

June 16, 2016
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)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Absent:

Nina McGrew (non-affiliated)
Daphne Holden

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

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 18, 2016 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: Consultation with UF IRB chairpersons

Karen Card described six suggestions UF consultants recommended to improve the DOH IRB. The consultants suggested IRB member recognition, contingent approval, tabling studies, incident inclusion of vulnerable populations in data studies, stamping consent forms, and continuing/modifications review.

Modifications:

(#1) Protocol Title: Falls Reported among Hispanic and non-Hispanic Employees in Residential Construction

Submission:

(Modification)

Principal Investigator:

Alberto Caban-Martinez, DO

Presenters:

Shamarial Roberson
Keshia Reid

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. The main aim of the research is to reduce near misses in accidents among residential construction workers. Modification requests an anonymous survey. The study is greater than minimal

risk and involves direct interaction with participants. The board clarified with the principal investigator that there is a \$10 gift card offered for filling in the survey, and a \$20 gift card for participating in a focus group. Some participants may take part in survey and focus groups. The board requests emphasis in consent, and a procedure for verifying with participants their understanding of the consent. The board clarified with the Principal Investigator that study activities still need to be completed by June 30, 2016. Dr. Caban described the survey instrument; the board examined it in the meeting.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 4 Negative: 1 Recusal: 0 Absent: 2

(#2) Protocol Title: [MK1439-018] A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects

Submission:

(Modification)

Principal Investigator:

Jose Montero, MD

Presenters:

Ovidiu Cotea
Sandra Schoenfisch

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. This study is a double-blind randomized clinical trial to investigate safety and efficacy of MK-1439 in HIV positive treatment naïve subjects. Modification concerned revised language in consent form regarding side effects of a study medication. In some patients, study medication can cause severe allergic reaction. Takes place at Hillsborough CHD, P.I. is Dr. Jose Montero. Participants are enrolled; recruitment continues. Secondary analysis is taking place. No vulnerable populations. Enough privacy and confidentiality provisions. Sponsor and researcher have made corrections to 23-page consent form. Protocol addresses patient follow-up and tracking. Changes are thorough, and all previous and current patients will be notified of changes.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: July 20, 2016

Other Business: None

Meeting Adjourned: 2:30pm