

May 15, 2019
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)
Bob Eadie (non-scientist) (Present by phone)
Barbara Frentzen (Present by phone) (non-affiliated)
Ovidiu Cotea (Present by phone)
Megan Macdonald (Expertise in Subpart D: Children)
Karen Card (Co – Chair)

Absent:

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

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 **April 17, 2019** 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:

Compensation or Inducement? – Primr Webinar

Continuing Review

Protocol Title: Compassionate Use of Delamanid for the treatment of Multidrug- Resistant (MDR) Tuberculosis in Patients with Limited Therapeutic Options. (Florida Department of Health)

Submission:

(Continuing Review)

Principal Investigator:

Ashkin, David MD

Presenters:

Cotea, Ovidiu MD, MPH
Card, Karen DrPH

Meeting Discussion: This is a previously approved treatment protocol for the compassionate use of Delamanid for the treatment of multi-drug resistant tuberculosis in patients with limited therapeutic options. Delamanid is unavailable for use in the United States without an FDA and IRB approved treatment protocol. This treatment protocol has been sponsored in partnership with the Centers of Disease Control.

The primary presenter (Dr. Cotea) reviewed the continuing review application and noted that this study is a greater than minimal risk study. No patients are enrolled but enrollment remains open. No modifications were made to the study during the approval year. Dr. Ashkin is qualified investigator with many years as a board-certified physician and expertise in tuberculosis. None of the research staff reported any conflicts of interest. The secondary presenter (Dr. Card) noted that this treatment protocol is important for patients with limited treatment options and soon could become the standard treatment of care. She also noted that the treatment protocol contains no deception to patients. Dr. Cotea recommended approval and Dr. Card seconded.

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

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

Continuing Review

Protocol Title: Clofazimine in the treatment of leprosy (Florida Department of Health)

Submission:

(Continuing Review)

Principal Investigator:

Casanas, Beata D.O.

Presenters:

Cotea, Ovidiu MD, MPH
Eadie, Robert JD

Meeting Discussion: This is a previously approved treatment protocol for the treatment of leprosy or Hansen's Disease. Dr Cotea (primary presenter) provided a general overview of the study. Leprosy is an extremely rare disease in the United States. Recently, there have been no reported cases of Leprosy in patients in the State of Florida. No patients have been identified for enrollment in the study. Hillsborough Clofazimine treatment protocol remains open for treatment. This treatment protocol is collaboration with the Centers of Disease control and the National Hansen's Disease program. Bob Eadie (secondary presenter) had no comments or questions. The primary presenter recommended approval and the secondary presenter seconded.

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

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

Next Meeting: June 19, 2019

Other Business: None

Meeting Adjourned: 2:30 pm