March 06, 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:

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

Nkechi Ichite (present by phone)

Julie Moore (non-affiliated; present by phone)

Julia Fashner (present by phone)

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

Dongming Cui

Absent:

Adrian Cooksey (present by phone)

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

Jamie Forrest (Chair)

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 meeting **February 6, 2019** 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:

Rotanya Bryan provided an update on the 45 CFR 46 revisions and the progress of the changes.

Continuing Review

Protocol Title: A double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia (#170015HD) (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Morano, Jamie MD	Ichite, Nkechi PharmD, PhD
		Arango, Jaime EdD

Meeting Discussion: This is a previously approved double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia study. The study drug is being tested to potential lower risks of cardiovascular disease. This investigational drug used in combination with a healthy diet could lower cholesterol. 15 patients were approved to enrolled in the study, four

remain. No study participants have withdrawn. No vulnerable populations were permitted to enroll. Study continues with patients still enrolled.

The primary presenter, Dr. Ichite, noted that during the approval period modifications to the study included changes to study personnel, revisions to the IB, and the addition of angodema as a side effect to the ICF. Study is progressing as planned. No complaints. Presenter recommended approval. The secondary presenter, Dr. Arango, had no additional comments and seconded approval.

Motion: A motion was made and seconded for approval of the study for an additional 12 months.

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

Modification

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Ashkin, David MD	Fashner, Julia MD, MPH Roberson, Shamarial

Meeting Discussion: Study was tabled because the secondary presenter was absent.

Next Meeting: April 3, 2019

Other Business: None

Meeting Adjourned: 9:30am