October 18, 2017
1:30-3:00 PM

Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea (Present by phone)
Daphne Holden
Karen Card
Barbara Frentzen (non-affiliated)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)

Absent:
Nina McGrew (non-affiliated)
Bob Eadie (non-scientist)

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, and Bonnie Gaughan-Bailey, MPA

Quorum

A quorum was present. A quorum is defined as the majority of the IRB members and representation of each of the members as identified in the requirements outlined in 45 CFR 46.108 as well as 21 CFR 56.107. At least one non-scientist and at least one non-affiliated member were present.

Approval of Previous Minutes:

Minutes from the **08/16/17** meeting were circulated by email and modified by member input.

Conflict of Interest:

Conflict of Interest: None declared

Members did not report any:

- Compensation or payments for services (e.g., consulting fees, lecture payments, bonus, royalties, paid authorship, honoraria, gifts, or in-kind products or services) related to the research of any value, except as otherwise excluded by this policy.
- Compensation or payments for services where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Equity interests (stocks, stock options, security, or other ownership interests) related to the research of any value.
- Equity interests whose value when aggregated for the individual and the individual's immediate family represents more than a five percent ownership interest in any single entity.
- Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family
- Equity interest related to the research of any amount to the researcher or any member of the researcher's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
- Intellectual property rights and interests (patents, copyrights, royalties, licensing agreements, and any other proprietary interest related to the research).
- Board or executive relationship related to the research, regardless of compensation.
- Involvement or participation in the design, conduct, or reporting of the research, including providing advice on Department registry data systems.
- Serving as the immediate supervisor of a researcher within the last year
- Any other interest that the IRB member believes would interfere with his or her ability to objectively review a protocol.
- Any travel related to research

Education:

IRB members went through a guided tour of the new IRB Manager system.

(#1) Protocol Title: The Total Environment and Hypertensive Disorders of Pregnancy: A Precision Public Health Approach

Submission:	**Principal Investigator:**	**Presenters:**
(Initial)	Hu Hui, PhD	Sandra Schoenfisch
		Keshia Reid

Meeting Discussion: The primary reviewer, Sandra Schoenfisch provided a general overview of the study. The principal investigator (PI) aims to analyze all of the environmental factors that contribute a woman's risk for developing hypertensive disorders of pregnancy (HDP). The researcher listed multiple aims that include determine the association between the total environment and HDP, analyze how the total environment contributes to racial disparities in HDP, and develop translational tools to support the dissemination of research findings. The PI will have access to various data bases and plans to complete data linkages to answer their hypothesis. The researcher plans to link Vital Statistics data with PRAMS.

Ultimately, the PI plans to develop a web app that will help pregnant women identify risk facts in their geographic areas. The long form consent was acceptable and provided ample information to participants. Staff are sufficiently qualified. Five women of childbearing age will be recruited to test the app. Participants will be paid $12.50 at the end of each month meeting. No potential risks to participants.

This was initially an expedited review, but the primary reviewer requested additional guidance in regard to the data linkages. Dr. Schoenfisch asked if Dr. Holden found any problems with the data or the researcher's requests. Dr. Holden responded that she had no problems. Dr. Holden and Dr. Schoenfisch recommended that the researcher consider enlisting more than five women to test the app and gain better results.

Motion: A motion to approve the study for another 12 months was made and seconded.

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

(#2) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE A5332)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Charurut Somboonwit, MD	Ovidiu Cotea Karen Card,

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. This is a previously approved protocol. Nothing has changed in regard to the protocol or the informed consent form. During the past approval period, one participant was incarcerated and subsequently removed from the study. The research was approved to enroll 75 participants. 60 subjects were enrolled, 45 remain. 15 withdrew and 12 did not qualify. There are no vulnerable populations, no changes to study staff. Dr. Card also commented that there would be a follow-up of participants from 2 ½ years to 5 ½ years. She also noted that there was a new self-identified gender question on the forms. Identifiers will continue to be stripped before they are sent to the study sponsors.

Barbara Frentzen asked for clarification about the incarcerated participant. Rotanya Bryan informed her the study subject was removed from the study and a problem report was completed. Ms. Frentzen had no further concerns.

Motion: A motion to approve the study for another 12 months was made and seconded.

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

(#3) Protocol Title: A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK1439) 100mg Once Daily Versus Darunavir 800mg Once Daily plus Ritonavir 100mg Once Daily, Each in Combination with Truvada or Epzicom/Kivexa, in Treatment-Naïve HIV-1 Infected Subjects [Protocol No.: MK1439-018]

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Jose Montero, MD	Ovidiu Cotea Sandra Schoenfisch

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. This is a previously approved study. Researchers were approved to enroll five participants, three remain. One of the participants withdrew from the study because of increased viral loads. Study participant was removed in May of 2017. They are doing well on a new drug regimen. There are no vulnerable populations. No changes in staff, informed consent, or protocol. Dr. Cotea had no concerns. Dr. Schoenfisch concurred.

Motion: A motion to approve the study for another 12 months was made and seconded.

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

(#4) Protocol Title: Biobank for African American Prostate Cancer Research in Florida

Submission:	**Principal Investigator:**	**Presenters:**
(Modification, Continuing)	Jong Park, PhD	Barbara Frentzen Daphne Holden

Meeting Discussion: The primary reviewer, Barbara Frentzen provided a general overview of the study. This is a previously approved study. This study is being conducting at several sites including Moffitt, University of Florida, and University of Miami. Research is funded by the Bankhead-Coley Cancer Research Program. 2,700 participants were approved to be enrolled in the study, 104 have been enrolled during the approval period. None of the participants have completed the study. Researchers requested a modification to the current list of staff. A research assistant (Mmadili Ilozumba) was added to the study. All of the qualifications were present and acceptable.

Ms. Frentzen noted that the “problem” section of the application must be checked and the full application should be signed. She also asked of the Department requested conflict of interest (COI) forms every year. She was informed that COIs were not required every approval year. Dr. Card asked if

board members would be willing to move the study to expedited review. No member made or seconded the motion. The study will continue to be reviewed during expedited meetings.

Motion: A motion to approve the study for another 12 months was made and seconded.

Total votes to approver for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: November 15, 2017

Other Business: None

Meeting Adjourned: 2:40pm