June 20, 2018
1:30-3:00 PM

Department of Health
2585 Merchants Row
Conference Rm. 310A
Tallahassee, Florida 32311

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)

Karen Card (Co-chair)

Megan Macdonald

Ovidiu Cotea (present by phone)

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

Barbara Frentzen (present by phone)

Daphne Holden

Shoshana Levy (present by phone)

Absent:

Nina McGrew (non-affiliated)

Robert Eadie

Other Attendees:

Rotanya Bryan, MPA

Gavin Grigg

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 05/16/18 were circulated by email and modified by member input.

Conflict of Interest: None.

Education: DOH Contact Information --Rotanya Bryan, MPA

Initial Submission

Protocol Title: Compassionate Use of Delamanid for the treatment of Multidrug- Resistant (MDR) Tuberculosis in Patients with Limited Therapeutic Options. (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Ashkin, David	Cotea, Ovidiu MD, MPH Macdonald, Megan MPH

Meeting Discussion: This is an initial review of the Compassionate Use of Delamanid for the treatment of Multidrug- Resistant (MDR) Tuberculosis in Patients with Limited Therapeutic Options. (Florida Department of Health). The primary presenter (Ovidiu Cotea) provided a detailed overview of the study. This is a new anti-TB drug and one of very few that have been developed in the last 50+ years. It is not available in the US. It has not been FDA approved. Only way to acquire the drug is through compassionate use programs. The drug has proved is worth worldwide in many trails. Has been approved by European Medical Association in 2013 and the WHO recommend the use of this drug for drug-resistant TB.

The aim is to improve treatment outcome and effectiveness for people who have limited options. Recommends approval for the study. No objection whatsoever.

Megan Macdonald: Agrees with everything that Dr. Cotea said. Regarding the consent form it wasn't clear: Consent form states patient will be taking drug for 24+ weeks but the research outline indicates 12-24 months. Brought to Rotanya and she has reached out to Dr. Ashkin. Consent form states patients will be hospitalized at beginning of treatment but doesn't indicate the duration. Form should notify patient of hospitalization.

Who will pay for harm from treatment? States it will be at the cost of the patient or patient's insurance company.

Many patients would already be in the hospital.

Megan recommends approval if they include modifications in consent form to describe if there is potential for a subject not to participate for failure to adhere to the regiment (standard phrasing).

Motion: Conditional approval with consent form being modified with the statement we have in other consent forms and clearly spelling out of financial responsibilities of client and insurance.

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

Protocol Title: Advancing New Computer-based Help On Risky Sex (ANCHORS) Study: UH2 Project (University of Florida)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Leeman, Robert PhD	Card, Karen DrPH Schoenfisch, Sandra PhD, MS, BSN, RN

Meeting Discussion: Karen Card: This is part 2 of a multipart study on HIV prevention. If the study did not involve sensitive information, we would call it a quality assessment type of study. it will recruit males age 18-30 who are HIV negative but have sex with men. It is a usability study of a mobile app that is interactive voice recording. The ultimate purpose of this IVR application is to prod people to be compliant with PREP (HIV infection daily administered drug). Researchers are developing the IVR to boost PREP compliance but there is no PREP in this study. They are using as proxies binge drinking, condomless sex, and other risky practices that might lead to HIV infection. They will screen people through an online application. They are recruited through clubs and bars as well as social media. The advertisements and qualifications are all in order. 683 people will be chosen to take a web survey, where they will be asked for baseline info on ability to prevent HIV infection, sex practices, and binge drinking. This will form the baseline for the participants that are recruited and later on they will use that baseline to measure improvement. They get paid $25 dollars.

30 of the 683 will be recruited for focus groups. Only risk identified to the patient is the chance you will go to a focus group and know somebody there. It was pointed out in the consent that they will not use real names and that they should keep the focus groups between themselves.

Then they will take 10 people and try out the IVR app on their phones. They will get $30 upfront, $1 a day, and then $35 at the end (total of $175). No problem with the payments. No personal identifying info collected until a volunteer is in the focus group.

Outcomes that they are measuring is based on the alcohol use and other HIV preventative behaviors from the baseline data. They will log for regular use and any changes in behavior. The study is important and valid, and no problems with its design. Originally assigned to other board, checked request changes and recommends approval.

Sandra Schoenfisch: Sound base as far as behavioral science is concerned. Very complicated. They addressed issues that were raised. Security aspects are there. Recommends approval.

Motion: For approval with second.

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

Protocol Title: Clofazamine use in the treatment of patients with Non-Tuberculosis Mycobacterium (NTM) Infections. (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Ashkin, David	Cotea, Ovidiu MD, MPH Levy, Shoshana MD, MPH

Meeting Discussion: Ovidiu Cotea: Study is about Clofazamine used in the treatment of patients with no-TB micro bacterial infections. Asking to modify the consent form (a new version). New info came into light about some side effects and risks. For example, the older form says the risk of vision problems was determined to be less than 1%. With the new info it was determined that the risk was more than 1%. Changes for patients who have already consented and they will be informed. Recommends approval.

Shoshana Levy: Agrees with Dr. Cotea. Recommends approval.

Motion: For approval with second.

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

Next Meeting: July 18, 2018

Other Business: none

Meeting Adjourned: 2:10 pm