

CTSA Consortium Oversight Committee Meeting

December 18, 2007

1:00pm-2:00pm

Webmeeting URL Recording: <https://webmeeting.nih.gov/p76581120/>

Attendees: L. Berglund, UC Davis; R. Califf, Duke; B. Alving, NCRR; G. Farber, NCRR; R. Filart, NCRR; E. Hadley, NIA; A. Hayward, NCRR; S. Hirschfeld, NICHD; K. Kidd, NCRR; D. McCloskey, NCRR; I. Orams, NCRR; G. Pearson, NHLBI; D. Rosenblum, NCRR; J. Sachs, NCRR; A. Sawczuk, NCRR; M. Scheideler, NINDS; C. Shreffler, NIEHS; B. Talbot, NCRR; L. Weiss, NCI; P. Appelbaum, Columbia; F. Arnett, Texas; G. Bernard, Vanderbilt; D. Clauw, Ann Arbor; B. Collier, Rockefeller; T. Fogg, Rochester; D. Ford, Johns Hopkins; H. Ginsberg, Columbia; G. Hunninghake, Iowa; J. Imperato-McGinley, Cornell; E. Orwoll, OHSU; K. Polonsky, Washington U; J. Puck, UCSF; S. Reis, Pittsburgh; J. Sands, Emory; J. Solway, Chicago; D. Warner, Mayo; C. Will, Emory

Updates from the Pediatrics Oversight Committee and Clinical Research Ethics Workgroup (Drs. Puck & Appelbaum)

Dr. Puck, the chair of the Pediatric Oversight Committee, presented the Committee's accomplishments. Three working groups will focus on high priority issues:

1. Ethics in Pediatrics is a consultation service that will guide and help researchers to respond to IRB issues in a uniform manner.
2. Rare Diseases will hold a call with experts in the field to promote rare disease research across CTSA's.
3. Drug and Device will identify companies that assist in the development of drugs and devices for pediatrics.

There was a suggestion to involve FDA in some of the meetings going forward, as FDA has funding for orphan drugs and is interested in rare diseases.

Dr. Appelbaum, the chair of the Clinical Research Ethics Workgroup, updated the CCOC on the workgroup's accomplishments. The workgroup's four taskforces focus on:

1. Conflict of Interest surveys at CTSA sites to gather policies and procedures for dealing with conflicts of interest in translational research.
2. Surveys of research ethics consultation services at CTSA sites. Emory University is taking the lead on developing an online archive/repository for clinical research ethics consultation so that knowledge can be shared across sites.
3. Educational Materials surveys CTSA sites on their current practices in teaching the responsible conduct of research, ascertaining what needs the sites have, and cataloguing the approaches that are being taken so best practices are identified.

4. Protocol/Consent Form Template is developing model language for protocol/consent forms. The taskforce's goal is to have a basic consent form structure that other sites would adopt.

Mentoring relationships between the 2006 and 2007 cohorts have been set up in this workgroup to help with the facilitation of activities going forward.

Discuss agenda for Jan 15-16 meeting (Drs. Califf & Berglund)

Dr. Berglund will send out a summary today of last week's call with Dr. Zerhouni to the CCOC. Dr. Zerhouni is scheduled to speak at 1pm on January 15th and the PIs were encouraged to communicate their plans and focus ideas with him in order to have a robust give-and-take.

Regarding committee management issues, it was suggested that the PIs take some time to review the committees and determine overlaps, synergies, etc. between them. This is a critical meeting to start fresh with both Cohorts, and they need to identify what they can do as a consortium instead of what the sites can do individually.

Breakout groups to deal with issues like informatics, education, clinical research management, specific scientific projects, etc. were proposed for the morning of the 15th. Drs. Califf and Berglund will write up suggestions on how to use this time, as twelve PIs will arrive the night before, and they will send these ideas out to the group for feedback and agreement.

The PIs requested time on their own as a group and the evening of the 15th was identified for this.

An agenda for January's meeting will be finalized by email with an embedded Wiki link.

Discuss optimizing CTSA Consortium Oversight Committee Wiki space (Dr. Kidd)

Dr. Kidd encouraged the PIs to communicate their thoughts about how the Wiki can be improved and better organized for their committee. Embedding the Wiki links within the email is effective, and the PIs were encouraged to send emails that include Wiki links.

Other business

Many CTSA members find the CTSA newsletter very informative and useful with its summaries and updates. Dr. Kidd emails the newsletter monthly to all members, and previous issues can be found on the articles page on ctsaweb.org.

Dr. McCune is unable to attend the Council meeting on January 30, 2008, and NCCR is happy to arrange the attendance of another member of the 2006 Cohort to attend in his place.

The CCOC webmeeting scheduled for January 15 is canceled because of the January face to face meeting.

January 30-31, 2008 is the CTSA Clinical Research Core Curriculum meeting in Bethesda.

March 24-26, 2008 meeting brings together the roadmap KL12 scholars and their compatriots.

A Translational workshop is planned between March 11 and April 11, 2008. Two additional workshops are in the planning stages: Public Private Partnerships in March and Clinical Research Management later in the year.

Meeting adjourned at 2pm

Action Items:

1. Slides from today's two presentations will be sent to everyone with links to the Wiki for feedback and input - Hadley
2. A summary from the December 10th call with Dr. Zerhouni will be sent today – Dr. Berglund
3. Suggestions for how to use the time in the morning of the 15th will be sent out for feedback and agreement – Drs. Berglund and Califf
4. Finalize the agenda and email to the group with a Wiki link – Dr. Hayward