

## **Program in Clinical Research – Activities for May 2011**

### **NIEHS Clinical Research Unit Related Activities**

- CRU staff met with Ericka Reid (NIEHS Education Outreach Specialist) and Joan Packenham to discuss the community outreach component for the proposed CRU asthma clinic (asthma natural history protocol).
- CRU staff hosted information tables at the NIEHS Health Fair, U.S. EPA Health Fair and the Annual North Carolina Asthma Summit to promote CRU services and bolster participant recruitment.
- Stavros Garantziotis attended the American Thoracic Society (ATS) 2011 International Conference in Denver, CO where he chaired/presented during a postgraduate course on health effects of engineered nanomaterials and a session on novel innate immune ligands, and was lead facilitator in a poster session.
- Stavros Garantziotis presented the NIEHS CRU in an invited talk at the U.S. EPA research facility. The goal was to encourage collaborative efforts between NIEHS CRU and the EPA.
- Stavros Garantziotis met with Eileen Storey, MD, MPH, Chief, Surveillance Branch at NIOSH at the 2011 ATS meeting and discussed a collaborative study for the detection of biomarkers for multi-wall carbon nanotube occupational exposures.
- CRU staff met with Sheetal Thakur, NIEHS Special Volunteer, to begin development of the hyaluronan responsive genes/ozon-induced airway hyperresponsiveness study.
- CRU staff met with Ed Gaunt (SRA) to discuss development of new laboratory standard operating procedures and clinical reference work instructions.
- There were 174 participant visits (encounters) under four active protocols at the CRU in the month of May 2011.
- Darryl Zeldin worked with Stavros Garantziotis and Laurie Johnson to develop a presentation for Dr. Birnbaum to request central budget support for the NIEHS CRU.
- Darryl Zeldin presented a clinical study proposal titled “The Role of the Functionally Relevant Single Nucleotide Polymorphisms CYP2J2\*7 and EPHX2 K55R in Human Endothelial Function” to the Clinical Advisory Council. A revised protocol is now being prepared for *ad hoc* scientific review.
- Vanessa Flores, a medical student at University of Pittsburgh, began work in the CRU under the NIH Undergraduate Scholarship Program (UGSP) sponsored by NIH OD.

### **Office of Human Research Compliance (OHRC) Related Activities**

- OHRC Staff completed IRB Actions including the following: 1 Expedited Continuing Review; 5 Expedited Protocol Amendments; 1 Expedited Protocol Violation/Deviation; 1 Request for Review of Activity.
- At the May 2, 2011 IRB meeting, OHRC completed draft minutes/stipulations and the IRB conducted 1 Initial Review, 1 continuing review and discussed disposition of samples obtained from an institution that did not have a Federal-

Wide Assurance (FWA). The IRB also heard from Drs. Zeldin and Garantziotis on phlebotomy training procedures at the CRU.

- During a continuing review, OHRC staff identified and suspended a study where the institution's FWA had lapsed. OHRC staff worked with the PI to resolve the issue and to assist the institution (Shanghai, China) in obtaining appropriate approvals.
- OHRC staff audited all studies with non-NIH investigators to determine whether the institutions' FWAs were current.
- OHRC staff attended IPAC (NIH IRB Professional Administrators Committee), PUG (PTMS Users Group) and HSRAC (Human Subjects Research Advisory Committee) meetings in Bethesda via teleconference.
- The OHRC represented NIEHS needs in development of new NIH protocol application and protocol templates and review of final drafts of relevant SOPs at the NIH Protocol Design Subcommittee.
- Joan Pakenham made a presentation on the NIEHS Human Research Protection Program to the National Advisory Environmental Health Sciences Council.
- OHRC Staff worked to coordinate a meeting for the 2012 OHRP Southeastern Atlantic Regional Conference Steering committee, including collecting suggestions for topics and speakers and constructing a draft (straw man) agenda for the two-day conference.
- OHRC staff continued to provide assistance and guidance to study staff in preparing submissions for IRB review.

### **Environmental Polymorphisms Registry (EPR)**

- Pat Chulada sat on an expert panel held by the Duke Institute for Genome Sciences & Policy Center for Genome Ethics, Law & Policy. The purpose was to draft guidelines for ethical approaches to genotype-driven research recruitment.
- The EPR manuscript "The Environmental Polymorphism Registry - a Unique Resource that Facilitates Translational Research of Environmental Disease" was officially accepted for publication in *Environmental Health Perspectives*.
- The EPR newsletter was finalized and will be mailed out to subjects after printing. A copy is appended.
- An EPR recruitment drive was held at the Murdock Developmental Center and ~180 minority participants were recruited.
- Pat Chulada completed the HHS Appropriations Law/Federal Appropriations Course.
- Darryl Zeldin, Stavros Garantziotis, Michael Fessler, Connie Percy and Sharon Hite toured the UNC Clinical Translational Research Center (CTRC) facility and met with UNC investigators to explore the possibility of linking the Environmental Polymorphisms Registry (EPR) database to the UNC DataWarehouse.

### **Environmental Autoimmunity Group (EAG)**

- EAG staff continued to screen subjects for and enroll subjects into the protocols: *Pathogenic Studies in Families with Twins or Siblings Discordant for Systemic Autoimmune Diseases*, *Studies in the Natural History and Pathogenesis of*

*Idiopathic Inflammatory Myopathies* and the new *MYORISK* protocol assessing environmental risk factors for myositis.

- Fred Miller presented a talk to the NIH Neuromuscular Interest Group on May 11, 2011 entitled “Close encounters with the myositis syndromes”.
- Fred Miller and Lisa Rider responded to a Department of Defense grant review based on a previously submitted application to assess the role of environmental agents in the increasing incidence of myositis in the military.
- Fred Miller and Lisa Rider attended Paul Plotz's NIH retirement symposium in Bethesda; Fred Miller's presentation overviewed the contributions that Dr. Plotz had made to the myositis research field over the last three decades.
- Lisa Rider attended the Children's Environmental Health Study symposium on May 13.
- Lisa Rider gave Pediatric Grand Rounds on juvenile myositis and was a visiting professor at Hackensack Medical Center in Hackensack NJ on May 11.
- Adrienne Yip presented a poster on the Rituximab in Myositis trial at the NIH Post-bac IRTA Research Festival on May 18.

#### **Other Activities**

- Kimberly Hoke completed the Purchase Card Training in Bethesda, Maryland.
- Darryl Zeldin attended Medical Executive Committee (MEC) meetings in Bethesda on May 3 and 17, 2011; discussion focused on plans to open the NIH CC to extramural investigators and the status of graduate medical education at the NIH CC.