April 03, 2019
9:00-11:00 AM

Department of Health
2585 Merchants Row
Conference Rm. 320 P
Tallahassee, Florida 32311

IRB 2 Convened Committee
Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair; present by phone)

Julie Moore (non-affiliated; present by phone)

Julia Fashner (present by phone)

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)

Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Dongming Cui

Absent:

Keshia Reid (Co-Chair) (Subpart B: Pregnant women)

Nkechi Ichite

Adrian Cooksey

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 meeting were circulated by email and modified by member input.

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 *Submissions for Convened Board Review*

Modification
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:**
(Modification)	Ashkin, David MD	Fashner, Julia MD, MPH
		Roberson, Shamarial, DrPH

Meeting Discussion: This is a previously approved treatment protocol to treat patients with disease caused by strains of multidrug resistant TB with the drug Clofazamine. This modification is to include children into the treatment protocol. Researchers have requested approval of the revised consent form and child assent form. Safe guards added to the protocol include information regarding pregnancy, dosing for children, and side effects on both forms.

The primary presenter, Dr. Fashner, noted the drug's QT prolongation. Other TB drugs have a certain QT prolongation and the response was that when clofazimine is used with these other drugs they may have

the cell EKG. She worries of a bad outcome for the children. Dr. Roberson mentions that this is a drug that is used to treat leprosy and there hasn't been a lot of formal studies with this drug in children. There is a different half-life of this drug so in the event that a child would need a lower dose they would have to do every other day treatment and can't reduce the dose for this drug. It only comes in 2 doses. 50 and 100 mg gel caps that cannot be split. In some articles it is recommended that you should have a monthly EKG whenever possible, especially when more than one QTC prolongation agent is used. Dr. Roberson recommends is to consult a pediatrician that specializes in this area before we decide. There is not a lot of research with children using this drug even though there have been observational studies in adults. This is to make sure that all safe guards are in place for children.

Dr. Cui agrees with Dr. Roberson. We table the study until consultation with a pediatrician. The other option would be that the researchers agree that they will do the EKG. Dr. Cui says that an EKG is not very sensitive to follow-up on liver and kidney functions. He does not think an EKG gives enough evidence to support. Will get consultation with pediatrician with specialty in infectious disease. Rotanya will also talk to Dr. Ashkin who is a main TB researcher.

Motion for approval: Dr. Fashner made motion to table modification until consultation with infectious disease pediatrician. Dr. Roberson seconds.

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

Modification

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

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Cook, Robert MD, MPH	Roberson, Shamarial DrPH Moore, Julie JD, PA

Meeting Discussion: This is a previously approved protocol to study health outcomes and cognitive effects of marijuana use among persons living HIV/AIDS. The proposed modification plans to add the collection of additional blood samples to participants to submit to a private lab for HIV viral load testing. The sample labels would only contain the participants ID number and no identifiable information. There would be prescreening questions to determine eligibility. There will be changes to the informed consent form clarify the language and add UF Health human subject payment language and add the summary section as required by the new common rule revisions. Current will be notified of the change at their follow-up visit and will be asked to sign an update informed consent form that would allow for the additional blood samples to be sent off to the labs. The principal investigator will not change but there are some modifications to staff.

Dr. Roberson recommends approval for the modification. Julie Moore agrees with the recommendation but noticed one inconsistency. The protocol and consent documents state the team will follow up with

participants by phone every 3 months or 4 times per year, but the recruitment flyer says they will follow up 3 times per year and that they will need to clean up that language. Julie Moore recommends approval with that one contingency. Jamie Forrest agrees that the inconsistency needs to be addressed. Jamie Forrest did not see documentation of approval from all CHD sites and ask if that is necessary, and if so does the DOH IRB have the documentation. Rotanya noted that she would double-check that all CHD approvals were included in the application.

Motion for approval: Dr. Roberson makes motion to approve with the contingency that the discrepancy between the number of follow up calls be revised appropriately. Seconded.

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

Next Meeting: May 1, 2019

Other Business: None

Meeting Adjourned: 10:00 am