

Program in Clinical Research – Activities for July 2011

NIEHS Clinical Research Unit Related Activities

- CRU staff interviewed and extended an offer to a part-time Respiratory Therapist to assist with pulmonary function studies and bronchoscopies. The offer was accepted and the individual will begin Aug 8, 2012.
- CRU staff held a conference call with Dinora Dominguez (Director, Patient Recruitment and Public Liaison office at the NIH Clinical Center) to determine if PRPL services could be applicable to screening participants for CRU studies.
- CRU staff held a follow-up meeting to finalize plans for a core clinical research curriculum for students rotating through the CRU.
- CRU staff completed two study amendments, one continuing review submission and two exemption requests for ongoing studies.
- There were 123 participant visits under four active protocols at the CRU in the month of July 2011.
- CRU personnel mentored a summers of discovery student in a nanomaterial related study.
- Drs. Zeldin and Garantzotis participated in the NIEHS strategic planning retreat.

Office of Human Research Compliance (OHRC) Related Activities

- OHRC Staff completed IRB Actions including the following: Full Board Review Actions: 1 Initial Review and 1 Continuing Review. Expedited Actions: 3 Expedited Continuing Reviews, 4 Expedited Protocol Amendments, 1 Expedited Unanticipated Problem, and 2 Requests for Review of Activity.
- At the July 7, 2011 IRB meeting, OHRC completed draft minutes and stipulations and the IRB conducted 1 Continuing Review and 1 Full Board Review of Amendment.
- OHRC staff continues to audit all studies with non-NIH investigators to determine whether the institutions' FWAs are current.
- OHRC Staff completed and sent information to NIH Office of Human Subjects Research Protections (OHSRP) 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) meeting 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.
- OHRC Staff worked to coordinate and complete minutes for 2 meetings for the 2012 OHRP Southeastern Atlantic Regional Conference Steering committee, including finalizing suggestions for topics and speakers and contacting speakers 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 wrote a short article about the EPR that was placed in the NIH Corner section of the *American Journal of Respiratory Cell and Molecular Biology*
- Pat Chulada received comments from epidemiology staff members for the EPR Health and Exposures Survey. She is meeting with SRA staff to incorporate these changes in August.
- The EPR Genotyping project is progressing, 35 of the 45 EPR map plates were genotyped.
- Pat Chulada reviewed three work assignments on the clinical contract and sent back comments to the contractor.
- Dr. Marie Lynn Miranda submitted a Statement of Work for Phase II of the EPR GIS. This will go through the contracts office next month for funding.

Environmental Autoimmunity Group (EAG)

- EAG staff continued to screen subjects for and enroll subjects into the following 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 gave Grand Rounds at the Hospital for Special Surgery in New York entitled “*Myositis revisited: New developments in diagnosis, pathogenesis and therapy*” on July 27.
- Lisa Rider attended the Arthritis Foundation’s Juvenile Arthritis conference in Alexandria, VA on July 8 to recruit patients for the Twin Sibling Study.
- Lisa Rider attended a webinar from the Children’s Environmental Health Study on July 19.
- Lisa Rider and Fred Miller worked on data clean up and developing analysis plans for The Myositis Association patient registry, MYOVISION, which has enrolled more than 1600 myositis patients from throughout the US and has a number of environmental exposure questions as part of the patient questionnaire.

Other Activities

- Kimberly Hoke completed the NIH Property Training in Bethesda, MD.
- A draft of the Statement of Work and other supporting documents was sent to the contract officer (Hamilton Brown) for recompletion of the clinical support contract
- Darryl Zeldin and Joan Packenham met with NICHD Scientific Director and Clinical Director on July 19, 2011 to discuss the NIEHS Human Research Protection Program; OHRC staff will assist NICHD to develop a similar program in Bethesda.
- Darryl Zeldin attended the Medical Executive Committee on July 19, 2011

- Darryl Zeldin and Stavros Garantziotis met with investigators at U.S. EPA to discuss possible collaborative projects