

February 07, 2017
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

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

Kelli Wells (present by phone)

Absent:

Kellie O'Dare (non-scientist)

Julie Moore (non-affiliated)

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

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:

Rotanya Bryan facilitated a conversation about the article [When A Tattoo Means Life Or Death. Literally.](#)

(#1) Protocol Title: GS-US-366-1160 A Phase 3b, Randomized, Double-Blind Study to Evaluate Switching from a Regimen Consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects

Submission:
(Continuing)

Principal Investigator:
Todd Wills, MD

Presenters:
Nkechi Ichite
Keshia Reid. PhD

Meeting Discussion: This is a previously approved study. The primary reviewer, Dr. Ichite, provided a general overview of the study. This study was designed to compare Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir

Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects. The drug was a test drug in the beginning but was later approved by the FDA during the course of the study. Two arms of the study were conducted with the purpose of collecting on safety and efficacy of the data. Eight patients were accrued during the life of the study, seven were enrolled. Study has accomplished its intended goal. Study will be open until the end of February.

The study has progressed as expected. No modifications, no changes in risks, no changes in standard of care, and no reportable events. The staff listed no conflicts of interests. All elements of consent are in place and monitored appropriately. Dr. Ichite recommended approval. Dr. Reid (secondary presenter) had nothing to add and recommended approval.

Motion: A motion to approve the study until the end of February was made and seconded.

Total votes to disapprove: Affirmative: ~~8~~6 Negative: 0 Recusal: 0 Absent: ~~23~~

Next Meeting: March 7, 2017

Other Business: None

Meeting Adjourned: 9:25