

Minutes
National CTSA Pediatrics Steering Committee Meeting
National Center for Research Resources
Bethesda, Maryland
March 22, 2007

(All meeting materials including PowerPoint presentations can be viewed at:
www.ctsaweb.org under the Pediatric Steering Committee)

CTSA Investigators

Silva Arslanian, Pittsburgh
Thomas Carpenter, Yale
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
Jennifer Puck, UCSF, Chair
Robert Steiner, Oregon
Peter Szilagyi, U Rochester (via telephone)

Additional Participants

Joseph St. Geme III, Duke
Bertram Lubin, Oakland

NIH Participants

Barbara Alving, NCRR
Cheryl Boyce, NIMH
Lynne Haverkos, NICHD
Anthony Hayward, NCRR
Rosemary Higgins, NICHD
Steven Hirschfeld, NICHD
James McNamara, NIAID
Deborah Merke, Clinical Center
Mirjana Nesin, NIAID
Gail Pearson, NHLBI
Victoria Pemberton, NHLBI
Jennifer Read, NICHD
Susan Shurin, NHLBI
Vince Smeriglio, NIDA
Malcolm Smith, NCI

Welcome and Introductions

Dr. Puck welcomed everyone to the first meeting of the National CTSA Pediatrics Steering Committee (SC) meeting, called the meeting to order at 8:30 am. CTSA investigators and NIH staff were introduced.

Overview of CTSA Organization

Dr. Hayward presented an overview of the CTSA program. When the program was established, NIH envisioned three main goals:

- To strengthen and support clinical research as a discipline;
- To integrate research activities horizontally throughout academic institutions rather than having isolated silos of research excellence; and
- To stimulate translational research to improve public health.

It is expected that 60 awards will eventually be made nationwide. Twelve awards were made initially, and another 8 awards are expected to be made in September 2007. Applications for the third funding cycle are due October 24, 2007. In addition to the 12 initial awards, 52 CTSA planning grants also were made. The CTSA budget will be approximately \$500 million per year by 2012.

A number of Steering Committees have been established by NCRR to facilitate the work of the CTSA, and to promote communication and collaboration across CTSA sites. The SCs consist of investigators from each CTSA site, and are supported by a parallel NIH subcommittee. It is expected that the number and focus of SCs will change over time as specific activities are accomplished and new issues emerge. The role of the SCs is to:

- Serve as a forum for dialogue with NIH staff
- Identify needs, goals, and priorities
- Share experiences and expertise
- Provide a platform to adopt common standards

The purpose of the CTSA Pediatrics SC is to ensure that pediatric populations can take advantage of CTSA resources by fostering the integration of pediatric research into CTSA. Like other SCs, the Pediatrics SC will discuss and formulate recommendations to present to the CTSA Principal Investigator SC at its twice-yearly meetings.

Since the current CTSA were funded, legislation re-authorizing NIH was enacted. This legislation includes the following language about pediatric research in CTSA:

SEC. 106. ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD.

(a) In General- In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by--

(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

(b) Report- As part of the biennial report under section 403 of the Public Health Service Act, the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

(c) Definition- For purposes of this section, the term 'Director of NIH' has the meaning given such term in section 401 of the Public Health Service Act.

In response to this, NCRR has incorporated a provision in the RFA for the FY2008 CTSA awards that will allow for multiple PIs of CTSA, one of whom could be a pediatrician. The CTSA sites already funded in the initial cycle are not required to make changes in response to this legislation, but can use it as a guide to discussing funding and infrastructure for pediatrics.

Ms. McDonald summarized the web resources currently available for communication among CTSA investigators, and between CTSA investigators and NIH staff. General program information can be found at <http://www.ncrr.nih.gov/clinicaldiscipline.asp>, and an interactive site that contains information about current CTSA sites, Steering Committee activities, training and careers, community engagement, and news and events, can be found at <http://ctsaweb.org/>. This site is still under development, and NCRR staff is interested in feedback on its contents, particularly on the Training & Careers and Community Engagement components. The process for submitting something to the web site is to work through the Communications Steering Committee representative at each CTSA site.

Site Presentations

Each Pediatric SC member gave a PowerPoint presentation to answer the questions posed prior to the meeting:

- How is pediatrics integrated into your CTSA?
- What are the key challenges faced by pediatric researchers at your site?
- What are the goals you see for this Steering Committee?

Slides shown at the meeting are posted at www.ctsaweb.org. A summary of the key challenges and goals discussed is included as **Appendix 1**.

Educational DVD

Ms. Pemberton presented the concept for a DVD that would help to educate parents about pediatric clinical research. NHLBI has provided the start-up funds for this project through the cooperative agreement that funds the Pediatric Heart Network's data coordinating center, the New England Research Institutes (NERI). NERI has considerable experience producing award-winning videos about clinical research and related topics. Because of this funding strategy, the DVD will be "owned" by NIH, rather than by NERI, facilitating widespread distribution of the final product. Both NHLBI and the American Academy of Pediatrics have agreed to host the DVD on their public web sites. The DVD will represent diverse populations and be designed to be as accessible as possible to families with limited educational backgrounds. In addition, it will be provided in both Spanish and English versions. The script has been outlined, and researchers, children and families are being identified to be filmed. Filming is expected to begin in the next several weeks. NHLBI will seek contributions from other NIH Institutes and Centers for the remainder of the budget. After discussion, the SC expressed their enthusiasm for this project, and requested that SC members be part of the development process. Drs. Kennedy and Kon offered to participate. Ms. Pemberton will begin working with them on script details, and on incorporating other recommendations from the discussion.

Recommendations

SC members discussed in more detail a number of the issues that had been raised during the individual site presentations. From this discussion, the following recommendations and action items were adopted.

- *Recommendations to the PI Steering Committee*
 - Each Steering Committee should include a pediatric researcher, and those individuals would report back to the Pediatric SC to help facilitate cross-CTSA communication on pediatric research issues.
 - It is a goal of this SC to stimulate an increase in the number of individuals choosing pediatric translational research as a career. To this end, the SC recommends that cross-institutional collaboration be encouraged, and that there be appropriate pediatric representation among K-grant awardees in CTSA. To facilitate the latter goal, it is recommended that each CTSA have one or more pediatricians on the K-grant selection committees.
 - It is recommended that CTSA budgets designate funds for ancillary (i.e., laboratory) expenses and for pilot projects.
- *Additional Action Items*
 - As mentioned above, the SC will be involved in development of the educational DVD.

- The Pediatric SC will form a Working Group to consider ways to foster collaborations among pediatric researchers across CTSAAs, to harness the resources of existing pediatric research networks, to develop pediatric research consensus statements, and to foster academic rewards for team research.
- It was agreed that ethical, IRB and related regulatory issues are paramount for pediatric research and present special challenges. To begin to tackle these issues, it was recommended that an OHRP representative be invited to attend the next SC meeting, that Steven Hirschfeld organize comments on pediatric guidance drafts from the SC to OHRP, and that further discussion of electronic IRB submission tools and central IRBs, among other issues, be continued in more detail at the next meeting.

NB: A summary of recommendations from the other Steering Committees that pertain to pediatric research or to items discussed today is included as Appendix 2.

Meeting Schedule

The SC decided that conference calls would be held quarterly, and that the group would attempt to meet in Toronto at the May PAS meeting. Dr. Pearson will determine who is attending the PAS meeting, and help coordinate a Pediatrics SC meeting there if possible. If not, the next meeting will occur by conference call at the end of June. The meeting was adjourned at 3:10 pm.

Attachment 1: Summary of Challenges and Goals

Money

- Challenges:
 - Rising nursing salaries with flat budgets
 - Reduced research \$\$
 - K restrictions for int'l grads
- Goals:
 - Seed grants for new pediatric projects
 - Ancillaries for pediatric projects

Education and personnel

- Challenges:
 - Fewer peds investigators
 - Education about special ped res issues
 - 75% dedicated time
 - Support for mentors
 - Hiring nurses
 - Unique skill sets
- Goals:
 - Foster links between CTSA sites for trainees and young faculty
 - Have pediatric representation on K committees

Collaboration/Linkages

- Goals:
 - Take advantage of existing Ped res networks/rare diseases
 - National Children's Study
 - Cross-CTSA projects
 - Consensus statements
 - Team research rewards
 - Develop collaborative protocols to collect normative data, biobanks

Communication/Informatics

- Goals:
 - Among peds CTSA leaders
 - Databases – shared; common platform
 - Pediatric representation on CTSA Informatics SC

Regulatory/Admin

- Goals:
 - Actively work to help IRBs understand and support pediatric issues
 - Define minimal risk and minor increase over minimal risk in pediatrics
 - Guidelines for inclusion of kids
 - Clinical care vs. research
 - Assent
 - Adverse events; uniform reporting

Research

- Goals:
 - Develop a common pediatric research agenda
 - Small studies methods
 - Translation
 - End points, biomarkers
 - Normative data, values, samples
 - Testing of drugs for uniquely pediatric conditions and settings
 - Develop joint studies for rare disorders

Integration of Pediatrics into CTSA's

- Goals:
 - Appropriate inclusion at leadership levels
 - Adequate peds representation on all CTSA SCs

Community engagement

- Goals:
 - Involve community physicians in pediatric research
 - Engage the public in pediatric research issues
 - Develop ways to recruit diverse populations

Appendix 2: Pertinent Topics from Other CTSA Steering Committees

Ethics

1. Sharing Ethics teaching materials between CTSA.
2. Developing methods that facilitate early ethics interventions in the creation of clinical protocols.
3. Sharing documents such as informed consent forms for special situations (impaired subjects, storage of materials in biorepositories) between CTSA.

Community Engagement

1. Develop a community engagement needs assessment.
2. Establish/leverage partnerships for funding.
3. Develop a curriculum.

Participant and Clinical Interactions (PCIR)

1. Multi-Institution Protocols, Collaboration Between CTSA.
2. IRB Reciprocity.

Translational Research

1. Create inventory of translational cores and other translational resources available at CTSA sites and elsewhere.
2. Identify, prioritize, and address issues and barriers to T1 research.
3. Develop a set of best practices and procedures for FDA regulatory issues involved in translational research.

Biomedical Informatics

1. Create inventory of informatics resources available at CTSA sites and elsewhere.
2. Develop working group on cross cutting priorities for development of integrated/interoperable Clinical Data Repositories.
3. Address adoption/adaptation of existing external standards and terminologies.
4. Develop CTSA-wide requirements for management tools for clinical studies or trials, including, but not limited to, protocol development, recruitment, identity, security, privacy, data collection and quality.
5. Design programs to educate clinical researchers in informatics.
6. Develop Working Group to address integration of consent management into tools and databases.
7. Consider how to interface clinical care systems (EMRs, LIMS) with clinical research informatics needs.

Evaluation

1. Acceleration of the translation of basic research to clinical studies.
2. Acceleration of clinical studies into community practice.
3. Recruitment, career advancement and retention of CTS researchers.
4. Dissemination of new methods, tools and resources into medical practice.