

August 3, 2016  
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:**

Carina Blackmore (Chair)

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

Jamie Forrest (person whose primary interest is non-scientific)

Dongming Cui

Nkechi Ichite (present by phone)

Kevin Sherin (present by phone)

Kelli Wells

### **Absent:**

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

Julie Moore (non-affiliated)

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**Other Attendees:** Karen Card, MPH, Rotanya Bryan, MPA and Bonnie Gaughan-Bailey, MPA

### **Quorum**

A quorum was present. A quorum is defined as a 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.

Members present by phone received all pertinent materials prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

**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

**Approval of Previous Minutes:**

Minutes from the **July 6, 2016** meeting were circulated by email and modified by member input.

**Education:** Overview of 45 CFR part 46, Federal Regulations,

Karen Card described the federal regulations that govern the Institutional Review Board. She went over the Common Rule which governs Institutional Review Boards, exempt studies, minimal risk, IRB compensation, types of reviews, and vulnerable populations.

**Modifications:**

**(#1) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE A5332)**

<b>Submission:</b>	<b>Principal Investigator:</b>	<b>Presenters:</b>
(Modification)	Charurut Somboonwit, M.D.	Kevin Sherin, MD Jamie Forrest, MS

**Meeting Discussion:** The primary reviewer provided an overview of the study and a description of the modification. Dr. Sherin expanded on the background of the need for this study: persons living with HIV are many times more likely to develop heart disease and major cerebrovascular events. He discussed enrollment criteria. This is a modification to amend the recruitment and enrollment materials: the notecard, brochure, etc. Previous participants will not be notified of changes. No vulnerable populations; efforts made to exclude pregnant women. No additional risks added by modification. Jaime Forrest compared these materials to previous versions; the branding differed, but the information is not changed.

**Motion:** A motion of approval was made and seconded.

**Total votes for approval:** Affirmative: 7 Negative: 0 Recusal: 0 absent: 2

**Next Meeting:** September 7, 2016

**Other Business:** IRB members had some concerns about the forms and their efficacy. HRPP staff promised to review and streamline the worksheets. Members were also reminded to turn in their evaluations and let HRPP staff know if they needed a copy of the Research and Ethics textbook.

**Meeting Adjourned:** 9:30am