March 9, 2016
9:00-10:30 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)
Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)
Cheryl Clark (Expertise in children, pregnant women)
Dongming Cui
Jamie Forrest
Nkechi Ichite (present by phone)
Kevin Sherin (present by phone)

Absent:
Kelli Wells

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 members present. The quorum also reflected the requirement 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 February 3, 2016 meeting were circulated by email and modified by member input.

Conflict of Interest: Declared

Dr. Sherin abstained from voting on protocol (1).

- Serving as the immediate supervisor of a researcher within the last year

Education:

Karen Card provided education on potential conflicts of interest. She reviewed the different levels of conflicts of interest, including the individual and institutional differences. She also advised members on how to manage conflicts of interest when they arise.

(1) Protocol Title: REPRIEVE (A5332) - Randomized Trial to Prevent Vascular Events in HIV infected patients

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Lynne Hopkins, MD	Nkechi Ichite
		Kelli Wells

Meeting Discussion: This study could not be reviewed because the secondary presenter was absent and their notes/comments were not present.

Motion: Tabled for the next agenda.

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

2) Protocol Title: Multicenter, Double-Blind, Randomized, 2-Part, Dose Ranging Study to Compare the Safety, and Antiretroviral Activity of MK-1439 Plus TRUVADA™ Versus Efavirenz Plus TRUVADA™ in Antiretroviral Treatment-Naive, HIV-1 Infected Patients [MK1439-007]

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Jose Montero, MD	Nkechi Ichite
		Kevin Sherin

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modifications to an ongoing study that has been reviewed several times. This study compares the study drug to a standard regimen, both with Truvada. There are changes in language to the consent form made by the sponsor Merck in December 2015. All else remains the same; the risk benefit ratio unchanged. The Dr. Ichite recommended approval of the modification and Dr. Sherin concurred.

Motion: A motion for approval was made and seconded. There was no further discussion.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 1

(3) Protocol Title: (GS-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:	**Principal Investigator:**	**Presenters:**
(Modification, Continuing Review)	Todd Wills, MD	Carina Blackmore Dongming Cui

Meeting Discussion: Dr. Blackmore provided an overview of the study and a description of the modifications/continuing review. The objective is to evaluate the effectiveness, safety, and tolerability of a drug combination compared to another drug combination in HIV+ subjects. Seven participants are enrolled and on treatment, one screen failure. Study is closed to enrollment at the site. No concerns with study conduct. No major changes to protocol. Some staff changes over course of the year. No changes to risk, COI; consent is the same. No vulnerable populations. Dr. Blackmore recommended approval of the modification and continuing review, and Dr. Cui concurred.

Motion: A motion for approval was made and seconded. There was no further discussion.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 1

(4) Protocol Title: Clofazamine in the long term treatment of Leprosy

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	David Ashkin, MD	Carina Blackmore Kevin Sherin

Meeting Discussion: Dr. Blackmore provided an overview of the study. This drug had FDA approval in the past, but now it is dispensed to individuals using and IND number. One patient remains under treatment (a two-year regimen). No concerns over the treatment or regimen. Dr. Sherin requested a change in protocol version date and DOH language in the consent form. No other concerns expressed.

Dr. Blackmore saw no major changes to note. This is a well-known drug and treatment for a rare disease. Dr. Blackmore recommended approval of the continuing review, and Dr. Sherin concurred.

Motion: A motion for approval was pending and later approved after the researcher sent an updated informed consent application.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 1

Next Meeting: April 6, 2016

Other Business: Bonnie Gaughan-Bailey requested referrals for new IRB members. Jamie Forrest requested a list of IRB member expertise.

Meeting Adjourned: 9:43 am