

February 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)
Daphne Holden
Nina McGrew (non-affiliated) (Present by phone)
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card
Barbara Frentzen (non-affiliated) (Present by phone)

Absent:

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)

Other Attendees: Rotanya Bryan, 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 **January 18, 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:

An interactive video from OHRP on ethical considerations in clinical research. Members watched the video and made ethical decisions on a hypothetical situation.

(#1) Protocol Title: Death of an Infant: Accessing Voices of Bereaved Parents to Create Healing

Submission:
(Problem Reporting)

Principal Investigator:
Dawn Hawthorne, Ph.D, RN

Presenters:
Sandra Schoenfisch
Keshia Reid

Meeting Discussion: The primary reviewer, Dr. Schoenfisch provided an overview of the study and the non-compliance reporting. This is a previously approved study that was suspended because the researcher failed to separate birth and death data when contacting parents for a bereavement study. The primary reviewer gave a brief summary of the proposed study and the history. She also stated that she still had concerns re the PI's description of how the subjects would be selected. The secondary reviewer, Dr. Keshia Reid also expressed some reservations as to handling of the data and the history of

problems with the study. The group discussed details of the corrective action plan and Drs. Holden and Card provided additional information re segmented sample selection and qualitative studies. After group discussion, a motion for approval was made and seconded.

Motion: A motion was made and seconded.

Total votes to approve: Affirmative:7 Negative: 0 Recusal: 1 Absent:1

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

Submission:
(Modification)

Principal Investigator:
Xiaoping He, MD
Lynne Hopkins, MD

Presenters:
Ovidiu Cotea
Daphne Holden

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modification. This is a retrospective study currently taking place at the Orange County Community Health Department. The researchers are seeking a waiver of consent. Their rationale for a waiver of consent is because participants on Harvoni for HIV/HCV co-infection with advanced fibrosis or cirrhosis are of lower economic status and it would be burdensome to ask them to return to the site to consent. Former and current subjects of the study will be notified of the waiver of consent. Ovidiu Cotea found no problem with waiving the consent. Daphne Holden questioned if the study is still recruiting participants. Sandra noted that the study ended recruitment in December 2016. Daphne wasn't clear as to why the researcher is asking for consent if they said that recruitment already ended. Barbara wanted to know if all of the data was collected originally and when the survey was completed.

Sandra recommended that additional information be requested. The Board members did not understand why a waiver of consent was needed at the time. There were also questions as to ongoing recruitment of subjects and when the survey is completed. The Board requested that additional information be requested from the PI and that the study be reviewed at the March meeting.

Motion: A motion to obtain additional information and to table the study for this month.

Total votes to table study: Affirmative:7 Negative: 0 Recusal: 1 Absent:1

Next Meeting: March 15, 2017

Other Business: Chair and co-chair were informed that a meeting would be scheduled about the common rule revisions and IRB procedural revisions.

Meeting Adjourned: 3:00pm