September 15, 2021
1:30pm
Virtual Meeting by TEAMS

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) (scientist) (affiliated)
Megan Macdonald (Co-chair, Expertise in Subpart D: Children) (scientist) (affiliated)
Bob Eadie (non-scientist) (affiliated)
Ovidiu Cotea (scientist) (affiliated)
Robin DeWalt (scientist) (affiliated)
Gina Larsen (non-scientist) (non-affiliated)

Absent:
Merlene Ramnon (scientist) (affiliated)

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

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.

Submissions for Convened Board Review

Initial review

Title: Adverse Coronavirus Disease 2019 (COVID-19)-related outcomes among persons living with HIV in Miami-Dade County (Florida Department of Health)

Primary Presenter: Sandra Schoenfisch, PhD, MS, BSN, RN

Secondary Presenter: Gina Larsen, MA

Meeting Discussion: scientific description of the protocol – address rationale, background, general overview, researcher qualifications, e.g.,

This is a small study, that is focusing on clients receiving services in Miami- Dade. The goal is to look at the impact of COVID-19 on people with HIV. It is a matched cohort study that will look at groups with HIV and matched comparison groups/individuals who are not HIV positive. It is data analysis, no interaction with subjects and will review PHI. The study size is expected to be approximately 212-272. The researcher described how they are going to collect the sample and have identified 280 subjects that would qualify to be in the study. The study has a short timeframe with a couple of months for data analysis. The research team designated it a not greater than minimal risk study but the reviewer stated that she thought it might a greater than minimal risk due to the sensitivity of the data being collected. With the safety measures in place and analysis of existing data only, it can be designated not greater than minimal risk.

Study staff are being trained regarding data collection methods and storage procedures indicate safe and secure data management. They have requested a waiver of consent which is appropriate in this study.

The primary reviewer stated that there are no issues with this study and her recommendation was approval of this study.

Gina Larsen:

The second reviewer agreed with Sandra. Her comments included that it was a retrospective record review study with appropriately trained and qualified study staff. The research team clearly described their risk mitigation and data analysis procedures. All of the proper DUAs are in place. The population being examined in the study was cited a having the highest number of new HIV cases in the US. This study will provide additional information for public health officials and the community regarding emerging patterns for persons living with HIV. The reviewer stated that is was a very important study.

Gina agreed that it could be greater than minimal risk, however waiver of informed consent and waiver of HIPPA information are appropriate in this setting.

Gina recommends approval of this study.

Sandra made a motion for approval, it was seconded by Gina.

Questions or concerns? None

All participants approved the recommendation. There were no nays or abstentions

(1) Reviewers determined the application was not-greater than minimal risk study and is consistent with sound research design and does not unnecessarily expose subjects to risk as annotated in above reviews.

(2) Risks are reasonable in relation to anticipated benefits because provides important knowledge which could not be obtained in an alternative fashion and do not significantly compromise the welfare or rights of participants.

(3) Selection of subjects is equitable.

(4) The researcher has chosen a waiver of consent which is appropriate for this study.

(5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. The sponsor's plan for safety monitoring is appropriate.

(6) Committee members discussed the provisions protecting privacy interests and determined that adequate provisions were in place.

(7) Committee members discussed the provisions protecting confidentiality and determined that adequate provisions were made to protect the confidentiality of data. Waiver for HIPAA was on file and was deemed appropriate for this study design.

(8) No vulnerable populations are enrolled in the study.

Children

None

Assent, parental permission

None

Pregnant women

None

Prisoners

FDOH IRB does not currently review Prisoner-involved studies.

Total votes to approve for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 1

Title: The Florida Pancreas Collaborative Next-Generation Biobank: Reducing Health Disparities and Improving Survival for Pancreatic Cancer (Moffitt)

Primary Reviewer: Robin DeWalt, MS, MBA

Secondary Reviewer: Mary Martinasek, PhD

Meeting Discussion:

The study is looking at pancreatic cancer which is the third leading cause of cancer related deaths in the US and health disparities for patients including survival of pancreatic cancer patients. The study is supported by a JEK research program grant from 2018. The purpose of the study is to build a biobank of medical images and viable tissues that would include a racially and ethnically diverse samples for data use purposes. It is a large study that is well designed with data requests for ACHA and FCDS. The appropriate DUAs in place. The researcher are requesting a waiver of consent which is appropriate for this study. They are requesting that the FDOH IRB to cede request to Advera, which is also appropriate. There are no vulnerable populations included within this study. The risk mitigation processes in place are appropriate. Study staff have sufficient training and their CITIs are all current and in place. The Primary reviewer recommended approval of the study and approval of ceding the study to Advera.

Mary is the second reviewer.

The second reviewer stated that Advera is already monitoring this study the Moffitt Cancer Center.

The reviewer stated that she saw no issues with the study. She stated that it is secondary data analysis at this point. She made a motion to second the approval and to cede review to Advera.

Questions or concerns? None

All participants approved the recommendation.

Affirmative: 6 Negative: 0 Recusal: 0 Absent:

(1) Reviewers determined the application was not-greater than minimal risk study and is consistent with sound research design and does not unnecessarily expose subjects to risk as annotated in above reviews.

(2) Risks are reasonable in relation to anticipated benefits because provides important knowledge which could not be obtained in an alternative fashion and do not significantly compromise the welfare or rights of participants.

(3) Selection of subjects is equitable.

(4) The researcher has chosen a waiver of consent which is appropriate for this study.

(5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. The sponsor's plan for safety monitoring is appropriate.

(6) Committee members discussed the provisions protecting privacy interests and determined that adequate provisions were in place.

(7) Committee members discussed the provisions protecting confidentiality and determined that adequate provisions were made to protect the confidentiality of data.

(8) No vulnerable populations are enrolled in the study.

Children

None

Assent, parental permission

None

Pregnant women

None

Prisoners

FDOH IRB does not currently review Prisoner-involved studies.

Total votes to approve for 12 months: Affirmative: 6 Negative: Recusal: Absent: 1

Education:

Reporting to OHRP (2): Non-compliance, Suspensions, and Terminations
https://www.youtube.com/watch?v=QJkA9p904u0

Unanticipated problems / Non-compliance Review: N/A

Final Business:

Next Meeting: October 20, 2021, at 1:30 PM

Adjournment