February 17, 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
Daphne Holden
Samantha Alford-Morales (present by phone)
Roland Reis (Non-Scientist)

Absent:
Nina McGrew
Keshia Reid
Shamarial Roberson

Other Attendees: Karen Card, M.P.H. and Rotanya Bryan, M.P.A.

Quorum

A quorum was present. A quorum is defined as a majority of the voting members of the IRB Committee. The quorum also reflected the requirement outlined in 45 CFR 46.108 as well as 21 CFR 56.107. Please note that the number of members present will not always match the total number of votes on items as the total number votes reflects the number of members present in the room at the time of discussion and vote. 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 January 20, 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 information on the importance of determining conflicts of interest.

Protocol Title: GS-0109 A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Todd Wills, MD	Ovidiu Cotea Samantha Alford-Morales

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. His review determined that the modifications did not modify the design or have any impact on the risks for the subject. Subjects were notified of changes. The secondary reviewer concurred with his findings.

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

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

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:**
Modification	Todd Wills, MD	Ovidiu Cotea Samantha Alford-Morales

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. Slight protocol amendment to repair grammatical errors with changes to the staff. Subjects will be notified of changes, no vulnerable population and no concerns by the reviewer. His review determined that the modifications did not modify the design or have any impact on the risks for the subject. The secondary reviewer concurred with his findings.

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

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

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:**
Modification	Todd Wills, MD	Ovidiu Cotea Samantha Alford-Morales

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. The reviewer found the modifications to be slight. Modifications include a revised consent form and additions to the staff. The study is closed to enrollment at the Hillsborough site and it is in the secondary analysis phase. Current subjects will be notified of changes. No vulnerable population and greater than minimal risk. The primary reviewer approved the modification and the second concurred.

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

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

Protocol Title: GS-0119 A Phase 3 Open-Label Study to Evaluate Switching from Optimized Stable Antiretroviral Regimens Containing Darunavir to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir\ Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) plus Darunavir (DRV) in Treatment Experienced HIV-1 Positive Adults

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Todd Wills, MD	Ovidiu Cotea Bob Eadie

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/modifications. Minor modifications which involved changed in staff and changes to the Investigator's Brochure. Subjects are being enrolled. Secondary analysis is taking place. Risks are still greater than minimum. Privacy is addressed satisfactorily. The primary reviewer approved the modification and the second concurred.

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

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

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

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Charurut Somboonwit, MD Patricia Emmanuel, M.D.	Sandra Schoenfisch Keshia Reid

Meeting Discussion: Secondary presenter was not present for the meeting. Study could not be voted on and will be tabled for next month's agenda.

Motion: Table the review for the next agenda

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

Protocol Title: GS-0109 A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Todd Wills, MD	Ovidiu Cotea Samantha Alford-Morales

Meeting Discussion: The study is in its second year and has enrolled 8 participants, five remain. This study is closed to enrollment; involves no vulnerable populations and is greater than minimum risk. The study is progressing normally, and there have been no new risks, no problems, and no new information. The primary reviewer recommended approval for another 12 months and the secondary presenter concurred.

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

Total votes to approve for 12 months: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 3

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

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Charurut Somboonwit, MD	Ovidiu Cotea Shamarial Roberson

Meeting Discussion: The study is in its second year and has enrolled 9 participants. No changes. The reviewer noted that this drug is promising and easy on the liver. The study is progressing normally, and there have been no new risks, no problems, and no new information. The primary reviewer recommended approval for another 12 months and the secondary presenter concurred.

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

Total votes to approve for 12 months: Affirmative: 5 Negative: 0 Recusal: 0 absent: 3

Next Meeting: March 16, 2016

Other Business: Rotanya solicited member input on the length of time to review studies.

Meeting Adjourned: 2:30pm