

January 17, 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)  
Ovidiu Cotea (Present by phone)  
Daphne Holden  
Karen Card  
Barbara Frentzen (non-affiliated) (Present by phone)  
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent) (Present by phone)  
Megan Macdonald (Expertise in Subpart D: Children)  
Shoshana Levy (Present by phone)

### **Absent:**

Nina McGrew (non-affiliated)  
Bob Eadie (non-scientist)

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**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 11/15/17 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:**

None.

**(#1) Protocol Title:** The Effect of Demographic, Behavioral and Cultural Factors on Chlamydia Trachomatis Infection

**Submission:**  
(Initial Review)

**Principal Investigator:**  
Philis Palmer

**Presenters:**  
Daphne Holden  
Karen Card

**Meeting Discussion:** This is an initial study of the Effects of Demographic, Behavioral and Cultural Factors on Chlamydia Trachomatous Infection. The primary review. Dr. Holden provided an overview of the project. This is a qualitative study. Researcher would like to examine how population demographics, and cultural and behavioral factors affect the risk for contraction of chlamydia trachomatis in the Miami, Florida area, as compared to other areas of the United States. The researcher would like to interview health care practitioners on their perception of chlamydia and survey an undefined number and population of people on their understanding of the disease.

Both Dr. Holden and Dr. Card determined the application to be greater than minimal risk because of the sensitive nature of the study and the researcher's seemingly unpreparedness to conduct the study. Dr.

Holden listed several problematic elements of the research. Firstly, the basic research question was unclear. The purpose in the outline did not match the purpose in the protocol. Secondly, the researcher failed to provide an adequate scholarly rationale for the study. Description of the procedures and recruitment were also inadequate. The consent process was contradictory and it was unclear as to what the health practitioners would be consenting to. Survey questions need basic proofreading and did not correlate to answering the research question.

Dr. Card was the secondary reviewer on this study. She also found that the study design does not match the survey questions. The researcher stated that they would be assessing the knowledge of chlamydia but asked questions geared toward personal sexual behaviors. The researcher also noted that they would be recording the interviews but the questions did not seem open-ended, leaving the reviewer confused as to why record the answers at all. Dr. Card also questioned if the researcher was going to make the survey questions identifiable.

Committee members felt that risks were not reasonable in relation to anticipated benefits because the researcher was not clear about what exactly they wanted to accomplish. Selection of subjects was not equitable because it was unclear about whom the researcher wanted to sample. The chosen long form written consent was inadequate because the researcher failed to clarify what participants would be consenting to. The protection of privacy and confidentiality were also inadequate because the reviewers were uncertain as to whether or not participants would be identifiable.

Dr. Schoenfisch asked if the study should be withdrawn and the researcher given a list of recommended changes. Rotanya Bryan noted that studies could not simply be withdrawn, they needed to be either approved, disapproved, or tabled. Dr. Holden recommended disapproval. Dr. Card seconded.

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

**Total votes to disapprove:** Affirmative: 8 Negative: 0 Recusal: 0 Absent: 2

**(#2) Protocol Title:** The Influence of Intersectional Stigma on Uptake of HIV Testing and Counseling Services among African American Women Residing in Rural Panhandle Florida: Intersectionality of Racism, Sexism and HIV-Related Stigma

**Submission:**  
(Initial Review)

**Principal Investigator:**  
Akrati Gupta

**Presenters:**  
Barbara Frentzen  
Robert Eadie

**Meeting Discussion:** This is an initial study of the Influence of Intersectional Stigma on Uptake of HIV Testing and Counseling Services among African American Women. The primary review, Barbara Frentzen, provided an overview of the project. The researcher intends to study intersectional factors

that impact black women's decision to test for HIV. Participants will be sampled from Jackson or Washington County, between the ages of 18-50. This study will utilize flyers to recruit participants. \$20 will be used as the monetary incentive to participate. Data will be collected through short self-reported survey and an in-depth face-to-face semi-structured individual interview with each participant. Interviews will be conducted by the Principal Investigator. Data analysis will be conducted with the analytical software program called NVivo. Florida is the first in the nation for newly diagnosed HIV patients and the highest in the number of people that do not know their HIV status. Study team is from Georgia Southern University.

Ms. Frentzen found the human subjects training to be complete and acceptable. Local Health Departments (Jackson and Washington) have permitted the researcher to hand out flyers at the site. Risks and benefits are reasonable and participant selection is equitable. The research is of a sensitive nature and the researcher took care to ask appropriate questions. The consent form is adequate. The Principal Investigator will also provide a list of local community mental health care providers and facilities that they can use as an information resource.

Ms. Frentzen noticed that the \$20 Walmart gift card was highlighted on the flyers and felt that there may be some issue with it. She asked the board for their input and opinion. The board viewed the flyer during the meeting and found no issue with the highlighted incentive. Mr. Eadie was not present during the meeting to provide his secondary review. Ms. Frentzen recommended approval. Dr. Schoenfisch suggested that the study be approved, contingent on administrative staff receiving Mr. Eadie's review.

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

**Total votes to approve:** Affirmative: 8 Negative: 0 Recusal: 0 Absent: 2

**(#3) Protocol Title:** Clofazamine use in the treatment of patient with disease caused by strains of Multidrug Resistant Tuberculosis

**Submission:**  
(Initial Review)

**Principal Investigator:**  
David Ashkin, MD

**Presenters:**  
Ovidiu Cotea  
Sandra Schoenfisch

**Meeting Discussion:** This is continuing review. The primary presenter, Dr. Cotea, provided a general overview of the study. Clofazamine is used in the treatment of patients with a disease caused by strains of multidrug resistant TB. This drug has been approved since 1986. The FDA will only accept patients. 12

patients were last enrolled in the treatment program. 76 have been enrolled during the life of the study. 14 have completed the study and only 10 remain. Dr. Ashkin is the board certified Principal Investigator. Long form consent remains adequate. Risks and benefits have not changed. No vulnerable populations are enrolled in the study. Dr. Schoenfisch concurred with the review and had no additional comments. Dr. Cotea and Dr. Schoenfisch recommended approval.

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

**Total votes to approve:** Affirmative: 8 Negative: 0 Recusal: 0 Absent: 2

**Next Meeting:** February 21, 2018

**Other Business:** None

**Meeting Adjourned:** 2:30pm