

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)**  
**Pediatric Drugs and Devices**  
**September 11, 2009**  
**4:00 PM – 5:00 PM ET**  
**Draft Minutes**

**Attendees:** Dr. Jennifer Li (Duke), Dr. Jonathan Davis (Tufts), Dr. Amira Al-Uzri (OHSU), Dr. Anne Willoughby (NIH/NCRR), Dr. Mary Purucker (NIH/NCRR), Ms. Farrell Bowen (BAH)

**Recorder:** Dr. Mary Purucker

1. Discussion about the proposed CTSA federated Scientific Review Group for pediatric multi-site protocols was postponed for a future meeting to allow the workgroup's co-chair, Dr. Carole Marcus (U-Penn, CHOP), to participate.

**2. Volunteers for Pediatric Research Ethic Workgroup's federated IRB project**

The Pediatric Research Ethics Workgroup (PREW) has the lead for this project but is presently transitioning its leadership and has requested assistance. The general principles of the CTSA "federated IRB" have been developed but the details as to how it might be implemented and which CTSA sites might wish to participate have not been determined. Drs. Jon Davis and Jennifer Li agreed to take on this task, and will develop an operational plan in a grant proposal format to share with the group. It was noted that keeping the CC-CHOC leadership informed and seeking endorsement of relevant CTSA consortium key function committees will be important for the future success of the proposal, in particular those committees aligned with the Clinical Research Innovation (CRI) key function committee (see 5., below). Copies of the presentation before the SACHRP given by Dr. Steven Hirschfeld (July 21, 2009) were circulated in preparation for this meeting. Additional information concerning the origin of this project is provided, below.

*Background: Delays and inconsistencies in IRB review have been identified by the CTSA Consortium as key barriers to clinical & translational research. Potential solutions that might address this problem and expedite multi-site clinical trial implementation are considered a Strategic Goal of the CTSA Consortium. The CC-CHOC has taken on the challenge of exploring consortium-wide solutions because delays and inconsistencies are a particular problem for IRB review of multisite pediatric studies. Two workshops have been co-sponsored by NCRR/CTSA and NICHD, the 2<sup>nd</sup> of which explored alternative models of IRB review of multisite pediatric studies in a systematic way (April 23, 2009; [http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com\\_ID=441#MID1320](http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=441#MID1320)) Four models were presented, Central, Reciprocal Agreement, Rotating, and Commercial/Professional IRB. When applied to multi-site protocol review, each may be considered variations on a theme of recognition of primary review plus ongoing information exchange. Subsequent discussion of the outcome of these conferences by members of the PREW lead to a proposal to "federate" interested CTSA sites, where member IRBs would be willing to sign on to a compact that outlines principles, process, and performance standards for review of multisite pediatric studies. The federated CTSA sites would implement and evaluate the pilot with opportunities for dynamic change. The proposal included an Operations Center that would ensure the protocol had received initial clearance by a Scientific Review Committee and would subsequently track the protocol through each IRB review, ensuring that the initial and any subsequent IRB reviews were available for consideration. This model was presented in broad outline to the SACHRP on July 21, 2009, where it positively received.*

### **3. Building a pediatric research network of networks**

A list of institutions where CTSA, National Children's Study (NCS) sites, or other NICHD-supported pediatric research networks are co-located was compiled by NICHD and included in the pre-meeting documents. It was suggested that this list could be used to promote collaboration and sharing between CTSA investigators and other investigators co-located at their institution, or to promote multi-site or cross-network collaborative activities. The group was appreciative of this resource. In the discussion that followed, it was suggested that the "Networks for Clinical Research" Inventory site <http://www.clinicalresearchnetworks.org/1.asp> might be used to identify additional pediatric clinical research networks, NIH-funded or other.

### **4. Upcoming Workshops**

**A. Methodologies to Set Priorities for Child Health Clinical Research:** This meeting has been scheduled for November 18-19, 2009 at Natcher Auditorium on NIH main campus and will be NIH videocast. It was announced that sponsorship of this meeting would be by NICHD, although NCCR and CC-CHOC leadership would be closely involved. This will be a 2-day meeting with breakout groups on Day 2 that will include sessions on BPCA and the pharmaceutical development prioritization process in addition to pediatric medical device development and prioritization. The preliminary agenda has been developed and will be circulated to this group as well as to others in the CC-CHOC for comment later next week.

**B. Quality Data Acquisition Workshop:** This meeting has been rescheduled from August 27 to a new date on February 25, 2010 and will be held at Natcher Auditorium on NIH main campus and NIH videocast. The meeting will be jointly sponsored by NCCR/CTSA Consortium Child Health Oversight Committee and NICHD. The focus will be on data acquisition and related activities that are unique to studies involving children conducted for regulatory purposes, but within the broader context of federally sponsored clinical research conducted by US academic health centers.

### **5. Opportunities to participate in other CTSA Key Function Committees/Working Groups**

The purpose is to explore opportunities for workgroup members to influence, be informed or leverage efforts to promote pediatric drug and medical device development with other interested groups within the CTSA. It was suggested that the Clinical Research Innovation (CRI) Key Function Committee would be the group most relevant to the goals of this workgroup. The CRI is a relatively new entity within the CTSA consortium that was assembled to simplify the reporting process for the 3 component committees, Clinical Research Management (CRM), Participant and Clinical Interactions Resources (PCIR), and Regulatory Knowledge, along with their associated workgroups or taskforces. See also the CTSA public website: [http://www.ctsaweb.org/index.cfm?fuseaction=committee.viewCommittee&com\\_ID=921&abbr=CRI](http://www.ctsaweb.org/index.cfm?fuseaction=committee.viewCommittee&com_ID=921&abbr=CRI)

### **6. Update on Demonstration Projects for Pediatric Device Development**

This information is FYI for workgroup members. On April 30, 2009, the FDA Office of Orphan Products issued an FOA for grant applications from nonprofit consortia to facilitate the development, production, and distribution of pediatric medical devices. The mechanism of support is a Specialized Center (P50) grant mechanism. Applications have been received, reviewed, and awards are expected to be announced next week with funding before the end of the fiscal year. The award total is \$2 million over 2 years. The program is pursuant to Section 305 of the Federal Food and Drug Administration Amendments Act of 2007 (FDAAA).