

October 4, 2017  
9:00-10:30 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)

Nkechi Ichite (present by phone)

Kevin Sherin (present by phone)

Dongming Cui

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

Julie Moore (non-affiliated; present by phone)

Kellie O'Dare (non-scientist)

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

Kelli Wells (present by phone)

### **Absent:**

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Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, and Dinithia Sampson

### **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 **9/6/17** 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 a tour of the IRB online system.

**(#1) Protocol Title:** Strategic Timing of Antiretroviral Treatment

**Submission:**

(Continuing Review)

**Principal Investigator:**

Charurut Somboonwit, M.D.

**Presenters:**

Kevin Sherin, MD

Jamie Forrest, MS

**Meeting Discussion:** This is a previously reviewed study that was tabled during the last IRB 2 meeting. The primary reviewer, Dr. Sherin provided a general overview of the study. Strategic Timing of Antiretroviral Treatment (START) is a part of policy change on a global level. Early treatment of care. Study site is in the Hillsborough area. This a multicenter trial approved by the National Institutes of Health (NIH) that has been carried out for many years. Study is currently in the 3.0 version and will be going into 4.0 in the beginning of 2018. Consent forms are fine. No problem with study methodologies. No vulnerable populations. Randomized participation. Study set to continue through 2026.

Dr. Sherin noted that certain documents need to be updated prior to January 2018 when version 4.0 starts. He suggested that study be tabled until the proper documents were provided. Dr. Arango suggested that the board approve the study, since provided documents are current and the researchers are aware that a modification would be required. Jamie Forrest asked if the demographics section should represent current number of participants or all participants, whether they withdrew or not. Drs. Arango and Moore responded that all participants should be included in the demographics table provided to the IRB.

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

**Total votes to approve for 12 months:** Affirmative: 10 Negative: 0 Recusal: 0 Absent: 0

**Next Meeting:** November 1, 2017

**Other Business:** None

**Meeting Adjourned:** 9:36am