

January 18, 2017
1:30-3:00 PM



Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 1 Convened Committee Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)
Ovidiu Cotea
Bob Eadie (non-scientist)
Daphne Holden
Keshia Reid (Expertise in Subpart B: Pregnant women)
Karen Card (Co-chair)
Katisa Donaldson (non-affiliated) (non-scientist)
Barbara Frentzen (non-affiliated)

Absent:

Nina McGrew (non-affiliated)

Other Attendees: Rotanya Bryan, MPA, Bonnie Gaughan-Bailey, MPA, and Dinithia Sampson, PhD

Quorum

A quorum was present. A quorum is defined as the majority of 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 12/21/16 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:

Rotanya Bryan provided a small overview of the changes to the Common Rule that will take effect January 19, 2017. Major changes to the common rule included the following: a broadening of the consent forms, use of a single IRB, establishment of new exemption categories, and the removal of continuing review for certain studies.

(#1) Protocol Title: Biobank for African American Prostate Cancer Research in Florida

Submission:
(Modification)

Principal Investigator:
Jong Park, PhD

Presenters:
Sandra Schoenfisch
Keshia Reid

Meeting Discussion: The primary reviewer provided an overview of the study and the proposed modifications. This a previously approved study conducted by the University of Florida and Moffitt

Cancer Center. This is a statewide study to research African American men with history of prostate cancer. The researchers are using the Department's cancer registry to recruit participants. Subjects are asked to complete information online. If participants agree to participate, they are then asked to provide tissue and DNA samples. Participants can receive up to three \$10.00 gift cards for the three parts of the study. This is a less than minimal risk study, using long-form consent applications.

The modification was to improve the recruitment flyer. Language about helping future generations was removed. The primary reviewer found no major issues with the revision. However, they did notice that the second page of flyer contained a typo and would need to be corrected. Primary reviewer recommended approval. The secondary reviewer concurred with the primary reviewers' review and had no further comments. Approval was seconded. Ms. Frentzen noticed that the initial brochure listed a prepaid envelope but the revised brochure did not. She asked that the researchers provide an explanation or correct the brochure. All members agreed to approve the study but the researcher must fix the typos. It was also recommended that modifications to document, flyers or supporting materials for any and all studies be identified and that the modifications be clearly marked or indicated.

Motion: A motion was made and seconded.

Total votes to approve: Affirmative:7 Negative: 0 Recusal: 1 Absent:1

(#2) Protocol Title: A Phase 3b, Randomized, Double-Blind Study to Evaluate Switching from a Regimen Consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects [Protocol No.: GS-US-366-1160]

Submission:
(Continuing)

Principal Investigator:
Todd Wills, MD

Presenters:
Ovidiu Cotea
Daphne Holden

Meeting Discussion: The primary reviewer provided an overview of the study and progress throughout the approval year. This is a stage 3 randomized double blind study to evaluate switching from a regimen consisting of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (EFV/FTC/TDF) Fixed Dose Combination (FDC) to Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) FDC in Virologically-Suppressed, HIV-1 Infected Subjects. Research takes place at the Hillsborough Community Health Department. The Principal Investigator is Dr. Todd Wills. There were no major changes. Study has progressed as expected. Researchers switched from 48 weeks to 98 weeks to collect efficacy data. Eight participants enrolled in the study seven remain.

Minor changes during review period consisted of staff changes. Researchers will notify participants of the change in staff because the lead coordinator is changing positions but will remain a part of the study. The study is permanently closed. Secondary analysis of data. No concerns from the primary presenter. Risks to subjects are minimized. Sound research design. No vulnerable populations. There were no reportable events during period Primary reviewer recommended approval. Secondary

presenter had no concerns and recommended approval. Ms. Frentzen asked about the dates on the consent form and how the Department keeps track them. She was informed that the Department does not require researchers to update their consent form unless they are making any modifications. In addition, researchers are asked to provide the last signed and dated consent form for the IRB to review.

Motion: A motion was made and seconded

Total votes to approve for 12 months: Affirmative: 7 Negative: 0 Recusal: 1 Absent: 1

(#3) Protocol Title: Clofazamine use in the treatment of patient with disease caused by strains of Multidrug Resistant Tuberculosis or Mycobacterium Avium Complex

Submission:
(Continuing)

Principal Investigator:
David Ashkin, MD

Presenters:
Ovidiu Cotea
Karen Card

Meeting Discussion: The primary reviewer provided an overview of the study and progress throughout the approval year. Clofazamine is a drug used in the treatment of patients with disease caused by strains of multidrug resistant tuberculosis or mycobacterium avium complex. Clofazamine was approved in 1986 but is no longer available in the US. Use of the drug is being provided with special arrangement by the Food and Drug Administration. Researcher must ask FDA for approval. This is an ongoing treatment protocol. No changes during the approval period. The primary reviewer had no concerns. Recruitment continues. No reportable events. No vulnerable populations. Approval was recommended by the primary reviewer. The secondary reviewer concurred. Researchers have very long and clean record. There are risks from medical treatment but not under review by committee. Consent is appropriate. No concerns. Secondary reviewer recommended approval.

Motion: A motion was made and seconded.

Total votes to approve for 12 months: Affirmative: 7 Negative: 0 Recusal: 1 Absent: 1

Next Meeting: February 15, 2017

Other Business: Bonnie announced Zika updates. Sandra introduced the newest IRB member, Barbara Frentzen.

Meeting Adjourned: 2:00pm