January 16, 2019
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)
Bob Eadie (non-scientist) (Present by phone)
Barbara Frentzen (Present by phone) (non-affiliated) **Joined the call during GS-US-380-4458 review**
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)

Alternate
Keshia Reid, PhD (Expertise in Pregnant Women)

Absent:
Megan Macdonald (Expertise in Subpart D: Children)

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, Dr. Morano, Mable Chow, 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 December 19, 2018 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

Protocol Title: Clofazimine use in the treatment of patients with disease caused by strains of Multidrug Resistant Tuberculosis (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Ashkin, David MD	Cotea, Ovidiu MD, MPH Eadie, Robert JD

Meeting Discussion: Clofazimine use in the treatment of patients with disease caused by strains of Multidrug Resistant Tuberculosis is a previously approved treatment protocol. The study drug is no longer available in the United States, so it must be administered through a special arrangement. Physicians will provide the drug to patients when other drugs are ineffective. Dr. Ashkin is a board-certified physician that has years of experience administering TB medications. Treatment protocol continues as expected. Study remains open for enrollment. No reportable events during the approval period. No conflict of interests reported by staff.

The primary presenter (Dr. Cotea) provided a recommendation of approval for an additional 12 months. The secondary presenter (Bob Eadie) seconded approval.

Motion: A motion was made and seconded to approve the study for an additional 12 months.

Total votes to approve for 12 months: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Protocol Title: Multiple Patient Program for Lamprene (Clofazimine) for the treatment of Non-Tuberculous Mycobacterial (NTM) Infections (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Ashkin, David MD	Cotea, Ovidiu MD, MPH Schoenfisch, Sandra PhD, MS, BSN, RN

Meeting Discussion: This is a previously approved protocol designed to treat patients diagnosed with Non-Tuberculous Mycobacterial (NTM) Infections with Lamprene (Clofazimine). The study drug is no longer available in the United States, so it must be administered through a special arrangement with CDC and the FDA. The medication benefits those that have drug resistant TB and Hansen's Disease (Leprosy). Dr. Ashkin is a board-certified physician that has years of experience administering TB medications. Treatment protocol continues as expected. Study remains open to enrollment. No reportable events during the approval period. No conflict of interests reported by staff. Minor changes to staff members.

The primary presenter (Dr. Cotea) provided a recommendation of approval for an additional 12 months. The secondary presenter (Bob Eadie) seconded approval.

Motion: A motion was made and seconded to approve the study for an additional 12 months.

Total votes to approve for 12 months: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Initial Submission

Protocol Title: Pilot case-control study to assess the association between Influenza A virus vaccination and the development of type 1 diabetes mellitus (University of Florida)

Submission:	**Principal Investigator:**	**Presenters:**

(Initial Submission)	Capua, Ilaria PhD, DVM	Keshia Reid, PhD
		Schoenfisch, Sandra PhD, MS, BSN, RN

Meeting Discussion: This is an initial review of a pilot study to assess the association of influenza A virus and the development of type 1 diabetes mellitus using influenza A vaccination records as a tool. The primary presenter (Dr. Reid) provided an overview of the study. Viral infections, including influenza A, have been proposed as a factor involved in the development of T1DM. The study questions ask whether influenza A virus is associated with the development of T1DM in young individuals between the ages of 0-18 years living in Alachua County. Data will be obtained for UF's integrated health system and the Department of Health SHOTS system. Contact would also be made to patients that previously agreed to participant in research studies and physicians for reference.

Dr. Reid noted that the study protocol was vague. The background of the research focuses on the influenza virus in animal subjects, but the hypothesis and study questions focus on human participants. Dr. Reid was unsure of what the investigator intended to do with the data and whether the information gathered would be generalizable. The secondary presenter (Dr. Schoenfisch) found that the there was an incomplete description of the intent. Researchers are requesting waivers of consent. Dr. Schoenfisch was concerned that there did not seem to be an end to the access of the patient's PHI. The background and aims of the research do not match and the protocol was unclear. Board members found that since there were many questions and the application and protocol required extensive revisions, the study should be tabled until all questions are addressed. The primary and secondary presenter recommended that the study be tabled.

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

Total votes to table: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Modification

Protocol Title: A double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia (#170015HD) (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Morano, Jamie MD	Cotea, Ovidiu MD, MPH Card, Karen DrPH

Meeting Discussion: This is a previously approved study of a double-blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia. The primary presenter

(Dr. Cotea) provided a description of the modifications proposed by the investigators. The researcher revised the consent form to add the risk of Angioedema (a skin condition) as an adverse drug reaction. Other common side effects include: a runny nose, back pain, joint pain, rash, and swelling. Current and new subjects will be notified by receiving and signing an updated informed consent on during their next scheduled visit. The investigator also included a revised ICF that listed the side effects of the drug Evolocumab.

Dr. Cotea noted that the investigator is experienced and highly qualified. Study takes place at the Hillsborough Health Department. Study modification is greater than minimum risk. Consent revisions are adequate and appropriate. The secondary presenter (Dr. Card) seconded the opinion and had no further comments. Dr. Cotea and Dr. Card both recommended approval of the modifications.

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

Total votes to approve: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Protocol Title: [GS-US-380-4458] A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Fixed Dose Combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide versus Dolutegravir + Emtricitabine/Tenofovir Disoproxil Fumarate in Treatment Naïve, HIV-1 and Hepatitis B Co-Infected Adults (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Morano, Jamie MD	Cotea, Ovidiu MD, MPH Holden, Daphne Ph.D, MS

Meeting Discussion: This is a previously approved protocol and tabled modification of a Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Fixed Dose Combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide versus Dolutegravir + Emtricitabine/Tenofovir Disoproxil Fumarate in Treatment Naïve, HIV-1 and Hepatitis B Co-Infected Adults. The primary presenter (Dr. Cotea) provided an over of the amendments. The researcher submitted amendments to the Investigational brochure of Truvada and Bictegravir that include the possibility of an unexpected worsening of hepatitis B, including severe impairment in the liver function or even liver failure if patient stops taking study medication. A recent study also found that babies born to women taking dolutegravir at the time of becoming pregnant or early in pregnancy may have a higher risk for a type of birth defect called neural tube defects, such as spina bifida. These defects occur early in pregnancy before many women even know they are pregnant. In addition to the revisions in the IBs, the researcher also submitted changes to the ICF and an investigator letter. A summary of the changes was also provided for the board's perusal.

The principal investigator (Dr. Morano) and the study coordinator (Mable Chow) joined the call to answer the board's questions about the revisions to the ICF. The secondary presenter (Dr. Holden) requested that the researchers add the information from the protocol regarding potential pregnancy and the definitions of "highly effective" birth control. Ms. Chow agreed to make the changes but

requested that the board provide specific language. Dr. Schoenfisch noted that a list of the revisions was provided and that information should be sufficient. Dr. Morano noted that they review the consent documents with patients very carefully. Clinically, women of childbearing age would not be enrolled in the study even though the study sponsor did not specifically exclude them. She also noted that they mostly enroll men that have sex with men and that pregnancy information would not necessarily be needed. Dr. Card noted that even though there were no plans to enroll women, they are not excluded and thus language about pregnancy and birth control methods were necessary and appropriate. Dr. Holden requested clarification on the definition of "highly effective" birth control. Dr. Morano responded that the language remained vague so that the patient could make the decision about was highly effective for them. Dr. Holden also questioned why the PI noted that pregnancy tests are never given at every visit. Rotanya responded that it may be because they never enroll women. The board discussed providing the researchers with an up-to-date list of revisions. The primary and secondary reviewer provided contingent approval.

Motion: A motion was made and seconded to approve the amendments contingent upon the revisions.

Total votes to approve contingently: Affirmative: 8 Negative: 0 Recusal: 0 Absent: 1

Next Meeting: February

Other Business: None

Meeting Adjourned: 2:30pm