December 7, 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:

Jamie Forrest (non-scientist)

Kevin Sherin (present by phone)

Carina Blackmore (Chair)

Dongming Cui

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

Kelli Wells

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

Julie Moore (non-affiliated)

Absent:

Nkechi Ichite (present by phone)

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

Quorum

A quorum was present. A quorum is defined as the majority of the IRB embers 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 **November 2, 2016** 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:

Karen Card, DrPH provided an overview of the intersection of HIPAA and public health research. She focused on what is considered Protected Health Information (PHI), data use agreements, and data linkages.

(#1) Protocol Title: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere) Version 2.0

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Patricia Emmanuel, MD	Kevin Sherin
		Dongming Cui

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modification. This study observes multiple drug combinations for HIV patients. Previously unknown information on the vertical transmission of HIV. The amendment provides information to the cohort on the changes to the product information, including new side effect profiles. The principal investigator is Dr. Emmanuel. The research is design is sound and expected to yield results. Risks are minimized and

pregnant women are not involved in the study. Dr. Blackmore asked if the study would continue. She was informed that the study would officially be closed once the current modification was approved.

Motion: A motion was made and seconded.

Total votes to approve: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

(#2) Protocol Title: [MK1439-018] A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Jose Montero, MD	Carina Blackmore Shamarial Roberson

Meeting Discussion: The primary reviewer provided an overview of the study. This study evaluates the antiretroviral activity, safety and tolerability, and immunologic effect of MK-1439 100 mg. q.d., compared to d darunavir/ritonavir (800 mg/100 mg) q.d., each in combination with TRUVADA™ or EPZICOM™/KIVEXA™, as measured by the proportion of subjects achieving HIV-1 RNA <40 copies/mL at Week 48. Participants are randomly assigning and the duration of participation is 96 weeks. Enrollment continues and no changes to the protocol. The study has sound design and was recommended for approval for another 12 months.

Motion: A motion was made and seconded.

Total votes for approval for 12 months: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

(#3) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE A5332)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing, Modification)	Charurut Somboonwit, MD	Kelli Wells Jamie Forrest

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modification. This study is a drug therapy to prevent heart disease for those with HIV. The first modification is related to changes made to the heart health questionnaire. The second modification

provides payment for those participating in the post entry study. This is a randomized clinical trial. Consent and research design are satisfactory. Enrollment continues with a goal of 75 participants. Dr. Blackmore asked why there was an increase in payment. Jamie Forrest stated that there was no real reason, but the amount was less than $100 and would not be coercive. Julie Moore noted that the USF number on the consent form was incorrect and would need to be changed.

Motion: A motion was made and seconded.

Total votes to approve for 12 months: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

(#4) Protocol Title: Cancer Epidemiology in Adventists

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Gary Fraser, PhD	Ichite Nkechinyere
		Jaime Arango

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modification. This study takes place at Loma Linda University. Dr. Fraser is the principal investigator. The researchers are studying Adventist diet vs. regular American diets and cancer rates. Researchers are utilizing Florida Cancer Data Systems. The study was approved for 96,500 participants. The researchers seek to answer whether or not the Adventist diet makes a difference to the development of certain cancers. The research is sound. Small incentive of a gift card and risks/benefits are reasonable.

The modification was submitted as sub-arm of the study. The sub -arm would review particular cancers in African Americans. Researchers are monitoring quintiles, dietary intake, calories, meat consumption, cancer outcomes, treatment, survival rates, BMI etc. Extraction of specimens and interview of participants. Prospective activity.

Dr. Arango was the initial reviewer under the expedited category. He was uncomfortable with the modification and listed the following concerns:

- HIPAA disclosure is set to expire in January
- NIH clinical grant did not match the protocol. Telephone script and letter missing.
- Consent form is contradictory

He offered the suggestion of making the modification into a separate study that would have a different review from the original. Dr. Sherin suggested that the study be tabled and sent back to the researcher for clarification and correction.

Motion: A motion was made and seconded.

Total votes to table study: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Next Meeting: January 4, 2017

Other Business: Bonnie Gaughan-Bailey announced hiring Dr. Sampson as administrative staff for the IRB and REI.

Meeting Adjourned: 10:15am