June 21, 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)

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

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 May 17, 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: A Double Blind, Randomized, Placebo Controlled, Multicenter Study to Evaluate Safety, Tolerability, and Efficacy on LDL-C of Evolocumab (AMG 145) in Subjects With HIV and With Hyperlipidemia and/or Mixed Dyslipidemia

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	Jamie Morano, MD, MPH	Ovidiu Cotea
		Barbara Frentzen

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study. There are 1.3 million people in the United States living with Human Immunodeficiency Virus (HIV). Since the advent of innovate and effective drugs, people with HIV are living longer lives. As a result of managing a chronic illness, people living with HIV run the risks of contracting myocardial infarction, stroke, and/or other cardiovascular events. Amgen is a double blind, randomized, placebo controlled, multicenter study to evaluate safety, tolerability, and efficacy on LDL-C of Evolocumab (AMG 145) in subjects with HIV and

with hyperlipidemia and/or mixed dyslipidemia. This drug was approved in 2015 and has been previously studied in the HIV population.

This is a new study taking place at Hillsborough and the Principal Investigator (Jamie Morano) has more than 20 years of experience. All other study staff are appropriately qualified. Subjects will be incentivized with a payment of $45 during screening and $15 for meals.

The researcher is using a long form written consent, which is appropriate for this study. The consent document includes all required disclosures, including whom to contact at the Department for additional information. Records will be stored in lab facilities and access to data will be limited to those indicated in the protocol. No vulnerable populations.

Barbara Frentzen noted that she had questions about the expired license of Dr. Addidsu, information on the IND, and the word "experimental" in regard to the drug delivery devise. Her questions were answered before the meeting, but she requested that the language of "experimental" be removed from the consent form. Members voted that the study would be approved contingent on the revised consent form.

Motion: A motion was made and seconded for one year.

Total votes for approval: Affirmative: 6 Negative:0 Recusal: 0 Absent: 3

(#2) Protocol Title: Clofazimine use in the treatment of patients with disease caused by strains of Multidrug Resistant Tuberculosis or Mycobacterium avium complex

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	David Ashkin, MD	Ovidiu Cotea Karen Card

Meeting Discussion: The primary reviewer, Dr. Cotea provided a general overview of the study and the modification. Clofaximine is used in the treatment of patients with disease caused by strains of multidrug resistant Tuberculosis or Mycobacterium avium complex. This treatment plan has been approved since the 1980's. Distribution of the drug is made through special arrangements with the Federal Drug and Food Administration.

The modification for review are the changes in procedures to enrollment. Currently, patients are enrolled by obtaining a single IND from the FDA. The new procedures will enroll patients in a multiple patient program treatment plan with Novartis Pharmaceuticals. Past participants will not be notified of the changes and there is no problem with the new protocol. Consent tracks closely with the protocol. Risks to participants are minor. Changes to enrollment are minor.

Dr. Schoenfisch asked if questions from the last meeting were answered. Rotanya Bryan noted that the questions about the change in protocol and change in study title were addressed. The researcher's

advised Rotanya that the new Multiple Patient Program Treatment Plan is a new protocol and that the new protocol title now corresponds with the consent form.

Motion: A motion was made and seconded.

Total votes for approval: Affirmative: 6 Negative:0 Recusal: 0 Absent: 3

Next Meeting: July 19, 2017

Other Business: None

Meeting Adjourned: 2:00pm