contacts the investigator and study coordinator to notify them of the upcoming review, set the date, and answer any questions. Investigators with pending grant deadlines, travel, or other time constraints can work

with the Auditor to identify a time that is mutually convenient. Once a time has been agreed to by both parties, the Auditor will send a formal notification letter detailing the dates of the audit and the documents to be reviewed.

Throughout the audit the Auditor will discuss any problems or questions that arise with the investigator and research team. Investigators are given the opportunity to resolve issues and locate missing documents before the audit report is written. The investigator may work with the Auditor to make corrections to documents and reports to the IRB, and to make changes in workflow that are necessary to bring study conduct into compliance with GCP.

A report detailing the issues identified during the audit is drafted and reviewed by the Clinical Research Officer before being sent to the investigator. Typically the report cites the relevant regulations and guidelines, along with recommendations for a Corrective Action Plan. The research team implements and documents the completed corrections before an Audit Closure Report is finalized. Occasionally the Corrective Action Plan calls for a specific training session for the research team (usually provided by the CRSO staff) or additional auditing or monitoring after a short interval to be sure the team has mastered the necessary tools to move forward successfully.

In our next installment: Common Audit Findings at Rockefeller University, Frequently Asked Questions, and 'Is Your Research Audit-Ready?'

NIH Now Requires Submission of All Manuscripts to PubMed Central (PMC)

By Angela Slattery

On May 25, 2008, the National Institutes of Health (NIH) changed its policy regarding public access to findings from federally supported research, mandating submission of manuscripts to PubMed Central. The NIH Public Access Policy ensures that the public has access to the published results of NIH-funded research. The policy requires that scientists submit accepted, peer-reviewed manuscripts that grew out of studies performed with NIH funds to the digital archive PubMed Central. To help advance science and improve human health, the policy requires that these journal papers are accessible to the public on PubMed Central no later than 12 months after publication.

This policy states that all NIH applications, proposals, and progress reports must include the PubMed Central reference number (PMCID) when citing an article that falls under the NIH Public Access policy or arose from an investigator's NIH award. The PMCID will need to be included on documents such as the Literature Cited section and the Publications List that are included as part of NIH applications, proposals, and progress reports. *It is important to note that the PMCID is not the same as the PubMed Identifier number (PMID)*, since the similarities in terminology may be confusing.

All final peer-reviewed manuscripts must be submitted to PMCID through the NIH Manuscript Submission (NIHMS) system. The scientist must:

- Deposit the final peer-reviewed manuscript files (e.g., Microsoft Word document and figures) in the NIHMS system;
- Indicate the NIH award(s) to which the final peer-reviewed manuscript is related;
- After the NIHMS converts the deposited files to a standard PubMed Central (PMC) format, NIHMS will notify the scientist via email to review the PMC-formatted final peer-reviewed manuscript to approve its release.

Some journals will deposit the final, peer-reviewed manuscript files into the NIHMS system automatically. In that case, the scientist will still have to provide the associated award information, and review and approve the final peer-reviewed manuscript. The NIHMS system will send notifications via email when these actions are needed and include a link to the NIH Manuscript Submission system web site. For more information about the NIHMS system, go to <http://www.nihms.nih.gov/>. An online tutorial is available at <http://www.nihms.nih.gov/web-help/index.html>.

This Public Access Policy applies to any manuscript that: (1) is peer-reviewed; (2) is accepted for publication in a journal on or after April 7, 2008; (3) arises from any direct funding from an NIH grant or cooperative agreement active in fiscal year 2008; (4) arises from any direct funding from an NIH contract signed on or after April 7, 2008; (5) arises from any direct funding from the NIH Intramural Program or an NIH employee. For more information on this policy please visit <http://www.rockefeller.edu/library/PMCID.php>

Center for Clinical and Translational Science Facilitation Office

By Donna Brassil

Prior to the Clinical and Translational Science Award (CTSA), there was no core of research coordinators to assist investigators. With the CTSA award in 2006, the leadership of the Center for Clinical and Translational Science created the Facilitation Office to provide experienced and certified research coordinators and data entry personnel to researchers. Research coordinators plan, design, and coordinate clinical research studies in collaboration with the investigator and the interdisciplinary team in accord with FDA and GCP (Good Clinical Practice) guidelines. The Research Coordinator can provide services, including:

- Collaborate with the investigator in developing a protocol, informed consent documents, and all other protocol-related documents
- Submit regulatory documents to the Advisory Committee on Clinical and Translational Science (ACCTS) and the Institutional Review Board (IRB)
- Create source documents
- Design Case Report Forms (CRFs)
- Assist in the conduct of research studies including obtaining informed consent from participants and conducting participant visits
- Assist in internal monitoring of studies
- Prepare for auditing of studies
- Maintain regulatory binders

Additionally, the Facilitation Office has developed the Navigation program at Rockefeller University. Under this program, Facilitation Office staff will arrange an interdisciplinary meeting to provide input into the study prior to ACCTS/IRB submission. The goal is to help the investigator by facilitating the investigator's interaction with staff members with expertise in different aspects of protocol development, implementation, and conduct. The advantages of this process include:

- Resources for support of protocol development are provided to the investigator
- Formal feasibility assessments are conducted
- Anticipated barriers to the conduct of the study are identified early, including those related to:
 - o Screening
 - o Inclusion/Exclusion Criteria
 - o Enrollment
 - o Study completion
 - o Study conduct
- A plan and available tools are put in place so the investigator can start her or his study immediately after approval

If you would like to learn about more the Facilitation Office's services, please contact Donna Brassil, MA, RN, CCRC (dbrasil@rockefeller.edu or ext -7886).

Rockefeller University Hospital Opens New Sleep Research Center (continued from page 1)

disorders, Parkinson's disease, addictive diseases, menopause and stress, can be affected by or can themselves affect sleeping patterns in a number of ways."

The center's first study aims to characterize the prevalence and type of sleep disorders seen in survivors of breast cancer. "Sleep problems are very common with cancer patients and survivors. We hope to identify clusters of poor sleepers with different etiologies, for example hot flashes and other endocrine-related symptoms, anxiety related to fear of recurrence, and apnea, to name a few," says Steven D. Passik, a clinical psychologist who works with cancer patients and their families at Memorial Sloan-Kettering Cancer Center and the principal investigator on the study. Study volunteers, all of whom are between 1 and 10 years post-treatment, spend two nights each under observation by a specialized technician at the Sleep Research Center.

Neil Kavey, a sleep medicine specialist and psychiatrist who directs the Sleep Disorders Center at Columbia University Medical Center and is co-principal investigator of the study, provided the equipment for the laboratory. "Sleep occupies a third of our lives," says Kavey. "Yet we've barely scratched the surface yet on the relationships between sleep and various disease processes and states."

"The Sleep Research Center is an exciting undertaking," says O'Sullivan. "The Rockefeller University Hospital, which is devoted entirely to clinical research, is in a unique position to conduct the type of research this center makes possible. This marks the beginning of an entirely new avenue of study for Rockefeller scientists, who have always been at the forefront of clinical initiatives."



Photo credit: Zach Veilleux

The Rockefeller University Hospital: Survey of Sleep Problems in Survivors of Early Stage Breast Cancer

<http://www.rucare.org/clinicalstudies/protocol.php?id=301&cat=50>

Funds Pledged to Endow the Heilbrunn Family Center for Research Nursing at The Rockefeller University Hospital (continued from page 2)

Part of this pledge includes a new collaboration with the highly successful Women & Science initiative, which was established in 1997 to: highlight the crucial role of basic research in addressing scientific challenges related to women's health, showcase the contributions of women scientists, create a program of support for women scientists, and encourage more women to embrace scientific research as a focus of their philanthropy. The annual Beatrice Renfield lecture, which highlights Nursing and is now part of Women & Science series, will now be dedicated to clinical research nursing. On April 28, 2009, Dr. Marilyn DeLuca, a consultant in healthcare and philanthropy, gave the inaugural lecture.

The Heilbrunn Research Nursing Center will focus on the nursing care of patients involved in research studies. It will provide the opportunity for nurses to continue the development of the specialty practice of clinical research nursing, including new standards of care specific to research patients, a clinical research nursing textbook, and new instructional materials. One of the Center's goals is to have clinical research nursing represented in undergraduate nursing curricula so that nursing students learn about the extraordinary opportunities in the field of clinical research nursing. The Center also plans to be a site for onsite training of undergraduate students with an interest in research nursing. "The Center will offer a home for the student

to be involved in research and learn more about research nursing." Melissa Offenhartz concluded, "It really is a wonderful opportunity to fully develop clinical research nursing as a specialty practice." Dr. Barry Collier, Physician-in-Chief, added, "The Heilbrunn family's support of the Rockefeller University Hospital and of research nursing is truly inspirational. Their vision and generosity will allow us to build on our great tradition in research nursing and become the center for education, research, and innovation in this vital component of clinical and translational research."

Recruitment Outreach and Support Service Hitting Its Stride (continued from page 1)

pre-screen volunteers for one or more specific studies, and manage referrals to coordinators and clinic appointments. These efforts have resulted in a doubling in the size of the IRB-approved Research Volunteer Repository (listing of volunteers who have consented to be called in the future for additional studies); smooth and consistent enrollment of appropriately diverse, eligible subjects for most research studies; and dramatic and rapid enrollment successes for some investigators using the service.

Dr. Andreas Mauer's study to test and validate a bleeding history phenotyping questionnaire (AMA-0637) has been enrolling at a record pace. Since October, the CRSO has referred more than 350 volunteers to this study, and many were pre-screened and directly scheduled for clinic appointments; more than half of his target enrollment of 500 completed the study at the time of this writing. Dr. Peter Schlegel's pilot study on MENT (7alpha-Methyl-19-Nortestosterone) a male contraceptive gel, was fully enrolled with six participants within two months of the recruitment start date. As reported in a previous e-Newsletter, the recruitment team helped Dr. Lisa Hudgins to initiate and complete enrollment of her fructose utilization study – including four day-long metabolism study visits—in less than six months. In addition to indentifying potential participants, the prescreening process also contributes to excellent retention rates, with study investigators reporting extremely low attrition and high compliance.

In the past year the Recruitment service has conducted more than 20 comprehensive recruitment consultations and has produced and run 30 print ads, more than 100 online ads, and two radio ad campaigns. These ads have been run in print publications such as AM New York, Metro, Our Town, and West Side Spirit; online sites such as Craigslist.

org, Centerwatch.com, and Backpage.com; and radio stations such as 1010WINS and LiteFM. The Recruitment Office has also posted and distributed hundreds of flyers and coordinated targeted mailings to practitioners for numerous studies. The service has provided more than \$30,000 to investigators in cost-sharing support of recruitment activities.

The calls to 1-800-RUCARES in response to targeted advertising represent a diverse population of interested volunteers. Of callers who provided their race during call-back interviews (some decline), 25% were Black or African American, 6% were Asian, 30% were White or Caucasian, and the remainder were mixed, Native American, Native Hawaiian or Pacific Islander, or other. Approximately 16% of referred volunteers who provided their ethnicity described themselves as Hispanic. The demographics of New York City are well represented in the populations reached by Recruitment Service efforts.

Looking ahead, the CRSO's Recruitment Service is working with Information Technology to bring online a Recruitment Assistant module in Integrated Research Information System (iRIS). The Recruitment Assistant would provide integration of the Recruitment Service database with the iRIS Study Management database affording one-time central capture of demographic and enrollment status information visible to recruitment and study team members. The CRSO will work with research study coordinators, principal investigators, and others involved in study enrollment to use the new program.

To schedule a recruitment consultation or for help with the creation and placement of advertisements, please contact Caryne Roey, Clinical Research Recruitment Specialist, at croey@rockefeller.edu or go to <http://clinfo.rockefeller.edu/recruitment/>.

Meet the Scholar: Manish Ponda, M.D. (continued from page 5)

talking about vitamin D, yet there have not been any studies investigating whether vitamin D is effective or if it merely a marker of health.” The study is only a few weeks away from completing the data collection phase, with the final patient due to finish in early June. “Diana Bernal-Messinger, a Clinical Research Nurse Practitioner in the CCTS Clinical Research Coordinator office, has been invaluable to the progress the study made.” The next step for this study and Dr. Ponda is data analysis and from those results develop a larger scale study.

Dr. Ponda's second project is a collaboration with investigators at NYU. “We are using an animal model to examine how kidney disease may affect the regression of atherosclerosis. Conventional therapy directed at atherosclerosis is ineffective in individuals that are already on dialysis. There is a great need for a new therapy to treat these individuals.” So far they have made the novel finding that kidney disease inhibits the regression of atherosclerosis. Their current work is focused on defining the molecular mechanisms behind the phenomenon. This work has also

formed the basis of Dr. Ponda's K08 proposal.

When asked about how the Clinical Scholars program has benefited him, he responded, “The challenges that young physician-scientists face are much greater than in the past and the Clinical Scholars program has helped me to overcome those challenges and become exposed to many amazing opportunities. Both the formal and informal training that I have received have become an integral part of the research that I am conducting.”

Dr. Ponda hopes to have his K08 proposal funded, which would allow him to remain in the Breslow lab and continue his studies. “The unique structure and facilities of the Rockefeller CTSA, such as the Rockefeller University Hospital and the Clinical Research Coordinators Office, makes it possible to move between bench and bedside. My five-year plan is to focus on the molecular mechanisms of atherosclerosis in the context of kidney disease, but also to continue to conduct clinical and translational science based on our findings to this point.”