May 17, 2017
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)

Bob Eadie (non-scientist)

Daphne Holden

Keshia Reid (Expertise in Subpart B: Pregnant women)

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

Barbara Frentzen (non-affiliated)

Absent:

Nina McGrew (non-affiliated)

Karen Card

Other Attendees: Rotanya Bryan, MPA 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.

Members present by phone received all pertinent materials prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

*Dr. Reid left around 1:00pm to attend another meeting. *

Approval of Previous Minutes:

Minutes from the April 19, 2017 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:

None

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, MD	Ovidiu Cotea
		Bob Eadie

Meeting Discussion: The primary reviewer, Dr. Cotea provided an overview of the study and the modification. This is a previously approved study. Since HIV patients are living longer, they experinceing comorbidities such as vascular events. This is a multicenter study taking place around the world. Dr. Somboonwit is the experienced principal investigator. The modifications to the study include a letter of amendment that would change the inclusion and exclusion criteria and cancel pill counts. The informed consent was updated to reflect these changes. In addition, current and former subjects will be signing the new informed consent. Enrollment continues. The amendment also removes a staff member from

the study. Dr. Cotea had no objections to the modifications. The secondary presenter, Bob Eadie had no further comments and approved the amendments.

Motion: A motion was made and seconded.

Total votes to approve: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 2

(#2) Protocol Title: Clofazamine use in the treatment of patient with disease caused by strains of Multidrug Resistant Tuberculosis or Mycobacterium Avium Complex

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	David Ashkin, MD	Ovidiu Cotea Barbara Frentzen

Meeting Discussion: The primary reviewer, Dr. Cotea provided an overview of the study and the modification. Clofazamine is used in treatment of patient with disease caused by strains of Multidrug Resistant Tuberculosis or Mycobacterium Avium Complex. The drug is not currently available in the US and requires an IND for its usage. The proposed amendment would change enrollment for patients from a single IND to a multiple patient program treatment plan with Novartis Pharmaceuticals. The secondary reviewer, Barbara Frentzen noted that there the revisions were not highlighted, underlined, or tracked, so it was difficult to know where changes were made. She also requested that researchers provide a clean copy of the informed consent form. Dr. Holden also questioned why the titles of the research study changed. Dr. Schoenfisch suggested that the study be tabled until these questions were answered and the requested materials were returned.

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

Total votes to approve: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 2

(#3) Protocol Title: CDC Protocol # 5811, "Clofazimine in the long-term treatment of leprosy Phase III (IND#67,033)"

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Beata Casanas, DO, FACP	Sandra Schoenfisch Daphne Holden

Meeting Discussion: The primary reviewer, Dr. Schoenfisch provided an overview of the study "Clofazimine in the long-term treatment of leprosy Phase III." The drug is not currently available in the US and requires an IND for its usage. The drug has a proven success rate and used when other treatments of Hansen's disease or "leprosy" are unsuccessful. This is a continuing review. The protocol has not changed and the informed consent remains appropriate. Exclusion and inclusion categories have

remained the same. No participants have enrolled in the study. Dr. Schoenfisch recommend approval and Dr. Holden (secondary reviewer) seconded her approval.

Motion: A motion was made and seconded.

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

Next Meeting: June 21, 2017

Other Business: Rotanya notified the IRB that a Yellow Fever vaccine protocol will be reviewed in the coming weeks. She also informed the board of plans to involve the chairs in the upcoming Common Rule revisions implementation.

Meeting Adjourned: 2:30pm