December 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)
Robin DeWalt (scientist) (affiliated)
Gina Larsen (non-scientist) (non-affiliated)
Merlene Ramnon (Scientist) (affiliated)

Absent:

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: Red Carpet Entry Implementation Evaluation (Default Site)

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

Secondary Presenter: Mary Martinasek PhD

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

HIV study, it is a multi-intervention study designed to get individuals who test positive for HIV early into care. They are given good screening, follow-ups, and assistance with all aspects of care including housing and mental health services. This study was originally started in Washington DC at the Whitman Walker Health Center which has a long history of working with HIV clients. They are seeking to evaluate the impact of this work which is supported by the CDC. This is a multi-site study and is an evaluation of a program and the impact of the intervention. Since this is a closer look and multiple sites for the CDC this is coming through as a research evaluation. The goal is to get clients in early and keep them in the program, they have shown dramatic impact to those included 72 hours after diagnosis.

They use a long form consent that they can opt out of, it is very thorough and optimal approach for working with these individuals.

Well designed study that has been developed in many areas. The program gets adapted and tailored to the community based on the center that is providing the services.

There is good follow-up and tracking of the individuals with modest advertisement and recruitment is equitable with nominal fees.

Sandra recommends approving the study.

Mary Martinasek is the secondary reviewer.

Mary agreed with Sandra's review for the study. She agrees it is a review of an established program. It is funded by RTI to be doing all of the training for the staff that is very organized and thorough. Sample size is 120 which is sufficient.

Questions: The protocol mentions in the payment to participants that it is $25 token of appreciation, but the consent states a gift card. Is it money or a gift card. The study site is the FDOH in Hillsborough county, as well as Rutgers University. Are we approving for Rutgers as well? It is mentioned under scientific rationale that USF was ceding approval to the FDOH.

There is a great history with DC and the group in Kenya and its associated data. One of the physicians listed has a license that expires in Feb (MD), this needs to be updated.

She did not see the intake form (that is very detailed) includes SSC and identifying information. I did not get a sense of when and how this would be administered and how the data would be used. It does describe how the data will be stored and secured. However, it wasn't clear how this information was going to be collected.

They mentioned a research office and I'm unsure where the office is located, USF? This will be where consent documents will be housed.

Mary's initial review shows that the study review is 8 months and total and seems reasonable. It does not mention how many clinic sites but does state work will be done at the clinic.

The study staff are mentioned on the protocol and would have access to the data and are properly trained.

Otherwise the study is sound and she would recommend to approve.

Sandra: she interpreted the token as the gift card as mentioned. We are only approving this for the Florida site, not for Rutgers, and the research office is at the University, but the clinic is at the health department and how the services will be delivered.

Sandra felt adequate information on the security of the personal information and how it will be handled.

Need to note the license of the physician that will expire needs to be updated.

Mary: RTI and clinical site is listed as where the documents will be stored securely.

Robin: Do we need clarification on how the intake form will be handled as you addressed the concern within the meeting.

Sandra: Felt the records would be adequately stored and in order to manage the records and to get the information that they need, they will be knowledgeable of this information to provide the services that

they need. The tool kit that they use they have spent a lot of time to generate and adapt them to the populations that they will be serving. The training of their research staff is also excellent so that these providers are properly trained and prepared.

Mary: They are doing the HIPPA signature is required which is great. However, maybe we need a little more information on how the intake form is going to be handled and secured once collected when they are matching the records and the interventions that they are stating here.

Bonnie: There was reference to $25 to the gift card and then the token of the appreciation. For the consent form are we recommending that the dollar amount be included?

Sandra: We can, but the gift card is standard at this point in research studies.

Mary: This should be explicit so we will ask for this information.

Asks:
Additional information on data security specifically the intake form

Expired license for physician in Feb. 2022

Consent should clearly state that the gift card amount for the study.

Sandra motioned to approve, and Mary seconded the motion.

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 long form 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: 7 Negative: 0 Recusal: 0 Absent: 0

Education:

Pdf article for discussion led by Bonnie Gaughan-Bailey

Published in final edited form as:
Suicide Life Threat Behav. 2008 October ; 38(5): 486–497. doi:10.1521/suli.2008.38.5.486.

Intervention Research with Youths at Elevated Risk for Suicide: Meeting the Ethical and Regulatory Challenges of Informed Consent and Assent

Cheryl A. King, PhD, ABPP and **Anne C. Kramer, LMSW**
Department of Psychiatry and University of Michigan Depression Center at the University of Michigan.

Unanticipated problems / Non-compliance Review: N/A

Final Business:

Next Meeting: January 19, 2022, at 1:30 PM

Adjournment