September 05, 2018
9:00-11:00 AM

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

IRB 2 Convened Committee
Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair)

Keshia Reid (Co-Chair)

Nkechi Ichite (present by phone)

Dongming Cui

Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Julie Moore (non-affiliated)

Julia Fashner (present by phone)

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)

Absent:

Adrian Cooksey (present by phone)

Other Attendees: Rotanya Bryan, MPA and Gavin Grigg

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.

Approval of Previous Minutes:

Minutes from the 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:

Big Data Research: Practical Solutions to Emerging Challenges for IRBs –PRIMR

Full Board Reviews:

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:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Montero, Jose	Ichite, Nkechi PharmD, PhD Forrest, Jamie MS

Meeting Discussion: This is a previously approved study. The presenter, Dr. Ichite, provided a general overview. MK-018 is a phase multicenter, double-blind, randomized, active comparator-controlled clinical trial to evaluate the safety and efficacy of Doravirine 100 mg once daily versus Darunavier 800 mg once daily plus Ritonavir 100 mg once daily. Doravirine is an inhibitor that will be taken in combination with Truvada. The research team hypothesized that MK-1439 100 mg q.d. is non-inferior to

darunavir/ritonavir (800 mg/100mg) q.d., each in combination with TRUVADA™ or EPZICOM™/KIVEXA™, as assessed by the proportion of subjects with HIV-1 RNA <40 copies/mL at Week 48. Superiority of MK-1439 100 mg q.d. to darunavir/ritonavir (800 mg/100 mg) q.d. will be assessed if non-inferiority is established.

Currently, there is one participant enrolled in the study. Two have withdrawn. One participant's viral was over 50. After a retest and VL was still >50, PI withdrew patient on 08-MAY-2017. He started a new regimen with his regular provider of Genvoya on 08-MAY-2017. Since then, patient has been doing well on his new regimen and his VL is <20. Another patient recently withdrew after reading articles regarding Truvada and how it could cause problems with bone density. His withdraw date was 05-JUL-2018 and he started a new regiment on same day of Descovy and Tivicay by his provider.

The study is progressing well. There are no new risks found by the investigators. No new findings to report. There have been no changes made to the study. No reportable events or problem reports, only personnel changes during the approval period.

Dr. Ichite had no objects with the study and recommended approval for another 12 months. The secondary presenter (Jamie Forrest) noted that the one remaining participant would remain in the study for an additional 96 weeks, as a part of the expanded portion of the research. She seconded approval of continuation. One of the reviewers noticed that one of the study consenters was not listed on the application. The board made the decision that an unauthorized staff member consenting participant into a study was a form of non-compliance. They requested that HRPP staff contact the research team and assure that the consenter was authorized to gain consent.

Motion: A motion to table the study was made and seconded.

Total votes to table the study: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Protocol Title: Strategic Timing of AntiRetroviral Treatment (START) (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Somboonwit, Charurut	Ichite, Nkechi PharmD, PhD Reid, Keshia PhD

Meeting Discussion: This is a previously approved study. The presenter, Dr. Ichite, provided a general overview. The two objectives of this protocol are to determine initiation of ART alters the rate of lung function decline compared to deferral of ART until the CD4+ declines below 350 cells/mm 3 in HIV-1 infected persons who are antiretroviral naïve with a CD4+ count above 500 cells/mm3 and to determine if immediate ART alters respiratory health status compared to deferred ART.

11 participants have completed the study one withdrew because they left the country to visit an ailing relative and never contacted the study team. After several weeks, site contacted patient (calls and emails) but patient never return any calls or emails after several months of attempts. Site will now start collecting information on participants through the end of 2021. Study wants to know how well HIV drugs will improve health over time for both groups in the study: those who began HIV drugs right away and those who waited to start.

Beginning in January 2018, participants at most sites will no longer have visit the clinic as part of the START study. The researchers will work with subject's doctors to collect information about their health from the medical chart. This will include the CD4 count, HIV viral load, and whether patient have been sick or in the hospital. The plan is to continue to collect this information each year through 2021. This is from version 4.0 of the protocol that was submitted in October 2017 and approved by the IRB in November 2017.

The study is progressing well. There are no new risks found by the investigators. No new findings to report. There have been no changes made to the study. No reportable events or problem reports. The primary present and secondary presenter (Dr. Reid) recommended approval for an additional 12 months.

Motion: A motion to approve the study for another 12 months was made and seconded.

Total votes to approve for 12 months: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Next Meeting: October 3, 2018

Other Business: None

Meeting Adjourned: 10:00am