

June 5, 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)

Nkechi Ichite (present by phone)

Julia Fashner (present by phone)

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

Dongming Cui

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

Absent:

Adrian Cooksey (present by phone)

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

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 **May 1, 2019** 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

Continuing Review

Protocol Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida (Florida Department of Health)

Submission:
(Continuing Review)

Principal Investigator:
Smith, Angela BS, MHA

Presenters:
Ichite, Nkechi PharmD, PhD
Roberson, Shamarial DrPH

Meeting Discussion: This is a previously approved treatment protocol to administer the vaccine Stamaril to patients in the Lee County region. Dr. Ichite (primary presenter) provided a general overview of the protocol. Stamaril is vaccine for the prevention of yellow fever and is not currently approved in the United States. In collaboration with the drug manufacturer Sanofi, the Department of Health in Lee county is providing the FDA/IRB regulated vaccine.

All participants that were enrolled have completed treatment. No patients withdrew. Enrollment into the protocol continues. Modifications to the study include changes in staff. No publications, no reports,

and no issues with vaccine. Investigator noted that staff turnover has reduced the amount of patient enrollment. Treatment plan has been going as planned. The secondary presenter (Dr. Roberson) noted that original YF vaccine is still unavailable and that Stamaril will continued to be used in its place. The primary presenter found no issues with the study and recommended approval for another 12 months. The secondary presenter seconded approval.

Motion for approval: A motion for approval was made and seconded.

Total votes to approve for 12 months: Affirmative: 5 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:
(Modification)

Principal Investigator:
Cook, Robert MD, MPH

Presenters:
Roberson, Shamarial DrPH
Arango, Jaime EdD

Meeting Discussion: This is a previously approved protocol to determine the association of regular and occasional marijuana use with HIV care engagement, viral suppression, and HIV disease progression, past and current marijuana use with aspects of cognitive function, and association of chronic marijuana use with markers of chronic inflammation. The primary presenter (Dr. Roberson) provided a description of the modification presented to the board. The researchers are requesting to add the collection of HIV medications and other clarifications in the protocol and ICF. They also provided a revised PHI authorization where the contact information was updated. The investigator also updated the pre-screen script to better confirm users and non-users. Additionally, they have requested to add an appointment reminder card, electronic pre-screen and appointment reminder form versions, and a letter to include the pre-appointment packet. The secondary presenter (Dr. Arango) did not have any additional comments.

The board found no additional risk with the addition of the revised materials. No further comments or questions were made during the discussion. The primary presenter recommended approval and the secondary reviewer seconded.

Motion for approval: A motion for approval was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 3

Next Meeting: July 3, 2019

Other Business: None

Meeting Adjourned: 10:15am