January 21, 2015
1:30-3:30 pm

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

IRB1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair)

Ron Brown (Present by Phone)

Becky Grigg (Absent)

Daphne Holden

Ovidiu Cotea (Present by Phone)

Roland Reis (Present by Phone)

Karen Reynolds (Absent)

Other Attendees:

Robert Hood, Ph.D, Public Health Research Unit

Derek Schwabe-Warf, Public Health Research Unit

Quorum was **present**. The 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.

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 discussed the IRB transition away from FluidReview noting we have all the data from the FluidReview system. Word forms will be used instead of the online system. IRB members are invited to comment on the new word forms.

Robert Hood presented a slideshow on consent. This slideshow focused on waivers of consent and waivers of consent documentation applicability.

(1) Protocol Title: [START] Strategic Timing of AntiRetroviral Treatment

Description: Continuing Review

P.I: Charurut Somboonwit

Primary Presenters: Cotea, 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.

Total votes for approval: (Total members voting: 6) Affirmative: 6 Negative: Recusal: Absent:

(2) Protocol Title: 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

Description: Continuing Review

P.I: Todd Wills

Primary Presenters: Cotea, 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 conflicts of interest were reported.
- No vulnerable populations present.

Total votes for approval: (Total members voting: 6) Affirmative: 6 Negative: Recusal: Absent:

(3) Protocol Title: Forteo Patient Registry

Description: Continuing Review

P.I: Alicia Gilsenan

Primary Presenters: Reynolds, Schoenfisch

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 not 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.

The board moved to have this study reviewed by expedited review in the future. They found the following conditions were met:

Expedited Category 9 (both conditions need to be met)

- Condition 1: The research is not conducted under an investigational new drug application or investigational device exemption.
- Condition 2: The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Total votes for approval: (Total members voting: 6) Affirmative: 6 Negative: Recusal: Absent:

Next Meeting: 2/18/2015

Other Buisness:

Meeting Adjourned: 2:45 pm