

April 17, 2019
1:30-1:50 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)
Bob Eadie (non-scientist) (Present by phone)
Ovidiu Cotea (Present by phone)
Daphne Holden
Karen Card (Co – Chair)

Absent:

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)
Megan Macdonald (Expertise in Subpart D: Children)
Barbara Frentzen (Present by phone) (non-affiliated)

Other Attendees: Rotanya Bryan, MPA, Dr. Ashkin, Bonnie Gaughan-Baily, MPA, and Gavin Grigg.

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 03/20/19 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:

Rotanya Bryan went over the status of the Common Rule Revisions and reminded members of the changes in forms and policy.

Protocol Title: Clofazimine use in the treatment of patients with disease caused by strains of Multidrug Resistant Tuberculosis (Florida Department of Health)

Submission:
(Modification)

Principal Investigator:
Ashkin, David MD

Presenters:
Cotea, Ovidiu MD, MPH
Schoenfisch, Sandra PhD, MS, BSN,
RN

Meeting Discussion: This is a previously approved treatment protocol to treat patients with disease caused by strains of Multidrug Resistant Tuberculosis. Clofazimine was approved in the 1980's but is no longer available in the United States. The drug is distributed through a special arrangement with the Food and Drug Administration when other treatment options are unavailable. Clofazimine has been found to have minor adverse effects in adults. The researcher submitted an amendment to add children ages 13 and up to the study. They also included an assent, consent, and revised protocol.

The primary presenter (Dr. Cotea) believed that the revised consent form and protocol addressed the last boards questions and request for revisions. Revisions include pediatric dosing, the inclusion of children, and any information collected on the child participants. The primary presenter (Dr. Ashkin) was present on the phone and addressed the question about dosing in children. Dosing recommendations were 1-3mg/kg a day. Dr Ashkin also noted that Clofazamine has been found to shorten TB therapy treatment and may be approved in US, in the future.

The treatment protocol does not have any children waiting for enrollment. However, the TB program would like to be able to add pediatric patients, if needed. The board found the request to add children to the protocol to be greater than minimum risk. They also found the permission of one parent to be sufficient. The primary presenter found no issues with the amendments and suggested approval. The secondary presenter (Dr. Schoenfisch) seconded that opinion.

Motion: A motion was made and seconded to approve the amendment.

Total votes to approve for 12 months: Affirmative: Negative: Recusal: Absent:

Next Meeting: May 15, 2019

Other Business: None

Meeting Adjourned: 2:15pm