July 18, 2018
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)
Ovidiu Cotea (Present by phone)
Daphne Holden
Karen Card (Co – Chair)
Megan Macdonald (Expertise in Subpart D: Children)
Shoshana Levy (Present by phone)
Bob Eadie (non-scientist)
Keshia Reid (Expertise in Subpart B: pregnant)
Dongming Cui
Barbara Frentzen (Present by phone) (non-affiliated)

Absent:
Nina McGrew (non-affiliated)
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)

Other Attendees: Rotanya Bryan, MPA, Gavin Grigg, Bonnie Gaughan-Bailey, MPA, Cheryl McFarland, Betsy Wood, and Anne Weidner.

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.

Approval of Previous Minutes:

Minutes from the June 20, 2018 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:

Problem Reporting – Rotanya Bryan

Protocol Title: Improving Public Health Practice: A Pilot Study of High Risk Infant Referrals in Three Florida Counties (Florida State University)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Rowan, Alan Rowan DRPh	Reid, Keshia PhD
		Cui, Dongming MD, MPH, DrPH

Meeting Discussion: This is an initial review of a pilot study of high risk infant Healthy Start screens. The primary presenter (Dr. Reid) provided an overview of the study. This study intends to examine the accurate prevalence of positive infant Healthy Start Risk screens in three rural counties in Florida. Study design is based on random sampling of women in the Healthy Start Coalition of Madison, Jefferson and Taylor (JMT Coalition) counties, areas in the Florida Panhandle where residents experience particularly poor outcomes related to high poverty, rural dispersed populations with limited access to care, racial segregation, and racial disparities in birth outcomes. Analysis will consist of birth certificate data and interviews with women whose infants scored a 4 or higher on the screen and are participating in the Healthy Start Program and women whose infants had a 4 or higher on the screen but are not participating (declined referral or were not offered services).

The study was determined to be greater than minimal risk because of potential identification of hospitals that fail to conduct infant screenings and potential distress caused to women who were eligible and not referred. Prior reviewers requested that the researchers omit identifying information of hospitals that take part in the study in order to mitigate any potential risks. The research design was found to be sound and does not unnecessarily expose subjects to risks. Risks are reasonable in relation to anticipated benefits.

The reviewer found the selection of subjects to be equitable. Study team will be recruiting women aged 18-65 living in Jefferson, Madison or Taylor counties and will be excluding non-English speaking women. A payment of $10 will be given to participants in the form of a gift card. Participants will be recruited with a letter or called by researchers with a telephone script. If research subjects decide to consent, they will be asked to sign a long-form consent document.

Committee members discussed some of their concerns with the study. One member found grammatical errors in the consent form that led them to believe that the researcher is not being as diligent as they should be. The researcher (Cheryl McFarland) promised to revise the consent form to fix. Members questioned whether women were referred for screening but declined or were never referred. Ms. McFarland noted that both options were possible, but they were only interested in participants that were never referred. Members also wanted to know what might have caused the decline in screening. Ms. McFarland stated that there may have been change in management of the medical record, since nothing has changed with the training institution. Florida statute mandates that screenings take place. Members were also concerned with the researchers conducting research on a topic that might put the hospital at legal or financial risk. The researchers had revised their protocol to mitigate any potential risks to hospital by completely de-identifying the hospitals and also coding the counties. No identifying information would be published. The primary and secondary reviewers recommended approval.

Motion: A motion to approve the study was made and seconded.

Total votes to approve for 12 months: Affirmative: 9 Negative: Recusal: 1 Absent: 2

Protocol Title: Black Women: Etiology and Survival of Triple-negative Breast Cancers (Best) Study (Vanderbilt University)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Pal, Tuya	Frentzen, Barbara MSN, ARNP Card, Karen DrPH

Meeting Discussion: This is a previously approved study conducted at Vanderbilt University by Dr. Tuya Pal. Study is funded by the Bankhead Coley grant and Cancer Society monies. The specific aims of this study are to:

- Recruit a population-based sample of African American women with early-onset invasive breast cancer through the Florida State Cancer Registry.
- Investigate genetic and lifestyle determinants of TN and other subtypes of breast cancer in premenopausal Black women.
- To conduct exploratory analyses to examine survival and prognostic markers according to TN subtype in this high-risk population.
- To evaluate the impact of BRCA test results on behavioral, psychological, and social health outcomes of genetic testing (GT) from baseline to 1 and 12 months post-GT results disclosure.

In addition to these specific aims, researchers will be evaluating high risk breast cancers and co-morbidities. Researchers will continue to follow the 2009-2011 cohort.

The presenter noted that the researcher planned to collect social security numbers, but removed that question from the survey once DOH asked. She also noted that this study has been reviewed and approved as expedited but she found it to be greater than minimal risk because of the impact of the genetic testing. The utilization of genetic counselors and genetic testing provides risk of psychological impact and insurance discrimination.

The amendments to the study include changes to personnel, changes to the consent form, collection of saliva samples and the use of genetic counselors. The secondary presenter noted that the researcher team would be moving from a quasi-site to a mail system. The primary presenter has no problem with the changes but asked that the researcher amend the language in the Contact Letter from “indicating” to “telling us” which simplifies the language without changing the study and removal of “at this time” and “by” which would apparently be for clarification and also do not change the study. Both reviewers recommended contingent approval.

Motion: A motion to approve the study was made and seconded.

Total votes for contingent approval: Affirmative: 10 Negative: 0 Recusal: 0 Absent: 2

Protocol Title: (A5332) Randomized Trial to Prevent Vascular Events in HIV REPRIEVE-Hillsborough CHD (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Somboonwit, Charurut	Cotea, Ovidiu MD, MPH Card, Karen DrPH

Meeting Discussion: This is a previously approved study taking place at the Hillsborough Health Department. The primary presenter (Dr. Cotea) provided a brief overview of the study. REPRIEVE is a prospective, double-blind, randomized, placebo-controlled, multicenter efficacy study in 6500 subjects, with individual subjects to be followed for up to 72 months. It is a randomized trial to prevent vascular events in HIV patients. The principal investigator is a well-known and qualified researcher.

The planned modifications are to increase enrollment to 7,000 participants, study visits are every 4 months for the next 2-6 years instead of 3 ½-5 ¾ years as previously noted, subjects will be in this study about 3-7 years (36-84 months) depending on when they join instead of the 3 ½ - 6 years previously noted, and total enrollment of individuals with very low cardiovascular risk (10 year ASCVD risk score <5.0%) will be capped at approximately 4200 participants. Current subjects will be asked to sign the new consent form and all subjects will be notified of these changes.

The secondary reviewer (Dr. Card) noted that the study lengthens the amount of follow-up and places caps on participants with low cardiovascular risk. Changes were found to be reasonable. Both reviewers recommended approval.

Motion: A motion to approve the study was made and seconded.

Total votes for approval: Affirmative: 10 Negative: 0 Recusal: 0 Absent: 2

Protocol Title: Clofazimine in the treatment of leprosy (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Casanas, Beata	Cotea, Ovidiu MD, MPH Levy, Shoshana MD, MPH

Meeting Discussion: This is a previously approved study taking place at the Hillsborough Health Department. The primary presenter (Dr. Cotea) provided a brief overview of the study. This a compassionate use drug to treat Hansen's disease or Leprosy. The drug is not currently available in the USA, so researchers have to apply for INDs in order to administer the drug.

Currently, no patients have been enrolled during the approval period. No changes have been made to the protocol. Researchers had a lapse in IRB approval. Reviewer recommended approval and the secondary reviewer (Dr. Levy) seconded.

Motion: A motion to approve the study was made and seconded.

Total votes to approve for 12 months: (Total members voting: 10) Affirmative: 10 Negative: Recusal: Absent: 2

Next Meeting: August 15, 2018

Other Business: None

Meeting Adjourned: 2:37pm