Meeting Date: February 5, 2020
Next Meeting:

Attendance:
Jamie Forrest (CHAIR)
Jaime Arango Ed.D.
Julie Moore J.D., M.S., P.A.
Julia Fashner M.D.
Nkechi Ichite Pharm.D., Ph.D.

4 needed for quorum

Quorum:
A quorum **was** present.

The quorum is defined as a majority of members present, one member whose primary interests are non-scientific, and one member who is not affiliated, and whose immediate family are not affiliated with DOH. 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.

Other Attendees:
Andrew Wentzell, IRB Coordinator
Gavin Grigg, IRB Analyst
Bonnie Gaughan-Bailey, Administrator, Office of Public Health Research

Attendance Notes:
Conflict of Interest: None
Members did not report any:
- Ownership interest, stock options, or other financial interest related to the research of any value.
- Compensation related to the research of any value.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.
- Interest that could be affected by the outcome of the research.

Attendance Note: Members present by phone received all pertinent material through IRB Manager 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.

Old Business: None

Other Business: There was no other business discussed at this meeting.

Notes: Applications reviewed and approved using the expedited procedure and exempt studies and non-research determinations were reported in the meeting agenda in IRB Manager; there were no questions or discussions about these actions.

Continual Approval:

Protocol Title: Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine given Daily for LTBI (ASTERoiD) (University of Florida)

Fashner, Julia is primary reviewer: This application the PI has asked to close protocol for this item they never had any enrollment and when theyhad the study approved, it was after the grant had expired. So there was zero patients that entered the study and in Dec 2019 they would like to close the study. No further review or follow-up was needed. She

moves to close the study.
Jamie Forrest is second reviewer: Jamie agrees and seconds the movement to close.

Motion:

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

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)

Nkechi Ichite is primary reviewer: This study is is a continuing review and has been ongoing for several years. This submission was made in August 2019 by the PI. There were three subjects enrolled and two withdrawls. Currently, the study has been closed and no one is enrolled and there is no follow-up. We want to get an update on that study and they would like to confirm that they want to close the study. He recommends that we close the study.

Jaime Arango is the secondary reviewer: Andy per Jaime.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111 to terminate the study:

(1) Reviewers determined that this study is not greater than minimal risk and is consistent with sound research design and does not unnecessarily expose subjects to risk.

(2) Risks are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.
There are no vulnerable populations associated with this study.

(4) The Investigator has chosen a waiver of informed consent, which is appropriate for this study.

(8) Safeguards are in place for the rights and welfare of vulnerable populations.
No vulnerable populations in this study.

Letter:

Motion: Contingent Approval continuing review as not greater than minimal risk for 12 months and the study will work toward termination.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

Meeting Adjourned.