

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)
Quarterly Web Meeting
November 2, 2009**

Meeting Summary

Time: 11:30 AM – 1:00 PM ET

CTSA Attendees: B. Ramsey (Univ. of Washington, Chair); S. Barkin (Vanderbilt, Chair-Elect); M. Aitken (Univ. of Arkansas); W. Allen (Univ. of Florida); S. Arslanian (Univ. of Pittsburgh); J. Barnard (Ohio State Univ.); H. Bauchner (Boston Univ); W. Borkowsky (NYU); J. Cody (Univ. of Texas Health Science Center at San Antonio); J. Davis (Tufts); L. Epstein (Northwestern); J. Fowlkes (Univ. of Arkansas); N. Green (Columbia); L. Guay-Woodford (Univ. of Alabama, Birmingham); J. Gurney (Univ of Michigan); J. Hall (Stanford); B. Hay (Univ. of Colorado, Denver); J. Herndon (Univ. of Florida); J. Heubi (Univ. of Cincinnati); C. Hobbs (Univ. of Arkansas); A Hoberman (Univ. of Pittsburgh); C. Huskins (Mayo); R. Jacobs (Univ. of Arkansas); F. Kaskel (Albert Einstein); A. Kemper (Duke); A. Kon (UC Davis); J. Li (Duke); J. MacHardy (Univ. of North Carolina, Chapel Hill); C. Marcus (Univ. of Pennsylvania/CHOP); E. Mendonca (Univ. of Chicago); J. Murray (Univ. of Iowa); E. Neufeld (Harvard); K. Peck (Univ. of Texas Southwestern Medical Center at Dallas); J. Perrin (Harvard); A. Phillips (UC Davis); J. Puck (UCSF); M. Rathore (Univ. of Florida); L. Ross (Univ. of Chicago); D. Schatz (Univ. of Florida); T. Shanley (Univ. of Michigan); B. Smith (Duke); P. Stacpoole (Univ. of Florida); B. Steiner (Oregon Health and Science Univ.); D. Stevenson (Stanford); P. Szilagyi (Univ. of Rochester); S. Vasan (Rockefeller); R. Yogev (Univ. of Chicago); C. Wagner (Medical Univ. of South Carolina); N. White (Washington U); P. Zeitlin (Johns Hopkins)

NIH Attendees: C. Boyce (NIDA); E. Collier (NCRR); S. Hirschfeld (NICHD); M. Purucker (NCRR); F. Bowen (Booz Allen PM)

All presentations are posted on CTSAweb.org at: http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=27#MID1537

I. BPCA Outcome Administrative Supplement Awards Overview (Dr. Bonnie Ramsey, Chair)

Dr. Ramsey provided an overview of the BPCA Outcome awards, and thanked NICHD for this opportunity. Dr. Hirschfeld said the amount awarded increased from the original \$5 million to \$8 million due to the high quality of applications received. The award is not recurrent, and the content of future RFAs have yet to be announced.

Dr. Purucker announced that the NCRR Office of Communications will issue a press release in the near future announcing the CTSA BPCA Outcome Awards as a successful joint effort between NCRR and NICHD.

II. CTSA Consortium Steering Committee (CCSC) face-to-face meeting, October 8-9 2009 (Dr. Bonnie Ramsey, Chair)

The purpose of the CC-CHOC presentation to the CCSC was to review the CC-CHOC accomplishments and the CC-CHOC two, seven and twenty year goals. In addition to the BPCA Outcome projects, the accomplishments include a multi-center IRB pilot proposal, a data collection tool to track child health activities at individual CTSA sites, a virtual biorepository for rare diseases, and development of active partnerships with NICHD and PAS. Dr. Ramsey noted that these accomplishments are well-aligned with CTSA Consortium strategic goals and key functions. The two, seven, and twenty year goals were reviewed, which initially build upon existing CC-CHOC accomplishments and later envision a comprehensive clinical and translational child health research community that supports career development and sponsors research studies spanning the entire lifespan from child to adult.

The key outcomes of the CCSC meeting are increased visibility of the CC-CHOC, renewed focus on issues important to child health such as Rare Disease and Lifespan research, and an improved linkage

between the CCSC and the CC-CHOC. To facilitate communication and collaboration, the CC-CHOC will present at the monthly CCSC meetings, which are on the 3rd Tuesday at 1 PM ET.

III. 2010 Pediatric Academic Society (PAS) and CC-CHOC Face-to-Face Meeting (Dr. Bonnie Ramsey, Chair)

This year the PAS meeting is in Vancouver, BC on May 1-4, 2010 and three submitted CTSA symposia have been accepted with two potential CTSA abstract platform sessions. Fellow/trainee support will not be possible unless the R13 is funded. As a reminder, abstracts are due November 18. CC-CHOC participants should remind those at their CTSA of the following instructions to submit an abstract: under "theme" select "CTSA supported pediatric clinical translational research."

The CC-CHOC annual face-to-face meeting will be held 8:00 AM -12:00 PMPT at a hotel (TBD) near the Vancouver Convention Center. The first annual CC-CHOC workshop will be held 1:00 -5:00 PM PT at the same location. The workshop is entitled "Informatics – *State-of-the-Art* Skills and Applications." The workshop will be supported by funds from the R13 grant proposal, assuming it is funded, but if not, the program will be the same, but a registration fee for all participants (\$50-\$100) will be necessary.

IV. Metrics of Success (Dr. Shari Barkin, Chair Elect)

The goal of the Metrics of Success data collection is to measure the spectrum of child health research supported by the CTSA grant at awardee institutions in order to develop a baseline for each institution to follow their progress over time. The data are not intended for comparisons across CTSA institutions. Only research that is supported by the CTSA grant should be collected. Data collections are to be submitted before the end of January 2010 in order for the results to be available at the annual CC-CHOC f2f meeting in Vancouver. The data collection should capture the past grant year (not fiscal or calendar year) for the most recent year that the institution has participated in the CTSA. The new 2009 CTSA should begin collecting data now, and will have only a few months of data to report in January.

The Metrics of Success Workgroup piloted the data collection effort at their sites, and revised the metrics based on this experience and the feedback received. The group anticipates there may be difficulties in gathering some of the data and requests this information be captured in the Metrics of Success tracker. In December, Dr. Barkin will distribute a reminder reemphasizing which data should be collected.

V. Upcoming Workshops Update (Dr. Steven Hirschfeld, NICHD)

The November 18-19, 2009 workshop, "Methodologies to Set Priorities for Child Health Clinical Research" will be held at the Natcher Auditorium (NIH campus) and videocast. Participants at this information-sharing conference will explore and discuss various approaches to establishing priorities once needs are identified for using resources in research investment. Agencies, funding organizations and companies need to develop systematic approaches to allocating available resources and infrastructure that account for factors such as public health need, scientific opportunity, available infrastructure, technical feasibility, project resource footprints, potential impacts, cultural willingness, investigator interest, availability of appropriate and informative populations, regulatory programs, and funding and economic incentives. This two-day meeting will focus on methods and approaches to populations of interest, whether they are defined by geographic region, age, condition, or other factors. A discussion of the Best Pharmaceuticals for Children Act initiative and activities will also be part of this workshop.

Presenters include representatives from the U.S. Department of Health and Human Services, the National Institutes of Health, the World Health Organization, the European Medicines Agency, the United Kingdom Economic and Social Research Council, the United States Agency for International Development, the William J. Clinton Foundation, the Alfred Mann Foundation, the Cystic Fibrosis Foundation, the Leukemia and Lymphoma Society, the London School of Pharmacy, major pharmaceutical companies, small biotech companies, investment advisors and other funding organizations.

General meeting information: <http://www.nichd.nih.gov/about/meetings/2009/111909.cfm>

Lodging information: <http://clinicalcenter.nih.gov/about/visitor/hotels.shtml>

Airport and directions: <http://www.nih.gov/about/directions.htm>

Please note that the listings under lodging that refer to a shuttle refers to a shuttle restricted to patients undergoing treatment at the NIH Clinical Center.

Participation in the meeting will also be available through *NIH Videocasting and Podcasting*. Please review the instructions at www.videocast.nih.gov and test the software and connection in advance using the "Test Computer" function.

The Data Acquisition Workshop has been rescheduled for February 25, 2010 (originally scheduled for August 27, 2009). The focus will still be pediatrics, but the agenda planning team will ensure it has a broad appeal across the CTSA Consortium. To plan the workshop, CC-CHOC will work with other CTSA committees who have an interest in the topic. More information will follow in the near future.

VI. NIH Coordinator CC-CHOC updates (Dr. Mary Purucker, NCRR)

An important goal of the CC-CHOC is to ensure child health interests are represented on all relevant CTSA consortium-wide committees. There is a particular need for volunteers for the Education, Training, & Career Development (ETCD), Communications, and Informatics Key Function Committees. Volunteer liaisons do not need to attend all of the committee meetings, but should connect with the committee leadership on a regular basis to ascertain need and provide the child health perspective on projects.

CTSA Consortium-recommended Core Competencies for the next generation of clinical and translational science investigators have been posted on www.ctsaweb.org since July 2009, however, the document does not include the pediatric/child health perspective. Volunteers are needed to review the Core Competencies document and to provide appropriate child health-related edits. Please contact Dr. Purucker or Farrell Bowen if interested.

The Pediatric-Adult Lifespan Workgroup is a new CC-CHOC workgroup being organized by Dr. Bill Hay (U-CO). Dr. Hay sent an email request to those who expressed interest in the group to develop the mission, goals and purpose of the workgroup. After responses are received, Dr. Hay will compile them and schedule a teleconference to discuss.

The Rare Diseases Workgroup will now be a Consortium-wide group. The new co-chairs are Drs. Peter Merkel (BU) and Robert (Berch) Griggs (U Rochester). Volunteers are being accepted for a third co-chair, focused on pediatric rare diseases.

The Pediatric Research Ethics Workgroup will continue to have strong ties with the Clinical Research Ethics Key Function Committee.

VII. Multi-Center Pediatric Clinical Trial Issues

a. Multi-Center Pediatric IRB Model Discussion (Dr. Hirschfeld, PREW co-chair)

The Pediatric Research Ethics Workgroup (PREW) has been gathering information and examining approaches to the Institutional Review Board (IRB) process for pediatric multisite studies in a systematic fashion that included two conferences, on September 11, 2007 and April 23, 2009. Following input from the conferences and a presentation and discussion with the Secretary's Advisory Committee on Human Research Protections on July 21, 2009, the PREW is preparing to implement a pilot project of a federated model for linking IRBs through an operations center and aligning IRB practice through a compact that outlines the principles, process and performance expectations of IRBs that volunteer to participate in the federation. Anyone interested in the topic is invited to join the effort. SACHRP Presentation: <http://www.ctsaweb.org/uploadedfiles/Hirschfeld%20SACHRP%2020090721c.pdf>.

b. Drugs & Devices Workgroup (Dr. Marcus, Drugs & Devices co-chair)

The Drugs and Devices Workgroup has discussed the potential benefit of centralizing scientific review of multisite pediatric studies conducted or supported by the CTSA's. While there is a parallel effort to improve the efficiency and decrease delays through coordinated IRB review, there are data to

suggest that delays caused by the scientific review process are equal to or greater in magnitude than those related to IRB review. The proposed approach is to focus on CTSA sites that are also participating in the National Children's Study (NCS), and have those sites to agree to a Memorandum of Understanding (MOU) for joint approval. The site where the PI of the study is located could be considered a lead site and complete the initial scientific review. For this effort, there will be a separation of the IRB process and the scientific review process, because of the many complexities of IRB review. It was felt that coordinated scientific review starting with federally funded studies that had undergone NIH scientific review would be the best candidates for such an effort. The next step is to inform the PIs at each CTSA site about the effort. There was a quick poll, and about half of the respondents do a scientific review for NIH funded studies. The long term goals are to expand to all pediatric CTSA studies, expand to all CTSA studies and then expand to all major foundation studies.

VIII. Planning Grant for Phase III Trials (Dr. Peter Stacpoole)

[Dr. Peter Stacpoole](#) discussed a potential planning grant for Phase III trials of therapeutics to benefit rare diseases. Please contact him for more information.

Workgroup Information- To join a CC-CHOC workgroup email [Farrell Bowen](#).

Workgroup	Chair(s)	Meetings (ET)
Metrics of Success	Dr. Shari Barkin	Quarterly - Dec 4 2 PM
Pediatric-Adult Lifespan	Dr. Bill Hay	TBD
Pediatric Drugs & Devices	Drs. Steven Hirschfeld, Jennifer Li, Carole Marcus	Monthly - 2 nd Fri, 4 PM - Nov 13
Pediatric Research Ethics	Drs. Steven Hirschfeld and Theresa O'Lonegan	Bi-monthly - 4 th Mon, 2 PM - Nov 23
Pediatric T2 Research	Drs. Alex Kemper and Eneida Mendonca	Monthly - 4 th Weds or Thurs, 4 PM - TBD
Rare Diseases	Drs. Robert Griggs and Peter Merkel	Monthly - 4 th Mon, 4:30 PM - Nov 23

Action Items

#	Action Items	Owner	Due Date
1	Speak with leadership at your CTSA about the importance of CC-CHOC	All	
2	Submit at least 1 abstract (ideally 2-4) to the PAS Abstract Program under "CTSA Supported Pediatric Clinical Translational Research"	Each CTSA site	November 18, 2009
3	Save-the-Date: CC-CHOC F2F meeting and Workshop is April 30, 2009 and PAS is May 1-4	All	
4	Collect Metrics of Success Data	Each CTSA site	January 2010
5	Attend the "Methodologies to Set Priorities for Child Health Clinical Research" Workshop at Natcher Auditorium or www.videocast.nih.gov/	All	November 18 – 19, 2009
6	Volunteer to be the CC-CHOC liaison to the Informatics, Communication and Education KFCs	All	
7	Inform PIs and develop next steps for the multi-center centralized scientific review pilot	Drugs & Devices Workgroup	
8	To be added to a Workgroup, email Farrell Bowen	Any interested CC-CHOC participant	Can join a Workgroup at any time