October 03, 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) (Subpart B: Pregnant women)

Nkechi Ichite (present by phone)

Julie Moore (non-affiliated; present by phone)

Julia Fashner (present by phone)(non-affiliated)

Alternate:

Bob Eadie, JD (person whose primary interest is non-scientific; present by phone)

Absent:

Adrian Cooksey (present by phone)

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

Dongming Cui

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

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, 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.

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: A webinar on the topic of "Big Data" was provided by PRIMR.

(#1) Protocol Title: MK-1439-018 A Phase 3 Multicenter, Double-Blind, Randomized, Active Compartator-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

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Montero, Jose MD	Nkechi Ichite Jamie Forrest

Meeting Discussion: This is a previously approved study that was tabled September 05, 2018. 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 load (VL) 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 objections to 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. Before the meeting, researchers confirmed with HRPP staff that that the consenter was authorized to consent.

Total votes to approve for 12 months: (Total members voting: 6) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 4

(#2) Protocol Title: THE EVALUATION OF PARTNER SERVICES AND DISEASE INTERVENTION SPECIALISTS (DIS) AND THE IMPACT ON TRENDS IN SYPHILIS CASES IN THE STATE FLORIDA

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	Baker, Charlotte DrPH	Keshia Reid
		Julie Moore

Meeting Discussion: This is an initial study being conducted by Florida Agricultural and Mechanical University in conjunction with the Florida Department of Health. Together these organizations identified an Institute of Public Health doctoral student to lead this evaluation with assistance from staff within the STD and Viral Hepatitis Section of the Florida Department of Health. The FAMU doctoral student worked with the Florida Department of Health to develop the survey instruments for interviewing disease intervention specialists (DIS), supervisory staff and clientele regarding partner services. According to the identified timelines, the FAMU doctoral student will begin interviewing these target populations and systematically collect the data. The doctoral student will be responsible for securely storing, managing, and the quality of data collected. In addition, when interviews are completed the FAMU doctoral student will extract, clean, and analyze the data collected from the interviews. At the conclusion of the data analysis period, the FAMU doctoral student will communicate the findings with

appropriate staff at the Florida Department of Health and Florida A&M University and work to share findings with internal and external stakeholders. Data will be collected through semi-structured interviews and quantitative surveys of DIS, supervisory staff and Area Managers. Only DIS with a minimum of 50 syphilis cases per calendar-year will be eligible to participate in the semi-structured interviews. Client participation is restricted to those cases with a syphilis disposition indicated in FDOH PRISM system. The researchers propose to interview disease intervention specialists, supervisory staff, and clients to evaluate the effectiveness and efficacy of the Partner Services model to determine potential approaches for improvement.

The board did not find the research design to be sound. The application states there are no client incentives but then mentions gift cards in several places, including recruitment letters. Consistency is needed. The board was also unclear if participants would be contacted through phone call first to gauge interest and then a consent form would be mailed to them or would they be sent the consent form first and then participate in an interview after consenting.

Risks were found to be greater than minimum because clients syphilis status could be disclosed if another person answers their phone, hears the conversation, or opens the mailed envelope with the consent letter. In addition, DIS supervisors and area managers data could be used for job performance evaluations. The board noted that researchers minimized risks for DIS but risks were still present for clients. Selection of subjects were found to be equitable but information about payment to participants was inconsistent. Investigators stated that clients would not receive any incentives but mentioned the use of gift cards in the recruitment letters.

The researchers submitted a long-form consent form for review. The board found it adequate for gaining legally acceptable consent. They also found that protection of confidentiality and privacy to be acceptable. Research staff were found to be sufficiently qualified.

The presenters had the following questions and concerns with the study:

- Graduate students conducting phone interviews with clients are not on the IRB protocol but are accessing PHI and gathering data on a sensitive topic. Please submit biographical sketches, CITI, and COI for them.
- The application states there are no client incentives but then goes on to mention gift cards in several places, including recruitment letters. Consistency is needed. Participants are being compensated with a $10 gift card for participating in the survey. The client consent says that participants will not be eligible for compensation unless they complete the entire session. This is coercive and may unduly influence participants to continue the interview beyond the point at which they feel comfortable doing so. Either all participants should receive the $10 gift card, even if they don't complete the entire interview, or compensation should be pro-rated.
- Clarification on study design for contacting clients is needed – it seems clients will first be contacted by phone to gauge interest in participating, then mailed a consent form before scheduling a call, but this wasn't quite clear. Please outline the step by step process in the attached protocol.
- Client syphilis disclosure -- researchers do not provide enough detail about precautions to eliminate the risk of disclosure from phone calls and letters. Need to consider ways to contact participants without revealing syphilis status.

- Study is not greater than minimal risk – remove this label from the study.
- Phase 2 consent e-mail for DIS: This document seems to mix up the online survey portion which will have already been completed by DIS' and the interview portion. I.e. it says "we are conducting all participant interviews via WebEx. . . . There are no wrong or right answers to this online survey." Then at the bottom it says "click the link to go to the next page." Isn't this the consent for the interview? Please revise.
- Clients--The Moderator Script asks clients to disclose county in which they live and the date on which they were diagnosed with syphilis. Please clarify whether the FAMU study team is part of the FAMU covered entity. If so, county and dates of diagnosis + health information = PHI, so HIPAA authorization must be obtained as part of the informed consent process. If the FAMU study team is not part of the FAMU covered entity, no HIPAA authorization is required.
- Phase 2 consent e-mail for Area Managers: also says "click the link to go to the next page." Isn't this the consent for the interview? Please revise.

The board found that the study required extensive revisions but would be less than minimal risk if the requested revisions were made. Board members voted to disapprove the study but asked that the researcher submit a new application with their revisions included.

Total votes for disapproval: Affirmative: 6 Negative: Recusal: Absent:4

Next Meeting: November 7, 2018

Other Business: None

Meeting Adjourned: 10:45am