

July 15, 2015
1:30-3:00 PM



Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children)
Ron Brown (Non-Scientist, Non-Affiliated, Present by Phone)
Ovidiu Cotea (Present by phone)
Becky Grigg
Daphne Holden
Roland Reis (Non-Scientist)

Other Attendees: Derek Schwabe-Warf, Robert Hood, Ph.D.

Quorum

A quorum was present. A quorum is defined as a majority of members present. The quorum also reflected the requirement outlined in 45 CFR 46.108 as well as 21 CFR 56.107. Please note that the number of members present will not always match the total number of votes on items as the total number votes reflects the number of members present in the room at the time of discussion and vote. At least one non-scientist and at least one non-affiliated member were present.

Members present by phone received all pertinent materials prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

Approval of Previous Minutes:

Minutes from the 6/17/2015 meeting were circulated by email and modified by member input.

Conflict of Interest:

Conflict of Interest: None Declared

Members did not report any:

- Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
- Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.
- Equity interests whose value when aggregated for the individual and the individual's immediate family represents more than a five percent ownership interest in any single entity.
- Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family
- Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest related to the research).
- Board or executive relationship related to the research, regardless of compensation.
- Involvement or participation in the design, conduct, or reporting of the research, including providing advice on Department registry data systems.
- Serving as the immediate supervisor of a researcher within the last year
- Any other interest that the IRB member believes would interfere with his or her ability to objectively review a protocol.
- Any travel related to research

Education:

A case study was presented by Robert Hood focusing on IRB review of community based participatory research (CBPR). The education focused on issues such as: when do researchers need to submit modifications when the design and implementation of their study is not complete until after initial IRB review, how does the IRB assess risks in CBPR, are community members a viable and ethical source of researchers to increase participant's trust and reach a broader sector of the population, and is parental permission necessary when dealing with children and under what conditions would parental permission be best waived.

Please note that no studies were up for review at this meeting.

Next Meeting: August 19, 2015

Other Business: None

Meeting Adjourned: 2:11pm