February 21, 2018
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)
Daphne Holden
Karen Card (Co – Chair)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)
Megan Macdonald
Shoshana Levy (Present by phone)
Bob Eadie (non-scientist)

Absent:
Nina McGrew (non-affiliated)
Barbara Frentzen (non-affiliated) (Present by phone)

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 **02/07/18** 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 facilitated a conversation about the article **When A Tattoo Means Life Or Death. Literally.**

(#1) Protocol Title: Clofazamine use in the treatment of patients with Non-Tuberculosis Mycobacterium (NTM) Infections.

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	David Ashkin, MD	Ovidiu Cotea Sandra Schoenfisch

Study Overview: This is an initial study of the Clofazamine use in the treatment of patients with Non-Tuberculosis Mycobacterium (NTM) Infections. Clofazamine is a drug (also sold under the name Lamprene) approved by the Food and Drug Administration in 1986 for the treatment of leprosy, but has also shown potential effectiveness in limited studies with multi-drug resistant tuberculosis and against other non-tuberculosis mycobacterium infections. The treatment protocol will be conducted at the Florid Department of Health – Delray Beach. The plan is to provide Clofazimine to patients with a history of culture positive non tuberculous mycobacterial disease who need to add a new drug to their existing regimen because of inadequate response. Clofazimine is not currently marketed in the US.

Meeting Discussion: The primary presenter (Dr. Cotea) noted that the Principal Investigator (Dr. Ashkin) was qualified to carry out the treatment protocol. Dr. Cotea and Dr. Schoenfisch commented that persons not responding to treatment are fortunate to have access to a physician and program that has the capacity to access CF through use of an IND. The protocol assures that all subjects are screened and understand the risks related to the drug. They are also monitored for side effects or adverse reactions to the drug. Subjects are only selected to receive CF after they have filed to respond to other FDA approved drugs. Selection for participation is based on morbidity. Exclusion criteria includes minors and pregnancy.

Dr. Cotea determined that the long form written consent was appropriate for the study. Information in the informed consent is provided in balanced way to participants. Dr. Schoenfisch noted that the consent and patient registry form were thorough and provided an adequate amount of information. The consent process will take place in an exam room and patients are allowed to take forms home for their perusal. Patients are being monitored while they are on the drug regimen.

Dr. Cotea found no issues with the protocol and recommended approval. Dr. Schoenfisch concurred and seconded approval.

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

Total votes to approve for 12 months: Affirmative: 8, Negative: 0, Recusal: 0, Absent: 2

(#2) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE A5332)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, MD	Ovidiu Cotea Karen Card

Meeting Discussion: (REPRIVE) Randomized Trial to Prevent Vascular Events in HIV is a previously approved study. The primary reviewer (Dr. Cotea) provided a general overview of the study. This treatment program is to determine the effects of pitavastatin as a primary prevention strategy for major adverse cardiovascular events (MACE) in HIV infected individuals. REPRIEVE has recently been approved by the Food and Drug Administration. Study takes place at Hillsborough's Health Department. The researcher proposed three modifications: Increase in gift card amount, change in the inclusion/exclusion criteria, and updated the after-hours number of the clinic.

Participants are enrolled and recruitment continues. Participants will receive a new consent form that reflects the changes to the recruitment criteria and they will be notified of the up-dated after-hours. The secondary presenter (Dr. Card) noted that the Data Safety Monitoring Board (DSMB) met and found no

issues with the conduct of the study. They also found that there were no inherent risks to the modifications.

Dr. Cotea found no issues with the amendments and recommended approval. Dr. Card concurred and seconded approval.

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

Total votes to approval: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: March 21, 2018

Other Business: The board was informed that there will be a IRBManager training session during next month's meeting.

Meeting Adjourned: 2:30pm