May 20, 2015
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)
Ron Brown (Non-Scientist, Non-Affiliated, Present by Phone)
Ovidiu Cotea (Present by phone)
Becky Grigg
Daphne Holden (absent)
Roland Reis (Non-Scientist)

Other Attendees: Derek Schwabe-Warf

Quorum

A quorum was present. A quorum is defined as a majority of members present. 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.

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 4/15/2015 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:

Education was not provided today due to Dr. Hood's absence.

(1) Protocol Title: Randomized Trial to Prevent Vascular Events in HIV- REPRIEVE (A5332)

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Charurut Somboonwit, MD	Ron Brown
		Ovidiu Cotea

Meeting Discussion:

This modification added several additional patient assessment surveys to increase the quality of data collection. In addition, a lipid and smoking reduction handout is provided to participants in an effort to improve lifestyle behaviors. No patients have been enrolled yet.

Reviewers determined the modifications to this greater than minimal risk study did not change the research design or exposure to risks because addition of a survey and informational pamphlet did not alter risks or change the fundamental design of the study. The modifications do not add new risks or change the probability or magnitude of existing risks, which were previously determined to be

reasonable. The modification does not change participant selection procedures. The modification does not change the consent procedures, which continue to be appropriate. The modification did not change plans for safety monitoring. There were no modifications to protections for privacy interests or confidentiality protections. The modification did not change inclusion criteria; there are no vulnerable populations are enrolled in the study.

Total votes for approval: Affirmative: 5 Negative: Recusal: Absent:

(2) Protocol Title: HAART Standard Version of the PROMISE Study

Submission:	**Principal Investigator:**	**Presenters:**
Modification	Patricia Emmanuel, MD	Becky Grigg Ovidiu Cotea

Meeting Discussion:

Clarifies procedures for grading the severity of adverse events. Breastfeeding isn't recommended while patients are using Epivir. However, this doesn't update treatment breastfeeding guidelines since breastfeed is not recommended in HIV positive women anyways. Same for Epzicom as for Epivir. Kaletra- revised package insert so that medication may be taken once or twice daily but once daily is recommended in children. Kaletra is not recommended with: efavirenz, nevirapine, or nelfinavir OR in pregnant women. Retrovir has been updated to include a latex allergic warning. Also, Retrovir is recommended to be taken more often with a less concentreated dose especially in patients with renal impairment.

Reviewers determined the modifications to this greater than minimal risk study did not change the research design or exposure to risks because it updated the risks and grading of adverse event severity, which could only reasonably reduce risks. The modifications do not add new risks or change the probability or magnitude of existing risks, which were previously determined to be reasonable. (3) The modification does not change participant selection procedures because participant enrollment has been closed at this site. The modification does not change the consent procedures, which continue to be appropriate. The modification did not change plans for safety monitoring. There were no modifications to protections for privacy interests or confidentiality protections. The modification did not change inclusion criteria even though pregnant women and children are included in the research study.

Children Category 405: The research is greater than minimal risk because it involves use of a drug regiment, whose effects on HIV transmission are unknown. There is the prospect of direct benefit to the children because the altered drug regiment may help reduced HIV transmission from mother to child.

The risks in the research, are justified by the potential benefit of reduced HIV transmission.

Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, because there is a direct benefit to the child that could not be obtained outside the research context

Pregnant women

Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. The protocol describes animal work and Phase I studies involving pregnant women, and the risks appear to be consistent with other studies in the drug class.

The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. The study is likely to reduce risk of contraction of HIV in the child.

Any risk is the least possible for achieving the objectives of the research because the study monitors the women and children closely and appropriate pre-clinical trials have been conducted.

Consent of the woman is obtained and documented in writing. The consent document provides information such that the mother is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus.

The consent of the woman and the father are obtained. The consent document provides information such that the mother and father are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

No inducements, monetary or otherwise, will be offered to terminate a pregnancy because there is no compensation in the research.

Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. The researcher attested no attempt will be made to attempt to terminate the pregnancy in the research.

Individuals engaged in the research will have no part in determining the viability of a neonate. The researcher attested they are not involved in determining the viability of the neonate.

Total votes for approval: Affirmative: 5 Negative: Recusal: Absent:

Next Meeting: June 17, 2015

Other Business: None

Meeting Adjourned: 2:30 PM