September 19, 2018
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)
Daphne Holden
Karen Card (Co – Chair)
Megan Macdonald (Expertise in Subpart D: Children)
Shoshana Levy (Present by phone)
Bob Eadie (non-scientist) (Present by phone)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)

Absent:
Nina McGrew (non-affiliated) (Present by phone)
Barbara Frentzen (Present by phone) (non-affiliated)

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 August 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:

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

Protocol Title: [GS-US-380-4458] A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Fixed Dose Combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide versus Dolutegravir + Emtricitabine/Tenofovir Disoproxil Fumarate in Treatment Naïve, HIV-1 and Hepatitis B Co-Infected Adults (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Morano, Jamie	Cotea, Ovidiu MD, MPH Holden, Daphne Ph.D, MS

Meeting Discussion: This is an initial review of the "Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Fixed Dose Combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide versus Dolutegravir + Emtricitabine/Tenofovir Disoproxil Fumarate in Treatment Naïve, HIV-1 and Hepatitis B Co-Infected Adults." The primary presenter (Dr. Cotea) provided a detailed overview of the study.

Bictegravir/Emtricitabine/Tenofovir Alafenamide is FDA approved for HIV positive patient use. The study aims to test the non-inferiority of FDC of B/F/TAF versus DTG + F/TDF, with respect to the portion of subjects who achieve HIV-1 RNA < 50 copies/mL at Week 48 as defined by the US FDA-defined snapshot algorithm and to the proportion of subjects with plasma HBV DNA < 29 IU/mL at Week 48. This is a multidrug, double-blind study that plans to enroll 240 patients at 70 global sites. There will be two treatment groups. 120 will be provided Bictegravir/Emtricitabine/Tenofovir Alafenamide, while the other group will take Dolutegravir + Emtricitabine/Tenofovir Disoproxil Fumarate. This study is blinded to both the investigators and subjects.

The committee found the researchers and staff qualifications to be adequate. None of the researchers reported any conflicts of interest. Review of anticipated risks and potential benefits were found to be greater than minimal risk. Subjects must be over the age of 18 with and HIV-1 co-infection. Research participants will be compensated $50 in a form of a debit card for each completed visit. There are approximately 14 visits in total. Treatment is free of charge and any injury will be reasonably compensated by Gilead.

The study will include a long form consent form. The board found the consent form to be adequate. All elements of the consent form are included. There are adequate provisions to protect the confidentiality of data, which will be monitored by the Data Monitoring Committee (DMC). Dr. Cotea and Dr. Holden had now objections with study and recommended approval for 12 months.

Motion: A motion was made for a 12-month approval.

Total votes for approval: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: October 17, 2018

Other Business: None

Meeting Adjourned: 2:25pm