September 7, 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:

Jamie Forrest (non-scientist)

Nkechi Ichite (present by phone)

Kevin Sherin (present by phone)

Carina Blackmore (Chair)

Dongming Cui

Julie Moore (non-affiliated)

Absent:

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

Kelli Wells

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

Other Attendees: 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

Approval of Previous Minutes:

Minutes from the **August 3, 2016** meeting were circulated by email and modified by member input.

Education: Overview of 45 CFR part 46, Federal Regulations continued.

Karen Card described the federal regulations that govern the Institutional Review Board. She described the vulnerable populations and the IRB's responsibilities to these protected participants. She also went over the various forms of consent and when they are appropriate.

Modification:

(#1) Protocol Title: GS-US-292-0111 A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide versus Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 positive, Antiretroviral Treatment Naive Adults

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Todd Wills, MD	Kevin Sherin Shamarial Roberson

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. Dr. Wills at Hillsborough CHD is the PI. Randomized control trial, a continuation study. Gilead is the sponsor; trial began in 2013. Two formulations of medication for HIV infected persons. The only change with this modification is change to information sheet for Stribald. Enrolled participants will be informed of the changes. All safety controls and monitoring, procedures, are same. This study involves $100 compensation.

Motion: A motion of approval was made and seconded.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 absent: 3

Continuing:

(#2) Protocol Title: EGRIFTA Long Term Observational Study (LTOS)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing)	Ewa Szczypinska, MD	Carina Blackmore Dongming Cui

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the modification. This study involves exposing HIV+ infected persons to EGRIFTA. Started in 2013. 120 sites in US. Continues through 2016. Looks at the side effects of use of EGRIFTA. The potential for malignancy, glucose metabolism, development of diabetes type 2; liver, cardio or other issues. The study is moving forward as planned. No changes to consent, protocol, no changes to side effects. No adverse events reported. Clinicians recruit the patients. No issues to report with patient safety. Privacy is maintained. Participants receive $25 per visit. No vulnerable populations. There are 10 enrolled at the site, 5 withdrawn primarily because they acquired insurance and can receive care. One could not adhere to the protocol. One was withdrawn because of comorbidities. One motion to approve the CR. This phase 4, multicenter safety study for HIV infected participants. Motion seconded. Dr. Sherin abstains for conflict. At a point in the past, this study was in peril because the supply of study drug was limited, but that is not the present case.

Motion: A motion of approval was made and seconded for 12 months.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 1 absent: 3

Initial:

(#3) Protocol Title: NATURAL HISTORY STUDY OF THE DEVELOPMENT OF TYPE 1 DIABETES: A Pathway to Prevention (TN01)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Review)	Henry Rodriguez, MD	Nkechi Ichite Jaime Forrest

Meeting Discussion: The primary reviewer provided an overview of the study and a description of the initial study. Principal Investigator is Henry Rodriguez. USF is the study site. The study tracks children and adults before and after development of T1D. To optimize management of T1D, which is not optimal. Dr. Ichite went over the justification of study of T1D to characterize the risks, identify subjects eligible for follow-up trials, and find factors contributing to development of T1D. Sponsor is Trialnet. The network funnels newly diagnosed children and adults into treatment and trials. Protocol involves periodic screening of patients and collecting risk factors. Monitor blood glucose level, HA1C level, autoimmune antibodies. Allows for predictive capacity of these with diagnosis of T1D. Children 4 years old and older with brother/sister with T1D. Adults can have secondary relative with T1D. Study focuses on familial relationships for eligibility of undiagnosed persons.

Design is thorough, informed consent thorough. A permission form for parents, and an assent for persons 12 to 17. Risks are minimal. Procedures are in doctor's office; no medications or drugs, procedures are blood draws. Confidentiality and privacy are adequate. Question: Participants will be advised on the frequency of follow-up visits based on the lab numbers; 6 months or a year. Two phases: screening and monitoring. Participants screened in are in semi-annual or yearly monitoring group, with possibility of moving from annual to semi-annual. There is $50 per visit compensation. Some persons not screened in are eligible for random selection into a control group study for those with no autoimmune antibodies. Some residual specimens will be stored for additional studies from consenting participants.

Tampa CMS will be a site for this study. However, the blood draws can be at other convenient locations. More discussion of the benefits to participants. Are participants in semi-annual monitoring required to collect and data themselves or do any self-monitoring themselves? Answer: No. Question: Are there other known risk factors for T1D that are in the persons' control that the participants will be counseled on? Answer: The protocol addresses some warning signs or symptoms, education on, but it is not known if there are such known risk factors that any at-risk person can address.

Motion: A motion of approval was made and seconded for 12 months.

Total votes for approval: Affirmative: 6 Negative: 0 Recusal: 0 absent: 3

Next Meeting: October 5, 2016

Other Business: None

Meeting Adjourned: 9:54am