February 3, 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)
Brenda Whittenberg (Expertise in Subpart C: Prisoners, non-affiliated)
Cheryl Clark (Expertise in Subpart B: Pregnant Women/Fetus/Neonates; and Subpart D: Children)
Dongming Cui
Jamie Forrest
Kelli Wells
Nkechi Ichite
Ovidiu Cotea (Alternate for Kevin Sherin)
Sandra Schoenfisch (Present by phone)

Absent:
Jamie Arango (non-scientist, non-affiliated)

Other Attendees: Rotanya Bryan, Shamarial Roberson, Keshia Reid and Karen Card

Quorum

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. 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.

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, MPH, reviewed the OHRP proposed changes to the common rule. The proposed rules include: changes to informed consent, new study exemptions, US institutions relying on a single IRB, eliminating continuing review for data analysis, and extending policy to all clinical trials. Rotanya, MPA reviewed points of contact between IRB staff and IRB members. Rotanya also educated members (using the IRB member worksheet) on the importance of providing rationale for approval in the worksheet. She gave the example of using 45 CFR 46 as validation for approving a study. She also stressed that in addition to being within compliance, AAHRPP looks for worksheet completion in order to reaccredit the FDOH Human Research Protection Program.

Continuing Review

Protocol Title: Clofazamine use in the treatment of patients with disease caused by strains of Multidrug Resistant Tuberculosis or Mycob acterium Avium Complex.

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	David Ashkin, MD	Ovidiu Cotea Brenda Whittenberg

Meeting Discussion: A reviewer presented a summary of the protocol, followed by discussion. The Committee reviewed a status report of the progress of this clinical investigation. Clofazamine has been in use for years, but is no longer available commercially. It is used by special arrangement with Novartis, the manufacturer, for use. FDA requires new drug investigation for each patient under treatment; a new drug investigation for each patient under treatment; a new drug IND is issued for each patient, and it is withdrawn at the end of treatment.

This study is progressing as expected. 16 patients currently; 47 total, 29 completed. Two patients withdrew due to adverse side effects. No vulnerable populations. All adult patients. No reportable events have occurred during this review period. No changes to the protocol. The Committee provided rationale for the basis of IRB approval under 21 CFR 56.111. The primary reviewer provided an overview of the study and recommended approval of the continuing review request. The secondary reviewer concurred and also recommended approval. Karen Card submitted a question to the investigator after the meeting from the IRB; this did not prevent approval of the CR.

Motion: Approve this greater than minimal risk study for another 12 months.

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

Protocol Title: GS-US-292-0111: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Positive, Antiretroviral Treatment- Naïve Adults

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review and modification	Todd Wills, MD	Ovidu Cotea Jamie Forrest

Meeting Discussion: Reviewers presented a summary of the study and progress report. Study has progressed as expected. Three patients remain on the study. One became pregnant and was withdrawn. Drug is approved by the FDA is on the market; this study is in secondary analysis. Changes to protocol are minor, including staff changes. Changes submitted in December 2015 for review. All current and former patients will be notified of changes to staff and protocol. No reportable events have occurred. All participants have been enrolled; study is closed at Hillsborough; secondary analysis continues. The Committee provided rationale for the basis of IRB approval under 21 CFR 56.111. The primary reviewer provided an overview of the study and recommended approval of the continuing review request. The secondary reviewer concurred and also recommended approval.

Motion: Approve this greater than minimal risk study for another 12 months.

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

Protocol Title: A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK1439) 100mg Once Daily Versus Darunavir 800mg Once Daily plus Ritonavir 100mg Once Daily, Each in Combination with Truvada or Epzicom/Kivexa, in Treatment-Naïve HIV-1 Infected Subjects [Protocol No.: MK1439-018]

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review	Jose Montero, MD	Ovidu Cotea Kelli Wells

Meeting Discussion: This study evaluates a new type of HIV medication. Participants will be randomized to the new medication (MK-1439) or standard regiment of daraunavir/ritonavir. Differences in HIV-1 RNA copies will be used to evaluate differential efficacy. ICF meets all applicable disclosures.

The Committee provided rationale for the basis of IRB approval under21 CFR 56.111. This study examines safety of the investigational drug. Study is progressing as expected. Three participants are enrolled. All completed 8-week visit. Changes to informed consent are included in this continuing review; there are new side effects added to the IC. Current subjects will be notified of changes. There are staff updates. No vulnerable populations involved. No concerns expressed by presenters. The primary reviewer provided an overview of the study and recommended approval of the continuing review request. The secondary reviewer concurred and also recommended approval.

Motion: Approve this greater than minimal risk study for another 12 months.

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

Protocol Title: 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 [Protocol No.: GS-US-292-0112]

Submission:	**Principal Investigator:**	**Presenters:**
Continuing Review and modification	Todd Wills, MD	Carina Blackmore Jamie Arango

Meeting Discussion: Reviewers presented a summary of the study and progress report. Study has progressed as expected. Six patients are enrolled in the study; two patients in the last 12 months. The study will conclude at week 144. No vulnerable populations. No changes or items of concern. The drug has been FDA approved while the study continues. The primary reviewer provided an overview of the

study and recommended approval of the continuing review request. The secondary reviewer concurred and also recommended approval.

Motion: Approve this greater than minimal risk study for another 12 months.

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

This study will be presented and voted on again at the meeting on February 17, 2016, because the reviewers did not receive all parts of the modification documents.

Next Meeting: March 2, 2016

Other Business: Bonnie Gaughan-Bailey reviewed AAHRPP comments from the site visit in December 2015.

Meeting Adjourned: 10:00 am