Meeting Date: August 5, 2020
Next Meeting: September 2, 2020

Attendance:
Jamie Forrest, M.S. (CHAIR)
Robin DeWalt, MSc MBA
Nkechi Ichite, Pharm.D., Ph.D.
Mary Martinasek

4 needed for quorum

Quorum:
A quorum **was** present.

The quorum is defined as a majority of members present, one member whose primary interests are non-scientific, and one member who is not affiliated, and whose immediate family are not affiliated with DOH. 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.

Other Attendees:
Andrew Wentzell, IRB Coordinator
Gavin Grigg, IRB Analyst
Bonnie Gaughan-Bailey, Administrator, Office of Public Health Research

Attendance Notes:
Conflict of Interest: None
Members did not report any:
- Ownership interest, stock options, or other financial interest related to the research of any value.
- Compensation related to the research of any value.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.
- Interest that could be affected by the outcome of the research.

Attendance Note: Due to COVID-19, all IRB members were present by phone. Members present by phone received all pertinent material through IRB Manager 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.

Old Business: None

Other Business: There was no other business discussed at this meeting.

Notes: Applications reviewed and approved using the expedited procedure and exempt studies and non-research determinations were reported in the meeting agenda in IRB Manager; there were no questions or discussions about these actions.

Board Review:

Protocol Title: Firefighter and Law Enforcement Officer Cardiac Screening Project (Default Site)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Haimes, Stan MD, MPH	Jamie Forrest, Julia Fashner, MD (not in attendance)

Description: Firefighters and Law enforcement have a higher incidence of heart disease compared to other populations. Want to assess the ability of lab markers to predict the markers of cardiac intervention as well as the cardiac screening and imaging service that can be performed that is within general practice. This increases the population to radiation exposure. They want to recruit 3000 active officers and fire fighters in Orange, Seminole, and Osceola counties. Pregnant women will be excluded. Each hospital is offering community screening services independent of this research activity and will continue to operate in that manner. This study will be focused on the statistical results of the screening service that the hospitals are offering within the service areas. Plan to recruit active members at their monthly meetings and have an open discussion at meetings, phone conversations, email, and website description of the project. They will have informed consent with electronic signature with option to print and review, also an opportunity to discuss with PI before or after consent signing and includes required language for the DOH and IRB. There is no money to be paid to participants, but a fee of $100-$125 to be paid by participants for imaging services, lab work, and lab results. Medical history questionnaire with anxiety and depression screen with a standardized assessment test. Some participants will require long time follow-up every six months and participants can opt out at any time. Data use agreements for sponsor and quest to provide analysis of results, also a data use agreement between PI and the hospital and individual specimen collection facility. HIPPA record release that is required for the use of this data, data will be secure, and password protected through liquid web which is the secure storage solution, but researchers provided information that that storage solution will not have access to the data. The PI will be the only person who has access to any of the personally identifiable information and it will be stored separate from identifying information to further protect confidentiality. Participants will receive copies for all their medical data with recommendation to send a copy to their physician. Elevated risk patients will be referred to a cardiologist and will have follow-up to ensure they are doing their follow-up with the indicated specialist, same applies for anxiety and depression.
Study stated as not greater than minimal risk.

Mary: How are we sure the third party contracted persons collecting the data will be secured and safe data collection (specifically quest). They need to let individuals know that the study will have their data and also that each facility be signing something, so the individuals know each facility has its own requirements for patient data protection and/or use.

Dr. Fashner review (per Andy Wentzell due to her absence): Issues with protocol as written, data collection sheet, and recruitment, have concern about urgent intervention and staff use. No inclusion and exclusion criteria, unsure of how patients are going to be included. Several areas say they are comparing to general population but are not sampling. Screening of labs is not explained well, all participants get them, so why two tiers of screening. What if someone is unable to pay the $100-$125 fee. Issues with who will have the data and who will make decisions around treatment. Author does not describe consent correctly and states research will be explained but they do not provide a script. There needs to be a standard release of records. With requirement of pay we should decide if this should move forward. Unsure that staff has proper experience with a study like this, only one previous study that is several years old. Does the physician need to be part of the study personnel or anyone else who is reading the results for the study. She says study is greater than minimal risk.
If the consent is adequately developed to describe the risk without coercion to have the test done. Recruitment was not addressed, and long form consent document should be addressed. Unclear who has access to the data. In the protocol it says employer will know results, but subject will not know all results. No vulnerable populations.
Reviewer determination: to disapprove

Consent worksheet from Dr. Fashner:

Open discussion: The way that individuals are being recruited and the lack of details, issues with consent and data access, and protocol issues at this point the direction should not be approved and discussing if we share with PI to give feedback for the study to be resubmitted so it could eventually be approved.

Motion: Jamie: Summary of discussion included in reviewer worksheet be provided back to the PI to give them the opportunity to address and re-propose it for additional review for the future.

Second: Dr. Ichite

Total votes for approval: (Total members voting:) Affirmative 4: Negative: 0 Recusal: 0 Absent: 0

Education:

Discussion: D-I-Y (Do It Yourself) Covid Vaccines (article from MIT Technology Review)

MIT Technology Review

Biotechnology

Some scientists are taking a DIY coronavirus vaccine, and nobody knows if it's legal or if it works

Famed geneticist George Church and at least 20 others didn't want to wait for the results of clinical trials: "I think we are at much bigger risk from covid."

by **Antonio Regalado** July 29, 2020

Other business:
Bonnie: Four new applications for review to join the IRB committees.

Meeting Adjourned.