

October 17 , 2018
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) (non-affiliated)
Shoshana Levy (Present by phone)
Bob Eadie (non-scientist) (Present by phone)
Barbara Frentzen (Present by phone) (non-affiliated)
Ovidiu Cotea (Present by phone)
Daphne Holden
Megan Macdonald (Expertise in Subpart D: Children)

Absent:

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)
Karen Card (Co – Chair)

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, and Bonnie Gaughan-Bailey, MPA

Quorum

A quorum was present. A quorum is defined as the majority of the IRB members and representation of each of the members as identified in the requirements outlined in 45 CFR 46.108 as well as 21 CFR 56.107. At least one non-scientist and at least one non-affiliated member were present.

Approval of Previous Minutes:

Minutes from the September 19, 2018 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:

Big Data Research: Practical Solutions to Emerging Challenges for IRBs PART 2—PRIMR

(#1) Protocol Title: (A5332) Randomized Trial to Prevent Vascular Events in HIV REPRIEVE-Hillsborough CHD (Florida Department of Health)

Submission:

(Continuing)

Principal Investigator:

Charurut Somboonwit, MD

Presenters:

Ovidiu Cotea, MD, MPH

Bob Eadie, JD

Meeting Discussion: This is a previously reviewed study taking place at Hillsborough Health Department. The principal investigator is Dr. Charurut Somboonwit. In addition to requesting an additional 12 months to continue their study, researchers asked to increase their enrollment numbers from 1,600 to 1,700. 53 participants remain in the study, 22 withdrew. One of the participants expired during the study, unrelated to the study medication. Recruitment continues. No vulnerable populations. No delays or issues and study progresses as expected.

The primary presenter had no objections with approving the study, the secondary presenter concurred. The board asked that HRPP staff follow-up with research to provide CITI certifications that are up-to-date. One CITI certification is set to expire before the end of the year.

Total votes to approve for 12 months: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: November 21, 2018

Other Business: None

Meeting Adjourned: 2:15pm