April 20, 2016
1:30-3:00 PM

Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea (Present by phone)
Bob Eadie (non-scientist)
Daphne Holden
Nina McGrew (non-affiliated)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Other Attendees: Karen Card, MPH and Rotanya Bryan, 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 **March 16, 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: Risk/Benefit Assessment: When Medical Treatment is a Research Procedure

Karen Card described the various risks and expected benefits of medical treatments. She noted that the IRB should do the following when reviewing protocols:

- Identify the risks
- Determine that the risks are minimized
- Identify the probable benefits
- Determine that the risks are reasonable given the probable benefits
- Ensure the subjects get accurate descriptions of the risks and probable benefits
- Determine appropriate intervals of periodic review and monitoring of data
- Examine protection of privacy and confidentiality provisions
- Examine additional safeguards for vulnerable populations

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modifications)	Lynne Hopkins, MD	Ovidiu Cotea Sandra Schoenfisch

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/ modifications. The study is a greater than minimal risk, multicenter study. Modifications to the study included a change in the risk cut off from 7.5% - 10% to broaden the eligibility of participants. In the past, African American men and smokers were excluded from the study. A modification to the study would allow for these populations to be included. Participants will be notified of changes. No changes in staff and no vulnerable populations. Dr. Cotea recommended approval and Dr. Schoenfisch seconded.

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

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

The following studies were not reviewed due to the fact that one of the required IRB members was called away and could not participate.

(#2) 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:	**Principal Investigator:**	**Presenters:**
(Continuing)	Todd Wills, MD	Ovidiu Cotea Daphne Holden

Meeting Discussion: This study was not reviewed.

Motion: Tabled for the next meeting.

Total votes for approval:

(#3) Protocol Title: Clofazimine in the long-term treatment of leprosy-Phase III

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Beata Casanas, DO	Sandra Schoenfisch Daphne Holden

Meeting Discussion: This study was not reviewed.

Motion: Tabled for the next meeting.

Total votes for approval:

(#4) Protocol Title: Falls Reported Among Minority and non-minority Employees (FRAME) in Residential Construction

Submission:	**Principal Investigator:**	**Presenters:**
(Initial)	Alberto Caban-Martinez, MD	Sandra Schoenfisch Bob Eadie

Meeting Discussion: The presenters listed some of the concerns they had with the study and the researcher was invited to provide answers. It was agreed upon that the researcher would revise their application materials and return it to the reviewer.

Motion: Tabled for the next meeting.

Total votes for approval:

(#5) Protocol Title: Use of an Online Immunization Registry in the Pediatric Emergency Department to Confirm Tetanus Vaccination as up to date with Injuries requiring tetanus vaccination in children who present to the Emergency Department

Submission:	**Principal Investigator:**	**Presenters:**
(Initial)	Cristina Zeretzke	Shamarial Roberson Keshia Reid

Meeting Discussion: The presenters listed some of the concerns they had with the study and the researcher was invited to provide answers. It was agreed upon that the researcher would revise their application materials and return it to the reviewer.

Motion: Tabled for the next meeting.

Total votes for approval:

Next Meeting: May 18, 2016

Other Business: None

Meeting Adjourned: 3:00 pm