

Meeting Date: May 20, 2020
Next Meeting: June 17, 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: Performance evaluation of the VIDAS® TB-IGRA assay: Active TB Study, High Risk for LTBI, and Precision Study (University of Florida)

Dr. Cotea is primary reviewer: No patients have been reviewed as of yet. Initial submission for clinical study trial. TB is one of the most common infections worldwide and 1/3 of world population is infected with TB. Some people have latent TB and some have active TB infection. It's very important to identify and treat the latent and TB infection in order to reduce the transmission. Testing has been the same for 100+ years and they are wanting to use a new test to identify latent TB with an IFNg measurement in comparison to the quantum serum. Clinical study will take place worldwide and one site will be in Gainesville, enrolling 253 patients age range 2+ years. The goal is to identify a new test that will help to identify the latent TB infection at UF in Gainesville. Risks are no greater than minimum, confidentiality, study requirements, informed consent, and parents will be responsible for the informed consent of the children. Dr. Cotea recommends the approval of this study.

Karen was second reviewer: She agrees with Dr. Cotea. Extend approval on this study

Sandra second motion to approve

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: 0 Recusal: 0 Absent: 0

New Business

Protocol Title: Role of Gut Microbial Dysbiosis and Aging on HIV-associated Neurocognitive and Brain Dysfunction

Sandra is the primary reviewer: HIV at the neurocognitive level and brain dysfunction. Federally funded study at University of Louisville, partnering with UF to conduct their study in HIV+ patients. Looking at diet, activity, saliva and stool tests, urine, etc. The protocol is confusing and the impact of the study. Looking at the role of microbe imbalances in the gut and the impact of HIV on the neurocognitive function of these individuals. 100 participants in the main study. They are also doing a sub-study (we want to look at approval to the add on) for collecting specimens (stool and urine) as well as survey information about behavioral habits. Original study excludes women from the study, and in this arm they are talking about including women that could be pregnant women and that they are not screening women for pregnancy. The concern is that there is not a connection or a follow-up for care. There is minimal risk to the subjects. The main question is why the women are now included or to request that they not be included.

Dr. Cotea second reviewer: Agrees with everything that Sandra is saying. Need more clarification around the women involvement. We know from many studies' inflammation is important in HIV and there is a lot of HIV cases in the state of Florida. This study should provide the information about the cognitive impacts, considering the fact that people with HIV are living longer and longer providing important information. Provide more clarification as to why they want to include women in the study. Otherwise he does not have problem with approval of this study.

Motion to approve study with clarification around the benefit of having the women included. Final decision delegated to Sandra and Dr. Cotea upon answering the question around women inclusion.

Motion 1: Sandra

Motion 2: Bob Eadie

Total votes for approval: (Total members voting:) Affirmative: 5 Negative: 0 Recusal: 0 Absent: 0

Other Business:

Gina Larson will be joining IRB committee 1.

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.