

July 6, 2016
9:00-10:00 AM



Department of Health
2585 Merchants Row
Conference Rm. 320 P
Tallahassee, Florida 32311

IRB 2 Convened Committee Meeting Minutes

IRB Attendance:

Carina Blackmore (Chair)
Jamie Forrest (non-scientific)
Kevin Sherin (present by phone)
Dongming Cui
Kelli Wells (present by phone)
Julie Moore (non-scientific) (non-voting)

Absent:

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)
Cheryl Clark (Expertise in children, pregnant women)
Nkechi Ichite (present by phone)

Other Attendees: Karen Card, MPH, Rotanya Bryan, MPA and Bonnie Gaughan-Bailey, MPA

Quorum

A quorum was present. A quorum is defined as a 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 **June 1, 2016** meeting were circulated by email and modified by member input.

Education: Consultation with UF IRB chairpersons

Karen Card described six suggestions UF consultants recommended to improve the DOH IRB. The consultants suggested IRB member recognition, contingent approval, tabling studies, incident inclusion of vulnerable populations in data studies, stamping consent forms, and continuing/modifications review.

Modifications:

(#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:

(Modification)

Principal Investigator:

Todd Wills, M.D.

Presenters:

Kevin Sherin
Dongming Cui

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. Dr. Sherin stated that the modifications would change follow-ups from 48 to 96 week for extended study of safety. Changes made to all appropriate documents including protocol, consent, treatment card; all documents are in order. Dr. Cui described the study of FDA- approved medication. He commented that it was a well-designed study; competent investigators. Risk is greater than minimal. Patient safety is protected; no vulnerable populations. \$50 to recruit participants; unbiased recruitment.

Motion: A motion of approval was made and seconded.

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

(#2) Protocol Title: GS-US-366-1216 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:

(Modification)

Principal Investigator:

Todd Wills, M.D.

Presenters:

Kelli Wells
Carina Blackmore

Meeting Discussion: Dr. Wells provided an overview of the study and a description of the modification. Dr. Wells stated that study modification extends the follow-up portion of study from 48 to 96 weeks to further examine long-term safety data. Study is well done and impressive in attention to detail, including informed consent. Modification requires more study visits and lab work as part of extended follow-up.

Language is adjusted in the consent. Editorial changes to the study documents. Changed definitions of efficacy endpoints. No other significant changes. Study well put together; appropriate attention put toward reflecting changes in the consent form. Dr. Blackmore echoes Dr. Wells' opinion. No negative impact on participants; changes clearly described.

Motion: A motion of approval was made and seconded.

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

Next Meeting: August 3, 2016

Other Business: IRB members had some concerns about the forms and their efficacy. They were informed that HRPP staff was in the process of contracting a new online system that would simplify the review process.

Meeting Adjourned: 9:33am