

MEETING SUMMARY

Alternative IRB Models at CTSAs August 15, 2007, 1:00 – 2:00 PM EDT

Telephone conference: 1-877-713-2255, Passcode 243769, participation by Breeze Conference available at <https://webmeeting.nih.gov/ctsapilotirbproject/>

Participants: Susan Bankowski (OHSU), Peter Davies (U Texas), Michael Joyner (Mayo), Rhonda Kost (Rockefeller), Laura Beskow (Duke), Tony Perez (UC Davis), Yvonne Higgins (U Pennsylvania), Sharon Friend (UC SF), Susan Uscinski (Yale), John Ennever (Columbia), Christopher Ryan (Pittsburgh), Mary Adams (Rochester), Rob Califf (Duke), Anthony Hayward, Jody Sachs, Elaine Collier, and Dan Rosenblum (NCRR)

Purpose: The CTSA Consortium created an Alternative IRB Work Group in response to numerous comments received by the NIH from many of the CTSA sites regarding the burdensome process of approval and implementation of clinical protocols at multiple sites. In preparation for the first meeting of the Work Group, we contacted each of the CTSA sites in search of comments regarding institutional barriers to adopting an alternative IRB model, leaders who might be interested in pursuing solutions to shared problems, and pilot projects that might be of interest to more than one site. The current meeting is intended to enable us to identify action items, assign tasks, and plan for our next meetings.

The meeting began with a summary report of discussions with each of the sites. The following salient points were made:

- 1) Most of the institutions contacted said that
 - a. They have some sort of "local" cooperative agreements with other institutions
 - b. They have national agreements via NCI protocols and their cancer centers.
 - c. Large-scale conceptual issues are not usually a limiting factor
 - d. Issues related to local culture and "geopolitics" slow approvals of protocols and, more often, informed consent documents.
- 2) An Alternative IRB or an inter-institutional agreement would take time and resources to establish and operate, regardless of whether it is local or with distant institutions. In addition, it may be more complex if it includes institutions in other states because of state regulations on research and privacy. Even institutions that share resources and research projects may encounter issues in developing agreements.
- 3) Each inter-institutional agreement, alternative IRB, or pilot project, has its own characteristic set of incentives for development, risk levels, and driving forces.
 - a. In the case of NCI it is at some level linked to access (or perceived faster access) to participation in key clinical trials.

- b. With respect to the CTSA Consortium, participants would want to know which studies would be targeted for facilitation of approval or implementation
 - c. No CTSA identified a pilot project for which an alternative IRB was urgently needed.
- 4) The CTSA sites believe they might be helped by resolution of apparent inconsistencies between Federal entities such as OHRP, FDA, and the VA.
 - 5) It would be important to include key individuals at each CTSA in order to preserve institutional autonomy, authority, and independence.

Participants supplemented the summary statements with the following comments:

1. Inter-institutional agreements to accept a single IRB review are a challenge at the local level, even between closely affiliated institutions. The VA, in particular, has a national policy that was reported to preclude acceptance of external IRB review under specified circumstances. It was noted that related issues will be the subjects of discussion in session C3 “A Conversation with the Veterans Administration’s Office of Research and Development, Including an Update on the VA Central IRB and Accreditation” on Monday, December 3rd at 11:00 AM – 1:05 PM during the 2007 Annual HRPP Conference.
2. Local issues have a variable effect upon the burdens of the review process including the following:
 - a. the individual/organization responsible for pursuing approval
 - b. the perception of the risks, benefits, and target population by the IRB
 - c. the speed of the process without facilitation because facilitation sometimes slows the process down,
 - d. the cost of preparing documents and facilitating approval,
 - e. the source of funds to pay those costs,
 - f. the amount of effort required,
 - g. data security and data sharing,
 - h. the level of risk associated with participation in the protocol,
 - i. geographic conditions (including state regulations, political relationships between institutions, and previous experiences with individual investigators).
3. Related meetings/activities could help guide the activities of the Alternative IRB Work Group
 - a. Potential presentation/participation in the Secretary's Advisory Committee on Human Research Protections (SACHRP) meeting sponsored by Office for Human Research Protections (OHRP) scheduled for October 29 – 30, 2007 in Arlington, VA <http://www.hhs.gov/ohrp/sachrp/>
 - b. The 2007 Annual HRPP meeting sponsored by PRIM&R, December 1 – 3, 2007 in Boston, MA <http://www.primr.org/Conferences.aspx?id=540>
 - c. A special conference sponsored by OHRP and UCD CTSA scheduled for February 8, 2008 in Sacramento, CA
4. Mike Joyner identified the following tasks and asked the following individuals to lead subcommittees that will gather information, develop suggestions for a

course of action, and report back to the Alternative IRB Working Group at its face-to-face meeting in October 2007.

- a. Data on metrics associated with protocol/informed consent document approval at CTSA sites, Laura Beskow and Rob Califf at Duke
- b. Pilot study on Alternative IRB, for example the Picker Research Participant Perception Project, Rhonda Kost
- c. Dialog at relevant national meetings, Tony Perez and Sharon Friend
- d. Local issues such as how CTSA's could develop best practices in clinical trials and increase accrual, Kathleen Uscinski
- e. Standardized forms for Informed Consent Documents, Susan Bankowski and CTSA CREW.

The group favored the idea of holding a face-to-face meeting in conjunction with a related national meeting, for example, the OHRP sponsored meeting of SACHRP in October, 2007.

In closing, the group agreed to seek to identify global issues for which the CTSA Consortium might be able to provide some assistance.

Meeting notes will be circulated by e-mail for editing by the participants and placed upon the CTSA website.