February 18, 2015
1:30-3:00

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)
Karen Reynolds (Absent)
Ovidiu Cotea (Present by Phone)
Becky Grigg (Present by Phone
Daphne Holden
Roland Reis (Present by Phone)

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 presented two articles looking at ethical considerations in comparative effectiveness research. The revised review process using word forms was discussed. We will be using protocol numbers although these numbers will be different from IRBwise. Sandra asked for general notes field on IRB review forms.

Robert addressed the responsibilities of IRB members when reviewing studies for convened meetings. Staff will send out folders with readings for everyone and readings for presenters. Staff will triage researcher documents into one of the folders using a worksheet, which will be sent out at each convened meeting.

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

Description: Continuing Review

P.I Nila Desai

Primary Presenters: Schoenfisch, 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.
- No issues brought up 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 enrolled.

There are 14 participants in the study. Two participants have moved from Orlando and thus are not enrolled at this site. However, they stayed in the START study at their residence. No significant changes. ICF was modified to reflect Nila Desai as P.I. Site underwent annual monitoring in June 2014 with no major findings.

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

(2) Protocol Title: A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects (MK-1439-018)

Description: Initial Review

P.I Jose Montero

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.
- No issues brought up 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 enrolled.

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. Ron Brown expressed concerns the CITI training expires for some personnel before the next continuing review.

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

Next Meeting: 3/18/2015

Other Buisness:

Meeting Adjourned: (2:45 pm)