April 06, 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

IRB Attendance:

Carina Blackmore (Chair)
Cheryl Clark (Expertise in children, pregnant women)
Jamie Forrest (non-scientific)
Nkechi Ichite (present by phone)
Kelli Wells (present by phone)

Absent:

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

Other Attendees: Karen Card, M.P.H., Bonnie Gaughan-Bailey, M.P.A., and Rotanya Bryan, M.P.A.

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.

Approval of Previous Minutes:

Minutes from the **March 16, 2016** meeting were circulated by email and modified by member input.

Conflict of Interest:

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: Unanticipated problems, adverse events, and non-compliance: IRB reporting and response

Karen Card provided an overview of how to respond to studies that experience unanticipated problems, adverse events, and non-compliance. She categorized and defined each incident, while providing examples of past non-compliance and unanticipated problems. She also discussed the role of staff, chairs, and the IRB when problems (during research) are reported to DOH HRRP staff.

(#1) Protocol Title: (GS-0109) A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects

Submission:	**Principal Investigator:**	**Presenters:**
(Modifications)	Todd Wills, MD	Kelli Wells Nkechi Ichite

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modifications. The study made changes to the investigator brochure and edits including new information related to drug interactions. This is a cross-resistance, pharmokinetic parameters, regarding Harmonie. The trial is ongoing. Information includes completed studies and results. Updated information added to the data section. No changes to the protocol. Dr. Wells stated that the changes and information is appropriate. Dr. Wells recommended approval and Dr. Ichite seconded.

Dr. Blackmore asked if the study is still enrolling, and how will the new information be given to current participants? This study is still enrolling patients. Dr. Wells replied that the investigators are being provided the new information; how participants will receive it is not clear. Dr. Blackmore followed-up with "Should we ask about a strategy from the investigator?" Dr. Wells says this amounts to clinical information that is considered by physicians. Harmonie is a relatively new drug. Dr. Wells does not advise that the information goes to the participants. Dr. Ichite said this new information should not affect the informed consent; the IC was not changed.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 absent: 3

(#2) Protocol Title: Strategic Timing of AntiRetroviral Treatment (START)

Submission:	**Principal Investigator:**	**Presenters:**
(Modifications)	Charurut Somboonwit	Nkechi Ichite Kelli Wells

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the changes/ modifications. This study was designed to find out if the immediate start of ART in HIV-positive persons benefits patients relative to lung function. DSMB has determined the question has been answered; the treatment arm is superior. The participants were offered treatment. Follow-up period extended; this modification justifies the longer follow-up from end in 2017 to end in 2021. More funding needs to be found (this is NIH study). No other changes, including recruitment or inclusion. The consent form has been revised to include longer follow-up period. Protection of patients is adequate. No vulnerable populations. Dr. Ichite recommended approval and Dr. Wells seconded.

Dr. Blackmore asked if the study participants would be re-consented. Dr. Ichite replied that the researchers plan to provide full disclosure to patients. Dr. Blackmore also commented that there are two pieces to consider: the study period will be extended and how that information will be shared with participants. In addition, there may not be funding to extend the follow-up period, so participants should be made aware.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 absent: 3

Next Meeting: June 1, 2016

Other Business: None

Meeting Adjourned: 9:45am