

February 21, 2018  
1:30-3:00 PM



Department of Health  
2585 Merchants Row  
Conference Rm. 310 A  
Tallahassee, Florida 32311

## IRB 1 Convened Committee Meeting Minutes

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### **IRB Attendance:**

Sandra Schoenfisch (Chair, Expertise in Subpart D: Children) (non-affiliated)

Daphne Holden

Karen Card (Co – Chair)

Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)

Megan Macdonald

Shoshana Levy (Present by phone)

Barbara Frentzen

### **Absent:**

Nina McGrew (non-affiliated)

Robert Eadie

Ovidiu Cotea

**Other Attendees:** Rotanya Bryan, MPA, Gavin Grigg, and Bonnie Gaughan-Bailey, MPA

### **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.

### **Approval of Previous Minutes:**

Minutes from the meeting were circulated by email and modified by member input.

### **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

**Education:**

Protocol Specific Determinations – Rotanya Bryan

**(#2) Protocol Title:** Telephone counseling to enhance the quality and safety of romantic and sexual relationships in people living and aging with HIV.

**Submission:**  
(Initial Review)

**Principal Investigator:**  
Travis Lovejoy, PhD, MPH

**Presenters:**  
Sandra Schoenfisch  
Katisa Donaldson

**Meeting Discussion:**

From Oregon; The primary reviewer (Dr. Schoenfisch) provided a general overview of the study. It is a multi-site study. The research uses procedures consistent with sound research design and is sound enough to yield the expected knowledge. The research is not greater than minimal risk. The research involves payments to participants. They will use long form consent and there are adequate provisions to protect confidentiality of data. No vulnerable populations. Other partners participating (UGA and Hunter College). Recruiting for a 12-month study, 50 years or older. Study will involve a process with telephone screening. If they are selected they will participate in a mailed or online survey. They also have telephone interview and telephone counseling. Has been conducted at other sites without adverse events. Looking to do survey in Florida, work through our AIDS service organizations and other

community organizations, health departments, and other service providers in the state. Received additional information that include hotline numbers for Florida and Dr. Schoenfisch had no additional concerns once that information was received and recommended for approval.

Katisa Donaldson recommended approval after receiving the additional information.

Barbara Frentzen brought up that the IRB approval provided expired April 3, 2018 and they will need an updated letter. Brought up concern with their screening consent: an audio recording will be kept but if the participant doesn't want that they do not read the consent to them. Not appropriate to keep an audio recording if someone decides not to participate.

Karen Card mentioned that they may keep the recordings so if their screening procedures are ever audited they have a record that they classed out the wrong people.

Barbara Frentzen mentioned that the brochure says that joining the may "improve the quality of your sexual and romantic relationship and alleviate stress you may be experiencing" – not the objective, may be misleading.

Also, she asks if someone is having sex without a condom, with HIV, is that something that gets reported?

Daphne mentions that the protocol reads that if they name their partner then the interviewers will have to inform that person – implying that if they give them the name then they are duty bound to follow up.

Sandra reference that today they are monitoring patient's viral lodes and at certain points it is not transmissible, especially with long-term partners.

Barbara was not sure where things get reported and thought it should be clear in the consent. If others thought that the consent matched the protocol she is fine with it – wasn't sure they matched.

Sandra felt it was addressed satisfactorily, ask Katisa her opinion.

Katisa agreed with Sandra.

Bonnie asked if anyone wants any other modifications to the consent form letting them know upfront if they talk about unprotected sex with people and give them their names that they will be contacted.

Rotanya asked if the board would want to vote with contingencies with more additional information in the consent form.

Barbara would like more in the consent form to specify to participants that a nurse/social worker has an obligation to report if they give names of sexual partners – so that participants understand they need to be careful when answering questions.

Dr. Levy: if a patient tells you they are having unprotected sex you are not allowed to do anything about it because of HIPPA laws (Katisa). You can try to convince them to tell their partner(s).

Daphne agreed that the protocol says that they are bound to tell the partner and if that is the case then she would like it in the consent form.

Karen Card commented that to make a contingency the board would have to generate the exact language to approve. Rotanya confirmed this statement.

Karen Card read the language in the protocol that covers Barbara and Daphne's concerns.

Katisa explained the HIPPA law; gave example at the clinic if a couple came in and one tested positive and the other did not and the positive tester said they were negative too, because of HIPPA laws they aren't allowed to tell the negative partner.

**Motion:** A motion to approve the study was made and seconded.

**Total votes to approval:** Affirmative:6 Negative:1 Recusal:0 Absent:3

**Next Meeting:** May 16, 2018 1:30pm – 3:00pm

**Other Business:** None

**Meeting Adjourned:** 2:00pm