January 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 (Present by Phone)
Samantha Alford-Morales (New member non-voting)
Ovidiu Cotea (Present by phone)
Daphne Holden
Nina McGrew (Present by Phone)
Keshia Reid (New member non-voting)
Shamarial Roberson (New member non-voting)
Roland Reis (Non-Scientist)

Absent:

Robert Eadie (New member non-voting)

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

Quorum

A quorum was present. A quorum of five voting members was 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 November 18, 2014 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, 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, MPA also reminded members to complete worksheets for compliance purposes.

Protocol Title: A Phase 3b, Randomized, Double-Blind Study to Evaluate Switching from a Regimen Consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects

Submission:	**Principal Investigator:**	**Presenters:** Ovidiu Cotea
(Modification)	Todd Wills, MD	Sandra Shoenfisch

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. Secondary analysis will continue. Changes to staff were minor

and documentation of staff qualifications was submitted. Modifications expanded the criteria for subject selection.

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: 0

Protocol Title: Strategic Timing of Antiretroviral Treatment (START) Hillsborough/ To determine whether early ART (start at CD4+ cell count > 500 cells/mm3) is superior to deferred ART (until CD4+ cell count < 350 cells/mm3 or AIDS develops, or certain other conditions and symptoms occur) in delaying the occurrence of a composite outcome consisting of AIDS, non-AIDS, or death from any cause. This is a multicenter study to determine the efficacy and timing for ART.

Submission:	**Principal Investigator:**	**Presenters: Ovidiu Cotea**
(Continuing Review and modification)	Charurut Somboonwit, MD	Daphne Holden

Meeting Discussion: The study is in its second year and has enrolled 42 participants, 1 participant was enrolled in the previous year. There have been 26 withdrawals, and 16 remain in the study. Five withdrew because of screen failure, 11 lost to follow-up, 6 withdrew, and four moved. The study is closed to enrollment and secondary analysis continues. There are no changes to the protocol or risks for subjects. Minor changes to research staff include addition of a clinical research coordinator. Documentation supporting qualifications of the new staff member were submitted. Study is scheduled to end on December 16, 2016. 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. There was no additional discussion.

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

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

Protocol Title: Strategic Timing of Antiretroviral Treatment (START) Orange/ To determine whether early ART (start at CD4+ cell count > 500 cells/mm3) is superior to deferred ART (until CD4+ cell count < 350 cells/mm3 or AIDS develops, or certain other conditions and symptoms occur) in delaying the occurrence of a composite outcome consisting of AIDS, non-AIDS, or death from any cause. This is a multicenter study to determine the efficacy and timing for ART.

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

Meeting Discussion: The study is in its second year and has enrolled 17 participants, 1 in the previous year. There have been 5 withdrawals, and 12 remain in the study. Five withdrew because of transfers to different sites, moving out of state, and participant did not want to continue to receive services. This year, the site reported as a result of the study DSMB endpoint notification, there were changes to the study that affected participants. The answer as to the benefit of starting ART early was favorable, and as it was recommended that all study participants be offered the opportunity start ART regardless of study arm assignment. 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. There was no additional discussion.

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

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

Protocol Title: EGRIFTA Diabetic Retinopathy/ A prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate whether EGRIFTA® (tesamorelin for injection), 2 mg once daily SC, increases the risk of development or progression of diabetic retinopathy when administered to HIV-infected subjects with abdominal lipohypertrophy and concomitant diabetes

Submission:	**Principal Investigator:**	**Presenters:** Ovidiu Cotea
(Continuing Review)	Ewa Szczypinska, MD	Daphne Holden

Meeting Discussion: The study is in its second year and has enrolled 6 participants, 0 in the previous year. There have been 3 withdrawals, and 3 remain in the study. Three withdrew due to homelessness, transportation and out-of-country travel. The study is progressing normally, and there have been no new risks, no problems, no new information or publications or other significant modifications to the study in the previous year. This year, the study reported a publication of DSMB report and Newsletters. The primary reviewer provided an overview of the study and determined that there were no changes to the protocol or risks to subjects. The reviewer recommend was for approval of the continuing review request. The secondary reviewer concurred and also recommended approval. There was no additional discussion.

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

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

Next Meeting: 02/17/16

Meeting Adjourned: (2:15 pm)