Meeting Date: June 17, 2020
Next Meeting: July 15, 2020

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

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:
Follow-up on study review

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

Robert Cook called into the IRB meeting to be available to answer questions from the IRB Chair regarding the study and how it could affect potential pregnant women. Dr. Cook responded, letting the IRB committee know that the study team would make resources available for pregnant women and would not enroll them in nor involve them in any aspect of the study that could be deleterious to their health or the health of the fetus.

After discussion, the IRB committee voted to approve this study and cede review to UF.

Letter:

Motion: Approval initial review and cede review to UF.

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

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.

Continuing Review:
Protocol Title: Clofazimine in the treatment of leprosy (Florida Department of Health)
PI: Beata Casanas

Cotea, Invidiu
Card, Karen

2 reviews submitted

Protocol Title: Clofazimine in the treatment of leprosy

Description: There have been no participants enrolled in the study. This study is ongoing for use of Clofazamine in the treatment of Hansen's Disease.

Meeting Discussion: A reviewer presented a summary of the continuing review followed by discussion. This is a continuing review of a previously approved protocol. All committee members reviewed the continuing review application, which provides a progress report about the study. All committee members reviewed all modified documents.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111:

(1) Reviewers determined that this study is greater than minimal risk and is consistent with sound research design and does not unnecessarily expose subjects to risk.

(2) Risks are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.
There are no vulnerable populations associated with this study.

(4) The Investigator has chosen long form informed consent, which is appropriate for this study.
A most recent signed informed consent document is attached to the application.

(8) Safeguards are in place for the rights and welfare of vulnerable populations.
No vulnerable populations in this study.

Letter:

Motion: Approval continuing review as greater than minimal risk for 12 months.

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

Modification:
Protocol Title: The Effects of Neighborhood Change on Geographic Mobility, Socioeconomic Status, and Health Outcomes of Low-Income Women (Hunter College)
PI: Jessica Van Parys

Schoenfisch, Sandra
Card, Karen

2 reviews submitted

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

Description: Our previous study design description said that we would identify where low-income women were born by using their mother's residential addresses on their birth certificates. However, mother's residential addresses are not available prior to 2004, so we are modifying our original application to request mother's mailing addresses, which were available prior to 2004. The rest of our requested data elements and study design features remain the same.

Meeting Discussion: A reviewer presented a summary of the continuing review followed by discussion. This is a continuing review of a previously approved protocol. All committee members reviewed the continuing review application, which provides a progress report about the study. All committee members reviewed all modified documents.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111:

(1) Reviewers determined that this study is not greater than minimal risk and is consistent with sound research design and does not unnecessarily expose subjects to risk.

(2) Risks are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.
There are no vulnerable populations associated with this study.

(4) An updated DUA with Vital Statistics was attached to the application.

(8) Safeguards are in place for the rights and welfare of vulnerable populations.
No vulnerable populations in this study.

Letter:

Motion: Approval of modification as not greater than minimal risk.

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

Meeting Adjourned.