March 15, 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)
Bob Eadie (non-scientist) (Present by phone)
Nina McGrew (non-affiliated) (Present by phone)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card (Co-chair)

**Absent:**
Barbara Frentzen (non-affiliated)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)
Daphne Holden

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**Other Attendees:** Rotanya Bryan, MPA, Bonnie Gaughan-Bailey, MPA and Dinithia Sampson, PhD

**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.

**Approval of Previous Minutes:**

Minutes from the February 15, 2017 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**:

Dr. Card provided education on clinical endpoints and how they impact IRB review. Clinical endpoints are the occurrence of a disease, symptom, sign or laboratory abnormality that is related to the target of the trials. There are various types of endpoints that may change during the length of a study. It is critical that changes in endpoints are documented before clinical trials can begin. IRB's must be aware of changes in endpoints and critically consider the ethics when these situations arise.

**Modifications**

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

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Modification) | Jong Park, PhD | Keshia Reid<br>Nina McGrew |

**Meeting Discussion**: The primary reviewer, Dr. Reid provided an overview of the study and the modification. This a previously approved study with two primary aims to build a biobank and using epidemiology and molecular data to test the hypothesis that smoking increases the prevalence of cancer in men. The researchers are seeking approval for a follow-up postcard. The postcard would be mailed out to potential participants that did not respond to the initial recruitment letter. The postcard does not alter risks to participants. No subjects will be notified of the additional postcard. The postcard is consistent with previously approved materials. The primary reviewer recommended approval. The secondary presenter, Nina McGrew agreed with the review and the acceptability of the postcard. Ms. McGrew also asked if the study aims may be two separate studies.

**Motion:** A motion was made and seconded.

**Total votes to approve:** Affirmative:6 Negative: 0 Recusal: Absent:3

**(#2) Protocol Title:** A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects [MK1439-018]

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Modification) | Jose Montero, MD | Ovidiu Cotea<br>Robert Eadie |

**Meeting Discussion**: The primary reviewer, Dr. Cotea provided an overview of the study and the proposed modification. This is a previously approved study with Dr. Montero as the principal investigation. The proposed modifications include a patient survey, revised patient questionnaire, addendum for text messages, and addendum to extend the study. The text message addendum would be used as a reminder of participant's appointments. The addendum to extend the study would allow for 96 weeks to collect safety data. The reviewer had no concerns with the modifications and provided approval. The secondary presenter, Bob Eadie had no concerns or additional comments and provided approval.

**Motion:** A motion was made and seconded.

**Total votes to approve:** Affirmative:6 Negative: 0 Recusal: Absent:3

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

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Modification) | Xiaoping He, MD and Lynne A. Hopkins, MD | Sandra Schoenfisch<br>Daphne Holden |

**Meeting Discussion:** The primary reviewer, Dr. Schoenfisch provided an overview of the study and the proposed modification. The research aims to study the long-term effects of using Harvoni for the treatment of HIV/HCV co-infection. The researchers are requesting a waiver of consent for the health records review portion of their study. They cited the following reasons for their waiver request: research involves minimal risk, waiver will not adversely affect the rights and welfare of participants, the research could not be practically carried out without waiver, and participants would be notified wherever appropriate. They also revised their protocol to have the survey portion of the study contingent on funding. Dr. Schoenfisch had no concerns with the request after the researchers addressed the questions from the last review and provided her approval. Dr. Holden seconded her approval.

**Motion:** A motion was made and seconded.

**Total votes to approve:** Affirmative:6 Negative: 0 Recusal: Absent:3

**Continuing Review**

**(#4) Protocol Title:** Clofazimine use in the Long-term treatment of leprosy, Phase 3

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Continuing) | David Ashkin, MD | Sandra Schoenfisch<br>Karen Card |

**Meeting Discussion:** The primary reviewer, Dr. Schoenfisch provided an overview of the study and the proposed modification. Clofazimine is a drug used in the long-term treatment of Leprosy and was approved by the FDA in 1986. It is no longer available in the United States and researchers must attain an IND in order to administer the drug. The proposed modification has updated the consent form to inform participants of the minor side effects, which include depression and bleeding. The study remains unchanged. No vulnerable populations. Risks and benefits remain the same. Dr. Schoenfisch provided approval and Dr. Card seconded.

**Motion:** A motion was made and seconded.

**Total votes to approve for another 12 months:** Affirmative:6 Negative: 0 Recusal: Absent:3

**Next Meeting:** April 19, 2017

**Other Business:** Rotanya Bryan and Dinithia Sampson will be working on short videos to educate researchers about the IRB process.

**Meeting Adjourned:** 2:30pm