

Meeting Date: March 18, 2020

Next Meeting:

Attendance:

Sandra Schoenfisch (CHAIR)

Karen Card (CO-CHAIR)

Ovidiu Cotea

Robert Eadie (had to leave early)

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

Robin DeWalt, Biomedical Scientific Advisor

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.

Attendance Note: Due to COVID-19, all IRB members were present by phone. Members present by phone received all pertinent material through IRB Manager prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

Old Business: None

New Business:

Data Systems Overview Presentation: Healthier Lake-Burger and Joe Lowry

Submissions for Convened Board Review:

Protocol Title: Offering women PrEP with education and shared decision-making (Florida Department of Health)

Sandra Schoenfisch is the primary reviewer: The study of women who are at risk or high risk of having contact with sexually transmitted infections and possible HIV. It's a study where they will be using clinics where women are seen for care in Duval county. Tools and resources have been used in other counties, this study has detailed protocol and women are offered based on their history and presentation to participate in the PREP protocol if criteria are met. Informed consent was received and eligibility is required, monitored once they are on the study to make sure there is drug tolerance and any side effects that are presenting and patients are made aware of the long term toxicities that may be involved with being on the program.

Revisions were asked to be made: Advisory board is in Jacksonville and administrative issues have been addressed, they had requested a HIPPA waiver and it was deemed HIPPA requirement was not appropriate and HIPPA compliance is recommended.

Barbara second reviewer: agrees with Sandra and they addressed minor administrative problems. They are collecting a lot of identifiers and sensitive information; they have a long form consent and they are advised to add HIPPA compliance to their informed consent but the HIPPA compliance form needs to be used.

Drug is FDA approved and it is an educational program therefore there was conversation around whether the study was considered greater than minimum risk.

After discussion, the IRB committee voted to check with DOH legal to determine how to write in requirements of HIPPA waiver and the informed consent disclosure.

Letter:

Motion: Sandra first motion, Barbara second

Total votes for approval: (Total members voting:) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0
➔ Will meet with Mr. Eadie by phone and will be conditional approval until his review.

Protocol Title: Tough Talks: Virtual Support for Difficult Conversations: Using Artificial Intelligence to Increase HIV Disclosure Among Young Men Who Have Sex With Men (Default Site)

Sandra was the primary reviewer: It is a study that the funding is from University of NC and taking place in multiple sites working with high risk men aging 16-29 with high risk behavior. Issues of this study resolves around disclosure and education around having those conversations around their high-risk behavior. Using online type resources and computer assisted learning to work with individuals on how to disclose and what do they say to their partners to help them get to a safe place. Provides them with a role play computer program for education and provides them with follow on resources. They want to test tools and adjust the interactive tools.

Sandra recommends approve the study located in Duval county.

Barbara was the second reviewer: Smart phone and tablet app was not provided so her concern was that she did not know what the app was. There was an advertisement with a barcode and was asking to scan the barcode for a qualification survey that was not provided to the IRB for the questions around the qualitative survey upon IRB submission and we are unable to review those variables. She is not aware of the regulations in Florida statute around the disclosure of HIV to their partners is technically a crime and we want to protect the participants around the risks especially because there are minors involved. They should provide the statute to the participants as well as preventative measures. She believes this study is potentially greater than minimal risk and needs more information to review. The biosketch and CITI training do not match so we need to get the corrected information.

After discussion the team decided to table until next month until we receive flyer, survey, script, and the app details from the submitter.

Protocol Title: Risk Factors of Infant Mortality Disparity in Indian River, County, Florida (Default Site)

Sandra primary reviewer: Doctoral candidate from Walden University using an existing database to look at Indian River county in Florida. Signed data use agreement in place already. Her Biosketch has much personal and professional interest that shows she has been involved in for some time. She is looking for approval to get the data for her study, no contact with subjects and has a good set of references and plan for why this study is important. Very thorough application. Recommends approval.

Karen Card second reviewer: Not as impressed with educational background but has a lot of experience with topic and data that she was using. She has a straightforward modeling exercise and Karen found over 6,000 births in Indian River county which confirms it is not a small issue and will give her statistical power. Indian River also has a very diverse demographic and she believes she can easily answer her questions around this question. No vulnerability to the subjects involved in this study and Karen recommends approval of the study.

After discussion the team has decided to approve the study.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0
➔ Will meet with Mr. Eadie by phone and will be conditional approval until his 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: 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.

Sandra was second reviewer: She agrees with Dr. Cotea. Study was presented well and very nicely laid out and she also recommends that the study be approved.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0
➔ Will meet with Mr. Eadie by phone and will be conditional approval until his review.

Protocol Title: The Effects of Neighborhood Change on Geographic Mobility, Socioeconomic Status, and Health Outcomes of Low-Income Women (Default Site)

Sandra is the primary reviewer: How women fair when it comes to their backgrounds and the support that they have. Secondary data analysis with no contact with participants. Data suggests low income children that move from places that lack upward mobility do better in areas where there are more opportunities. Low income women born between 1985-1990, track demographics, etc. Sandra thought study was acceptable and they have a probability model that looks reasonable. She recommends to approve.

Karen Card second reviewer: Secondary data analysis with no interaction with patients. Vital statistics will be doing the matching and will be issuing them the data use agreement. She studied the analysis closely to see what they were going to do, they are looking at a cohort of females, and when they give birth use that data from vital statistics. They have a point of birth data set and then another from when they give birth. No particular risk to the subjects and she recommends to approve this study.

Total votes for approval: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0
➔ Will meet with Mr. Eadie by phone and will be conditional approval until his review.

Other Business: There was no other business discussed at this meeting.

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.