March 20, 2015
1:30-3:00 pm

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

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair)

Ron Brown (Present by Phone)

Becky Grigg

Daphne Holden (Absent)

Ovidiu Cotea (Present by Phone)

Roland Reis (Present by Phone)

Karen Reynolds (Absent)

Other Attendees:

Derek Schwabe-Warf, IRB Analyst, Public Health Research Unit

Robert Hood, Ph.D, Public Health Research Unit

Quorum **was** present. Quorum is defined as a majority of members present. 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.

Attendance Notes:

Conflict of Interest: None Declared

Members did not report any:

- Ownership interest, stock options, or other financial interest related to the research of any value.

- Compensation related to the research of any value.

- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

- Board or executive relationship related to the research, regardless of compensation.

- Interest that could be affected by the outcome of the research.

Education: Robert Hood initiated a discussion of qualifications researchers and research staff obtaining consent. For FDA regulated studies, who has sufficient qualifications and expertise to obtain consent? Members discussed the qualifications of physicians, nurses, and study coordinators in terms of obtaining consent. Members asked for this discussion to continue at the next board meeting so they had time to reflect on the issue. In addition, Robert Hood presented information concerning updated Federal Regulations for Conflict of Interest disclosures. All IRB members and staff will fill out Conflict of Interest. In addition, all researchers, staff, and IRB members will take training concerning conflict of interests and will report training to staff.

(1) **Protocol Title**: GS-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 Naive Adults

Submission: Modification

Description: Modification to present updated IB with additional risks for Tenofovir Alafenamide related to inflammation of the middle eye in one human subject and dogs.

P.I: Todd Wills, MD

Primary Presenters: Ovidiu Cotea, Roland Reis

Meeting Discussion:

- Risks to subjects are minimized by using procedures consistent with sound research design.
- Researcher has sufficient qualifications and expertise to conduct the research and protect participants.
- Risks to subjects are reasonable in relation to anticipated benefits, if any and the importance of the knowledge that may reasonably be expected to result.
- Research is greater than minimal risk.
- Subject selection is equitable.
- The Investigator has chosen long form written informed consent, which is appropriate for this study. All applicable elements of disclosure are present in the consent document.
- No issues with safety monitoring.
- Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants.
- Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data.
- No problems or complaints from participants.

- No conflicts of interest were reported.
- No vulnerable populations.

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: Recusal: Absent:

(2) **Protocol Title**: GS-US-292-0109 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: Continuing Review

Description: Modification to present updated IB with additional risks for Tenofovir Alafenamide related to inflammation of the middle eye in one human subject and dogs.

P.I: Todd Wills, MD

Primary Presenters: Ovidiu Cotea, Ron Brown

Meeting Discussion:

- Risks to subjects are minimized by using procedures consistent with sound research design.
- Researcher has sufficient qualifications and expertise to conduct the research and protect participants.
- Risks to subjects are reasonable in relation to anticipated benefits, if any and the importance of the knowledge that may reasonably be expected to result.
- Research is greater than minimal risk.
- Subject selection is equitable.
- The Investigator has chosen long form written informed consent, which is appropriate for this study. All applicable elements of disclosure are present in the consent document.
- No issues with safety monitoring.
- Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants.
- Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data.
- No conflicts of interest were reported.
- No vulnerable populations
- 6 patients currently enrolled in the study.
- No problems or complaints from participants.
- Ron Brown noted some of the study personnel's CITI will expire in the next few months, staff will check with site.
- Ron Brown noted that the consent document did not clearly state each drug alone was approved but not the combination. Asked staff to confirm this change occurs.

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: Recusal: Absent:

(3) **Protocol Title**: GS-US-292-0112 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: Continuing Review

Description: Closed to Enrollment, Modification to present updated IB with additional risks for Tenofovir Alafenamide related to inflammation of the middle eye in one human subject and dogs.

P.I: Todd Wills, MD

Primary Presenters: Ovidiu Cotea, Ron Brown

Meeting Discussion:

- Risks to subjects are minimized by using procedures consistent with sound research design.
- Researcher has sufficient qualifications and expertise to conduct the research and protect participants.
- Risks to subjects are reasonable in relation to anticipated benefits, if any and the importance of the knowledge that may reasonably be expected to result.
- Research is greater than minimal risk.
- Subject selection is equitable.
- The Investigator has chosen long form written informed consent, which is appropriate for this study. All applicable elements of disclosure are present in the consent document.
- No issues with safety monitoring.
- Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants.
- Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data.
- No complaints from participants.
- No conflicts of interest were reported.
- No vulnerable populations.
- One problem/issue of non-compliance reported, patient was seen outside of study visit window. Members asked staff to gather additional information from the site.

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: Recusal: Absent:

(4) **Protocol Title**: Diabetic Retinopathy in HIV subjects treated with EGRIFTA

Submission: Continuing Review

Description: Recruitment previously stopped because short supply of drugs. Change in sponsor from EMD Serano to Theratechnologies.

P.I: Ewa Szczypinksa, MD

Primary Presenters: Ovidiu Cotea, Becky Grigg

Meeting Discussion:

- Risks to subjects are minimized by using procedures consistent with sound research design.
- Researcher has sufficient qualifications and expertise to conduct the research and protect participants.
- Risks to subjects are reasonable in relation to anticipated benefits, if any and the importance of the knowledge that may reasonably be expected to result.
- Research is greater than minimal risk.
- Subject selection is equitable.
- The Investigator has chosen long form written informed consent, which is appropriate for this study. All applicable elements of disclosure are present in the consent document.
- No issues with safety monitoring.
- Committee members discussed the provisions protecting privacy interests in the application and determined that adequate provisions were made to protect the privacy of participants.
- Committee members discussed the provisions protecting confidentiality interests in the application and determined that adequate provisions were made to protect the confidentiality of data.
- No conflicts of interest were reported.
- No problems or complaints from participants.
- No vulnerable populations.
- Two participants discontinued but not due to error on site.
- Ron Brown noted the ICF needs to be changed to reflect 2-1 mg injections instead of 1-2mg injections. Asked staff to confirm this change.

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: Recusal: Absent:

Next Meeting: April 15, 2015

Other Business: IRB annual education days-April 24th in Tallahassee, at the central office from 10:00 am-3:00 pm. Conference room TBA. June 22nd at Orlando County Health Department from 10:00 am- 3:00 pm in the main auditorium.

Meeting Adjourned: 2:20