

Mar-20-2019



Department of Health
2585 Merchants Row
Conference Rm. 320 P
Tallahassee, Florida 32311

IRB 1 Convened Committee Meeting Agenda

Agenda Status: Finalized

Attendance

Sandra Schoenfisch, RN, Ph.D, MS (Chair, Expertise in Subpart D: Children) (Non-affiliated)

Robert Eadie, JD (Non-Scientist)

Katisa Donaldson, MSW (Non-affiliated) (non-scientist) (children and adults unable to consent)

Karen Card, MPH, Dr.PH (Co-chair)

Ovidiu Cotea, MD, MPH

Daphne Holden, MS, Ph.D

Absent

Megan Macdonald, MPH (Expertise in Pregnant Women and Children)

Barbara Frentzen, ARNP, MSN (Non-affiliated)

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, and Joy

Quorum

A quorum was present. A quorum is defined as most 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 12.17.18 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

Common Rules Follow-up --Rotanya Bryan

Rotanya Bryan reminded members that HRPP staff would be developing new applications in the IRBMANGER website.

Submissions for Convened Board Review (2)

Modification

Protocol Title: MK-1439-018 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, eac (Florida Department of Health)

Submission:

(Modification)

Principal Investigator:

Montero, Jose

Presenters:

Cotea, Ovidiu MD, MPH

Meeting Discussion: This is a previously approved phase 3 multicenter, double-blind, randomized, active comparator controlled clinical trial to evaluate the safety and efficacy of Doravirine. The study is currently closed to enrollment but still open to following study subjects. The researchers have submitted a protocol clarification letter and a revised consent form. Revised documents include the changes to IB Edition 10 and the Amendment 10. The revisions to the consent form include:

- Updated footer to reflect current information, such as, revision date, revision number, and protocol number.
- Updated information about extended study, MK-1439 (doravirine), risk information on MK-1439, and other minor editorial changes.

The board found no new risks to the participants. Patients will be notified of the changes. The primary presenter recommended approval and the secondary presenter seconded.

Motion: A motion to vote for approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Protocol Title: A double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocumab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia (#170015HD) (Florida Department of Health)

Submission:
(Modification)

Principal Investigator:
Morano, Jamie MD

Presenters:
Cotea, Ovidiu MD, MPH
Card, Karen DrPH

Meeting Discussion: This is a previously approved study of a double-blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocumab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia. The researcher submitted a revised investigator brochure edition 13. A summary of the changes includes approval of the study drug in 65+ countries, results supporting the effectiveness of the drug, open label extensions, and other minor editorial changes. No new risks were found during the study process. Enrollment continues. Patients will not be notified of the new changes to the due to no safety concerns.

The primary presenter, Dr. Cotea, found the changes acceptable and a made a motion for approval. Secondary presenter, Dr. Card, seconded.

Motion: A motion to vote for approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: April 17, 2019

Other Business: None

Meeting Adjourned: 2:11pm