

**CTSA Consortium-Child Health and Oversight Committee (CC-CHOC)
Face-to-Face Meeting
May 1, 2009
Meeting Summary**

CC-CHOC Face-to-Face Meeting

Attendees: B. Ramsey, Univ. of Washington (Chair); S. Hirschfeld, NICHD (NIH Coordinator); M. Purucker, NCRR (NIH Coordinator); S. Barkin, Vanderbilt Univ.; J. Barnard, Ohio State; H. Bauchner, Boston Univ.; C. Boyce, NIDA; J. Cody, UT-San Antonio; C. Dampier, Atlanta; J. Davis, Tufts Univ.; S. Denne, Indiana Univ.; D. DiMichele, Weill Cornell; L. Epstein, Northwestern Univ.; P. Giardina, Weill Cornell; D. Gipson, UNC; L. Guay-Woodford, UAB; D. Hale, UT-San Antonio; W. Hay, Univ. of Colorado Denver; A. Hayward, NCRR; R. Higgins, NICHD; A. Hoberman, Univ. of Pittsburgh; C. Huskins, Mayo; S. Kashyap, Columbia Univ.; F. Kaskel, Einstein; A. Kon, UC-Davis; L. Leslie, Tufts Univ.; B. Lubin, UCSF/CHORI; Y. Maddox, NICHD; C. Marcus, Univ. of Pennsylvania/CHOP; E. Mendonca, Univ. of Chicago; A. Morrow, Cincinnati; M. Msall, Univ. of Chicago; E. Neufeld, Harvard Univ.; D. Peden, UNC; J. Perrin, Harvard; A. Philipps, UC-Davis; J. Puck, UCSF; C. Quinn, UT-Southwestern; L. Ross, Univ. of Chicago; P. Scheidt, NICHD; T. Shanley, Univ. of Michigan; T. Simon, Utah; B. Smith, Duke Univ.; B. Smoyer, Ohio State; R. Sokol, Univ. of Colorado Denver; R. Steiner, OHSU; J. St. Geme, Duke Univ.; D. Stevenson, Stanford Univ.; B. Stoll, Atlanta; A. Willoughby, NCRR; R. Yogev, Northwestern Univ.; A. Zajicek, NICHD; F. Bowen, Booz Allen; M. Greene, Booz Allen; P. Hashemi, Booz Allen; R. Samavedam, Booz Allen

I. Welcome and Operations Group Report

Dr. Jennifer Puck

Dr. Puck welcomed the meeting attendees and thanked the meeting organizers for their efforts.

Dr. Puck reviewed the CC-CHOC organizational structure, including the leadership of the Operations Group and the workgroups. The entire CC-CHOC meets quarterly as a web conference and annually for a Face-to-Face meeting. The Operations Group meets monthly via teleconference. Workgroups meet at varying intervals depending upon need and activities. The CC-CHOC has resources with which to conduct these recurring teleconferencing/web conferencing activities, some of which are supported by Booz Allen Hamilton consultants. Other resources include an electronic Wiki space.

The CC-CHOC's goals were reviewed, as well as the original and current structure of the CTSA Consortium Steering Committee (CCSC). The current CC-CHOC goals are to build partnerships (e.g. PAS, NICHD), to build infrastructure (e.g. sharing resources) and to support the training of new investigators in child health research. Dr. Puck encouraged attendees to keep these goals in mind throughout the meeting.

II. Status of Child Health Translational Research, opportunities and challenges in the CTSA

Dr. Anthony Hayward

Dr. Hayward, Director, Division of Clinical Research Resources, NCRR, introduced the NIH program liaisons, Dr. Purucker and Dr. Hirschfeld. He also introduced a new member of NCRR, Dr. Anne Willoughby, who recently transitioned from NICHD and is a pediatrician.

Dr. Hayward explained the genesis of the CTSA program as a NIH Roadmap initiative that was originally envisioned as a consortium comprised of 60 CTSA sites. The first 12 CTSA sites were funded in 2006. Twelve (12) more CTSA sites were added in 2007 and 14 in 2008. The funding of

the University of Cincinnati CTSA as the first of the 2009 cohort was announced a few weeks before the CC-CHOC annual meeting, bringing the current total to 39, more than halfway to the goal of 60 CTSA sites.

The goal of the CTSA Consortium is to transform the clinical research enterprise and thereby to improve the process of developing treatments for humans, the so-called bench-top to bedside process. NIH has a considerable investment in the sites receiving CTSA awards. Last year in 2008, the then-38 CTSA sites accounted for 41% of NIH's extramural funds. From the NCRP perspective, the CTSA Consortium secures cross-efficiency by providing an infrastructure that can be shared across CTSA sites.

The current governance structure of the Consortium includes the CTSA Consortium Steering Committee (CCSC), which is comprised of the PIs from each CTSA site and who each have one vote on the Committee. There are five Strategic Goal Committees (SGC) and a greater number of Key Function Committees (KFC), which map to the SGCs. Details of this mapping will be covered during the afternoon session. There are NIH liaisons on all the CTSA Consortium committees who participate in committee-specific activities.

NCRP supports CTSA Consortium-wide activities through the awarding of administrative supplements. This has included a CC-CHOC virtual biobank project intended to support multicenter research on pediatric rare diseases.

This year, through funds generously provided by the NICHD, it was possible to offer administrative supplements for pediatric outcome research in support of the Best Pharmaceuticals for Children Act (BPCA). In addition, approximately \$310M of the American Recovery and Reinvestment Act (ARRA) funds will be allotted to NCRP awardees through administrative and competing supplements and RFAs, some of which will benefit child health research.

The funding of child health research ought to enhance the likelihood of preventing adult diseases, benefiting the health of the nation. Dr. Hayward noted that pediatricians participate on most CTSA consortium committees, including the CCSC. Pediatrics is also represented through the 18 dedicated children's hospitals within the CTSA sites. The CC-CHOC facilitates additional opportunities for collaboration.

Opportunities for regional and national partnerships were described, including for states that do not presently have CTSA sites. The training more child health researchers is considered to be an initiative of great importance. Many conference attendees agreed that the number of researchers entering the field is too low at less than 10% of total researchers.

III. Collaborative Opportunities between the CTSA and NICHD

Collaborative Opportunities between the CTSA and NICHD

Dr. Yvonne Maddox

Dr. Yvonne Maddox, Deputy Director, NICHD, presented an overview of the clinical research portfolio of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

Established in 1962, the NICHD mission is "to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation." NICHD has a budget of \$1.26B, 90% of which is dedicated to extramural funding. There are approximately 2000 clinical research projects with an estimated 1700 PIs at 500 institutions doing work in 27 countries with a budget of about \$650M. The total

annual NIH budget for pediatric research is approximately \$3B. The NICHD Extramural program is organized into 4 centers, each with a specific focus.

- Center for Population Research
- Center for Developmental Biology and Perinatal Medicine
- Center for Research for Mothers and Children
- National Center for Medical Rehabilitation Research

Dr. Maddox also described NICHD's multi-institution support, with NICHD completely or partially supporting 60 clinical research consortia or networks. She emphasized that building fruitful partnerships, such as those which NICHD have with other NIH ICs and other Department of Health and Human Services agencies and non-government organizations, requires time, planning and commitment, but is necessary for effective resource use. Dr. Maddox noted extensive overlap between NICHD funded clinical research network sites and CTSA sites.

Additional information is listed on the Clinical Research section of the NICHD public web page (<http://www.nichd.nih.gov/health/clinicalresearch/NICHD.cfm>). For an NIH-wide inventory of Clinical Research Networks, please visit <https://www.clinicalresearchnetworks.org/>.

The National Children's Study

Dr. Peter Scheidt

Dr. Peter Scheidt, Director, National Children's Study (NCS), provided a brief overview of the study aims, the concept and the planning process. Prior to the formation of the NCS (www.NationalChildrensStudy.gov), there was a series of converging factors, including children's critical windows of vulnerability, environmental effects (e.g. lead, fetal alcohol), identified exposures of concern, and diseases and conditions with possible environmental cause. This led to the formation of the President's Task Force on Environmental Health and Safety Risks to Children in 2000, and later, necessitated by the Children's Health Act of 2000, which stated that NICHD is "to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development."

The study, which has a planned sample size of 100,000, aims to identify potential environmental effects, determine potential preventable causes of conditions and diseases in children, and serve as a national data resource for future studies. The study begins enrollment with pregnant women and then follows the children for 20 years

The planning process for the NCS included interagency coordination, advice and input from federal and non-federal scientists, workshops, pilot studies, and other diverse entities, including the public. The NCS started with seven vanguard sites, which are fully funded through 2010. Enrollment began in 2009. There are 36 Centers awarded to conduct the study in 88 study locations (17 un-awarded locations) and a Data and Clinical Coordinating Center has been established. Dr. Scheidt noted that there is extensive overlap between NCS locations and CTSA sites.

The structure for enrollment consists of household recruitment and supplemental recruitment. Household recruitment consists of women in their first trimester of pregnancy, women who are planning a pregnancy and women of child-bearing age who are not planning pregnancy but could become pregnant during the four-year enrollment period. Supplemental recruitment comprises prenatal providers and community-based recruitment of eligible women. Data collection mechanisms include interviews, physical examinations, environmental samples, biospecimen collection, ultrasounds, questionnaires, diaries and observation outside the home.

Dr. Scheidt stated that the NCS is a platform for adjunct studies (e.g. genomic analysis of subgroup specimens for targeted gene-environment interactions, functional neuro-imaging of exposed subgroup for mechanism of effect on child development). With respect to use and

access to data, de-identified data will be made available to qualified researchers. Access to disclosed datasets will require legally binding agreements between investigators, organizational officials and the US government.

Harmonizing Terminology for Child Health Research

Rajni Samavedam

Ms. Rajni Samavedam, Booz Allen, described an effort being led by NICHD to harmonize terminology for child health research beginning with the examination of the newborn, and noted that arriving at a consensus terminology is a fundamental step toward enabling interoperability among systems associated with pediatric clinical research. Currently, there is a robust yet highly fragmented enterprise that must compete for limited resources with other endeavors. A major goal is to transform the infrastructure into one with interoperable components to leverage the expertise but eliminate redundancies and improve efficiency.

Ms. Samavedam discussed that identifying and curating terminology is a systematic process that involves tools and workflows. One of the tools is an open-sourced repository available through the National Cancer Institute (NCI), which allows researchers to collect data for a study. The workflow consists of identifying concepts and reference terminology, developing a model, annotating a model and then loading metadata and generating forms. To facilitate data sharing and collaborative research, NICHD initiated a prototype pediatric terminology project. To date, an initial newborn examination model has been developed for community review and input, to be followed by terminology identification, consensus and curation.

If there are any questions about or interest in providing input into the Newborn Examination Prototype effort, CC-CHOC members are encouraged to contact Dr. Steven Hirschfeld, Associate Director for Clinical Research, NICHD (hirschfs@mail.nih.gov).

Administrative Supplements Update

Dr. Anne Zajicek

The deadline date for the recent administrative supplements was April 30, 2009, which was the day before this year's CC-CHOC conference. Information is preliminary, but at present, NCRP is conducting a series of administrative reviews. Drs. Purucker and Zajicek offered positive remarks about the projects submitted.

IV. CC-CHOC Workgroup Overview Reports: Mission and rundown of past year's accomplishments. Identify Workgroups for purpose of breakout sessions

Pediatric Drugs and Devices

Dr. Carole Marcus

Dr. Marcus stated that the Workgroup goals are to facilitate collaborative translational and clinical research so that drugs and devices that meet the needs of children may be more effectively developed. This will be achieved through partnership between industry, academia, and NIH. She noted that the breakout session would focus on next steps following the February 26 workshop on "Pediatric Drug and Medical Device Development."

Pediatric Research Ethics

Dr. Alex Kon

Dr. Kon described the Pediatric Research Ethics Workgroup as a combined effort between the CC-CHOC and the Clinical Research Ethics KFC. He reported that the PREWG had held a web-based videoconference on April 23, 2009, entitled "Comparing IRB Models for Multisite Pediatric Studies", and that the breakout session would focus on the next steps following that conference.

Metrics of Success*Dr. Shari Barkin*

Dr. Barkin stated that she will she present the Starter Metrics in the afternoon. She noted that the metrics were vetted by approximately 10 institutions. The goal of the breakout session was to ascertain next steps on utilizing the Starter Metrics to achieve goals.

Rare Diseases*Dr. Robert Steiner*

Dr. Steiner described the origin of the Rare Diseases Workgroup, as well as its current activities and potential for future collaboration. He emphasized the importance of facilitating the systematic study of patients with rare diseases as well as providing training on rare disease research to new and junior investigators. He added that he would like the Workgroup to be a platform for education on rare diseases and for providing resources for researchers.

Pediatric T2 Research*Dr. Deb Gipson*

Dr. Gipson stated the Pediatric T2 Research Workgroup is open to additional membership. Potential milestones include developing a project and network registry, establishing partnerships for collaborative research, and developing an educational curriculum. Dr. Gipson also invited CC-CHOC to a special interest group meeting on T2 Research taking place on the morning of May 5.

Pediatric-Adult Life Span Workgroup and Other Workgroups

Dr. Hay reported that the Pediatric-Adult Life Span Workgroup will assemble and schedule meetings in the near future. CC-CHOC members who are interested in this workgroup should contact Dr. Hay and Ms. Farrell Bowen.

Members discussed the formation of a workgroup focused on Child Health Research Education. If an individual is interested in leading this group, he/she should contact Drs. Ramsey and Barkin.

Dr. Puck then invited CC-CHOC members to offer ideas for new groups. There was a suggestion from Dr. Carole Lannon (carole.lannon@cchmc.org) to have a child health workgroup that addresses study design from an Informatics orientation.

V. Nominee statements for CC-CHOC Chair Elect and Conduct Voting Process*Moderator: Dr. Bonnie Ramsey*

Dr. Ramsey reviewed the Operations Group membership positions, including the voting members, NIH Coordinators and the ex officio members. The Chair position is a two-year commitment with an option for serving as an ex officio member the following year. Prior to the voting process, each Chair-Elect and Operations Group candidate provided a statement to meeting attendees about what they would like to accomplish as a leader of the CC-CHOC. During this time, Dr. Leon Epstein withdrew his nomination for Chair-Elect.

The election was held. Results may be found in the table, below, with newly elected individuals identified by an asterisk*.

For the 2009-2010 term, Dr. Shari Barkin will be the Chair-Elect. This opened an additional (third) position on the Operations Group. Winners of the election to the Operations Group, Drs. Nancy Green, Bill Hay and Bertram Lubin, will serve for two years.

CC-CHOC Operations Group

Position & Term	Name	Member Institution
Elected Voting Members		
Chair (until 2010)	Dr. Bonnie Ramsey	University of Washington
Chair-Elect (until 2011)	Dr. Shari Barkin*	Vanderbilt University
Operations Group (until 2011)	Dr. Nancy Green*	Columbia University
Operations Group (until 2011)	Dr. Bill Hay (re-elected)*	University of Colorado Denver
Operations Group (until 2011)	Dr. Bertram Lubin*	UCSF/CHORI
Operations Group (until 2010)	Dr. Carole Marcus	University of Pennsylvania/CHOP
Non-Elected Federal Members		
NIH Coordinator	Dr. Steven Hirschfeld	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
NIH Coordinator	Dr. Mary Purucker	National Center for Research Resources (NCRR)
Non-voting Ex Officio Members		
Ex Officio	Dr. Lisa Guay-Woodford	University of Alabama, Birmingham
Ex Officio	Dr. James E. Heubi	University of Cincinnati
Ex Officio, Past Chair	Dr. Jennifer Puck	UCSF
Ex Officio	Dr. Ronald Sokol	University of Colorado Denver

VI. Reports from CC-CHOC Workgroup Breakout sessions

a. Pediatric Drugs and Devices

Dr. Carole Marcus

Dr. Marcus provided a description of the original goals, which have been narrowed in an effort to focus the time and energy of the workgroup. An achievement of this workgroup was the CTSA Consortium Pediatric Drug and Medical Device Development Workshop, which occurred on February 26, 2009. Dr. Marcus also discussed current problems with pediatric academic multicenter studies, such as delays from the IRB, technology transfer, and scientific review. Current initiatives of the workgroup include following up on the February 26 workshop, exploring methods to facilitate and expedite regulatory processes while ensuring subject safety and scientific integrity, exploring other models for developing a research consortium, and reviewing other CTSA committees and workgroups charges in relation to that of this workgroup. With regard to mapping to the SGCs and KFCs, Dr. Marcus emphasized the importance of having representation on the Regulatory Knowledge KFC; she noted, however, that the priorities of this workgroup are not currently being actively addressed by this KFC. There was also a suggestion for the workgroup to collaborate with the Public-Private Partnerships KFC.

In addition to the current initiatives, the workgroup aims to develop a consortium for performing pediatric drug and device studies, construct a post-marketing device surveillance registry, and provide consultative services.

b. Pediatric Research Ethics

Dr. Alex Kon

Dr. Kon reported that the Pediatric Research Ethics Workgroup reviewed exemplar protocols for genetic research involving children, which are posted on the Wiki. The workgroup also called for protocols with significant variability in IRB reviews. To date, the University of Colorado Denver has submitted protocols. With respect to mapping to other Consortium committees, the workgroup maps to SGCs 1 and 3 and to the Clinical Research Ethics, Regulatory Knowledge and Participant and Clinical Interactions Resources KFCs. Current initiatives are to facilitate multicenter pediatric research to ensure excellent protection of children while increasing speed

and simplifying the process for investigators, and writing a white paper on “Appropriate Referrals for 407 Panel Review”. The white paper is expected to be completed by summer 2010.

c. Metrics of Success

Dr. Shari Barkin

Dr. Barkin described that during last spring’s Face-to-Face meeting, Drs. Hayward and Alving emphasized the importance of demonstrating that child health research adds value at CTSA sites. They also emphasized the importance of collaborating with other CTSA sites. As a result of this call for action, this workgroup formed with two objectives.

The first objective is to develop measureable outcomes to capture CTSA infrastructure “value-added” to child health research. The second objective is to identify consistent ways for individual institutions to track their own trajectory over time. Dr. Barkin also emphasized that the key with the metrics is comparing your own institution’s past progress to your own institution’s current progress, and the goal of the metrics of success is to improve upon past performance rather than to be punitive.

Over the last year, the Metrics of Success Workgroup held conference calls to develop the value of metrics and the starter metrics. To determine whether an institution can obtain data, the workgroup pilot tested the metrics at workgroup member institutions.

In reviewing the eight starter metrics with attendees, Dr. Barkin shared a few caveats. She noted that this is an effort to capture existing data rather than investing time in developing new data capture systems. The workgroup aimed to look for common denominators that cross most institutions. The starter metrics can be viewed on CTSAWeb.org.

Potential next steps include the following:

- Bring the metrics to CTSA member’s institutions and initiate a discussion with their PI.
- Consider which metrics are easiest and most meaningful to gather at member institutions and track those metrics over time.
- Work with the Evaluation KFC to integrate metrics throughout the CTSA process.
- Provide starter metrics to external reviewers who go to CTSA sites.
- Determine definition of child health research.

d. Rare Diseases

Dr. Robert Steiner

Dr. Steiner described the accomplishments of the Rare Diseases Workgroup, which include working with the NIH Rare Diseases Clinical Research Network (RDCRN) investigators on a conference grant application and the agenda for the combined 2010 RDCRN / Office of Rare Diseases / CTSA Rare Disease Symposium. Other accomplishments include collaboration with the NICHD-funded Newborn Screening Translational Research Network and a successful administrative supplement application for Rare Disease biobanking. Dr. Puck provided a snapshot of governance issues, rare disease use cases (Down syndrome and severe combined immunodeficiency) and collaboration with an awardee from the Translational KFC to develop the informatics framework for accessing biobank information and samples distributed at sites across the Consortium.

Dr. Steiner also noted that the Rare Diseases Workgroup and the American College of Medical Genetics share common goals, providing opportunities for synergy and collaboration.

With respect to proposed connections to SGCs, the Rare Disease Workgroup may assist SGC 1 by developing a reference library or toolkit that shares documents relevant to IRB review. The workgroup is applying for a R13 conference grant for a Rare Diseases Research Day targeted at junior and new investigators and trainees, consistent with the goals of SGC 2. The distributed

biobanks project maps to the Data Sharing subgroup of SGC 3. These efforts also align with the Clinical Research Management, Education and Career Development, and Informatics KFCs, respectively.

A few key themes signaling potential action are the following:

- Address issue of IRB activities that do not enhance protection of human subjects and may unintentionally impede rare disease research.
- Collaboration in developing and sharing informed consent documents and research protocols
- Database harmonization across research networks
- Demonstrate value of the CTSA's to the greater pediatric research community

A potential action item for the workgroup is to decide whether to recommend legislative action to update the definition of a "rare disease", which is presently defined as an absolute prevalence of $\leq 200,000$ individuals in the United States. This number had been derived during the 1970s as 0.1% of the total population, which was 200 million at the time.

e. Collaboration with National Children's Study

Dr. Dan Hale

Dr. Hale described collaborative efforts with the National Children's Study. He emphasized the need to decide what data to collect and what data fields to use when collecting it in order to assess phenotype. Although the NCS enhances participant volume and thereby potentially study recruitment, limitations include participant burden, the process for acquisition of samples, access to samples, and temporal issues.

f. Pediatric T2 Research

Dr. Gipson reported that they are looking for membership. She added that the workgroup maps to SGC 4.

VII. Relationship Map to Strategic Goals- Presentation and Discussion

Dr. Lisa Guay-Woodford

Dr. Guay-Woodford stated that the exercise of mapping CC-CHOC activities to the strategic goals of the CTSA Consortium was a useful communication tool for describing the accomplishments of CC-CHOC. Moreover, it could also be used to inform CC-CHOC goals. The CTSA Consortium structure was reviewed, including the history of the CC-CHOC. The emphasis on pediatrics, rather than child health, was noted as still present in committee descriptions. After some discussion, it was agreed to move forward with using "child health" to describe activities, in order to include a broader audience.

Dr. Guay-Woodford stated that the SGC formation process is dynamic, demonstrated by the recent addition of SGC 5 to SGC 1-4. In January 2009, the original four SGCs selected their top priorities based on what deliverables could be achieved within a one-year timeframe. The fifth SGC, formed in April 2009, was in the process of developing priorities.

Dr. Guay-Woodford presented the following information about the Strategic Goal Committees and their current activities:

Strategic Goal Committee 1 - Clinical and Translational Research Management Capability

"Improve study process by reducing the time taken to achieve the protocol and contract approval needed to initiate a clinical study" is this SGC's key priority. The committee's deliverable will consist of two pilot studies (one for contracting and one for IRB) which began in April 2009. Following the pilots, which will establish a baseline for future studies of metrics at CTSA

institutions, the data will go through a preliminary analysis and the results will be reported at the Clinical Research Management Workshop in Bethesda, Maryland on June 22-23, 2009.

Strategic Goal Committee 2 - Training & Career Development of Clinical and Translational Scientists

This committee's priority is to provide "open access to training resources across the Consortium." To meet that goal, members will map core competencies and curricula over the next 9-12 months. The deliverable will be a repository of courses accessible through the NIH Clinical Center that will educate and train an increased number of translational scientists. This open access training resource is expected to be available nationally and internationally.

Strategic Goal Committee 3 - Enhancing Consortium-Wide Collaborations

"Research networking capability" is this committee's top priority because it has high impact and high feasibility within the given timeframe, and broad application to the entire spectrum of translational sciences. Committee members will work with the Collaboration Facilitation Group, as the group already has representatives from multiple KFCs. The two primary use-cases that this committee would like to explore are:

1. A tool that gives junior investigators the ability to find experts in any given field, within their own institutions and across the multiple institutions for research projects
2. A tool that assists investigators who seek to build multi-disciplinary research teams

Strategic Goal Committee 4 - Enhancing the Health of Our Communities and the Nation

This Strategic Goal Committee developed two goals to focus on in the next 9-12 months:

1. Sub-goal 4a: "Link and facilitate collaboration among community-based research networks to implement research and best practices"
2. Sub-goal 4b: "Develop capacity and methods for the translation of research results into practice across the healthcare system, including but not limited to health services and health policy research, comparative effectiveness research, and research into the generation and implementation of evidence-based medicine."

Strategic Goal Committee 5 - T1 Translational Research

The current draft definition of T1 research is as follows: T1 research is the component in the continuum of translational research in which scientific advances made in the laboratory are translated into applications relevant for the improvement of human health. This includes developments in diagnosis, therapy, and prevention, through their initial testing in humans, up to the end of phase two in the drug development milieu, incorporating detailed phenotyping in small numbers of patients.

Priorities of the committee may include education and training requirements for T1 investigators, establishing collaborative demonstration projects, and easing the roadblocks for technology transfer. Close collaboration with the Public Private Partnership KFC is anticipated. SGC 5 was formed in April 2009 and is in the process of determining their membership, priorities and outcomes.

Mapping Team

A sub-group of Administrators formed the Mapping Team which performed an extensive data gathering process with the output of a SGC and KFC relationship map. The Mapping Team conducted multiple interviews, collated survey questions and used a mind mapping technique to

draft their final deliverable. A general consensus was that committee members understand their own committee initiatives, but do not have information about other committee's projects.

CC-CHOC Mapping to CTSA Committees

It is a challenge for the CC-CHOC to be mapped to specific committees because the goals and priorities of child health overlap with almost all of the committees. Therefore, the CC-CHOC should brainstorm how to incorporate their priorities into each SGC, beginning with ensuring there are CC-CHOC liaisons on each committee. It was noted that there may be a representative on a committee, but that does not necessarily equate to communicating the CC-CHOC priorities.

The idea of drafting a short synopsis regarding the CC-CHOC priorities was proposed to ensure a unified, effective message is delivered to other Consortium members. When distributed to committee Chairs and NIH coordinators, the document will allow other committees to understand the CC-CHOC goals and deliverables, and relevance to other CTSA initiatives. To draft the synopsis, the group will need a consensus on what the priorities are and how to achieve them.

VIII. Priorities for the Next Year

In early 2009, the Operations Group polled CC-CHOC members to gain consensus about priorities for the next year in relation to the Consortium strategic goals. Although there were a limited number of responses, the Operations Group concluded that a strong connection exists between SGC 1 and the Clinical Research Management Key Function Committee goals. Those two committees are focusing on coordinating IRB processes, recruiting special populations, and developing a mechanism for multi-site collaboration. It was suggested that the CC-CHOC may want to lead an effort to define best practices, identify challenges, and report examples in these areas.

Recently, the CCSC encouraged SGC 5 to develop four to six demonstration projects to facilitate a multi-site study in T1 research. A priority of the CC-CHOC may be to submit one or two proposals for these demonstration projects to ensure child health research is represented.

Meeting participants were asked for input regarding CC-CHOC goals and interaction with the other committees. Representation on each CTSA committee is important so that the CC-CHOC understands all committees' activities and ensures they are functioning with child health goals represented. A main communication issue with this approach is the difficulty of receiving committee updates from the CC-CHOC representative. One proposed solution is for each representative to submit a short paragraph or bulleted list of activities to be distributed to CC-CHOC. In addition, the proposal for CC-CHOC to develop a synopsis of priorities to distribute to other committees was highlighted.

A meeting participant stated the importance of focusing on operational collectives around key functions and then delivering pilot projects involving CTSA's with existing networks and partnerships that involve other CTSA's. Operational efficiencies, such as projects that aim to improve clinical research processes would be particularly valuable. This topic was suggested to be incorporated into the CC-CHOC initiatives.

The R13 conference grant letter of intent is due July 1, 2009. A small group of volunteers will work with the Operations Group to write the letter of intent and to submit the application, which is due on August 12, 2009. Dr. Hayward said that other CTSA Consortium committees have R13 awards for conferences, and speaking with them about the application process may be helpful. All agreed that partnering with the Pediatric Academic Society (PAS) will strengthen the application, although it is unlikely that an application submitted according to the above timeline will be able to fund next year's face-to-face meeting, which is scheduled for May 1-4, 2010 in Vancouver, B.C., Canada.

IX. Summary: Next Steps and Action Items

Dr. Ramsey provided a brief summary of the next steps and action items, which are listed below. She thanked CC-CHOC members for their participation.

#	Action Items	Owner	Due Date
1	If interested in the Pediatric-Adult Life Span Workgroup, contact Dr. Hay and Ms. Farrell Bowen	CC-CHOC members	Ongoing
2	If interested in leading the Education Workgroup, contact Drs. Ramsey and Barkin	CC-CHOC members	Ongoing
3	Initiate a discussion with their CTSA Site PI about the Starter Metrics recommended by the Metrics of Success Workgroup	CC-CHOC members	TBD
4	Synopsis of CC-CHOC priorities (2-3 pages)	Operations Group	TBD
5	PAS Topic Symposium application	Operations Group	July 1, 2009
6	R13 grant letter of intent	Operations Group	July 1, 2009
7	R13 grant application	Operations Group	August 12, 2009
8	Update CTSAweb.org description to replace "pediatrics" with "child health"	Farrell Bowen Paymon Hashemi	May 15, 2009