

May 01, 2019
9:00-11:00 AM



Department of Health
2585 Merchants Row
Conference Rm. 320 P
Tallahassee, Florida 32311

IRB 2 Convened Committee Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair)

Nkechi Ichite (present by phone)

Julia Fashner (present by phone)

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)

Dongming Cui

Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Absent:

Adrian Cooksey (~~present by phone~~)

Julie Moore (non-affiliated; ~~present by phone~~)

Keshia Reid (Co-Chair) (Subpart B: Pregnant women)

Other Attendees: Rotanya Bryan, 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 April 3, 2019 meeting were circulated by email and modified by member input.

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:

Primr webinar on compensation versus inducement.

Protocol Title: Clofazimine use in the long-term treatment of leprosy, Phase 3 (Florida Department of Health)

Submission:
(Continuing Review)

Principal Investigator:
Ashkin, David MD

Presenters:
Fashner, Julia MD, MPH
Arango, Jaime EdD

Meeting Discussion: This is a previously approved treatment protocol to treat patients with leprosy or Hansen's Disease. Initially, the researchers requested to enroll six patients into the study; only one patient enrolled. No changes or modifications to the study. Treatment protocol remains open to patients in need of the drug.

The primary presenter (Dr. Fashner) had no concerns or questions and recommended approval. The secondary presenter (Dr. Arango) seconded. The board recommended that study be approved for an additional 12 months.

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

Next Meeting: June 5, 2019

Other Business: None

Meeting Adjourned: 10:00am