

**CTSA Clinical Research Ethics Workgroup (CREW)**  
**Meeting Summary**  
December 17, 2007  
2:00 p.m. – 4:00 p.m. EST  
**Teleconference**

**Call-in number:** 866-285-7778

**Passcode:** 2739273

**Attendees:** P. Appelbaum, Chair (Columbia Univ.); D. Rosenblum, NIH Coordinator (NCRR); C. Grady, NIH Coordinator (NCC); J. Banja (Emory Univ.); R. Berry (Emory Univ.); E. Collier (NCRR); J. DuBois (Washington Univ.); K. Akers for J. Fins (Weill Cornell); K. Fryer-Edwards (Univ. of Washington); J. Goldberg (NCI); S. Goldkind (FDA); E. Heitman (Vanderbilt Univ.); S. Hirschfeld (NICHD); B. Holloway (Univ. of Rochester); A. Iltis (Washington Univ.); L. Kaldjian (Univ. of Iowa); B. Koenig (Mayo); A. Kon (UC Davis); R. Kost (Rockefeller Univ.); J. Merz (Univ. of Pennsylvania); M. Michel (NIDA); K. Neal (Emory Univ.); R. Pentz (Emory Univ.); T. Koogler for L. Ross (Univ. of Chicago); J. Sadler (UT-Southwestern); R. Sharp (CWRU); Y. Shenker (Univ. of Wisconsin); N. Steneck (Univ. of Michigan); G. Geller for J. Sugarman (Johns Hopkins Univ.); B. Wilfond (Univ. of Washington); P. Hashemi (BAH)

**Absent:** E. Ayres (NCC); S. Bankowski (OHSU); D. Barnard (Pittsburgh Univ.); R. Barnett (OD); L. Beskow (Duke Univ.); E. Boisabuin (Univ. of Texas HSC); A. Chapman (Emory Univ.); L. Churchill (Vanderbilt Univ.); E. Clayton (Vanderbilt Univ.); D. Clem (Emory Univ.); D. Dixon (NIAID); R. Dresser (Washington Univ.); M. Elks (Emory Univ.); B. Fureman (NINDS); V. Gordon (NIBIB); A. Hayward (NCRR); G. Jenkins (OER); P. Johnson (Emory Univ.); J. Karlawish (Univ. of Pennsylvania); N. Kass (Johns Hopkins Univ.); P. Kauffman (NHLBI); K. Kinlaw (Emory Univ.); R. Levine (Yale Univ.); B. Lo (UCSF); D. Markel (Univ. of Michigan); P. Marshall (CWRU); L. Marunycz (NCC); R. McKinney (Duke Univ.); C. Moretto (NIMH); R. Nelson (Univ. of Pennsylvania); S. Olson (Mayo); K. Peck (UT-Southwestern); L. Rodriguez (NHGRI); J. Rush (UT-Southwestern); A. Sawczuk (NCRR); D. Shore (NIMH); B. Sina (FIC); H. Taylor (Johns Hopkins Univ.); M. Temple-O'Connor (NIGMS); N. Vangsnes (Duke Univ.); K. Weinfurt (Duke Univ.); P. Wiethorn (NINDS); C. Will (Emory Univ.)

**Welcome and Introductions**

Dr. Appelbaum welcomed CREW members to the meeting.

**Task Force Updates**

At the November 2 meeting of the CTSA CREW Operations Committee, Task Force chairs were asked to provide a brief report on current activities and on planned milestone, action items, goals/deliverables for the next calendar year.

## **Conflict of Interest**

Dr. Holloway reported growth in the number of members of the Conflict of Interest (COI) Task Force. The COI Task Force plans to collect information from CTSA institutions about faculty and institutional COI policies with regard to first-in-human clinical research.

Action items for the COI Task Force include

- Two meetings: a conference call in January or February 2008 and a face-to-face meeting at the September 2008 AAMC Forum on Conflict of Interest in Academe in Rochester, Minnesota
- Development of a survey to improve the data base on faculty and institutional COI policies with regard to first-in-human clinical research

The goal product for the task force will be to develop a white paper or publication that summarizes key findings from the information collected about faculty and institutional COI policies in first-in-human translational research. The target date for the goal product is Summer 2009.

## **Consultation**

On behalf of Dr. Beskow, Dr. Appelbaum reported that there was discussion about the possibility of pooling the experiences gained in research ethics consultation and making those consultations available to the broader CTSA CREW community. In discussion prior to the meeting, Dr. Beskow conveyed that her task force's milestone would include completion of a survey on the relationship between IRBs and research ethics consultation, the goal would be to improve best practices at the site and to share practices on difficult or first-in-human studies and the deliverable would be a publication regarding consultation practices at different institutions.

Dr. Banja described an ongoing initiative at Emory that could be shared with the CTSA Consortium under the right circumstances. Emory proposes to construct a web-based, cataloged and searchable repository for completed ethics consultations of particular interest. Emory is open to receiving similar consultations from other sites and to structuring the site to make it accessible to ethicists elsewhere in the Consortium.

Some members pointed to privacy issues in posting consultations. The task force is aware of these issues, but believes that they are manageable and will deal with them in formulating its recommendations. Dr. Sadler volunteered to help construct an ethics consultation template. Dr. Wilfond stated that the University of Washington has a database for tracking consults which might, in the future, be a source for a template. The milestone would be the collection of consultations and the construction of a searchable, fully functional website. The goal is improved sharing of consultations and consistency of the ethical decision-making process across institutions. The deliverables are consultations obtained from the website.

## **Educational Materials**

Dr. Kon reported that the Educational Materials Task Force will move forward with a two-pronged approach with goal products being made available over the next two years.

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The task force will develop two deliverables: an inventory of education materials and courses on the [Responsible Conduct of Research \(RCR\)](#) across the CTSA Consortium and model RCR education curricula. The inventory will be made available on the Wiki. At present, Dr. Kon is assembling a proposal for possible consideration by to the CTSA Consortium Oversight Committee (CCOC). Dr. Kon noted that this is a complex undertaking because the work with RCR education at each CTSA is not done by or limited to members of the CTSA CREW. He also requested assistance due to the high volume of work.

Leadership in developing model RCR education curricula will be headed by Dr. Steneck. The task force will meet face -to-face at the [Office of Research Integrity \(ORI\) Annual Meeting from April 17-19 in St. Louis](#). Dr. Steneck will provide meeting space for the morning of April 17<sup>th</sup> for the CREW to continue to work on this project. He further noted that he hopes to have a preliminary portion of the curricula in six months.

### **Consent Document Templates**

There is no report for this task force.

### **Reports to CTSA Consortium Oversight Committee**

Dr. Appelbaum stated that the CREW will conduct its first report to the CCOC on December 18. He added that there are pressures on all CTSA components, given limited budgets, to demonstrate their productivity. Hence, the CREW needs to prioritize its activities in order to make optimal use of human resources and to focus its attention on the most urgent tasks confronting the Consortium.

Individual CTSA institutional products do not constitute Consortium activities or products unless they are extended to other CTSA sites.

### **Workshops**

Dr. Rosenblum noted that workshops are considered valuable Consortium products. The CTSA plans to hold four workshops in the next six months.

Committee Workgroup/Workshop Topics	Planned Date
Education/Career Development	January 30-31, 2008
Core Competencies in Clinical and Translational Research	
Public Private Partnerships	March 2008
Intellectual Property	
Translational	April/May 2008
Decision Making in Translational Research	
Clinical Research Management	June 2008
To be determined	

### **Publications**

Dr. Rosenblum reminded the CREW that Dr. Beskow is looking for a volunteer to write a first draft for a publication on the results of the consultation survey. The publication process would include circulating the draft among the authors and returning it to the lead author. When it is read for review, Dr. Beskow will send the manuscript to Dr.

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Appelbaum. He will obtain sign-off from the CCOC before it is published. The CREW may wish to develop a written publication policy that may be used across the CTSA.

### **Discussion of Founding Journal in Clinical Research Ethics**

Dr. Sadler described his vision of a journal in Clinical Research Ethics that focuses on human research and incorporates the full scope of relevant topics, e.g. RCR, rational order of authorship and fair-minded peer review. He noted that an issue for consideration is to determine how to make the journal appealing as a business prospect to a publisher. It will not be a CTSA publication or an NIH publication. Interested CREW members were encouraged to contact Dr. Sadler directly.

### **Mentoring Relationships**

To ease the transition into the Consortium for the 2007 CTSA Cohort, Dr. Rosenblum matched 2007 sites with 2006 sites, mostly based on geographical considerations. The mentoring relationship is a suggestion only and participation is voluntary.

### **Role of Booz Allen Hamilton (BAH)**

Mr. Hashemi provided a description of his role as a project manager. He noted that he serves as the single point of contact to the CREW and is responsible for meeting preparation and summaries. BAH will also take responsibility for the support of communications including CTSAweb.org and the CTSA Wiki.

### **Other New Business**

Dr. Appelbaum stated that the CREW will need to consider future governance issues as the number of CTSA sites grows. Possibilities include developing an Executive Committee (a group of about 8 members that meet in place of meetings that include all CTSA sites). This will be an agenda item at the next CREW meeting.

Dr. Geller stated that Johns Hopkins is planning to undertake an institutional needs assessment and would like to share materials with other sites that have done formal needs assessments.

### **Action Items**

1. Conflict of Interest
  - a. Dr. Holloway will work with Mr. Hashemi to set up a COI Task Force conference call in January/February 2008.
  - b. Dr. Holloway will help organize a COI Task Force meeting at next year's AAMC Forum on Conflict on Interest in Academe in Rochester, Minnesota in September 2008.
2. Consultation
  - a. Drs. Wilfond and Sadler will work with Drs. Beskow and Banja in providing template material to develop a database for tracking consults.
3. Educational Materials

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- a. Mr. Hashemi will post information about the ORI Annual Meeting on the Wiki.
  - b. Drs. Kon and Steneck will develop an inventory containing RCR educational course information and also assemble model RCR education curricula.
4. Journal Proposal
- a. Dr. Sadler will develop and send a one-page proposal to Dr. Appelbaum on the creation of a journal publication for circulation to the CREW.

**Key Decisions**

1. All items with the CTSA imprimatur for publication should pass first through the CTSA CREW Chair, Dr. Appelbaum, and then to the CTSA Consortium Oversight Committee.

**Goal Products**

1. The COI Task Force will create a white paper or publication that summarizes key findings from the information collected about faculty and institutional COI policies in first-in-human translational research. The target date for the goal product is Summer 2009.
2. The Educational Materials Task Force will develop an inventory containing RCR educational course information and also assemble model RCR education curricula.
3. The Consultation Task Force will develop a publication. The Emory CTSA will develop a website to share with the Consortium.

**Next Meeting**

The CREW will convene by conference call on Monday, March 10, 2008, from 2:00pm – 4:00 pm. At the next meeting, the CREW will discuss future governance options. Dr. Appelbaum also encourages CREW members to think about additional areas of activity that they believe the CREW should address. Members should send additional agenda items to Drs. Appelbaum and Rosenblum.

The meeting was adjourned at 3:22pm.