August 17, 2016
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)

Bob Eadie (non-scientist)

Daphne Holden

Keshia Reid (Expertise in Subpart B: Pregnant women)

Katisa Donaldson (non-affiliated)

Absent:
Ovidiu Cotea (Present by phone)
Nina McGrew (non-affiliated)

Other Attendees: Karen Card, MPH, Rotanya Bryan, MPA, and Bonnie Gaughan-Bailey, MPA

Quorum

A quorum was present. A quorum is defined as the majority of the IRB embers 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 July 20, 2016 meeting were circulated by email and modified by member input.

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: None.

Initial:

PRISM: Utilizing Text Messaging to Notify Adolescents of their STI Results in the Teen Health Centers of Duval County

Submission:	Principal Investigator:	Presenters:
(Initial Review)	Felicia Mallet, MPH	Sandra Schoenfich Keshia Reid

Meeting Discussion: This study was originally under expedited review, but was turned over to the board when the reviewer could not approve the study in its current state. The primary reviewer provided a general overview and some the concerns she had about the study. Site is Duval County; Principal Investigator (PI) is a school nurse. Her goal is to have school nurses follow-up with students with STI test results by text message. The premise is that students will have better rates of follow-up. This modifies the usual activities of the County Health Departments (CHD). PI has support of the local CHD and school health. Keshia Reid stated that the PI made an incorrect justification for waiver of assent. Daphne Holden asked if the PI's CITI training was current. She stated that if data is being given to statistician, they should be part of the study team. Keshia

wanted a description of the analysis. Study collects demographics only, and timing of contact following text message. Keshia also asked if the PI was comparing texts to phone calls or comparing school nurses to DIS intervention. The hypothesis of the PI was unclear. She also asked how the effectiveness of the intervention will be assessed.

Motion: A motion was made and seconded to table the study until such time as the PI had addressed member's concerns.

Total votes for approval: Affirmative: 5 Negative: 0 Recusal: 0 Absent: 2

Unanticipated problems:

Death of an Infant: Accessing Voices of Bereaved Parents to Create Healing

Submission:	**Principal Investigator:**	**Presenters:**
(Non-compliance/problem reporting)	Dawn Hawthorne, PhD, RN	Sandra Schoenfich Daphne Holden

Meeting Discussion: The primary reviewer provider a general overview of the study and the unanticipated problems. This study is a pilot study to describe the health challenges of losing an infant, describe approaches used to resolve health challenges, and create a scripted bereavement intervention based on the findings. Birth and death records were requested from the Bureau of Vital Statistics.

The PI's Institutional Review Board (IRB) sent a report dated July 29, 2016. The PI described the violation in the following way: The study is intended for whose infant died within 18 months of birth. Seventy-two letters of invitation were sent to parents using a list provided by the Florida office of Vital Statistics with a Data Use Agreement. Sixty-nine of the 72 parents received the letter of invitation in error as all these parents had not experience a death of an infant. In addition to sending out letters of invitation to the wrong participants, the PI also modified the consent forms without prior authorization of the Department of Health's IRB.

In the PI's report she stated that she "will request correct dataset" in the future to prevent future incidents similar to this one. Daphne objected to language that blames the Department for a function (filtering data) they are not prepared to carry out; response showed a lack of reflection. The researcher currently has all necessary data. Should our IRB have had the opportunity to review the apology letter before it was sent out? Sandra points out that the volume of records received should have indicated the possibility of the problem. Bob expresses his central question, "Can this investigator be trusted to continue the study competently?" A motion was made to terminate the study. A motion was made to suspend the research, pending a plan for improvement; this was seconded. Sandra went over items for an action plan with the researcher. The board requested a letter of explanation of the altered documents (consent and introduction letter). Daphne pointed to two issues: the incorrect use of data and the lack of understanding of what her role is, and the lack of understanding of the IRB process.

Motion: A motion was made a seconded to suspend the research until such time as the PI demonstrates the capacity to carry out the research correctly and ethically.

Total votes for approval: Affirmative: 4 Negative: 0 Recusal: 0 Absent: 3

Next Meeting: September 21, 2016

Other Business: Bonnie informed members that HRPP staff had procured an online system and that the members would receive training within a couple of months.

Meeting Adjourned: 3:00pm