

May 18, 2017
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)
Ovidiu Cotea (Present by phone)
Bob Eadie (non-scientist)
Daphne Holden
Nina McGrew (non-affiliated)
Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Absent:

Keshia Reid (Expertise in Subpart B: Pregnant women)

Other Attendees: Karen Card, MPH and Rotanya Bryan, 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.

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 **May 5, 2016** meeting were circulated by email and modified by member input.

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: None

Modifications:

(#1) Protocol Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1Positive, Antiretroviral Treatment- Naïve Adults

Submission:
(Modification)

Principal Investigator:
Todd Wills, MD

Presenters:
Ovidiu Cotea
Nina McGrew

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. The medication compares similar drugs, one standard FDA-approved and another, in HIV+ patients. This modification makes minor administrative changes to protocol: correction and clarification of tests, no changes to data quality or patient experience, or risks. Participants are presently enrolled and recruitment continues. There is one change in staff. No vulnerable populations. Dr. Cotea recommended approval and Ms. McGrew seconded.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

(#2) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE A5332)

Submission:
(Modification)

Principal Investigator:
Charurut Somboonwit

Presenters:
Ovidiu Cotea
Shamarial Roberson

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. There are minor changes to the recruitment brochure, the flyer, postcard, and poster. Participants are enrolled and analysis is occurring. No conflict of interest. No adverse events during period. No vulnerable populations. No changes to the consent document. This is a greater than minimal risk study. Dr. Cotea recommends approval and Dr. Roberson concurred.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

(#3) Protocol Title: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere)

Submission:
(Modification)

Principal Investigator:
Patricia Emmanuel

Presenters:
Sandra Schoenfisch
Robert Eadie

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. Additional information about Truvada is being provided to participants; this is the substance of the change. No subjects are being enrolled at this site, and no subjects are on the Truvada arm of the study. Sandra recommends approval of the modification. Bob concurs.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Next Meeting: June 15, 2016

Other Business: None

Meeting Adjourned: 1:50 pm