

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)  
January 26, 2009  
Meeting Summary**

**CC-CHOC**

**Time:** 12:00 PM – 1:30 PM EST

**URL:** <https://webmeeting.nih.gov/p43705069/>

**Attendees:** J. Puck, UCSF (Co-Chair); B. Ramsey, Univ. of Washington (Co-Chair); S. Hirschfeld, NICHD (NIH Coordinator); G. Pearson, NHLBI (NIH Coordinator); M. Purucker, NCCR (NIH Coordinator); R. Sokol, Colorado Denver (PI Liaison); M. Balsam, NICHD; C. Boyce, NIMH; T. Carpenter, Yale; J. Cody, UT-San Antonio; C. Dampier, Emory; P. Giardina, Cornell; D. Gipson, North Carolina; C. Huskins, Mayo; D. Johnson, Chicago; S. Kashyap, Columbia; J. Li, Duke; C. Marcus, UPenn; S. Massie, North Carolina; J. McNamara, NIAID; E. Mendonca, Chicago; J. Murray, Iowa; E. Neufeld, Harvard; S. Pasquali, Duke; D. Peden, North Carolina; J. Perrin, Harvard; A. Philipps, UC Davis; L. Ross, Chicago; B. Smith, Duke; R. Steiner, OHSU

**I. PAS and Face-to-Face Meeting (May 1) Plans**

The CC-CHOC Face-to-Face Meeting, in conjunction with the PAS Meetings, will take place on May 1 from 8:00 AM – 5:30 PM ET at the Hilton Hotel in Baltimore. As a result of the partnership with the PAS, the CC-CHOC has been given several sessions, including a symposium and two platform sessions for oral presentations. Drs. Puck and Ramsey will chair one platform session and Drs. Barkin and Neufeld will lead the other.

Dr. Ramsey will follow up with CC-CHOC members regarding meeting logistics. There will be a charge for refreshments and lunch for all attendees (amount to be determined), but no other registration fee. Dr. Ramsey is also applying for an R13 grant to support future CC-CHOC meetings.

**II. Future Interaction with the National Children's Study (NCS) and CTSA**

The CC-CHOC liaisons with the NCS are Drs. Dan Hale at UT-San Antonio and Jeff Murray at the University Iowa, as well as Steven Hirschfeld at NICHD. CC-CHOC members can contact these individuals directly to keep up with developments. Dr. Hirschfeld introduced Dr. Marion Balsam, the official in charge of collaboration and support of projects for the National Children's Study. Dr. Balsam noted that the NCS is the largest, long-term study ever to be conducted in the United States with regard to environment and its effects on children. Infants will be enrolled at birth and extensive data and samples will be collected over a period of many years. DNA will be collected from cord blood and placenta at birth. There are no plans to transform cell lines. She indicated there will be many opportunities to leverage resources with the NCS to do additional research. The full study is scheduled to begin in July 2010.

Dr. Balsam described planned opportunities for adjunct studies that will utilize the NCS infrastructure (e.g. participants, biospecimens, environmental samples), involve a subset of the cohort, and occur concurrently with the main study. These will not take place during the vanguard study, nor will core NCS funding cover the cost of adjunct studies. It

is anticipated that most adjunct studies will be funded by government grants, such as R01s.

The NCS will review each request to perform an adjunct study; factors to be considered will include the burden on patient, the burden on study structure (e.g. personnel, logistics) and the effect on human subjects (e.g. ethical, legal).

Dr. Murray stated that Iowa is a Wave 2 NCS center and indicated preliminary involvement in the study. He shared that there is a great opportunity for the CTSA and the NCS to leverage one another.

### **III. Update from Drugs and Devices Workshop on February 26**

The goal of the upcoming meeting is to determine how the CTSA pediatric infrastructure can help with the development and approval or licensure of pharmaceuticals and medical devices for children. The meeting will have representation from CTSA members, NIH staff, FDA, industry, non-profit organizations, academicians, advocacy and patient/parent groups, and pediatric representatives from Europe.

The meeting has moved to the Natcher Conference Center on the NIH Campus in Bethesda. To date, 116 individuals have registered. The meeting is open to the public. To register, please visit the registration web site: <https://www.seeuthere.com/pediatric>.

### **IV. Updates on CTSA Reorganization and Strategic Goal Committees**

Dr. Puck noted that the Drs. Guay-Woodford, Sokol and Ramsey currently serve on the Strategic Goal Committees (SGCs). Dr. Sokol indicated that the original goal of the SGCs was to align the work of the Key Function Committees (KFCs). Dr. Ramsey reported that she sent a message along with comments to SGC #4 to include child health in their strategic goal and shared that the message was well-received by the PI Co-Chairs of the SGC. She also emphasized the need for pediatricians to populate the KFCs and to report back to CC-CHOC leadership.

### **V. Workgroup Reports**

- A. Seeking Leadership for Education and Pediatric-Adult Life Span Groups  
Dr. Puck noted that the CC-CHOC has not yet designated a group that focuses on education in child health. Members interested in working on Child Health Education should convey their interest to Dr. Puck, Dr. Ramsey and Mr. Hashemi. The Pediatric-Adult Life Span topic is also in need of input. Dr. David Peden from UNC has offered to become active in this effort, and others are invited to join by contacting him directly or the CC-CHOC leaders as above.
- B. Pediatric Research Ethics  
Drs. Ross and Hirschfeld noted that the Pediatric Research Ethics Group is planning a second web conference that addresses issues of sharing IRB reviews, central IRBs and streamlining approval for multicenter protocols. The meeting will occur on April 23 from 11:00 AM to 5:00 PM ET. Each participating institution will be asked to set up a central auditorium for their CTSA site and presenters will use a webcam. There will be open planning teleconferences, which are tentatively scheduled to take place on the following dates and times:

Thursday, February 5	3:00 – 4:00 PM ET
Wednesday, February 11	2:00 – 3:00 PM ET
Friday, February 27	1:00 – 2:00 PM ET

This meeting, which is to be more didactic than participatory in nature, will have a list of formats and structures for regulatory review. Various IRB models (e.g. contract, rotating, central, subject matter expert), organizations (e.g. Veterans Health Administration) that are working with centralized/cooperative processes will be showcased.

### C. Rare Diseases

Drs. Steiner and Green reported that the CTSA will participate at the Rare Diseases Clinical Research Network (RDCRN) Symposium in 2010. Dr. Peter Merkel will serve as the point person on behalf of the CTSA for the RDCRN Symposium, which will invite participants from the Office of Rare Diseases, FDA, NIH and the CTSA Rare Diseases Group. Dr. Sokol suggested including Dr. Steve Groft in the planning, who was instrumental in the execution of the first RDCRN conference.

Dr. Carpenter mentioned that a conference on Rare Bone Diseases took place in September 2008, that may be a useful organizational model, and noted that Drs. Craig Langman at Northwestern and Michael Econs at Indiana played an integral role in engaging support groups and affected people with rare bone diseases. Dr. Sokol recommended inclusion of patient advocacy (e.g. giving presentations and being available for one-to-one interactions) as required by the RDCRN.

Dr. Green stated the Rare Diseases Group is collecting documents – protocols and consent forms for genetic testing – to be posted on the Wiki.

Dr. Puck provided a brief report on an administrative supplement to examine sharing of samples from patients with rare conditions across CTSA sites. She noted that the financial resources are not available to develop an independent biobank for each rare disease. She intends to use two test diseases to develop rules, tests and structure.

### VI. Other New Business

Dr. Purucker stated that the awards for the new CTSA cohort will not be announced until the end of May. To date, the first round of applicants for FY2009 funding (Cohort 4A) have been reviewed and scored. The second round of applicants (Cohort 4B), which includes more applicants, will undergo peer review in mid-February and is still subject to Council review. The two cohorts will be considered together for purposes of funding. Thus new sites will not be chosen in time for their pediatric investigators to be included in the CC-CHOC face to face meeting.

**VII. Action Items**

#	Action Items	Owner	Due Date
1	Send agendas for the Drugs and Devices Workshop and CC-CHOC Face-to-Face Meeting along with the meeting summary to CC-CHOC members	Mr. Hashemi	2/2/09
2	Indicate interest in leading or participating in Pediatric-Adult Life Span or Education Groups to Dr. Puck, Dr. Ramsey and Mr. Hashemi ( <a href="mailto:hashemi_paymon@bah.com">hashemi_paymon@bah.com</a> )	CC-CHOC Members	2/6/09
3	Send protocol and consent forms for genetic testing to Drs. Green ( <a href="mailto:nsg11@columbia.edu">nsg11@columbia.edu</a> ) and Steiner ( <a href="mailto:steinerr@ohsu.edu">steinerr@ohsu.edu</a> )	CC-CHOC Members	Ongoing
4.	Plant to attend PAS meeting, including the all-day CC-CHOC meeting in Baltimore on May 1, 2009. <b>Encourage translational investigators and trainees from your sites to attend our CTSA Topic Platform Presentation sessions and Symposium.</b>	CC-CHOC Members	Ongoing