November 18, 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)
Ovidiu Cotea
Becky Grigg
Daphne Holden
Roland Reis (Non-Scientist)

HRPP staff in attendance
Robert Hood, Ph.D.
Rotanya Bryan

The meeting started at 1:35

Announcements
Dr. Schoenfisch introduced Rotanya Bryan, new staff in the HRPP.

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.

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:

Dr. Hood reviewed the Notice of Proposed Rulemaking to revise DHHS regulations governing protection of human participants in research. The current regulations have been in place since 1981, and the revised regulations make significant changes. The proposed revisions eliminate the requirement for continuing review of research that is not greater than minimal risk; create a new category of "excluded" research that clarifies when public health activities are not research; require single IRB review of certain federally-sponsored research studies; requires that almost all research involving human tissues have IRB approval (in contrast to the current state of affairs, where tissues that do not have identifiers are not considered to be "human subjects" and do not require IRB review); and make revisions to consent documentation; and include other changes.

Review of non-compliance and determination of actions to protect participants:

(1) Research Site/Protocol:	Principal Investigator:	Summary of Issue:
Florida Department of Health in Hillsborough County	Todd S. Wills, MD	DEXA scans not conducted per protocol; sponsor informed site participant data will not be included in trial

The Chair reviewed the history of non-compliance with this phase III study involving a procedure that occurred outside timeframe in the sponsor protocol. The site completed education and conducted monitoring, and HRPP staff conducted a site visit and provided education. In addition to education and monitoring, the IRB requested at the October 21, 2015 meeting a description of a revised process to improve compliance. The researcher submitted a checklist to monitor research and provided staff education on the use of the checklist. The IRB determined the checklist was adequate and that the checklist, education on the checklist, and plan for implementation completed requirements for corrective action.

Total votes to approve the corrective action plan: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Protocol Title: The Antiretroviral Pregnancy Registry

Submission:	**Principal Investigator:**	**Presenters:**
Initial Review	Ana Rua Dobles, M.S.N.	Sandra Schoenfisch
		Daphne Holden

The IRB reviewed this research study at the October 21, 2015 meeting at the same time it reviewed non-compliance concerning the study to coordinate review and discussion of the protocol. The IRB determined the study is not greater than minimal risk, and eligible for review using the expedited procedure. The IRB voted to approve the study with a waiver of consent. However, a staff quality assurance review identified the study is FDA-regulated, and therefore not eligible for a waiver of consent documentation. The IRB discussed the fact that FDA regulations apply when research involves collecting data that will be held for inspection by or submitted to the FDA as part of an application for marketing, and the fact that FDA regulations do not allow a waiver in this circumstance. The IRB reviewed the consent document, and determined all required disclosures were present, and the document met requirements for consent documentation.

Total votes to approve this not greater than minimal risk study for 12 months and review the study in the future using the expedited procedure: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Next Meeting: December 16, 2015

Other Business: none

Meeting Adjourned: 2:25
