

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)
October 27, 2008
Meeting Summary**

CC-CHOC

Time: 12:00 PM – 1:30 PM EDT

Attendees: J. Puck, UCSF (Chair); B. Ramsey, Univ. of Washington (Chair-Elect); S. Hirschfeld, NICHD (NIH Coordinator); G. Pearson, NHLBI (NIH Coordinator); M. Purucker, NCCR (NIH Coordinator); S. Barkin, Vanderbilt Univ.; C. Boyce, NIMH; T. Carpenter, Yale Univ.; J. Cody, UT-San Antonio; S. Cohn, Univ. of Chicago; E. Collier, NCCR; J. Davis, Tufts Univ.; D. DiMichele, Weill Cornell; F. Dunston, Emory Univ.; L. Epstein, Northwestern Univ.; P. Giardina, Weill Cornell; D. Gipson, Univ. of North Carolina; J. Glade Bender, Columbia Univ.; N. Green, Columbia Univ.; L. Guay-Woodford, Univ. of Alabama-Birmingham; J. Gurney, Univ. of Michigan; D. Hagler, Mayo; R. Higgins, NICHD; M. Jessup, Univ. of Michigan; S. Kashyap, Columbia Univ.; F. Kaskel, Einstein; L. Katz, Univ. of Pennsylvania; A. Kon, UC Davis; J. Li, Duke Univ.; B. Lubin, CHORI; C. Marcus, Univ. of Pennsylvania; E. Mendonca, Univ. of Chicago; M. Moxey-Mims, NIDDK; E. Neufeld, Harvard Univ.; D. Peden, Univ. of North Carolina; V. Pemberton, NHLBI; A. Philipps, UC Davis; G. Retsch-Bogart, Univ. of North Carolina; L. Rose, Univ. of Washington; M. Smith, NCI; J. St. Geme, Duke Univ.; R. Steiner, OHSU; P. Szilagyi, Univ. of Rochester; J. Tyson, UT-Houston; D. Wara, UCSF; S. Vasan, Rockefeller Univ.; P. Zeitlin, Johns Hopkins Univ.

I. Identification of Child Health representatives on CTSA Consortium Key Function Committees

Dr. Puck informed members that as a result of the recent CTSA Consortium Steering Committee (CCSC) meeting on October 6-7, the POC changed its name to the CTSA-Consortium Child Health Oversight Committee (CC-CHOC) in order to better reflect the scope and functions of the committee; however, the mission and vision remain the same.

Dr. Purucker described the purpose of the CCSC meeting as two-fold: First, to complete the strategic planning process necessary to identify the Consortium's strategic goals. Second, to modify the governance structure of the Consortium to better support the 4 Strategic Goals. There were nine strategic priorities at the start of the CCSC meeting that were consolidated into the four strategic goals by the end. These goals will be driven by Strategic Goal Committees (SGCs).

To recap, the 4 Strategic Goals are:

- A. Enhancing National Clinical and Translational Research Capacity
- B. Enhancing the Training and Career Development of Clinical and Translational Scientists
- C. Enhancing Consortium-Wide Collaborations
- D. Enhancing the Health of Our Communities and the Nation

Dr. Hirschfeld added a few common themes from the meeting. First, multiple initiatives proliferated around the CTSA community which were not coordinated well; therefore, the reorganization of the program allows for improved communication and coordination efforts. Second, the PIs identified the four major strategic goals in part for mapping current projects to them. The mapping process is under discussion and ongoing. Third,

committees like the CC-CHOC or the Clinical Research Ethics Workgroup (PREW) would be charged with developing priorities and objectives for projects. Once projects are selected and aligned with one or more of the four major strategic goals, a separate project team composed of members of the committee would be formed for implementation and could reach out to other CTSA groups to partner with in meeting the project objectives. The project implementation teams would then report back to all of the involved CTSA policy bodies in a coordinated fashion. In sum, the CC-CHOC should have pediatricians oriented towards priorities and a framework that is aligned with the strategic goals.

Dr. Ramsey made note of the contribution made by Dr. Sokol resulting in the CC-CHOC being an integral part of the CTSA rather than a group on the side. She reiterated that the CC-CHOC needs to decide upon common goals and send representatives into CTSA groups in order to make certain that the pediatric voice is heard. Dr. Puck stated that the CC-CHOC has an opportunity for pediatricians to be leaders in this new structure, because pediatricians have an established ability to undertake multicenter collaborations. Dr. Guay-Woodford later shared her optimism for the CC-CHOC to chart its own future through the process of setting priorities and aligning with the four strategic goals.

II. Review of CTSA Strategic Plan Initiatives

A. Membership of groups overseeing implementation of Strategic Goals

At present, the CCSC Executive Committee is in the process of asking for CTSA Site PI volunteers to serve on the 4 SGCs. These SGCs will be comprised of 3 PIs, one of whom must be a member of the Executive Committee. Dr. Collier shared that there will likely be an opportunity for CC-CHOC members who are not PIs to participate in the SGCs, but that the process for this has not been worked out yet.

Dr. Puck suggested that CC-CHOC members volunteer to serve on one of the four SGCs. Drs. Gipson and Kon volunteered to serve on SGCs #1 and #3, respectively.

Dr. Guay-Woodford suggested that the CC-CHOC should map the awarded administrative supplement to the appropriate SGC. Dr. Puck offered a brief description of the project, which will be coordinated with another award to the Translation Committee. Both projects are to look at biobanks.

III. Report from CC-CHOC Workgroups

A. Metrics of Success – Dr. Barkin

In describing the origin of the workgroup, Dr. Barkin reminded the group that at the June Face-to-Face meeting, Drs. Alving and Hayward challenged the CC-CHOC (then called the POC, Pediatric Oversight Committee) to demonstrate how the program is creating value and how its value can be measured and tracked. They also noted that pediatric information is required for periodic progress reports to Congress. In response, the workgroup aims to create a dashboard that will indicate whether the starter metrics (below) reflect the value-added element that the CTSA program seeks. The seven metrics decided upon in order of priority are:

1. Number of child health research grants (% funded)
2. Number of child health/pediatric trainees in clinical/translational research
 - a. Indication of mentoring: number of pediatric research mentors with K24 funding; number of pediatric researchers with K23 funding.
 - b. Examine if training needs are met; include subspecialty involvement
3. Number of pilot grants in child health research
4. GCRC pediatric studies
 - a. Number of FTE study nurses available to support pediatric research
5. Proportion of funding spent on pediatrics as a percentage of CTSA budget
6. Number of submitted child health grants working with other CTSA
7. Pediatric participation in CTSA leadership by institution.

Currently, the workgroup, which includes representatives from 10 different CTSA, is in the process of operationalizing the metrics. In the long term, the workgroup would like to interdigitate with groups, such as the Informatics Key Function Committee, in order to determine common approaches. The next step is to determine what exists across CTSA sites in a systematic manner. Dr. Gipson indicated that communication with IT groups is taking place on an institutional level and encouraged earlier interaction between the CC-CHOC and other CTSA Key Function Committees.

B. Pediatric Drug and Device – Drs. Li and Marcus

Dr. Li provided a brief overview of the workgroup mission and goals. She also shared that the Drug and Devices Workshop Face-to-Face meeting has been rescheduled for February 26, 2009 and will take place on the 6th Floor of Building 31 at the NIH campus in Bethesda. The purpose of the meeting is to have members of the CTSA Consortium, other academia, industry, FDA and NIH collaborate and arrive at shared goals to work on together. The preliminary agenda has been circulated and an announcement will be sent shortly to CC-CHOC members. Dr. Puck suggested including leadership of the four new SGCs and pediatricians who are members of existing CTSA working groups in meetings.

Dr. Marcus stated that the workgroup had begun work on another activity, a “centralized IRB”, which might be piloted using pediatric clinical trials being conducted within the CTSA Consortium. The goal of this endeavor would be to shorten the duration of IRB review of pediatric trials and potentially improve the quality. The workgroup discussed several different IRB models, including but not limited to outsourcing to a commercial IRB and developing their own IRB analogous to COG. Dr. Marcus then noted that development of “alternative IRB models” is the goal of at least 4 separate CC-CHOC workgroups within the CC-CHOC. This highlights the importance of the issue to Child Health, so it is important to avoid project overlap, duplication of efforts, and inefficient use of resources. The drug & device workgroup will therefore suspend its independent efforts and will instead assist the Pediatric Research Ethics workgroup.

Drs. Kon and Hirschfeld, representing the Pediatric Research Ethics Workgroup (PREW) added that they plan to hold a web-based conference in Spring 2009 to present alternative IRB models suggested by members of the CC-CHOC and the Clinical Research Ethics and Regulatory Knowledge Key Function Committees.

The desired result of the conference is to select one or two models to conduct a pilot study using pediatric clinical trials being conducted within the CTSA. Dr. Kon noted that any model trial would require significant support, probably through an administrative supplement.

The Pediatric Drug and Device workgroup sees itself mapping to Strategic Goals #1, #2, and #4, and will redirect efforts to set up a network within the CTSA for conducting pediatric drug and device studies.

C. Pediatric T2 Research – Dr. Gipson

Dr. Gipson discussed the goals of the workgroup, which include creating a project registry to support clinical research, expanding the NICHD network listing, promoting partnerships in funding and disseminating research opportunities from NIH and other federal entities. She noted that the workgroup maps into SGCs #1, #2 and #4.

She also discussed the recent Feasibility Awards announcement, which allows for one application per institution. She noted that within an institution, there may be competing opportunities that end up shutting out child health research. Dr. Gipson would like to request specific language allowing more than one application per institution if a pediatric project is to be included.

IV. Spring Meeting with PAS

A. Deadline to Submit Abstracts – December 3

The next CC-CHOC Face-to-Face meeting will be on Friday, May 1, 2009, a day prior to the start of the PAS Meetings in Baltimore (May 2-5, 2009). Dr. Puck reported that the CC-CHOC is now a PAS alliance society, which allows usage of meeting space and the opportunity to network with other organizations. There will be a two-hour symposium on CTSA activities, which will be co-chaired by Drs. Hay and Guay-Woodford. There will also be a platform session designated for CTSA research. Each CTSA institution is asked to submit one or more abstracts under this topic, which can be done using the instructions below on the PAS website (<http://www.call4abstracts.com/pas/>).

* Using the online PAS abstract submission program, please note that item #6, question 1, is "Topic Choice". In this section, there is a special note on the CTSA activities. Enter the appropriate "Subspecialty Choice". Under the "Theme Choice" menu, please select "CTSA Supported Pediatric Clinical Translational Research."

V. Other New Business

A. Collaboration with the National Children's Study (NCS)

Dr. Hirschfeld noted that he frequently gets asked about CTSA overlap with the NCS. He suggested that CC-CHOC members may meet with NCS leadership at any time to determine opportunities for collaboration and information sharing. He also suggested having NCS leadership present at either an ad hoc or scheduled CC-CHOC meeting. Dr. Puck asked for CC-CHOC members who are involved with the NCS to act as liaisons and to identify themselves to Dr. Hirschfeld.

VI. Action Items

| # | Action Items | Owner | Due Date |
|----------|--|--|-----------------|
| 1 | Submit multi-institutional protocols to Dr. Kon to be considered as a model | CC-CHOC Members | 1/19/09 |
| 2 | Volunteer to serve on Strategic Goal Committees, as Child Health liaison on existing CTSA consortium workgroups, or on current CC-CHOC Workgroups (send e-mail to the PI at your CTSA site and to hashemi_paymon@bah.com) | CC-CHOC Members | 11/7/08 |
| 3 | Contact Drs. Li and Marcus re: examining research opportunities concerning delivery systems to reduce medical errors and finding devices to decrease those errors | Dr. Zwerdling | 11/7/08 |
| 4 | Find out information re: specific language in Feasibility Awards & extent of "lead time" in advance of release of RFP; request that to accommodate Pediatrics requests a 2 nd application per institution be allowed | Dr. Purucker | 11/7/08 |
| 5 | Follow up on potential collaboration with NCS; CC-CHOC members who are involved, or whose institutions are involved with NCS are asked to email Dr. Hirschfeld with suggestions on forming linkages with CC-CHOC | Dr. Hirschfeld | 11/30/08 |
| 6 | Present brief workgroup report at next CC-CHOC web conference | Drs. Green/Steiner and Drs. Hirschfeld/Kon | 1/26/09 |