

Minutes
National CTSA Pediatrics Oversight Committee Call
June 21, 2007

(Meeting materials: www.ctsaweb.org under Pediatric Oversight Committee)

CTSA Investigators

Jennifer Puck, UCSF, Chair
Silva Arslanian, Pittsburgh
Kevin Heller, Rockefeller
W. Charles Huskins, Mayo Clinic
Sudha Kashyap, Columbia
Kathleen Kennedy, UT Houston
Alex Kon, UC Davis
Jennifer Li, Duke
Carole Marcus, CHOP
Robert Steiner, Oregon
Peter Szilagyi, U Rochester

NIH Participants

Cheryl Boyce, NIMH
Nancy Bridges, NIAID
Joe Frascella, NIDA
Lynne Haverkos, NICHD
Anthony Hayward, NCRR
Steven Hirschfeld, NICHD
Mirjana Nesin, NIAID
Gail Pearson, NHLBI
Victoria Pemberton, NHLBI
Jennifer Read, NICHD
Vince Smeriglio, NIDA
Malcolm Smith, NCI

Additional Participants

Bertram Lubin, Oakland

Welcome and Introductions

Dr. Puck welcomed everyone and called the meeting to order at noon.

Update, CTSA Governance Structure

Dr. Pearson directed the group's attention to the revised schematic of the new CTSA governance structure that had been sent out with the agenda. She noted that the number of steering committees had been decreased to improve efficiency and flexibility, and that the Pediatric Steering Committee had now become the Pediatric Oversight Committee (POC). The fundamental functions of the POC have not changed, and there is still a direct line of communication to the CTSA Consortium Oversight Committee (previously called the PI Steering Committee). In response to a question, it was noted that IRB issues, as well as ethics and regulatory issues were now included in the Clinical Integration Steering Committee.

Response of PI Steering committee to Pediatric Recommendations

Dr. Puck reviewed and the POC discussed the recommendations made at the March meeting, and the responses from the Consortium Oversight Committee (page 2 of the Agenda).

Action Items:

- NCRR staff to determine which steering committees lack pediatric representation. The POC will then recommend one or more pediatricians to serve on these steering committees as non-voting members, to establish lines of communication between the POC and every steering committee.
- Each POC member will review the pediatric membership on their local K awards committees, and report back prior to the next call.

Update on IRB Workshop

Dr. Hirschfeld discussed the current status of the IRB Workshop Meeting and reported on the planning call which had taken place earlier in the week. The Workshop is now planned for September 11, from 11-5 via videoconference. Details of format and schedule were refined, and each POC member agreed to publicize the event as much as possible at their respective

institutions. A formal invitation from NIH will be sent to the POC, the CTSA PIs, the CTSA Clinical Integration Steering Committee and invited IRB chairs shortly.

Action Items:

- NIH staff will locate a conference room in Bethesda and determine the technical details of the videoconference, so that those participating by videoconference from distant sites will know what format is required.
- The POC will contact their institution's PIs, recruit IRB participants, and solicit and forward case scenarios to Dr. Hirschfeld.

Update, Pediatric Networks and Consortia

Dr. Pearson drew the POC's attention to the list of NIH-funded networks and consortia sent out as pages 4-8 of the agenda. She noted that this list was incomplete, reflecting the lack of a central database at NIH designed to accommodate this type of query. There are intentions to develop such a database, but implementation will not occur for at least a year. Dr. Pearson mentioned that she had already received corrections to the list from CTSA sites, and noted that the local sites' business offices were probably a better source of this information at the moment.

The discussion focused on how information about pediatric networks could be used to identify studies that need additional patients, and to facilitate sites contributing patients if they are not a network site. It was mentioned that in the pediatric cancer cooperative groups, only member institutions could formally enroll patients in a protocol, but that in other networks, patient recruitment was expanded through the use of auxiliary sites for one or more protocols. One way in which the CTSA's could interface with networks would be to conduct pilot studies for planned protocols. The issue of academic recognition within a collaborative network structure was discussed. Dr. Hirschfeld also mentioned that NICHD funded as many as 16 networks at one academic institution, and is exploring possibilities to increase efficiencies such as resource sharing to allow more research.

Action Items:

- POC members will update the list of networks and consortia at their sites periodically, using the list provided for this call as a starting point. The CTSA web site, www.ctsaweb.org, will host this information.
- POC members will review this process periodically to determine its usefulness.

New Business

Dr. Puck asked the POC to discuss new activities to undertake. There was discussion of the question, sent out with the agenda, of which inpatient research costs would be reimbursed from the CTSA grants, and which from individual investigators' grants. It was agreed that this was not solely a pediatric issue, but that information would be provided to the investigator requesting it off-line.

Action Item:

- Dr. Pearson will send a list of proposed new activities to POC members with a request for input on priorities. This list will be updated from the version sent in the agenda.

Next Meeting

Based on the schedule set at the March meeting, the next quarterly call will be scheduled for mid-September, after the IRB Working Group. It is hoped that regular POC phone meetings can accomplish their goals in one hour, striving to use email and subgroups to pursue future goals.

Action Item:

- Dr. Pearson's office will schedule the next call.