

CTSA Consortium Oversight Committee Meeting

November 20, 2007

1:00pm-2:00pm

Attendees:

L. Berglund, UC Davis; R. Califf, Duke; B. Alving, NCRR; T. Johnson, Yale; S. Olson, Mayo; C. Will, Emory; J. Atkinson, NIDCR; E. Collier, NCRR; R. Filart, NCRR; F. Grieder, NCRR; A. Hayward, NCRR; K. Kidd, NCRR; C. Lomonaco, NCI; D. McCloskey, NCRR; I. O'Brans, NCRR; C. Rosa, NIDA; D. Rosenblum, NCRR; J. Sachs, NCRR; A. Sawczuk, NCRR; M. Scheideler, NINDS; C. Shreffler, NIEHS; B. Talbot, NCRR; L. Weiss, NCI; D. West, NCRR; A. Austin, Ann Arbor; W. Bajwa, Duke; B. Burnett, Duke; G. Chadwick, Rochester; B. Collier, Rockefeller; P. Davis, Case Western; B. Evans, Washington U; D. Ford, Johns Hopkins; G. Fromell, UPenn; M. Gillis, UC Davis; H. Ginsberg, Columbia; M. Goode, UTHSC; K. Hartman, Mayo; G. Hunninghake, Iowa; P. Johnson, Atlanta-CTSI; J. Kosmyrna, Ann Arbor; J. Malone, UWashington; G. Monroe, UTHSC; E. Orwoll, OHSU; M. Packer, Dallas; K. Schuff, OHSU; R. Sherwin, Yale; R. Sohn, Case Western; J. Solway, Chicago; D. Stephens, Emory; K. Weatherwax, Ann Arbor; T. Wun, UC-Davis; L. Yasko, Pittsburgh; J. Dorries, Booz Allen Hamilton; M. Greene, Booz Allen Hamilton; P. Hashemi, Booz Allen Hamilton; H. White, Booz Allen Hamilton

Welcome and Introductions

Dr. Anthony Hayward welcomed the Oversight Committee members and guests, facilitated the roll call and introductions, and gave a brief summary of the agenda.

1. CTSA Workgroup Updates

Ms. Tesheia Johnson of Yale University provided an update to the Regulatory Knowledge workgroup. Ms. Johnson stated that the workgroup promotes the protection of human subjects and facilitates communicating shared regulatory compliance issues and improvements. The workgroup will work towards providing investigators with integrated training, services, or tools for protocol and informed consent authoring and translation, adverse event reporting, safety and regulatory management and compliance, etc. It will also disseminate best practices that reduce or remove institutional impediments to clinical and translational research and that enhance inter-institutional collaborations.

The priority areas of the Regulatory Knowledge workgroup are to:

- Define and develop the mission, scope and model for the Research Subject Advocacy (RSA) role in the CTSA
- Define and develop the mission, scope and model for the Clinical Research Coordinator (CRC) role in the CTSA
- Facilitate IND/IDE support for the CTSAs
- Facilitate understanding of the changing CMS regulations and the impact on regulatory activities

Year 1 goals have been the initiation of an Alternative IRB Working Group and the first meeting of the Regulatory Working Group on Sept 12, 2007. In Year 2 the group will focus on work on the priority areas as well as collecting metrics of study implementation timelines.

Dr. Michael Joyner of the Mayo Clinic provided an update on the Alternative IRB Model Pilots Workgroup and a report on the Secretary's Advisory Committee on Human Research Protections (SACHRP) Meeting. He indicated that the workgroup was constituted to identify circumstances where alternative IRB models would speed the multi-CTSA implementation of clinical research protocols, and propose piloting of relevant alternative IRB models to the CTSA Consortium Oversight Committee. A meeting was held on August 15 where CTSA IRB issues were identified and discussed, including lack of uniformity of the review process among a multitude of IRBs; the development and implementation of alternative models for IRB review; and the establishment of ethically acceptable policies for data sharing, privacy and integrity of public databases.

Dr. Joyner stated that the SACHRP on October 30, 2007 charged a CTSA Panel to discuss the challenges and opportunities in Human Subjects Research that emerge as CTSAs transform the field of clinical and translational science. The panel discussions included an overview of the CTSA Program, an investigator's perspective of the implementation of the NIH vision, a CTSA Administrator's perspective of challenges to CTSAs, and a CTSA IRB Administrator's perspective of opportunities afforded by the CTSA Consortium. Dr. Joyner ended by stating that participants should reach out to Dr. Tony Perez from UC Davis so he can share his experience with implementing IRB reciprocities.

Dr. Daniel Rosenblum of NCRR discussed the planned workshop to further discuss alternative IRB issues. There may be a series of three workshops starting in 2008, with publications issued as a result of the workshop findings. Dr. Rosenblum stated that a taskforce needed to be formed to organize the initial workshop.

Dr. Robert Califf of Duke University reinforced the need for the workshop, stating there were urgent matters to discuss. One key area to focus on is to agree upon the use of metrics to measure the individual steps of the IRB process.

Dr. Lars Berglund of UC Davis pointed out that there are conflicting governance bodies that need consistency. As an example, he indicated that pharma faces difficulties getting through the process due to the inconsistencies within the same organization.

Dr. Hayward requested that a group of approximately six PIs should volunteer to work on this issue. They should e-mail Dr. Hayward with their interest. He also pointed out that the consortium should partner with State universities that have expertise in this area.

Dr. Barbara Alving reinforced that concept. She stated that CTSAAs should work with their business schools and other institutions that have mastered the engineering process, and also can better articulate the Health Insurance Portability and Accountability Act (HIPAA) process.

2. Meeting Updates

Dr. Hayward pointed out several key upcoming meetings. These included:

- Conference call with Dr. Zerhouni on Monday, December 10, 2007 10:00 AM - 11:00 AM about Jan 15-16 meeting in Bethesda.
- Dr. Zerhouni will attend CCOC meeting on Tuesday, January 15, 2008 from 1:00 PM - 3:00 PM in Bethesda.
- Many volunteers to attend NCRR Council meeting Jan 30th. Dr. Alving to reply.

Additionally, Dr. Hayward mentioned other upcoming meetings of note. These included:

- The CTSA Clinical Research Core Curriculum meeting, which will be held on January 30-31 at the Hyatt in Bethesda, MD

- The CTSA and other KL2/K12 meeting will be held March 24-26 and will include scholars in the participation.
- A CTSA Translational Meeting is being planned for between March 11 and April 11

3. Discussion/Draft Charges to Proposed New Workgroups

Dr. Hayward discussed the proposed formation of new workgroups to the CTSA program. Imaging would be under the Translational steering committee and would be formed to help foster communication, coordination, and resource sharing among CTSA's in areas related to biomedical imaging research and technological infrastructure. Clinical Research Management would be under the Regulatory Knowledge workgroup. The first workshop in 2008 will be devoted to improving processing of protocols arising from extra-institutional sources. Dr. Hayward mentioned that the Pediatrics committee would report out on the proposed formation of a rare diseases workgroup at the next Oversight Committee meeting.

Dr. Hayward closed by stating that the December 18 Oversight Committee Meeting will include reports from the Pediatrics Oversight Committee and the Clinical Research Ethics workgroup. The formation of new workgroups will be discussed, as well as the agenda for the January 15-16 face to face meeting.

The meeting adjourned at 2:00 pm