

August 1, 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:**

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

Nkechi Ichite (present by phone)

Dongming Cui

Julie Moore (non-affiliated)

Julia Fashner (present by phone)

### **Alternate:**

Bob Eadie, JD (non-scientist)

### **Absent:**

Jamie Forrest (Chair)

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

Adrian Cooksey (present by phone)

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

Kelli Wells (present by phone)

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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:** Problem Reporting/Healthy Start

Sarah Beard provided a presentation on the Healthy Start program and Rotanya Bryan listed out the steps to review and handle problem reports.

**Protocol Title:** HIV Surveillance – Data Analysis

**Submission:**

(Initial Submission)

**Principal Investigator:**

Cook, Robert

**Presenters:**

Moore, Julie JD, PA  
Reid, Keshia, PhD

**Meeting Discussion:** This is an initial study. The primacy presenter, Julie Moore, provided an overview of the study. The purpose of this research is to complete secondary analysis of existing surveillance data collected through the Florida Department of Health (FLDOH) and its partner entities. Investigators aim to

use surveillance data sets to understand health care utilization and determinants of health among a population of persons living with HIV in Florida. The research team will conduct a range of analyses with the data, focusing primarily on whether persons with HIV are engaged in healthcare, to identify reasons for disparities in outcomes of PLWH, and to understand HIV related stigma in Florida. By using data from several surveillance data sources, they will be able to better understand the range of issues that affect HIV health outcomes. The initial data analyses will consist of cross-sectional analyses of stigma and HIV in Florida using data from 2013-2015 using CDC questionnaires. They will be able to use results to influence the development of targeted interventions for populations with HIV related stigma at risk for poor outcomes.

The board found the research design sound enough to yield the expected knowledge. The research team's qualifications are sufficient. Risks to subjects were deemed to be greater than minimal risk by HRPP staff but were found by Julie Moore and Keshia Reid to be less than minimal risk. Risks to subjects were reasonable in relation to anticipated benefits to subjects. Since the study is a secondary analysis with no attempt to contact participants, no recruitment materials were involved. Investigators requested a waiver of consent. The board found the justification for a waiver to be adequate. Confidentiality and privacy protections were clearly outlined and satisfied the board's requirements.

Julie Moore had some questions about what dataset the study team would receive. It was also unclear as to why questionnaires were attached to the application and it was suggested that they should be removed. She also suggested that the HIPAA authorization waiver be removed since the study had a data use agreement in place. The secondary presenter, Keshia Reid, concurred with the requested revisions.

**Motion:** A motion to approve the study with contingencies was made and seconded.

**Total votes to approve for 12 months:** Affirmative: 6 Negative: 0 Recusal: 0 Absent: 5

Next Meeting: September 5, 2018

Other Business: None

Meeting Adjourned: 10:30am