Meeting Date: February 19, 2020
Next Meeting: March 18, 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

Dr. Robert Cook, PI for "old business" study discussion

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

Submissions for Convened Board Continuing Review:

Protocol Title: The Florida Cohort to Monitor and Improve Health Outcomes: Wave 3 (Florida Department of Health)

Dr. Schoenfisch is primary reviewer: Study that is looking at health outcomes and access to health care for people who have HIV for have potential for becoming positive for HIV. Patient population does not always have access care and have a high attrition rate. The goal is to combine traditional treatments with new approaches to decrease attrition and educate clients so they can have the best health outcomes that they can related to their HIV and their other health outcomes. Florida has high HIV burden and new cases of HIV infection. Mixed aspects of longitudinal cohort design taking place in Tampa and Gainesville. They have a long form consent that will be used in Florida and they meet all FDOH requirements. The goal is to get a better understanding of the barriers that are keeping people from getting HIV and maintaining treatment. They have had community partnership and HIV infected individuals involved in the design of this program. There is not a lot of individual risk to be involved in this study and they are using the Red Cap data system to capture the data, and they are moving to use laptops and online programs to gather data for sexual histories and self-assessments which will be provided to them. They have private space for interviews and have 6- and 12-month follow-up and follow-up longitudinally for 5 years to determine the outcomes. They have qualified staff, three similar studies they are involved in, and of note we need to ensure current licenses are submitted to be sure we have access. Sandra did not have concerns and they have data safe storage and trained staff. They study will be tapping into all the people that have HIV which means they may have an opportunity to interact with pregnant women.

Dr. Cotea was second reviewer: Agree with Sandra's assessment of the study. The study is looking at a clinical study to find more information about varies factors of people living with HIV and the problems related with substance abuse and health issues. He has no concern whatsoever about the study and he recommends approval of the study.

Dr. Cotea moves to approve the study and Robert Eadie second the motion.

Total votes for approval: (Total members voting:) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

New Business

Protocol Title: Improving Sexually Transmitted Infection (STI) Testing and Treatment among People with HIV or at Risk for HIV (Florida Department of Health)

Sandra is the primary reviewer: This study is a federally funded study that involved Rutgers University of Nursing and UF and it is incorporating behavioral and social interventions to change the way that we receive services to get patients into services and keep them in the services. This study is using a lot of digital and computer assisted assessment tools for basic assessment, educational components, and sexual history, etc. It is a collaborative study with a heavy emphasis on behavioral interventions and assessments. Study focuses on barriers on the access to services where patients do not follow through and they are therefore using self-treatment. This study will use evidence-based interventions that focus on behavior and perspective of the individuals and a cost-based approach to their study.

Megan Macdonald second reviewer: two-year pilot study evaluating the implementation of four different interventions aimed at approving detection, diagnosis, and treatment of bacterial STI or people with HIV or at risk of contracting HIV. Computer based approach that is to collect pre and post appointments. There are patient self-collected specimens' option to determine what patients feel most comfortable with. They will have a provider training on documenting sexual histories and culturally sensitive conversations about sexuality and STI risk and implementation of LGBTQ welcoming space. Goal is to get high risk patients in for testing and treatment. Megan thought study design looked great overall. A couple concerns on consent form that she noticed: Different PI for each consent form for each of the different sites, but that does not match the PI on the protocol; no circumstances on consent form was presented about termination about participant termination. Megan also felt that the benefits to the participant listed did not seem direct benefits to the participants, they seemed more aligned with objectives vs being beneficial to the patient. She said it was slightly unclear that study procedures would only happen during regularly scheduled appointments, and that they will not have to come in for additional appointments.

Motion 1: Sandra
Motion 2: Megan

Total votes for approval: (Total members voting:) Affirmative: 6 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: This study was previously discussed. The concern was the PI was in place with as a study coordinator and we did not think this would be acceptable. Otherwise there is no objection to this study stated.

Karen Card is the secondary reviewer: Same concern as Dr. Cotea

Andy: They are planning on adding another medical coordinator/consultant to the study either as the PI or the CO-PI, but they have not submitted a modified application at this time. This was previously requested that there was an addition and modification to their application, and it was not received.

Sandra: Clinical studies need to have a licensed physician to be on the study or in charge of the study throughout so that the drug company agrees with the change that they are making. A physician needs to be in charge in order to analyze the data and have a consultant to protect the patients.

Dr. Cotea agrees with concern and that says we need to have a licensed physician as a PI added to the study to fully protect and educate the patients. Motions that we need a PI that is a physician.

Robert Eadie: seconds Dr. Cotea's motion.

Motion to require that a PI needs to be a physician on this study and the sponsor needs to be modified. More follow-up needed and the study will be suspended until the issue is addressed. We require documentation from the sponsor saying that they are satisfied about the change.

No one had any disagreements with this proposed suspension.

Other Business:
Bonnie: Biomedical research continues to be involved with the Healthy Brain Initiative

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.