Meeting Date: January 22, 2020
Next Meeting: February 19, 2020

Attendance:
Sandra Schoenfisch (CHAIR)
Karen Card (CO-CHAIR)
Ovidiu Cotea
Robert Eadie
Barbara Frentzen
Megan MacDonald

4 needed for quorum

Quorum:
A quorum **was** present.

The quorum is defined as a majority of members present, one member whose primary interests are non-scientific, and one member who is not affiliated, and whose immediate family are not affiliated with DOH. 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.

Other Attendees:
Andrew Wentzell, IRB Coordinator
Gavin Grigg, IRB Analyst
Bonnie Gaughan-Bailey, Administrator, Office of Public Health Research

Attendance Notes:
Conflict of Interest: None
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.

Old Business: None

Unable to formally vote because the notice was not sent out in time. Therefore, we can discuss but we will not take formal votes at this meeting today.

Continuing Review

Protocol Title: Multiple Patient Program for Lamprene (clofazimine) for the treatment of Non-Tuberculous Mycobacterial (NTM) Infections (Florida Department of Health)

Dr. Cotea is the primary reviewer: Study is asking that this medication needs IRB approval to continue treatment of patients. No problem with this study. Continuing review.

Dr. Schoenfisch is the secondary reviewer: This is another request to get an IND approved which is required each time he adds a client. Client is prescribed the treatment regime because everything else has failed and this is the last step to deal with the infection. Protocol is very well done and designed study in which the attentiveness to the patients on study is high. Sandra would recommend approval of the study when we are able to vote on the study.

Motion1:
Motion 2:

Total votes for approval: (Total members voting:) Affirmative: 0 Negative: 0 Recusal: 0 Absent: 0

Protocol Title: EGRIFTA LTO Study A Phase 4, observational, multicenter, 10-year prospective cohort safety study comparing subjects with HIV-associated abdominal liophypertrophy exposed to EGRIFTA (tesamorelin for injection) to a similar group of subjects not exposed to (Florida Department of Health)

Dr. Cotea is the primary reviewer: Needs to review protocol and will make recommendation. From what he understands based on what they are requesting that they would need to verify the drug company does not require a licensed MD on the protocol and if that was approved then we can decide.

Dr. Karen Card second reviewer: Have reviewed this study a few times. The PI has left the department and they are requesting modifying the protocol to make the study coordinator now the PI. The coordinator does not have a great deal of post-secondary information but is very familiar with the study. This would typically be unacceptable, but they have gone into a data collection phase even though the study is open, it is not enrolling. She considers this to be acceptable to approve the PI change request to the protocol. When the time comes her recommendation would be to recommend approval of the study.
Sandra was wondering if there was a requirement of a licensed physician to be on the protocol per the pharmaceutical company sponsor requirements. Karen will check and she will reconvene so we can take an official vote.

Andy will reach out to determine if the PI will need to be licensed per the pharmaceutical company at this stage in the study protocol to maintain the sponsorship.

No motion will be made today, but additional information will be gathered prior to the next meeting to make an informed decision and will be tabled.

Motion 1:
Motion 2:

Total votes for approval: (Total members voting:) Affirmative: 0 Negative: 0 Recusal: 0 Absent: 0

Other Business:
AHRPP reaccreditation process is ongoing

Notes: Applications reviewed and approved using the expedited procedure and exempt studies and non-research determinations were reported in the meeting agenda in IRB Manager; there were no questions or discussions about these actions.

Meeting Adjourned.