

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)  
Pediatric Drugs and Devices Group  
Minutes from June 12, 2009**

**1. Update on the February 26, 2009 “Pediatric Drug and Medical Device Development Workshop” was given by Drs. Hirschfeld, Li, Marcus.** The meeting documents can be viewed at:

[http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com\\_ID=282#mtg\\_ID\\_908](http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=282#mtg_ID_908)

Dr. Hirschfeld announced a follow-up Data Acquisition Workshop to be scheduled for August 26 at the Natcher Auditorium.

- **Action Item:** A public planning conference call will be held July 10. All committee members are invited to participate.

**2. Update on the April 23, 2009 “Pediatric Research Ethics Group - Comparing IRB Models for Multisite Pediatric Studies” workshop was provided by Dr. Hirschfeld.** The meeting documents can be viewed at:

[http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com\\_ID=441#mtg\\_ID\\_1320](http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=441#mtg_ID_1320)

The Research Ethics Subcommittee is primarily developing a model whereby one of the CTSA consortium sites will house the primary IRB for a specific study and the remainder of the consortium will agree to provide IRB reviews in a defined time frame (e.g., 30 days). The Subcommittee is currently developing a written description of this model. Future updates will be provided by Dr. Hirschfeld as well as at the CC-CHOC meetings.

**3. Joint Scientific Review Process.** The Subcommittee plans to develop a process for central CTSA consortium scientific reviews for protocols related to pediatric drug and device development, in order to facilitate and expedite multicenter studies. Dr. Marcus (Penn) will lead this process; additional volunteers included Jon Davis (Tufts), Dan Hale (San Antonio) and Rick Kaskel (Albert Einstein).

- **Action Item:** Any additional volunteers should contact Farrell Bowen. Dr. Marcus will be in further contact with the other participants to start developing this process.

**4. Registry:** We have been approached by the pediatric Center for Education and Research in Therapeutics (CERT) at Cincinnati Children's Hospital Medical Center), which is working with the FDA, to assist the FDA by compiling a compendium of pediatric registries with data collection that might lend themselves to use in postmarket surveillance activities for implantable medical devices in the pediatric population.

- **Action Item:** Anyone with knowledge of additional such registries should send the information to Farrell Bowen.

**5. Next meeting:** The next meeting will be part of the planning conference call for the Data Acquisition Workshop on July 10, and will be chaired by Dr. Hirschfeld.