

## Meeting Summary CTSA Ethics Steering Committee

**Location:** 6701 Democracy Blvd (Democracy 1), 9<sup>th</sup> Floor Conference Room  
**Date:** Meeting, February 26, 2007  
**Time:** 8:00 AM – 3:30 PM EST  
**Participants:** Jason Karlawish, Acting Chair, Susan Bankowski, David Barnard, Eugene Boisabubin, Bob Holloway, Barbara Koenig, Alexander Kon, Rhonda Kost, Robert Levine for CTSA's, Christine Grady, Mary Ellen Michel, and Dan Rosenblum (Co-Chairs for NIH subcommittee), Barbara Alving, Elaine Ayres, Elaine Collier, Dennis Dixon, Brandy Fureman, Jacquelyn Goldberg, Valery Gordon, Anthony Hayward, Gwynne Jenkins, Peter Kaufmann, Laura Rodriguez, Andrea Sawczuk, David Shore, Meredith Temple-Oconnor, and Phillip Wiethorn (NIH)  
Participants not present in the meeting room used Breeze for audio and video communication. Paul Appelbaum, Laura Beskow, and Bernie Lo (CTSA); Jack Scott (Madrillon Group)  
*For participation in other Steering Committees by NIH staff, see attached list.  
For full list of CTSA and NIH members and communication information, see attached list.  
For titles and institutional affiliations, see attached meeting attendance roster.*

**Call to Order:** Co Chair Dan Rosenblum called the first meeting of the Committee to order at 8:30 AM. The other Co-Chairs are Christine Grady and Mary Ellen Michel. Presentation material will be stored on the CTSA website at <http://ctsaweb.org> under Committees and Meetings.

**Barbara Alving**, Acting Director, NCRP welcomed the participants. She provided an overview of the expectations of the committee and the CTSA's. She asked the participants to consider how Clinical Research Ethics could best fit into a committee structure to support the CTSA Consortium.

**Anthony Hayward**, Director Division of Clinical Research Resources, NCRP, presented an overview of the CTSA's.

**Introductions** followed.

**Christine Grady** discussed issues identified by members of the NIH CTSA ethics subcommittee as priorities for their ICs. Details are contained in her visual presentation. She then asked the CTSA participants to describe briefly the ethics activities at their sites, most of whom used visual presentations to support their oral statements.

- Paul Appelbaum, MD, Co-Director of Design, Biostatistics, and Clinical Research Ethics Irving Institute for Clinical and Translational Research, Columbia University Health Sciences
- Laura Beskow, PhD, Co-Director, Clinical and Translational Research Ethics, Duke Clinical and Translational Science Institute, Duke University
- Barbara Koenig, PhD, Co-Core Director, Center for Clinical and Translational Research Mayo Clinic College of Medicine
- Susan Bankowski, MS, JD, IRB Co-Chair, Director of Program in Research Ethics, Oregon Health & Sciences University
- Rhonda Kost, MD, Director, Clinical Research Support Office, Co-Director Advisory Committee, Center for Clinical and Translational Science, Rockefeller University

- Alexander Kon, MD, Chair, Education Subcommittee, UCDCM Hospital Ethics Committee, University of California, Davis
- Bernie Lo, MD, Co-Director Research Design Biostatistics and Ethics Program, Clinical and Translational Science Institute, University of California, San Francisco
- Jason Karlawish, MD, Director, CTSA Research Ethics Program, Institute for Translational Medicine and Therapeutics, University of Pennsylvania
- David Barnard, PhD (for Alan Meisel), Clinical Research Ethicist, Design, Biostatistics and Ethics Clinical and Translational Science Institute, University of Pittsburgh
- Robert Holloway, MD, MPH, Co-Director, Biostatistics, Epidemiology, and Clinical Research Ethics, Clinical and Translational Science Institute, University of Rochester
- Eugene Boisaubin, MD, Director, Ethics and Advocacy Component, Center for Clinical and Translational Sciences, University of Texas Health Sciences Center at Houston
- Robert Levine, MD, Co-director, Yale University Interdisciplinary Center for Bioethics Yale Center for Clinical Investigation, Yale University School of Medicine

**Jason Karlawish** summarized the presentations. He emphasized the responses to the questions the participants had addressed, “What can the CTSA Ethics Steering Committee do for your CTSA?” and “How can your CTSA serve as a resource to the CTSA Ethics Steering Committee?”

- Each of the CTSA's contributes a member to the Ethics Steering Committee. There are 12 now, but will rise rapidly toward a planned 60. We should think in terms of a larger group.
- Each CTSA participant has two roles: as a member of an individual institution and as a member of this consortium. There may be tensions created by those dual roles. Individuals should manage those tensions to be maximally effective. The CTSA Ethics Steering Committee is in a unique position to inform a broad national effort in Clinical Research Ethics.
- Each of the CTSA members described broadly similar local challenges and tasks. They expressed broad support for the following:
  - **Educational program** – potential for **sharing**
    - Members would like to make use of teaching modules provided by others with expertise.
    - Members would like to share their work and avoid redundancy of effort
    - The committee should assess the expertise at each site
  - **Research**
    - Identify research questions.
    - Design trials
    - Collect data that could inform issues of general concern
  - **Consultation** –
    - **Early interventions** might improve studies and avoid crisis interventions. Stanford, Case Western, and JHH reportedly have created models for early intervention.
    - **Late interventions:** Ethics could have an impact on translational contributions after completion of trials.
    - **Crisis intervention:** A measure of a successful ethics program could be a reduction in crisis interventions.
  - **Information** –
    - Dissemination of information into CTSA network
  - **Evaluation** – methods of evaluating Clinical Research Ethics
  - **Conflicts of Interest**
    - Should not be only focus of this committee
    - Will need some attention

- **Interactions** with other organizations:
  - National IRB network
  - Subjects advocates networks
  - Cancer research networks
- **Recruitment and retention** of trial participants
  - Ethically justifiable ways to increase recruitment and retention
  - Not a primary Clinical Research Ethics issue
  - Often a major trial issue that involves ethical decisions
- **Compliance** issues engage the issue of tending to language and culture.
  - Requires time and effort
  - Culture changes improve compliance and function of IRBs
  - Leadership will help sites present material to IRBs.
  - Compliance is a surrogate for ethics; it may be possible to achieve ethical outcomes by requiring compliance; requiring compliance may be more efficient than changing culture.
- **Methods and Modeling**
  - A variety of qualitative, quantitative, and modeling methods could be used to examine Clinical Research Ethics issues
- **Committee structure**
  - Where is the best fit for Clinical Research Ethics in the overall CTSA Committee structure?
  - Should we be one committee, a group of subcommittees, or part of other committees? Would another structure be better?

**Dan Rosenblum** discussed NIH Resources

- **The CTSA Communications Steering Committee**
  - Centralized CTSA communication is under development. Members should look to the CTSA website at <http://ctsaweb.org/> for support. NCRR will develop a password protected, members-only site. Participant input would be invaluable in this pursuit.
  - NCRR has a staff site, (CTSA Management System, CTSAMS) to facilitate committee management. Information about committee members is stored at this site.
- **The CTSA Evaluations Steering Committee** [Lori Mulligan provided details]
  - Evaluation standards are being developed in collaboration with CTSAs and an independent contractor who will be conducting an evaluation of the national CTSA Consortium.
  - The contractor, represented by Jack Scott, participated in the meeting and welcomed comments by the committee.
- **Distribution lists.** Each of the participants has received a list of the CTSA members and NIH participants that includes their e-mail contact information. (*attached below*)

### **Proposed Action on Priorities**

**Jason Karlawish** and **Christine Grady** led a discussion on possible priorities and action items. The Steering Committee should place high priority on support of the members' individual functions within their own CTSAs. One way to achieve this goal would be to share research ethics teaching materials. They suggested the following:

- **A Central Repository For Teaching Materials.**
  - A librarian and a cataloging system are essential to manage the risks of accumulating material of inconsistent value, age, relevance, and reliability.
- **Development of a teaching syllabus of rated, approved, and updated materials**
  - A responsible CTSA member ("librarian") should take the lead.
  - The Center for Information Technology Integration (CITI) might have a syllabus of this kind.
- **Other priorities/action items**
  - **Conflicts of Interest,**
  - **Emergency Waivers,**
  - **Emerging Issues** [Biorepositories]

- **Working Groups** – NOTE – membership here is not fixed – others are encouraged to join on
  - **Educational materials** [feasibility and process for developing a syllabus or a repository for documents]
    - Alex Kon
    - Rhonda Kost
    - Meredith Temple-Oconnor
    - Dan Rosenblum
  - **Communication**
    - Each member is encouraged to create an email address for the steering committee that has all the of members listed below. Note that the list will grow. This will allow the committee to communicate
    - The Duke U based listserv provides a means for all CTSA research ethics people to communicate and share ideas
  - **Nominating Committee**
    - Barbara Koenig
    - Alex Kon
    - Jason Karlawish
  - **Mission Statement**
    - Susan Bankowski
    - Robert Levine
    - Jason Karlawish
    - Christine Grady
  - **Consultation**
    - Susan Bankowski
    - Laura Beskow
    - Jason Karlawish
    - Barbara Koenig
    - Christine Grady

#### **Responsibilities of the Interim Chair**

- Select a nominating committee to nominate a Chair for a 2-year term.
- Conduct an election – election needs to occur by the end of April
- Facilitate communication within the CTSA Ethics Steering Committee and between the committee and the CTSA Consortium.

#### **Election of Chair:** Participants received draft rules for the nomination and election of a chair.

- Nominating committee may adopt or modify draft rules
- All CTSA members (but not NIH members) are eligible to be nominated for chair including all members of the nominating committee and the interim chair
- Members may nominate themselves or others
- The nominating committee may ask nominees if they are able and willing to commit to the task of serving as chair
- The nominating committee will determine the rules for voting.
- The election shall take place within two months.

#### **Future meetings:**

- Working groups listed above need to set up a timeline to have materials ready for the teleconference
  - Plan a meeting via telephone within the next six weeks – should include the chair and NIH co-chairs in the meeting (though all may not be available – at least one)
- **Telephone conference:** August-September 2007
- **Face-to-Face:** March 2008, location to be determined.

<b>NIH CTSA Ethics Subcommittee Memberships</b>		
Participant	I/C	Other Subcommittee Memberships
Christine Grady	CC/BEP	
Mary Ellen Michel	NIDA	Executive Committee/Principal Investigator
Elaine Ayres	CC/OD	CR Informatics, Pub/Private Partnerships
Dennis O Dixon	NIAID	Biostatistics
Brandy Fureman	NINDS	(Regulatory if committee or working group established)
Jacquelyn Goldberg	NCI	
Valery Gordon	OD	
Anthony Hayward	NCRR	Every committee
Peter Kaufmann	NHLBI	Biostatistics
Meredith Temple-O' Connor	NIGMS	Education CD
Dan Rosenblum	NCRR	Translation, Evaluation
Andrea Sawczuk	NCRR	Administration, Translation,
David Shore	NIMH	
Philip Wiethorn	NINDS	
Elaine Collier	NCRR	CR Informatics
Barbara Sina	FIC	
Laura Rodriguez	NHGRI	
Claudia Moy	NINDS	Biostatistics
Gwynne Jenkins	OD	Community Engagement

2006 Membership List CTSA Ethics Steering Committee

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# National CTSA Clinical Research Ethics Steering Committee

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February 26, 2007

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