Meeting Date: March 4, 2020
Next Meeting:

Attendance:
Jamie Forrest (Chair)
Jaime Arango
Nkechi Ichite
Julia Fashner

4 needed for quorum

Quorum:
A quorum **was** present.

The quorum is defined as a majority of members present, one member whose primary interests are non-scientific, and one member who is not affiliated, and whose immediate family are not affiliated with DOH. The quorum also reflected the requirement outlined in 45 CFR 46.108 as well as 21 CFR 56.107. Please note that the number of members present will not always match the total number of votes on items as the total number votes reflects the number of members present in the room at the time of discussion and vote. At least one non-scientist and at least one non-affiliated member were present.

Other Attendees:
Andrew Wentzell, IRB Coordinator
Gavin Grigg, IRB Analyst
Bonnie Gaughan-Bailey, Administrator, Office of Public Health Research

Attendance Notes:
Conflict of Interest: None
Members did not report any:
- Ownership interest, stock options, or other financial interest related to the research of any value.
- Compensation related to the research of any value.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.
- Interest that could be affected by the outcome of the research.

Attendance Note: Due to COVID-19, all IRB members were present by phone. Members present by phone received all pertinent material through IRB Manager 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.

Old Business: None

Other Business: There was no other business discussed at this meeting.

Notes: Applications reviewed and approved using the expedited procedure and exempt studies and non-research determinations were reported in the meeting agenda in IRB Manager; there were no questions or discussions about these actions.

Continuing Review:
Protocol Title: Strategic Timing of AntiRetroviral Treatment (START) (Florida Department of Health)
PI: Charurut Somboonwit

Fashner, Julia
Ichite, Nkechi

2 reviews submitted

Description: Thus far, site has not seen any patients since 2018. Site is only collecting information on participants through the end of 2021. Study wants to know how well HIV drugs will improve health over time for both groups in the study: those who began HIV drugs right away and those who waited to start. We will work with subject's doctors to collect

information about their health from the medical chart. This will include the CD4 count, HIV viral load, and whether patient have been sick or in the hospital. The plan is to continue collect this information each year through 2021. This is from version 4.0 of the protocol that was submitted in October 2017 and approved by the IRB in November 2017.

Meeting Discussion: A reviewer presented a summary of the continuing review followed by discussion. This is a continuing review of a previously approved protocol. All committee members reviewed the continuing review application, which provides a progress report about the study. All committee members reviewed all modified documents.

The Committee provided rationale for the basis of IRB approval under 45 CFR 46.111 and 21 CFR 56.111:

(1) Reviewers determined that this study is not greater than minimal risk and is consistent with sound research design and does not unnecessarily expose subjects to risk.

(2) Risks are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.
There are no vulnerable populations associated with this study.

(4) The Investigator has chosen a waiver of informed consent, which is appropriate for this study.

(8) Safeguards are in place for the rights and welfare of vulnerable populations.
No vulnerable populations in this study.

Letter:

Motion: Contingent Approval continuing review as not greater than minimal risk for 12 months. Contingent based on need for Nagesh CITI to be updated. Upon successful update and notice to FDOH IRB, study is approved to continue.

Total votes for approval: (Total members voting:) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Meeting Adjourned.