May 5 , 2021
9:00 – 10:30 AM

Department of Health
2585 Merchants Row
Microsoft TEAMS
Tallahassee, Florida 32311

IRB 2 Convened Committee
Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair) (non-scientist) (affiliated)
Nkechi Ichite (scientist) (affiliated)
Mary Martinasek (scientist) (non-affiliated)
Merlene Ramnon (scientist) (affiliated)

Absent:
Julia Fashner (scientist) (non-affiliated)

Other Attendees: Gavin Grigg, and Bonnie Gaughan-Bailey, Robin DeWalt

Announcements: Andy Wentzell on extended medical leave. Please contact Bonnie, Robin or Gavin as needed.

Calendar Invites: Delete old IRB appointments that Rotanya and Andy to remove them from your calendar. Th new meetings will be from Robin DeWalt and are reoccurring meetings utilizing TEAMS.

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 conflicts, including:

- 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

Continuing Study Application

Title: Strategic Timing of AntiRetroviral Treatment (START) (Florida Department of Health)

PI: Desai, Nila MD

Discussion:

Primary Reviewer: Dr. Ichite

This protocol was reviewed recently and does not need to be included.

Initial Review

Title: Culturally Adapted Cognitive Behavioral Stress and Self-Management (C-CBSM) Intervention for Prostate Cancer. Short Title: Encuentros de Salud - Por tu Salud Despues del Cancer

PI: Penedo, Frank PhD

Discussion:

Primary Reviewer: Jamie Forrest

This is a study that was discussed in the March meeting and we had some concerns largely that there were some inconsistencies between the protocol and what was in the IRB application. We did send those concerns to the researcher and got clarification that there have been modifications to the protocol since It has been submitted. The study wants to add an additional recruitment strategy to leverage FCDS to identify additional participants. They are requesting UM be the single IRB of record. We asked that they upload their approved protocol from Miami, they did, February 24th the UM IRB reviewed and approved a modification that did include revised documents and the protocol as well.

We did not ask them to see the updated versions of these materials, so we will need the new versions of the screeners and the brochures. We did see the revised screeners and the revised protocol. All of our concerns had been addressed upon receiving these materials.

We will need them to submit the additional documents as a result of the UM modification to us so we can review those details. There seems to be an issue with communication with the study staff. Our specific asks were addressed, but they did not update our IRB manager as they did UM and therefore in a ceded study, what is our role as the UM IRB of record and their role in the approval of the study documents.

Bonnie: Department IRB needs enough information to make a decision and feel confident in it. We have a responsibility to look at the documents that directly involve the data from the Department. Additionally, we have a responsibility to have enough information so that we can clearly make a determination that we are comfortable with. With a ceded review, the IRB of record does need to keep us informed if anything changes.

Mary: Some of the information that we were asking from them does not impact human protection. For example, a brochure changing does not impact the participants. What is our role of overseeing materials vs protecting the participant? Flyers are still dated 2019 and some of them are cut off, we do not have the current versions.

Jamie: Well-designed study that has the potential to have a positive contribution to knowledge, but the materials that are shown in IRB manager are not complete and updated.

Jamie motioned to table the study pending more information and correspondence with research to clearly outline involvement in FCDS recruitment strategy and a better understanding of how these participants fit into the overall approach and if there are any materials that will be used directly when contacting participants we will need to see that as well.

Mary seconds that motion

Questions or comments?

(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.

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

(3) Selection of subjects is equitable because subjects are selected based on inclusion criteria which is based on based on registry data, and advertising and recruitment does not involve coercion or undue influence to participate.

(4) The researcher has chosen a consent discussion but waiver of consent documentation, which is appropriate for this study. The consent document includes all required disclosures, including whom to contact at the Department for additional information.

(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. The researcher is responsible for monitoring the research and the plans for monitoring described in the protocol are 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 because file drawers housing hard copies of records are locked and/or password protected computers are used. Study is HIPAA compliant.

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

Total votes to approve for 12 months: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

Continuing Review

Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida

PI: Smith, Angela BS, MHA

Discussion:

Continuing review

Jamie primary presenter: This is an ongoing study seen many times, Stamaril vaccine- this is a continuing review to continuing to allow the use of the vaccine. A total of 156 individuals have received the vaccine and there was a decrease in users due to COVID. Nothing has changed or of concern since last review.

Dr. Ichite secondary reviewer and there is nothing unusual to be stated today.

No vulnerable populations in this study and nothing has changed in the past year (no new findings, no risks or adverse events, not changes in monitor, they are protecting the privacy, and nothing has changed from their original protocol)

Questions around the study? There were no questions.

Dr. Ichite motions to approve the study for the next 12 months.

Jamie Forrest to second the motion to approve.

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Total votes to approve for 12 months: (Total members voting:) Affirmative: 4 Negative: 0 Recusal: 0 Absent: 0

Education: None.

Other Business: None.

Next Meeting: June 2, 2021 at 9:00 AM

Meeting Adjourned