

Meeting Minutes

CLINICAL RESEARCH ETHICS WORKGROUP

Monday, September 24, 2007

**Call in number:** 888-790-1711

**Passcode:** 66066

**Time:** 2:00 PM – 4:00 PM EDT

**Participants:** CTSA representatives, NIH voting members, NIH non-voting members. New CTSA representatives are welcome to participate.

2006 Cohort:

Paul Appelbaum, Columbia (Chair)

Susan Bankowski OHSU

Laura Beskow, Duke

Bob Holloway, Rochester,

Jon Merz, Pennsylvania

Alex Kon, UC Davis

Rhonda Kost, Rockefeller

Robert Levine, Yale

Ross McKinney, Duke

2007 Cohort

Elizabeth Heitman, Vanderbilt

Kirk Laine, Vanderbilt

Jeremy Sugarman, JHOC

Jim DuBois, Washington University (St.L)

John Banja, Emory

Ellen Wright Clayton, Vanderbilt

Yoram Shenker, Wisconsin

Dorene Merkel, U of Michigan

NIH

Christine Grady, Co-Chair

Mary Ellen Michel, Co-Chair

Dan Rosenblum, Co-Chair

Brandy Fureman, NINDS

Philip Wiethorn, NINDS

Elaine Ayres, NCC

Jackie Goldberg, NCI

Steven Hirschfeld, NICHD

Lisa Marunycz, NCC

Ronald Barnett, OSP/OBA

## **Tentative Agenda**

1. Roll call and Introduction of CREW members from new CTSA sites – 5 minutes
2. Minutes from meeting of 1/31/2007 2 minutes
  - a. Approved without revisions
3. Discussion of orientation for new members – 5 minutes
  - a. Two methods will be used.
    - i. Each representative from the 2007 Cohort of CTSA's will choose a corresponding representative from the 2006 Cohort of CTSA's as a "buddy" to help with orientation.
    - ii. Paul Appelbaum will schedule a meeting for the new members to review details about their programs and to interact.
  - b. A face-to-face meeting will be planned, time not yet determined
4. Update on current activities
  - a. COI - Bob Holloway 10 minutes
    - i. Agreed that topic is important
    - ii. Not sure what topics to emphasize or how to approach it
    - iii. Need better contacts to inform taskforce of direction that will be most helpful
    - iv. Have accumulated tables of information, but the data are not ideal for the purpose
    - v. Forum in September 2007, AAMC involved, many members of 2006 Cohort were there (maybe members of 2007 Cohort as well)
    - vi. Need a conference call to agree on goal, incorporate new members
    - vii. Will survey group on action items, volunteers for membership
  - b. Consultation - Laura Beskow 10 minutes
    - i. Conference calls starting in April
    - ii. Data from several centers, some not in CTSA
    - iii. Information posted on CTSA Wiki
    - iv. May write a paper
    - v. Meeting on 9/26/2007, call in information 888 395 3520, Passcode 49192
  - c. Educational materials - Alex Kon/Mary Ellen Michel 10 minutes
    - i. Lots of interest in sharing within CTSA consortium and with outsiders
    - ii. Divided about need for peer review of stored materials
    - iii. Might try Wiki as temporary home for materials – either stored files or urls for larger files
    - iv. What to store – free ranging discussion about RCR courses, organization. Could target audience for material or arrange by topics.
    - v. Users would have to respect sources, copyrights

- vi. Nature of courses different at CTSA sites – some have comprehensive course for whole institution, some selective for CTSA.
- vii. Purpose might be to save money or to identify potential areas that need supplementation in different CTSA
- viii. ORI putting on Conference at Washington University/St Louis – full information available at <http://ori.hhs.gov/conferences/08RCR.shtml> First Biennial ORI Conference on Responsible Conduct of Research Education, Instruction, and Training

5. Report from meeting on alternative IRB models –

Dan Rosenblum

10 minutes

- a. The intent of the CTSA Consortium governance program is to solve problems, give CTSA Sites access to expertise at NIH and ability to share, relieve PIs of the burden of doing everything themselves, and to economize on effort. Workgroups and committees may be created with limited goals and for a brief period of time. The Alternative IRB models pilots may be one of those workgroups. It will survey what is being done currently at the CTSA sites and report back to the PIs. It may also look at potential studies that could benefit from an alternative IRB if approval was sought at multiple CTSA sites. Meanwhile, the CTSA CREW has ample opportunity to offer suggestions or to work on methods that improve the throughput of protocols.

- b. Informed consent templates - Susan Bankowski

15 minutes

Volunteered to work on the language of informed consent documents and other instruments where language might help to make protocols more ethically correct and improve the approval rate.

- c. Other efficiencies in protocol/informed consent processing

Susan Bankowski

10 minutes

Other documents such as liability language and HIPPA compliance issues might benefit from the development of templates. Although institutional buy-in was sought, some counseled that it may take years to develop and that action could continue without uniform acceptance.

6. Report from pediatric conference - Alex Kon

10 minutes

A highly successful telephone conference with over 300 actively engaged participants was conducted through the support of NICHD (S. Hirschfeld) and can be viewed at [www.CTSAweb.org](http://www.CTSAweb.org) under Pediatrics Oversight, September 11, 2007 or [http://ctsaweb.org/meeting.cfm?year=2007&com\\_ID=27#mtg\\_ID\\_124](http://ctsaweb.org/meeting.cfm?year=2007&com_ID=27#mtg_ID_124)

The principal concerns identified were: (1) The definition of a minimal risk, (2) The definition of a Minor Increase over a minimal risk, and (3) The definition of a disorder or condition. The group also noted that part of the difficulty in performing studies in pediatrics derives from the perception that risks associated with research are perceived as less acceptable than risks associated with life (such as school sports). A publication will be forthcoming. Dr. Hirschfeld reported that he will post the slides, recordings and related documents to the website shortly.

7. New business

- a. Collaborative research projects for CREW  
Paul Appelbaum 15 minutes  
Although several people expressed interest in sharing or collaborating on a research project, no project was identified. Instead, all of the participants will be invited to post their research interests on the Wiki so that interest can be developed or sought.
- b. Other new business  
Paul Appelbaum 10 minutes  
Note was made of the revised guidelines that effectively reduce the budgets of the CTSA sites. For information, go to [http://www.ncrr.nih.gov/clinical\\_research\\_resources/clinical\\_and\\_translational\\_science\\_awards/funding\\_guidelines.asp](http://www.ncrr.nih.gov/clinical_research_resources/clinical_and_translational_science_awards/funding_guidelines.asp) or <http://ctsaweb.org/nihctsainfo.cfm> and click on CTSA Funding Guidelines. Dr. Appelbaum volunteered to discuss issues with any participants who choose to call him.
- c. A face to face meeting might be added to another meeting to which many members of the CTSA CREW are going. A query will be added to an e-mail.