

Program in Clinical Research – Activities for June 2011

NIEHS Clinical Research Unit Related Activities

- CRU staff worked with Ed Gaunt (SRA) to develop new laboratory standard operating procedures and clinical reference work instructions for the collection of blood and urine samples at the CRU for BPA testing.
- CRU staff held a meeting to develop a core clinical research curriculum for students rotating through the CRU.
- There were 189 participant encounters in the CRU in the month of June 2011. Total number of encounter number topped 1500.

Office of Human Research Compliance (OHRC) Related Activities

- OHRC Staff completed the following IRB actions: Full Board Review Actions: 2 Continuing Reviews and 1 Protocol Violation. Expedited Actions: 1 Expedited Continuing Review, 1 Expedited Protocol Amendment, 3 Expedited Protocol Violation/Deviations and 1 Request for Review of Activity.
- At the June 2, 2011 IRB meeting, OHRC completed draft minutes and stipulations and the IRB conducted 1 Initial Review, 2 Continuing Reviews and discussed the Protocol Violation identified in May by OHRC staff. The Federal Wide Assurance (FWA) for the institution in Shanghai China had been allowed to lapse.
- OHRC staff continues to audit all studies with non-NIH investigators to determine whether the institutions' FWAs are current.
- OHRC Staff began compiling information on the overall NIEHS Human Research Protection Program (HRPP) and information about the Institutional Review Boards (IRBs). This information was requested by Dr. Gottesman for completion of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) application.
- OHRC staff attended IPAC (NIH IRB Professional Administrators Committee), and PUG (PTMS Users Group) meetings in Bethesda, MD 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.
- 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 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)

- A paper titled "The Environmental Polymorphisms Registry – a Unique Resource that Facilitates Translational Research of Environmental Disease" was published on-line in *Environmental Health Perspectives*.

- Pat Chulada met with Brent Lamm to discuss linking EPR subjects with their UNC Healthcare electronic medical records.
- Pat Chulada and Darryl Zeldin attended a phone conference to discuss linking EPR subjects with their Duke Healthcare electronic medical records.
- Pat Chulada and staff from the CRU and MGCF scanned 4427 EPR DNAs and 2119 EPR bloods into MGCF LIMS.
- The EPR genotyping project is progressing; 33 of the 45 EPR map plates were successfully genotyped.
- A draft version of the EPR health and environmental exposure questionnaire has been circulated to in-house scientists for review.
- Pat Chulada sent Dr. Howard McLeod at UNC information about the American Indian population in the EPR. The possibility of running DMETplus chips on the subjects was discussed as a potential collaboration. DMETplus chips encompass 1,936 drug metabolism markers in 230 genes.

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.
- EAG members attended the EAG Retreat in Potomac, MD to discuss future research plans and how to best work together as a team on June 8-9, 2011.
- Fred Miller gave the plenary talk “*Myositis 2011: Past, Present and Future*” at the Rheumatism Society Fellows Forum in Washington, DC on June 11.
- Fred Miller attended the Henry Kunkel Society meeting in Washington, DC on June 22-23.
- Lisa Rider attended the Childhood Arthritis and Rheumatology Research Alliance (CARRA) meeting in Miami, FL from May 31 – June 3, where she presented work on assessing myositis skin disease, as well as progress on the International Myositis Classification Criteria Project and the NIEHS Twin Sibling Study.
- Lisa Rider traveled to the US Public Health Service Scientific and Training Symposium in New Orleans, LA from June 20-21, where she received the Physicians’ Professional Advisory Committee award as Physician Researcher of the Year.
- Lisa Rider gave Pediatric Grand Rounds at Seattle Children’s Hospital on June 23 in a talk entitled “*Juvenile Myositis, From Seattle’s Bedside to Bethesda*”. She also participated in an educational forum/case discussion at Seattle Children’s Hospital with health professionals from the Pacific Northwest region.
- Lisa Rider presented at the Cure JM Annual conference on June 24 in Seattle, WA. Her talk was entitled: “*Juvenile Myositis News from the NIH: Genetic and Environmental Studies.*”
- Adrienne Yip, the EAG post-bac IRTA fellow, presented her work on the Rituximab in Myositis trial at the DC Rheumatism Society Fellows Forum in Washington DC on June 11. She received this year’s poster award.

Other Activities

- Kimberly Hoke and Pat Chulada completed the Contract Officer Technical Representative (COTR) training in Research Triangle Park.
- Darryl Zeldin participated in several media interviews on topics ranging from dust mite exposure in bedding, outdoor air quality, health effects of climate change and lipidomics and environmental disease.
- Darryl Zeldin attended the Medical Executive Committee meeting in Bethesda, MD on June 7, 2011. Topics covered included lessons learned from the near-miss closure of the government and supervision of IRTA fellows with clinical responsibilities.
- Darryl Zeldin served as the Attending Physician in the MICU at the Durham VA Hospital in Durham, NC