September 21, 2016
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, PhD, RN (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea, MD (Present by phone)
Bob Eadie (non-scientist)
Daphne Holden, PhD
Nina McGrew (non-affiliated)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card

Absent:
Katisa Donaldson (non-affiliated)

Other Attendees: Rotanya Bryan, MPA 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.

Members present by phone received all pertinent materials 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.

*Nina was absent for the first two studies but was able to call in for the last three.

Approval of Previous Minutes:

Minutes from the **August 17, 2016** 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:

Education did not occur.

Initial review

(#1) Protocol Title: Harvoni for HIV/HCV co-infection with advanced fibrosis or cirrhosis.

Submission:	**Principal Investigator:**	**Presenters:**
Initial	Lynne Hopkins, MD	Ovidiu Cotea Sandra Schoenfisch

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the initial review. This a retrospective study drug study of HIV/Hepatitis C Genotype 1 with advanced fibrosis or cirrhosis. Study takes place at DOH-Orange. Study reviews the tolerability and efficacy of Harvoni. Drug has been in use for two years. Morbidity has been high in patients with HIV and liver disease.

Treatment options were limited just a few years ago. Harvoni medication has been approved by the FDA but there is not enough data on the safety of the drug. 50 participants have been recruited for the study. They have already taken the drug or currently on it. Information will be taken from their charts. Study also looks at the virological response of participants. Subjects will need to complete questionnaires on drug abuse and alcohol.

Study is found to be not greater than minimal risk. Confidentiality and privacy are addressed. Long-form consent will be used to consent participants. Researchers are qualified and have several years of experience of performing similar research. No vulnerable populations.

Motion: A motion was made and seconded for another 12 months.

Total votes to approve for 12 months: Affirmative: 6, Negative: 0, Recusal: 0, Absent: 2.

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

Submission:	**Principal Investigator:**	**Presenters:**
Initial	Jong Park, PhD, MPH, MS	Keshia Reid Nina McGrew

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the initial review. This study proposes to create a statewide biobank of pre-existing specimens in African American men with prostate cancer. It also uses epidemiologic and molecular biological approaches to test the hypothesis that smoking increases the aggressiveness of prostate cancer among AA men. The research includes surveys, secondary analysis of Protected Health Information, Florida Cancer Data System and biological samples. Tumor tissue is obtained from pre-existing specimens. Study takes place at the Moffitt cancer center. Recruitment materials were adequate. Dr. Reid and Ms. McGrew approved the final version of the consent form.

Dr. Reid had some concerns with the research. She requested additional information with regard to how the researchers would be controlling the data, how data would be outlined, how the linkage of Medicare data and national death index relates to the research. Dr. Reid also requested additional information as to minimum standards and /or protocols for establishment of a biobank and if researchers other than those currently listed in the proposed study would have access to the data.

Motion: Study was tabled until additional information and concerns were addressed

Continuing

(#3) Protocol Title: HAART Standard Version of the PROMISE Study (Promoting Maternal and Infant Survival Everywhere)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Patricia Emmanuel, MD	Sandra Schoenfisch Keshia Reid

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the continuing review. This is a multi-center greater than minimal risk study. Enrollment has closed. Six subjects were enrolled, one completed the study. No modifications. No problem reporting. Dr. Reid questioned why only one subject completed the study. Dr. Schoenfisch answered that some participants are at different sites and others were lost to follow-ups.

Motion: A motion was made and seconded for another 12 months.

Total votes to approve for 12 months: Affirmative: 7, Negative: 0, Recusal: 0, Absent: 1.

(#4) Protocol Title: REPRIEVE (A5332)-Randomized Trial to Prevent Vascular Events in HIV infected patients.

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Lynne Hopkins, MD	Ovidiu Cotea Daphne Holden

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the continuing review. This study takes place at the Department of Health-Orange. New medication. There were few changes to the study. No participants have been recruited. Staff completed new certifications and trainings. A meeting will take place on June 21, 2016 to propose changes to risk factors for cardiovascular disease to a low of 3.6%. Smokers and African American's not enrolled and are underrepresented, so the proposed changes would widen the criteria. Risks to subjects are minimized. No vulnerable populations. Provisions for privacy and confidentiality are in place.

Motion: A motion was made and seconded for approval for 12 months.

Total votes to approve for 12 months: Affirmative: 7, Negative:0, Recusal: 0, Absent: 1.

Modification

(#5) Protocol Title: REPRIEVE (A5332)-Randomized Trial to Prevent Vascular Events in HIV infected patients.

Submission:	Principal Investigator:	Presenters:
(Modification)	Charurut Somboonwit, MD	Ovidiu Cotea
		Robert Eadie

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. This study takes place in DOH-Hillsborough. Criteria expanded to enroll more people including African Americans and smokers. Participants will not be notified of these changes. No participants are currently enrolled. The principal investigator is Dr. Charurut Somboonwit. The study is greater than minimal risk. No payments to participants and no vulnerable populations. Dr. Schoenfisch discussed why review of payment is critical to ethics review of research. She indicated the possibility of coercion if participants were offered sums of money that they could not refuse. Mr. Eadie had questions about modifications and if they qualify as minimal risk. Dr. Schoenfisch replied that expanding the criteria would allow additional subjects to be eligible for participation in the study.

Motion: A motion was made and seconded.

Total votes to approve for 12 months: Affirmative: 7, Negative: 0, Recusal: 0, Absent: 1.

Next Meeting: October 19, 2016

Other Business: Master's in Public Health at Benedictine University student (Erika Horne) sat in on the meeting for her education requirements. HRPP staff are recruiting a new IRB coordinator. Karen Card is now a member of the IRB and was appointed in the beginning of the month. IRB members were updated on the status of the new online system and questions regarding use of the current forms and some areas where there appears to be duplication of information were addressed.

Meeting Adjourned: 3:00pm