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) (Present by phone)
Megan Macdonald
Shoshana Levy (Present by phone)

Alternate Member:
Keshia Reid

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

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 02/21/18 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:

Presentation by IRBMANAGER IT on how to operate the new IRB online application intake system.

(#1) Protocol Title: MAPLE: Health outcomes and cognitive effects of marijuana use among persons living with HIV/AIDS

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	Robert Cook, MD, MPH	Karen Card
		Keshia Reid

Meeting discussion: This is an initial prospective cohort study to determine the health outcomes and cognitive effects of marijuana use among persons living with HIV/AIDS. The primary presenter, Dr. Card, provided an overview of the study. This is an NIH/UF funded study where the research team intends to follow 360 study subjects who are HIV positive and use marijuana and 320 that do not use marijuana but are HIV positive. There will be one in person meeting a year and several periodic phone calls, with a plan to provide mental health referrals if there is a determined need. They will also conduct cognitive tests, urine and blood analysis, as well as a review of patient records to answer the research question. The

researcher's overall hypothesis is that the continued use of marijuana in HIV patients will lead to negative physical and mental health outcomes.

Dr. Card found the study procedures and design to sound based on their approval by the National Health Institute. In addition, she found the researchers and research staff to be qualified with no reported conflicts of interest. She noted that Dr. Somboonwit, a respected PI for the Department is on the protocol. Dr. Card found that the only inherent risks to the study were the sensitivity of the cognitive questions, blood draws, and a breach of confidentially, but found these risks to be minimal at best.

The primary presenter went over the participant selection and recruitment. Participants would be recruited from HIV registries such as the Florida Cohort, in addition to being recruited from advertising flyers. The study population are expected to contain 680, 18 and up adult patients that are HIV/AIDs positive, and use or do not use marijuana. Researchers also intend to recruitment pregnant women. Some of the study population will be recruited from the Hillsborough County Health Department. Participants will be compensated with $75 for each visit including blood draws, urine sample, and cognitive tests; $10 for each follow-up phone call; and $20 for medical records. Dr. Reid observed that the $20 amount on the protocol did not match the $25 amount on the flyer and recommended that the researcher change the discrepancy. Dr. Card found the subject selection to be equitable.

The consent form is a long form consent that includes all of the elements of legal and effective consent. However, Dr. Card noticed that the consent title did not match the protocol. Dr. Reid noticed that as well and recommended that the researchers revise the consent title to match the protocol. In addition to the long form consent, the principal investigator will be providing a HIPAA authorization form in order to access the participant's patient records. Dr. Card found this acceptable because it would be a way to track the subject's health outcomes.

This study included pregnant women that are considered to be vulnerable populations, as defined by 45 CFR 46. Pregnant women would be included in the study to assess their health outcomes after continued use of marijuana. Katisa Donaldson raised some concerns about whether this study would be promoting marijuana use in pregnant women. Dr. Reid (pregnant women representative) did not feel that the study actively or passively promoted marijuana use because the researchers were sampling from a population that already admitted to drug use. Katisa Donaldson also found that this study may be a form of medical neglect of children. Dr. Schoenfisch noted that the expectant mother would be counseled against marijuana use during their time in the study. A majority of the board members did not feel that the study would promote drug use during pregnancy and did not feel that the addition of pregnant women introduced any unnecessary negative effects.

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

Total votes to approve: Affirmative: 7 Negative: 1 Recusal: 0 Absent: 3

(#2) Protocol Title: Telephone counseling to enhance the quality and safety of romantic and sexual relationships in people living and aging with HIV.

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	Travis Lovejoy, PhD, MPH	Sandra Schoenfisch Katisa Donaldson

Meeting Discussion: The primary review, Dr. Schoenfisch provided a limited overview of the study. This is a large initial project to study HIV positive subjects that are 50 years and up. The researchers intend to understand the sexual practices and coping mechanisms used by HIV positive patients as they age. Dr. Schoenfisch was concerned about levels of risks in the study, dealing with a population that has a high rate of mental health issues. She required additional information on how adverse events would be handled and how mental health issues would be addressed. Katisa Donaldson was also concerned with the lack of mental health services provided in the consent form. Both reviewers requested additional information and recommended that the study be tabled.

(#3) 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:**
(Continuing)	Jamie Morano, MD	Ovidiu Cotea Daphne Holden

Meeting Discussion: The primary reviewer, Dr. Cotea, provided a general overview of the study and proposed modification. The study is a continuing review of the 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 is FDA approved and the researchers would like to test the efficacy of the drug on HIV patients with high cholesterol. This study is taking place at Hillsborough County Health Department.

In addition to continuing the study, the researcher would like to increase enrollment from 10 to 15. Currently, nine patients are enrolled with 450 total participants at various sites. The consent form is up-to-date and adequate. No new findings have been found by the researcher. Study continues to be sponsored by AMGEN. Dr. Cotea had no objections to continuing this study and recommended another 12-month approval. Dr. Holden had no concerns but had a question about the patient safety form. She wanted to know how to read the form and its relevance. She was informed that the researchers are responsible to report to all IRBs any comorbidities that occurred while the patient was on the study

drug. She also recommended approval for another 12 months.

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

Total votes to approve: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 3

Next Meeting: March 21, 2018

Other Business: None

Meeting Adjourned: 2:30pm