May 19, 2021
1:30 – 3:00 PM

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

IRB 1 Convened Committee
Meeting Minutes

IRB Attendance:

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (scientist) (affiliated)
Karen Card (scientist) (affiliated)
Bob Eadie (non-scientist) (affiliated)
Ovidiu Cotea (scientist) (affiliated)
Megan Macdonald (Expertise in Subpart D: Children) (scientist) (affiliated)
Robin DeWalt (scientist) (affiliated)
Gina Larsen (non-scientist) (non-affiliated)

Absent: None

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

Jamie Forrest: IRB2

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

Study name: Adaptability as a moderator on the impact of childhood sexual abuse and the development of posttraumatic stress symptoms (Default Site)

PI: Kalmanson, Courtney M.S.

Study Number: 2021-455

Meeting Discussion:

Primary Reviewer: Megan MacDonald

Health indicator study looking at the role of adaptability and moderating the effects of childhood sexual abuse on the development of Posttraumatic stress syndrome. Study using archival data for children ages 3-12 who were seen at the Family Learning program from the FIT. Children and/or caregivers seen at the clinic are asked to sign a consent form at the initial intake agreeing that their data can be used to broad research and therefore the researchers have requested a waiver of consent which is appropriate and will use data from children and caregivers. They are using impact event scale to evaluate PTSS symptoms and a parenting stress index instrument for caregivers to measure adaptability.

Note: This impact event scale is for children but does not appear to be used in young children (study as young as 3years). Is this tool reasonable for younger children?

Additionally, a copy of the parenting stress scale was not provided and curious how this is measuring adaptability in the child.

Study is minimal risk and limited to data analysis only and no interaction with participants. Data accessed by electronic health record and have entered research study data into a HIPPA

compliant database with de-identified data. Data will be only electronic, but we need to verify there isn't anything printed as it states a locked cabinet, but protocol says electronic data only. Researchers still haven't provided exemption letter from FIT and CITI training for Dr. Bennett.

Ask for them to provide the information to move forward with the study.

Sandra Schoenfisch: Secondary reviewer

Similar challenges going through this study, in that some of the tings were missing and there were some tense issues in regard to what they are doing. All archival data and documents and forms used in this program targeted for these children. They will be abstracting information from this data and there will be no contact with the subjects. Summarizing data that will be collected. Would like to have more information around exclusion criteria? Excluding based on incomplete records? It is not greater than minimal risk. Based on conversations that she has had with staff. Resumes and CITI need to be available.

Recommends being approved conditional upon those items being collected.

Challenging study, but also an area that needs to be studied and there is not a lot of data on this topic and could be great for the future.

Questions on the study? None

Options: Talk to her since she is available.

Call in PI: Courtney Kalmanson

Megan: First question about impact event scale and curious how the instrument will be applied for the younger children to understand the questions in the study? How are you mitigating that?

- Only applied to children that are older and performed upon intake. The younger children would be using data from diagnosis and data gathered from clinical interview

We would like to see a copy of parenting stress scale that will be measured for adaptability.

- The TSI scale is copyrighted and may not be able to provide a copy.

The application indicated that the records would be accessed through electronic health record, but stated hardcopies in locked file cabinets, can you clarify if there will be hard copy materials?

- That was an error with submission, everything will be electronic.

Sandra questions: Missing Resume and CITI training for the researchers

- Supervisor just sent CITI training and CV was sent.

Exclusion criteria - abstracting documents for data that you are collecting, and some subjects may have incomplete data. Is this the exclusion criteria you will be using.

- That is correct.

Thank you for being available Courtney and that is all for this study.

Megan: Motion to approve contingent upon receiving documentation (CITI training and FIT materials)

Sandra: Need to be received and entered IRB manager for study completion

(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: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Initial review

Study name: 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

Study Number: 2021-004-UM

Meeting Discussion:

Continued Discussion from previous meeting.

Jamie Forrest to present.

IRB2 committee reviewed back in March and we had some outstanding questions where there were updates that were made to the study protocol and were not reflected in the materials.

Five-year study evaluating a 10 wk group based translated culturally adapted stress related management program for Hispanic men with prostate cancer. Culturally adapted stress management intervention compared to the linguistically translated study. Previously looking at translated study vs a one-day study. This study is looking at it further to look at the culturally adapted version of this program to involve the adaptation of focus group and stress management and is funded by the National Institute of Cancer. University of Miami is the IRB of record and is a request to cede IRB to UM to be the single IRB of record. There is a proposed modification to include FCDS data. The original recruitment plan was to include clients from community-based recruitment and UM, however, the challenge of achieving 260 Hispanic men they want to incorporate the FCDS as an additional recruitment strategy. They have submitted paperwork and gained approval from FCDS to access records from 2014- present of Hispanic men. They are requesting contact information for individuals. Item of challenge, from provided materials she can see the plan to mail a letter to the individual to FCDS identified individuals to introduce the study and a postage paid envelope to participate in the study, and if there is no response they will contact the client in three weeks by telephone to follow-up on the mail out. Individuals may also call to enroll or request more information.

Largest challenge is looking at the protocol vs what is submitted to IRB manager, this recruitment arm has not been explicitly spelled out and you need to extrapolate the full picture of the study. Once have approval from FDOH IRB they will submit the modification to UM for this protocol change.

Study does involve a review of medical records from UM or an authorization for 3rd party disclosure for study team to access their records. Full screening 18+, Hispanic men, now including bilingual Hispanic men willing to participate in a Spanish speaking intervention. Baseline and three quarterly follow-ups using a variety of instruments to assess symptom burden and quality of life. They have introduced a COVID-19 screener tool as an additional piece. They did originally have more of the study happening in person and have shifted to a telehealth intervention. Participant feedback and supplementary questionnaires and there will be a blood draw in person at a lab or completed remotely by a finger prick and a dried blood sample sent to their homes. Participants will be asked for 10 virtual 90-minute sessions in one of the two study arms using video conferencing with 4-8 participants.

Primary study site in Miami but will include Broward and Palm Beach counties and Chicago to look at those two locations.

High level not greater than minimal risk, aspects are in place to ensure patient confidentiality, maintenance of records, study has potential to contribute to the potential benefits of looking at culturally adapted benefits.

Biggest concern is FCDS protocol piece has not been spelled out clearly and there is still a gap. With ceding perspective as long as they make the modification to determine how those individuals will be recruited to the study through FCDS.

Bonnie to comment on Mary Martinesek review as a secondary reviewer.

She too had some concerns, she really wanted to see more of the materials that were going to the participants and that was provided to Mary and then Mary said that she felt comfortable making a motion to approve. She did not focus on the FCDS points that Jamie has brought up, she was looking from the materials perspective.

Jamie: Motion to approve considering they provide additional FCDS patient recruitment documentation and contingent upon UM approval of protocol modification.

Any questions or concerns from other participants prior to voting?

(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: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Initial review

Study name: Hospital quality, obstetric and neonatal volume, regionalization, and maternal and infant outcomes.

PI: Boghossian, Nansi PhD

Study Number: 2021-460-DFT

Meeting Discussion:

Primary Reviewer: Sandra Schoenfisch

Study that is looking at hospitals and the type of care that pregnant women receive and looking at adverse outcomes. Looking at volume of deliveries at different hospitals and NICU and high-risk pregnancies and looking at trying to well document the issues with children that have problems with delivery. A challenging study looking at hospitals, the data that is accessed as a result of this study and will be difficult, a lot of data that will be requested and think there are a lot of social and economic factors that will play into these results. They have an outline, not greater than minimal risk, reasonable study design, information will be valuable that they will be getting out of this.

Recommends approval for the study.

Karen Card: secondary reviewer

Interesting study as it is a very thorny subject. Looking at hospital quality by maternal outcomes is a hard subject to tease out. Impressed by what they are describing for this study. The study design is fine, interesting that the intersection with the DOH is that they want to use matched vital stats data with birth registry data set. Florida participation is important looking at the impact of Medicaid expansion and over half the states (lots of data points) but Florida is a non-Medicaid expansion state and will be a nice comparison of the study.

One of Aims is to look at what characterizes access to higher and lower quality hospitals which is an import part of the outcomes of this study.

Secondary data analysis with no interaction with participants, it does have PHI and location and birth data. However, the nature of the study justifies this entirely. Sensitive population including pregnant women and children as well as poorer and minorities, however there is no interaction with the participants and no coercion and there will be no negative characterization as a result of this study.

Recommend also that we approve the study.

Sandra: limitations of access to the highest level of care

Questions regarding the study?

(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: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Education:

Lee Hollowell to present IRB manager updates

Final Business: none

Next Meeting: June 16, 2021, 1:30 – 3:00 PM

Adjournment