November 16, 2016
1:30-3:00 PM

Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea (Present by phone)
Bob Eadie (non-scientist)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card

Absent:
Daphne Holden
Nina McGrew (non-affiliated)
Katisa Donaldson (non-affiliated) (non-scientist)

Other Attendees: Rotanya Bryan, MPA 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.

Members present by phone received all pertinent materials 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.

Approval of Previous Minutes:

Minutes from the October 19, 2016 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:

Karen Card, DrPH provided an overview of the intersection of HIPAA and public health research. She focused on what is considered Protected Health Information (PHI), data use agreements, and data linkages.

(#1) Protocol Title: [MK1439-018] 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, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Jose Montero, MD	Ovidiu Cotea Karen Card

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modifications. The two proposed modification contained revised consent for sponsors. Minor changes in risk. Some language modifications. Sponsor would like to give a bottle to patients as a thank you. No new side effects. Participants will be notified. Secondary analysis of data. No conflict of interests from researchers. Sound research design. Staff qualified. No vulnerable populations. Participant selection is equitable. Karen agrees that modification does not add extra risk. Change in study coordinator. Gift of

water bottle is minimal**.**

Motion: A motion was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 3

(#2) Protocol Title: Strategic Timing of Antiretroviral Treatment (START) Orange

Submission:	**Principal Investigator:**	**Presenters:**
(Modification, Continuing)	Nila Desai, MD	Ovidiu Cotea Daphne Holden Sandra Schoenfisch

Meeting Discussion: The primary reviewer provides an overview of the study and the proposed modifications. This study wanted to test whether or not it was beneficial to start retroviral treatments early. Study is taking place at Orange. 12 participants are still enrolled and five have withdrawn. Secondary analysis is taking place. Participants are due for a follow-up in December 2017. Dr. Schoenfisch explained how the modification was to discontinue the pulmonary arm of the study. Participants will be notified of these changes. Study is no longer enrolling participants. Dr. Card asked why there were withdrawals. Dr. Schoenfisch explained that the withdrawals happened in prior years and are common during drug trials.

Motion: A motion was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 3

(#2) Protocol Title: Strategic Timing of Antiretroviral Treatment (START) Hillsborough

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Charurut Somboonwit, MD	Sandra Schoenfisch Keshia Reid

Meeting Discussion: The primary reviewer provided and overview of the study. Subjects were selected based on their morbidity. Study ends in 2021. Pulmonary arm of the study has stopped. Enrollment for participants has ended. Data is secure. No new incidence. Dr. Reid asked for clarification on when the study would end. She was informed that it would end in 2021.

Motion: A motion was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal:0 Absent: 3

Next Meeting: December 21, 2016

Other Business: Rotanya Bryan discussed threetopics that were presented at the OHRP conference. Bonnie Gaughan-Bailey updated members on the new ZIKA funding opportunity announcements.

Meeting Adjourned: 2:15pm