

**Minutes**  
**National CTSA Pediatrics Oversight Committee (POC) Call**  
**September 25, 2007**

**CTSA Pediatric Oversight Committee Members**

Jennifer Puck, UCSF, Chair  
W. Charles Huskins, Mayo Clinic  
Sudha Kashyap, Columbia  
Kathleen Kennedy, UT Houston  
Jennifer Li, Duke  
Carole Marcus, CHOP  
Dan Marks, Oregon  
Lynette Orlanski, Pittsburgh  
Tony Phillips, UC Davis  
Peter Szilagyi, U Rochester  
Sandy Vasan, Rockefeller

**Representative from CTSA Clinical Research Ethics Workgroup**

Alex Kon, UC Davis

**Additional Participants**

Bertram Lubin, Oakland  
Joseph St. Geme, Duke

**NIH Participants**

Gail Pearson, NHLBI; NIH Liaison to POC  
Anthony Hayward, NCCR  
Rose Higgins, NICHD  
Steven Hirschfeld, NICHD  
Mirjana Nesin, NIAID  
Victoria Pemberton, NHLBI  
Malcolm Smith, NCI

**Welcome and Introductions**

Dr. Puck welcomed everyone and called the meeting to order at 5 pm EDT. Dr. Sandy Vasan, the new pediatric representative from Rockefeller, and Dr. Tony Phillips, the new pediatric representative from UC Davis, were introduced and welcomed. Dr. Kon has stepped down as the pediatric representative to the POC, but will continue to be involved on the CTSA Clinical Research Ethics Committee.

**Pediatric IRB Conference Report**

Steven Hirschfeld summarized the successful web conference, "Pediatric Challenges for Institutional Review Boards", held September 11. He thanked Dr. Puck for an excellent job chairing the first part of the meeting, and Dr. Kon for leading the summary discussion to conclude the meeting. Approximately 400 people from 130 sites, including IRB members, researchers, and federal employees participated in the web conference. Dr. Hirschfeld said that he would be preparing an outline and summary of the discussion to support development of each of the topics presented into manuscripts, and would circulate those soon. Dr. Kon described potential future activities related to pediatric IRB issues. Dr. Kon outlined two major issues for further exploration and clarification. The first is defining the level of risk in pediatric studies. The second is defining who can be considered to have a condition or disorder, since minor increases over minimal risk can be acceptable for children with a condition, whereas above minimal risk research on healthy children is problematic and requires a high-level review.

**Vision for Next Steps, Pediatric IRB Activities**

The POC was determined to build on the success of the web conference, and discussions led to several suggestions for future topics and mechanisms to address them. Improved communication between IRBs at different sites, increased participation of pediatricians on IRB panels, ironing out local variations in interpretation of regulations and streamlining the approval process for multi-center studies were mentioned. One way to have these issues addressed

would be to designate a panel of experts to consider specific questions, from which generalities could emerge. Suggested experts could include:

Alex Kon (UC Davis)  
Dave Wendler (NIH Clinical Center)  
Steven Hirschfeld (NICHD)  
Robert Nelson (CHOP and FDA)

Lainie Ross (University of Chicago)  
Rick Kodish (Cleveland Clinic)  
Ben Wilfond (University of Washington)  
John Tyson (UT Houston)

While this was not an exhaustive list, it clearly shows that there is a nationwide cadre of experts whom we could enlist. The Pediatric IRB Expert Panel could evaluate questions related to level of risk and classification of a disease or condition for studies that would be evaluated under 45CFR46.406. The panel could deliberate by conference call. Proactive submission by investigators prior to local IRB review would allow the experts to:

- Clarify the issues and help the investigator develop a protocol that would be generally accepted,
- Provide a written opinion as a reference point for the local IRB, and
- Develop an archive of summary statements and IRB stipulations for cases of similar type to advance the field of pediatric research ethics and provide general guidance for future cases.

In addition, a proposal for IRBs to submit summary statements of their determinations during the review of multi-institutional studies to a Wiki board sponsored by the CTSA would allow individual IRBs to become aware of what other IRBs were considering during the review process.

The POC unanimously endorsed establishment of an expert panel and construction of a Wiki board for Pediatric ethical issues to be integrated with the CTSA website.

### **New CTSA Awards**

Dr. Hayward announced that 12 additional CTSA sites had been funded as of early September. The PIs are being asked to nominate pediatric representatives, who will be contacted shortly and invited to join our POC. The new sites are:

Case Western Reserve University  
Emory University  
Johns Hopkins  
University of Chicago  
University of Iowa  
University of Michigan

University of Texas Southwestern  
University of Washington (Seattle)  
University of Wisconsin  
Vanderbilt University  
Washington University (St. Louis)  
Weill Cornell Medical College

### **Discussion of Future Directions**

POC members reviewed the priority ranking for proposed new activities included with the minutes. The ideas previously suggested were ranked as follows:

1. Sharing resources for training (e.g., specialized courses) and research (e.g., consent templates).
2. Networking to conduct systematic research on rare disorders.
3. Conducting joint pediatric and adult studies.
3. (tie) Identifying drug and device companies that support pediatric research and development.
4. Evaluating the impact of the POC.

Dr. Steiner expressed interest in the networking initiative, and Drs. Hirschfeld and Li expressed interest in identifying drug and device companies that support pediatric research. There was discussion of posting ideas for activities, studies, and other topics on a POC web site.

Given the success of the web conference and the anticipated availability of internet-based Wiki board communications, it was agreed that POC issues should be posted. A leader or team of leaders for each topic should be identified, and expert panels could be engaged as sounding boards as delineated above for Pediatric IRB issues. NIH staff were charged with looking into how this could be set up.

### **Next Meeting**

The next meeting is due in January, 2008. It was agreed that a face-to-face meeting of the POC in addition to quarterly conference calls would be valuable every year if possible. There was discussion of coordinating future POC meetings with national pediatric meetings.

### ***Action Items:***

- Dr. Pearson will work with NCCR staff to set up the CTSA Pediatric Wiki board to be used to post ideas for future directions.
- Dr. Pearson will circulate a calendar of 2008 pediatric meetings to help schedule the next several POC phone conferences and evaluate whether a face-to-face meeting could be scheduled.
- Dr. Pearson will communicate with Dr. Steiner and Drs. Hirschfeld and Li about developing Wiki board entries.
- Dr. Pearson will circulate email asking for volunteers to lead the remaining identified POC activities and to suggest additional activities for future discussion.
- The pediatric representatives from the new CTSA sites will be contacted.
- Drs. Kon and Hirschfeld will solicit members for an expert pediatric ethics panel and report back to the POC at the next meeting on the process.