August 4, 2021
9:00 – 10:30 AM

Department of Health
2585 Merchants Row
Conference Rm. 310 A
Tallahassee, Florida 32311

IRB 2 Convened Committee
Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair) (non-scientist) (affiliated)- Yes
Nkechi Ichite (scientist) (affiliated) - Yes
Robin DeWalt (scientist) (affiliated) - Yes
Merlene Ramnon (scientist) (affiliated) - Yes
Meredith Hennon (scientist) (affiliated) - Yes

Absent:
Julia Fashner (scientist) (non-affiliated)
Mary Martinasek (scientist) (non-affiliated)
Jamie Arango (non-scientist) (non-affiliated)

Other Attendees: Andrew Wentzell, Gavin Grigg, and Bonnie Gaughan-Bailey, Lea Hollowell

Quorum

A quorum was present. A quorum is defined as the 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.

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

Meeting Discussion

Initial Review

Title: Evaluating Late Enrollment in Florida's Nurse-Family Partnership (Default Site)

PI: Allison, Mandy MD, MA, MSPH

Presenters: Forrest, Jamie MS and Ramnon, Merlene, PhD, MPH, MSN, BSN

Discussion:

This is another ceding study where the researchers are requesting we cede IRB review to University of Colorado. This is a secondary data analysis study, the Florida nurse family partnership is an option through Florida's healthy start program, pairing a nurse with a new and expectant mother. Typically, this is done prior to 28 weeks gestation, the current pilot pairs and allowed women to participate at a later gestational age of post 28 weeks. Jan 2020 this pilot project started; Colorado is leading the expansion for the national nurse family partnership group. They are requesting vital stats, pre-natal risk screen and healthy start enrollment data for their secondary data analysis with a data linkage between the different systems. Once linked there will be a unique identifier that will be properly protected and controlled. Limited staff will have access.

Goal: Describe characteristics of women referred after 28 weeks of gestation. They also want to look at proportion of women who have the late referral enroll, and those who enroll after 28 weeks but did not

enroll on time. Looking to evaluate the program, and, also to clearly define the program and its advantages. Partnership has shown a positive impact on outcomes for both mother and baby.

Children and pregnant women are involved, but there are no direct interactions. It is a not greater than minimal risk study, with a waiver of consent. All study participants have been properly trained. The researchers do have substantial experience and a strong study design. No conflict of interest reported.

They do plan to publish findings and it is a sponsored study to conduct this work.

Secondary presenter, Dr. Ramnon:

Seven people involved in the research, they are all qualified, they are looking at multiple data variables from the health risk screen related to the demographic characteristics to describe the population and their health history including previous birth outcome information.

For infant risk screen measures, looking at abnormal conditions, NICU, insurance, etc.

Previous history and pre-term medical history details from the mother and past pregnancies.

Their study presentation is a non-risk study, they're looking at a lot of information for the children they will not be contacting the parents or the children. The research will be kept confidential and protected even though it is from vulnerable populations.

This research presents very minimal risk based on the protections that are in place here.

She wanted to discuss how they described their hypothesis in this study. They hypothesize that women referred after 28 weeks will have multiple risks of pregnancy outcome. Also, the rates of enrollment for post 28weeks registration would be lower than those prior to 28 weeks enrollment.

They have identified this gap from previous studies reported so this is the importance of including this data in their study.

They plan to publish their findings and disseminated to the partnership and stakeholders and to characterize the women referred to the national partnership program. This program will serve as a model for a nationwide outreach.

Jamie: This came to the full board as it is a ceded review. Therefore, is the board the person voting on the ceding or is it up to the reviewers?

Bonnie: The chair can make that decision, but when it comes to the full group and we go through the process it would be appropriate for the IRB committee as a whole to go ahead and vote on whether to cede or not to cede. It's really about the research and whether it is appropriate and if we feel comfortable with ceding.

Jamie: Motion to approve this study and a motion to cede review to the Colorado multiple institutional review board for this study.

Merlene to second the motion of approval

(1) This study is not greater than minimal and the design remains consistent with sound research design and does not unnecessarily expose subjects to risk. (2) Risks are reasonable in relation to anticipated benefits, and there have been no new risks identified in the previous year. (3) Selection of subjects is equitable. (4) Waiver of consent was present and reasonable. (5) The PI is responsible for monitoring safety. (6) Provisions to protect privacy interests of participants and confidentiality of data are appropriate. (8) Children and pregnant women are involved in this study, but no contact will be made and data will be protected appropriately to make this a not greater than minimal risk study.

Total votes to approve for 12 months: (Total members voting:) Affirmative: 5 Negative: 0 Recusal: 0 Absent: 0

Education:

Lea Hollowell from IRB Manager to present updates to IRB manager

Discussion:

Other Business: Mary Martinasek (scientist) (non-affiliated) has a teaching conflict starting 9/1 and will transition to the IRB1 board during this assignment.

Next Meeting: September 1, 2021 at 9:00 AM

Meeting Adjourned: 9:36 AM