November 15, 2017
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)
Karen Card
Barbara Frentzen (non-affiliated)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)

Absent:
Nina McGrew (non-affiliated)
Daphne Holden

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 **October 18, 2017** 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:

Rotanya Bryan updated members on the Common Rule Revisions. An NPRM was posted. Revised regulations maybe on hold. HRPP staff will continue to provide updates.

(#1) Protocol Title: Strategic Timing of AntiRetroviral Treatment (Hillsborough)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, MD	Ovidiu Cotea
		Karen Card

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. This is a previously approved study under the supervision of the principal investigator (PI) Dr. Charurut Somboonwit. The researcher proposed modifications that include changes to the protocol, consent, funding, and participant letter. The protocol lists changes to data collection methods. No other lab data will be collected other than CD4 counts. The trial will no longer include subsidies. SAEs will no longer be reported on a real-time basis, unscheduled hospitalizations will be included as a part of the annual data collection. Participants will be notified of these changes. No changes to study personnel or conflict of interests were reported. Dr. Cotea had no objections to the modifications and recommended approval.

Dr. Card was the secondary presenter on this study and provided a couple of additions to Dr. Cotea's review. The principal hypothesis of this study has been answered. As a result, all HIV positive patients

will be offered antiretroviral treatments, regardless of their CD4 count. The study is closed to enrollment. Consent only applies if study participants move from one site to another. Dr. Card suggested approval and possibly expediting this review in the future.

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

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

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

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

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. This is a previously approved protocol that includes the same modifications as Hillsborough. Researchers will now be starting version four of the study in January 2018. It was recommended that all patients start retroviral treatment regardless of CD4 count. Patients will no longer receive medication from the old study. No vulnerable populations and no additional risks to participants. Dr. Cotea recommended approval of the study.

Dr. Schoenfisch noted that patients will be transitioned to the ADAPT study. No withdraws within the last 12 months. HIV is now essentially a chronic disease.

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

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

(#3) Protocol Title: 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 [MK1439-018]

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Jose Montero, MD	Ovidiu Cotea Barbara Frentzen

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. This is a previously approved study. The researchers requested two modifications. The first modification is to the Investigation Brochure (IB) 9 dated October 18, 2017 that included minor grammatical changes. The

second modification involved removing the sub-investigator (Sally Alrabaa). Participants will not be notified of these changes. Secondary analysis of the study continues. No vulnerable populations. Reviewer recommended approval. Secondary reviewer concurred with the primary reviewer. Ms. Frentzen asked if the study site was permanently closed. She was informed that it in fact was.

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

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: December 20, 2017

Other Business: None

Meeting Adjourned: 2:00pm