

April 19, 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

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### **IRB Attendance:**

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)

Ovidiu Cotea (Present by phone)

Daphne Holden

Keshia Reid (Expertise in Subpart B: Pregnant women)

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)

Barbara Frentzen (non-affiliated)

### **Absent:**

Bob Eadie (non-scientist)

Nina McGrew (non-affiliated)

Karen Card (Co-chair)

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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 March 15, 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, MPA provided education on the Common Rule revisions and NIH single IRB. PRIMR provided a snapshot of the Common Rule revisions which include broad consent guidelines, change in IRB operations, defining the scope of research and guidelines of exemptions. The NIH single IRB policy guide listed the definition of 'grant funded' and who is responsible for implementation.

## Continuing

**(#1) Protocol Title:** GS-1216 A Phase 3b, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed Dose Combination (FDC) in HIV-1 Positive Subjects who are Virologically Suppressed on Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF)

**Submission:**  
(Continuing)

**Principal Investigator:**  
Todd Wills, MD

**Presenters:**  
Ovidiu Cotea  
Daphne Holden

**Meeting Discussion:** The primary reviewer, Dr. Cotea provided an overview of the study and the modification. This is a previously approved study. A Phase 3b, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed Dose Combination (FDC) in HIV-1 Positive Subjects who are Virologically Suppressed on Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF). Researchers are testing the safety and efficacy of this drug versus the old drug. There were no changes to the protocol or informed consent. A monitoring site visit was conducted in January. Site monitors only found scheduling conflicts. No safety events and no discrepancies. Three participants are currently enrolled. The study has progressed as expected. No reportable events. Changes to the study personnel. Research continues with no vulnerable populations. The primary reviewer recommended approval. The secondary presenter, Dr. Holden did not have any concerns and provided approval.

**Motion:** A motion was made and seconded.

**Total votes to approve for 12 months:** Affirmative: 6 Negative: 0 Recusal: 0 Absent: 3

**Next Meeting:** May 18, 2017

**Other Business:** None

**Meeting Adjourned:** 2:30pm