

November 07, 2018  
9:00-11:00 AM



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

## IRB 2 Convened Committee Meeting Minutes

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### **IRB Attendance:**

Jamie Forrest (Chair)

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

Nkechi Ichite (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)

### **Absent:**

Adrian Cooksey (present by phone)

Dongming Cui

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

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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:** Part 2 of the webinar on the topic of "Big Data" was provided by PRIMR.

**Protocol Title:** Assessment of the Safety, Tolerability, and Effectiveness of Rifapentine given Daily for LTBI (ASTERoid) (University of Florida)

**Submission:**  
(Initial Submission)

**Principal Investigator:**  
Lauzardo, Michael

**Presenters:**  
Ichite, Nkechi PharmD, PhD  
Reid, Keshia PhD

**Meeting Discussion:** This is an initial study to assess the safety, tolerability, and effectiveness of rifapentine given daily for Latent Tuberculosis Infection (LTBI) ASTERoid. Approximately 1.4 million people die of tuberculosis (TB) each year, making it the most common infectious cause of death in the world. In 2015, there were 10.4 million new cases of TB disease globally. Of these new cases, more than 40% (> 4 million) were smear-positive and at high risk for transmitting TB to their close contacts. The contacts infected with latent Mycobacterium tuberculosis become the source of new TB cases in the future.

The epidemiology of TB is influenced by two important factors. Infection with *M. tuberculosis* in the environment usually occurs through contact with a person with untreated pulmonary TB via droplet nuclei that are expelled by coughing and sneezing. After close contact with a patient with infectious TB, 30-50% of exposed susceptible persons acquire the infection, as determined by the TST.<sup>3-5</sup> The second factor that contributes to TB incidence is progression to active disease among infected persons. Conditions that alter host cellular immunity increase the risk of developing TB disease. These conditions include HIV infection, extremes of age, diabetes, smoking, severe malnutrition and anti-tumor necrosis factor alpha (TNF- $\alpha$ ) treatment.<sup>6, 7</sup> Although TB disease can occur immediately after the initial infection in a small proportion of patients, *M. tuberculosis* infection remains clinically silent and microbiologically latent in most persons. However, approximately 5-10% of otherwise healthy *M. tuberculosis* -infected persons will progress to active clinical disease, becoming the source of infection for others.<sup>8-11</sup> Therefore, preventing patients with LTBI from developing active TB disease is an important step to break the cycle of transmission and decrease the overall burden of TB worldwide.

The aims of the study are to Compare the safety of daily 6wP to a comparator arm of 12-16 week rifamycin-based treatment (3HP, 3HR, or 4R) for the prevention of TB in persons > 18 years old with LTBI. If safe, compare the effectiveness of daily 6wP to a comparator arm of 12-16 week rifamycin-based treatment (3HP, 3HR, or 4R) for the prevention of TB in persons > 18 years old with LTBI.

This study will be conducted at the University of Florida. However, participants will be recruited from the Miami-Dade and Alachua TB clinics at the Health Department. The board found the study protocol to have a sound research design. Research staff are sufficiently qualified. Risks are reasonably minimized. Recruitment methods and participant selection are not adequate. All elements of consent are in place. Safety and monitoring will be completed by a DSMB and through data collection forms. Privacy and confidentiality are adequately protected.

The reviewers found that the recruitment and advertising materials needed to be revised to lower the reading level, use plain language, and spell out all acronyms. The board voted to approve the study contingent on the investigator submitting revised recruitment materials. The primary presenter (Dr. Ichite) approved the study and the secondary presenter (Dr. Reid) seconded approval.

**Motion:** A motion to vote for contingent approval was made and seconded.

**Total votes to approve for 12 months:** Affirmative: 6 Negative: 0 Recusal: 0 Absent: 3

**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:**  
(Modification)

**Principal Investigator:**  
Morano, Jamie MD

**Presenters:**  
Fashner, Julia MD, MPH  
Forrest, Jamie MS

**Meeting Discussion:** AMG 145 is a double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocumab in subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia. The study is now FDA approved. The investigators submitted an amendment to update the Investigator’s Brochure (IB) to version 11. The new IB updates the drug name, changes how dosing is done, and improves what the investigator knows about the drug. Participants will not be notified of changes due to no safety concerns. The primary presenter (Dr. Fashner) found the modifications acceptable and the secondary presenter (Jamie Forrest) concurred.

**Motion:** A motion to vote for approval was made and seconded.

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

**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

**Presenters:**  
Reid, Keshia PhD  
Moore, Julie JD, PA

**Meeting Discussion:** The MAPLE study is a previously approved protocol to assess the health outcomes and cognitive effects of marijuana use among persons living with HIV/AIDS. Research has not started as of yet. However, investigators are adding the phone screen, California Verbal Learning Task, Core Survey, Life Goals Inventory, MAPLE Study Contact Information Form.docx, Marijuana Questionnaire, Memory for Intentions Test, Memory for Intentions Test, NIH Examiner - Planning Task NIH Toolbox - Cognition Battery, NIH Toolbox - Cognition Battery, NIH Toolbox - Cognition Battery, Phone Call Questionnaire.docx, Substance Abuse Module – Marijuana, Wechsler Test for Adult Reading, Auth-to-Request-PHI-from-Other-Providers-.docx, Maple Release of Medical Record Cover Letter, Permission to contact Form.docx Recruitment Brochure, Timeline Follow Back Instructions, Adult Leisure Activities, Apathy Evaluation Scale, Timeline Follow Back, TLFB Calendar\_June 2018 to May 2019.pdf. They are also requesting to revise the protocol and informed consent form (ICF). The ICF was revised to include grammatical changes, language about voluntary participation, length of baseline visits, recordings of participants, information about other studies, and compensation for providing urine specimens. In addition to new study materials, the investigator has added new staff to the study.

The primary presenter and secondary presenter found the additions to be appropriate for the study. They also found the changes to the ICF and protocol to be necessary and in order. Staff were also found to be sufficiently qualified. However, the primary presenter (Dr. Reid) questioned whether the medical release form would match the authorization to release PHI documentation. Dr. Reid recommended contingent approval, until the investigator satisfied the question. The secondary presenter (Julie Moore) concurred.

**Motion:** A motion to vote for contingent approval was made and seconded.

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

**Protocol Title:** Strategic Timing of AntiRetroviral Treatment (START) (Florida Department of Health)

**Submission:**  
(Continuing Review)

**Principal Investigator:**  
Desai, Nila MD

**Presenters:**  
Ichite, Nkechi PharmD, PhD  
Reid, Keshia PhD

**Meeting Discussion:** START is a previously approved study to determine if immediate initiation of ART alters the rate of lung function decline compared to deferral of ART until the CD4+ declines below 350 cells/mm in HIV-1 infected persons who are antiretroviral naïve with a CD4+ count above 500 cells/mm. The study also aims to determine if immediate ART alters respiratory health status compared to deferred ART. The research is taking place at the Orange County Health Department. 10 patients remain with two withdrawals at the discretion of the Principal investigator (Dr. Desai). Secondary analysis of data continues. Participants have completed all protocol mandated interventions. No modifications or changes to the study. No new findings during the research process. The primary presenter (Dr. Ichite) recommended an additional 12-month approval and the secondary presenter (Dr. Reid) concurred.

**Motion:** A motion to vote for approval was made and seconded.

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

**Next Meeting:** December 5, 2018

**Other Business:** None

**Meeting Adjourned:** 10:30am