August 16, 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
Karen Card
Barbara Frentzen (non-affiliated)
Keshia Reid (Expertise in Subpart B: Pregnant women)

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

Other Attendees: Rotanya Bryan, MPA, Dinithia Sampson, PhD, 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 7/19/17 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 provided an overview of the Department's data registries. She discussed the types of data registries, sources of data, data use agreements, confidentiality, and misconceptions about data.

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Charurut Somboonwit, M.D.	Ovidiu Cotea, MD, MPH
		Robert Eadie, JD

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. REPRIEVE A5332 is a study sponsored by the National Institutes for Health. This is a relatively new drug, currently approved by the FDA. The aim of this study is improve the cardiovascular events in patients with HIV. Research is taking place at the Health Department in Hillsborough County.

The modification for review is the increase in payment to participants. Study participants will now be paid $40 from $25 at the entry and annual visits. $25 from $10 during each scheduled non-annual visit. An addendum was added to the consent form to reflect these changes. Current and former subjects will

be notified of these changes. No changes to the protocol and Dr. Cotea recommended approval. Bob Eadie seconded the approval.

Motion: A motion was made and seconded.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 2

(#2) Protocol Title: Egrifta Long Term Observational Study (LTOS)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Richard Solero, MD	Ovidiu Cotea, MD, MPH Daphne Holden, MS, Ph.D

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. Egrfita LTOS is a ten year, long-term study to test the safety and efficacy of the drug for those with HIV and abominable fat. Seven participants remain in the study, fourteen have withdrawn. One serious adverse advent was reported to the board from this site. No further action was required. The data safety monitoring board recommended that this study be discontinued because of the low enrollment numbers.

The modifications for review are Dr. Solero replacing Dr. Syzpinsky as the principal investigator and the addition of a new research coordinator (Cynthia StroppDyce) to the study. Small formatting and version updates of the informed consent form (ICF). Current and former subjects will be notified of these changes.

Dr. Holden asked Dr. Cotea about his understanding of the DMC's and the FDA's recommendation of the continuation of the study. Dr. Cotea answered that there are two different studies being conducted using Egrifita and that the LTO study was recommended to be discontinued. Barbara Frentzen made the recommendation that researchers provide additional information on why the FDA did not accept the DMC's decision.

Motion: A motion was made to approve the study contingent upon the FDA's recommendation to continue or discontinue the study.

Total votes for approval: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: 9/20/17

Other Business: Bonnie listed the activities of the biomedical research staff.

Meeting Adjourned: 2:10pm