March 16, 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)
Robert Eadie
Daphne Holden
Samantha Alford-Morales
Keshia Reid
Shamarial Roberson

Absent:

Ovidiu Cotea
Nina McGrew

Other Attendees: Karen Card, MPH. Bonnie Gaughan-Bailey, MPA, and Rotanya Bryan, 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 17, 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 presented a review of unanticipated problems, adverse events, and non-compliance reporting. She guided board members on responses to allegations of non-compliance and the correct agencies for reporting.

Modification

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, MD	Sandra Schoenfisch
	Patricia Emmanuel, MD	Bob Eadie

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. The study is greater than minimal risk, multicenter study at Hillsborough CHD. In 2012, the research question was answered. Modifications were minor. Changes were made in regard to the treatment for grade 1,2 rashes. Enrollment of subjects has ended. Dr. Schoenfisch recommended approval: Bob Eadie concurred.

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

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, MD	Sandra Schoenfisch
		Keshia Reid

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. Study is a multi-center, greater than minimal risk clinical drug trial. Uses statins to address chronic issues in HIV patients. Minor changes in language. No changes to risk. Dr. Schoenfisch recommended approval and Dr. Reid concurred.

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

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Protocol Title: Strategic Timing of AntiRetroviral Treatment (START)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Nila Desai, MD	Ovidiu Cotea
		Daphne Holden

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. Study observed two groups, one with early START treatments and the other with later treatments. Researchers found significant differences (including morbidity) and are requesting long-term follow-ups. Protocol objectives were modified and participants will be re-consented. Dr. Holden recommended approval and Dr. Schoenfisch seconded.

Motion: A motion for approval was made and seconded. Dr. Holden noted that bio specimens were subject to language in consent: some future research purpose. Shamarial Roberson asked how this would impact research in the future. Karen Card replied that future regulations would make the use of bio specimens limited to what participants consented to.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Continuing Review

Protocol Title: GS-0112 A Phase 3 Open-label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide single tablet Regimen in HIV-1 Positive Patients with Mild to Moderate Renal Impairment

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Todd Wills, MD	Ovidiu Cotea
		Shamarial Roberson

Meeting Discussion: The primary reviewer provided an overview of the study. This study observes the safety of HIV medication single tablet regimen. Eight patients were enrolled in the study. Two have completed the study and six remain. Changes to the consent form included longer participation, from 90 weeks to 144. Protocol is sound. Staff qualified. No reported problems. Participants have continued access to the drug. Shamarial Roberson recommended approval and Dr. Schoenfisch seconded.

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

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 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	Samantha Alford
		Ovidiu Cotea

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

Next Meeting: April 20, 2016

Other Business: Bonnie Gaughan-Bailey requested referrals for new IRB members.

Meeting Adjourned: 2:30 pm