

**NAACCR Institutional Review Board (IRB)
Conference Call Summary
April 30, 2010 at 11:30 AM ET and 10:30 AM CT**

Present: John Fulton (Chair), Cynthia O'Malley, Won Silva, John Morgan, Jack Finch, Linda Muul, Vivien Chen, Will Athas, Deirdre Rogers

NAACCR Staff: Royale Anne Hinds, Betsy Kohler

Absent: Suzanne Hornbeck, Ron Dewar, Tara Hylton

Agenda Items

1. A quorum was established for the meeting. John Fulton welcomed everyone.
2. No Expedited IRB reviews were completed during the past six months.
3. Three reviews were completed that qualified as Exempt.
4. There were three outstanding reviews at the time the agenda was compiled. Bruce Riddle's review has been completed as Exempt.
5. The annual progress reports section of the agenda shows seven projects were completed and access to the data file was terminated within the last six months. An additional five research projects are still active with annual monitoring being completed within the last six months.
6. John Fulton clarified the difference between the terms "expedited" and "exempt." IRB submissions are reviewed either by a quorum of IRB members meeting for this purpose ("full board" review), or on an "expedited" basis. So... "expedited" is a "process" category.* "Exempt" is an "outcome" category. When a review is performed – either a full board review or an expedited review, there are three potential outcomes: exempt, approved,** or disapproved.

* Expedited reviews may be performed either by the IRB Chair or by another IRB member selected by the Chair. The outcome of an expedited review is noted on NAACCR's Proposal Review Summary Form and sent to all members of the IRB. At any time within a two-week window (from the time of transmission), any member of the IRB may request more information to clarify the review outcome, or may request a full board review of the proposal in question. Therefore, it is important that the Proposal Review Summary Form be completed (by the reviewer) with sufficient information to facilitate evaluation of the review by IRB members who know nothing else about the proposal in question. Contact Royale Anne if there is not sufficient information on the form.

** Approvals may come with caveats, requests for revisions, etc.

7. John Fulton mentioned that some studies have been active for a long period of time. From the IRB perspective, if the researcher completes annual monitoring, indicates that

the study is ongoing, and there is no harm to human subjects, the IRB will approve another year of research. Studies go back to 2003, which is over six years. John is concerned because the longer the project is open, the easier it is for NAACCR to lose track of the data. Betsy Kohler will look at the older projects.

Upcoming Call Information

1. The next meeting will be held Friday, October 15, 2010 at 11:30 AM Eastern, 10:30 AM Central, 9:30 AM Mountain, and 8:30am Pacific.

Meeting name: NAACCR IRB

Date: October 15, 2010

Time (Eastern): 11:30am-1:00pm

Leader: John Fulton

Toll free number: 1-877-953-0411

Passcode: 9206148