December 16, 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)

Jamie Arango (non-scientific member, non-affiliated member; member who represents the general perspective of participants)

Alternate for Ron Brown (non-scientific member, non-affiliated member; member who represents the general perspective of participants)

Ovidiu Cotea (Present by phone)

Daphne Holden

Jamie Forrest

Alternate for Keshia Reid

Dongming Cui

Becky Grigg

Cheryl Clark

Alternate for Shamarial Roberson

8 of 10 members, including non-scientist and non-affiliated

Other Attendees: Karen Card, Bonnie Gaughan-Bailey; Rotanya Bryan, Robert Hood, Ph.D.

Announcements

Dr. Grigg announced this is her last meeting because she is retiring from the Department

Education

Dr. Schoenfisch announced that education will occur starting in January and continuing throughout next year.

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: Dr. Clark declared that she plans to join the study as a researcher, and currently uses PRAMS data as a core part of her research day to day. She was not present for the vote

Dr. Cui is the current principal investigator, and was not present for the vote

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

Continuing Review

Meeting Discussion: PRAMS is a national study funded by the Centers for Disease Control and Prevention, and is covered by DHHS regulations. The study is requesting a modification and review to continue research. This is a request to modify the principal investigator for the study at the Department. The new principal investigator had sufficient qualifications and expertise to conduct the research. She serves as a Training and Research Consultant. The study is not greater than minimal risk, but was reviewed at the meeting of the convened board because review requires review by multiple board members with expertise in children, pregnant women, and prisoners. The prisoner representative reviewed all materials in advance and provided a reviewer comment form. However, Dr. Whittenberg had to be absent for an unexpected health event.

The Committee reviewed a status report of the progress of the research. The study is proceeding normally. There are 1395 participants remaining in the Florida portion of the national PRAMS study. There were no problems, including adverse events or adverse outcomes, unanticipated problems involving risks to participants or others or serious or continuing non-compliance in the previous review period. There were no participant withdrawals (participation involves a one-time phone survey) or complaints about the research. During the previous approval period there were staff changes. There have been no significant new findings in literature, or interim findings, or multi-center reports that might relate to the participants' willingness to continue or affect the criteria for approval.

Reviewers provided rationale for the basis of IRB approval under 45 CFR 46.111: 1) Risks to participants posed by the research, which involves a telephone survey, are not greater than minimal. 2) Study procedures continue to be consistent with sound research design, and included revisions to improve sampling. Risks are reasonable in relation to anticipated benefits of a better understanding of the factors that influence pregnancy-related mortality. 3) No changes were made to participant selection; selection of participants continues to be equitable. Participants are contacted through the mail, then are followed up with a phone call. Subject selection is based on a random sample of people in Florida. 4) Consent is appropriate; a waiver of documentation of consent was granted by the IRB and there have been no changes. 5) There continue to be adequate provisions to protect the privacy of participants. 6) There are appropriate provisions to protect the confidentiality of data. 7) The study involves pregnant women, and may involve children and prisoners.

Children

Category 404: The research is not greater than minimal risk because PRAMS is a survey and the identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

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.

Assent of all children is acceptable.

Pregnant Women

The study is not a biomedical study, so preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, did not need to be conducted and the IRB did not need to consider data for assessing potential risks to pregnant women and fetuses.

The risk to the fetus from surveys is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot obtained by any other means. Any risk is the least possible for achieving the objectives of the research because the design of the research provides alternatives of care.

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.

No inducements, monetary or otherwise, will be offered to terminate a pregnancy because there is no compensation in the research and the researcher has attested no attempt will be made to terminate the pregnancy 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. This is not a clinical study or study does not occur during labor where such a determination is made and the researcher attested they are not involved in determining the viability of the neonate.

Prisoners

This involves surveys and interviews conducted by people outside the prison staff, and does not provide advantages to a prisoner through their participation in the research, when compared to the general living conditions of prisoners. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers since everyone receives the same treatment. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners because individuals are randomly selected. The information is presented in language which is understandable to prisoners. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no

effect on his or her parole. If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact because participants will be treated in the hospital until they are well.

Motion: Approve study for not more than 12 months as not greater than minimal risk. The study may be reviewed in the future using the expedited procedure.

Total votes for approval: (Total members voting: 8) Affirmative: 0 Negative: 2 Recusal: 0 Absent: 0
Dr. Clark recused because she had a non-financial conflict of interest because she was planning on joining the research study.

Dr Cui was present to answer questions about the study, but the board had no questions.

Next Meeting: January 6, 2015

Meeting Adjourned: (1:45pm)