Meeting Date: January 5, 2020
Next Meeting: February 5, 2020

Attendance:
Jamie Forrest, M.S. (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)
Description: The primary investigator has asked for the protocol to be closed because they did not have any enrollment and they did not receive IRB approval until the grant had actually expired. Therefore, they would like to request to close the study.

Fashner, Julia
Jamie Forrest: did not have any comments to add
Motion: Dr. Fashner moved to close the study, Jamie Forrest moved to second the motion

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

Protocol Title: MK1439018 phase 3 multi-center double blind randomized active comparator controlled clinical trial to evaluate the efficacy and safety of MK1439 100mg QD vs darunavir 800mg QD + ritonavir 100mg QD

Description: Dr. Ichite primary reviewer: The study is almost identical to the previous study submission. To continue review of the education and has been going on for several years. This submission was made in August 2019 and they have begun enrolling subjects. Currently, one patient on follow-up. They are no longer enrolling patients and we would like an update on this study to ensure that it was closed. There is nothing further to review at this point as the study has been closed.

Andy speaking for Jamie Arango approval for criteria worksheet. It is a continuation and no research areas impacted by modifications. Researchers have expertise and there are no conflicts of interest. Determines to approve the submission.

Motion: Dr. Ichite motion to approve the continuation of the study with the intent to terminate. Second: Julie Moore

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.