

June 6, 2018
9:00-11:00 AM



Department of Health
2585 Merchants Row
Conference Rm. 320 P
Tallahassee, Florida 32311

IRB 2 Convened Committee Meeting Minutes

IRB Attendance:

Jamie Forrest (Chair)

Keshia Reid (Co-Chair)

Nkechi Ichite (present by phone)

Dongming Cui

Shamarial Roberson (Expertise in Subpart D: Children; Subpart B: Pregnant women)

Julie Moore (non-affiliated; present by phone)

Jaime Arango (non-affiliated; person whose primary interest is non-scientific; present by phone)

Absent:

Kelli Wells (present by phone)

Other Attendees: Rotanya Bryan, 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: Declared by Shamarial Roberson, DrPH.

Education: None.

Initial Submission

Protocol Title: Advancing New Computer-based Help On Risky Sex (ANCHORS) Study: UH2 Project

Submission:

(Initial Submission)

Principal Investigator:

Leeman, Robert PhD

Presenters:

Jamie Forrest, MS

Julie Moore, JD, MS, PA

Meeting Discussion: This is an initial review of the Advancing New Computer-based Help On Risky Sex (ANCHORS) Study: UH2 Project (University of Florida). The primary presenter (Jamie Forrest) provided a detailed overview of the study. The ANCHORS' goal is to reduce alcohol use and risky sex and prevent HIV among young adult men that have sex with men (MSM).

The research has three aims:

- Collect alcohol and sexual activity data via web survey from 683 young MSM to yield normative data for the alcohol and HIV preventive intervention in a follow-up study (UH3). The survey will also help to establish feasibility.
- Conduct focus groups (N=30) with young MSM who drink regularly to inform the content of the alcohol and HIV preventive intervention tested in the UH3 phase and ensure the intervention is culturally appropriate for MSM.
- The combined alcohol/HIV preventive intervention will be finalized based on the web survey and focus groups. Preliminary testing (N=10) will establish usability, acceptability and correct any functionality issues.

Jamie Forrest determined the study is not greater than minimal risk, consistent with sound research design, and does not unnecessarily expose subjects to risk. Risks are reasonable in relation to anticipated benefits.

Selection of subjects is equitable because subjects are selected based on an inclusion criterion that includes participants that are male at birth, between the ages of 18-30, have one or more instances of sexual activity with another man in the past three months and are HIV-negative. During the usability phase of the study, participants will include those that have five or more drinks in a day in the past month, have had intercourse with another man without a condom, and are willing to try PreEP, but have never tried it before. Participants will be compensated \$25 in electronic gift card for the web survey, \$35 for the focus group, and a \$35 payment for the interview at the end. Jamie Forrest noted that the researchers had an interesting payment strategy. Participants receive \$1 per day, banked in an electronic account plus an extra 10 bonus "points" (\$2 value each) for completing 7 of 7 days in a week. If participants miss a day, they lose bonus points for the week but can recover 7 lost points for weeks with missing data if they do not miss more than 2 consecutive days. Should participants miss a day, they can call a separate number and leave the prior day's responses in a voicemail. Participants receive daily payment for "makeup" calls but are not figured into bonus eligibility

The researcher has chosen a long form written consent, which is appropriate for this study. The consent document includes all required disclosures, including whom to contact at the Department for additional information.

Committee members discussed the provisions protecting confidentiality and determined that the researchers did not provide any information on what software they plan to use. They found the COC language confusing and determined that it needed to be revised for clarity. The committee also suggested that the protocol should not have information about collecting IP addresses as other portions of the study documentation state that they are not collecting this information.

Julie Moore suggested that the study be approved with contingencies, but members noted that there were too many requested revisions and that the study would need to be tabled for another review.

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

Total votes to table: Affirmative: 7 Negative: 0 Recusal: 0 Absent: 1

Protocol Title: Improving Public Health Practice: A Pilot Study of High Risk Infant Referrals in Three Florida Counties

Submission:
(Initial Submission)

Principal Investigator:
Rowan, Alan DrPH

Presenters:
Keshia Reid, PhD
Dongming Cui, MD, PhD

Meeting Discussion: This is an initial review of a pilot study of high risk infant Healthy Start screens. The primary presenter (Dr. Reid) provided an overview of the study. This study intends to examine the accurate prevalence of positive infant Healthy Start Risk screens in three rural counties in Florida. Study design is based on random sampling of women in the Healthy Start Coalition of Madison, Jefferson and Taylor (JMT Coalition) counties, areas in the Florida Panhandle where residents experience particularly poor outcomes related to high poverty, rural dispersed populations with limited access to care, racial segregation, and racial disparities in birth outcomes. Analysis will consist of birth certificate data and interviews with women whose infants scored a 4 or higher on the screen and are participating in the Healthy Start Program and women whose infants had a 4 or higher on the screen but are not participating (declined referral or were not offered services).

The study was determined to be greater than minimal risk because of potential identification of hospitals that fail to conduct infant screenings and potential distress caused to women who were eligible and not referred. Prior reviewers requested that the researchers omit identifying information of hospitals that take part in the study in order to mitigate any potential risks. The research design was found to be sound and does not unnecessarily expose subjects to risks. Risks are reasonable in relation to anticipated benefits.

The reviewer found the selection of subjects to be equitable. Study team will be recruiting women aged 18-65 living in Jefferson, Madison or Taylor counties and will be excluding non-English speaking women. A payment of \$10 will be given to participants in the form of a gift card. Participants will be recruited with a letter or called by researchers with a telephone script. If research subjects decide to consent, they will be asked to sign a long-form consent document.

Committee members discussed the study and were unclear about whether infant screening was statutorily required. Members were concerned about possible legal, political, and financial risks to hospitals and health care providers that did not comply with the statute. Members were also concerned about the variables that were collected. They were unsure if they were needed to properly conduct the research.

Members requested that a representative of the Healthy Start program and legal counsel review the protocol. The committee then suggested that the study be tabled until they received consultation.

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

Total votes to table: Affirmative: 6 Negative: 0 Recusal: 1 Absent: 1

Protocol Title: Clofazimine use in the long-term treatment of leprosy, Phase 3

Submission:

(Continuing Review)

Principal Investigator:

Ashkin, David

Presenters:

Nkechi Ichite, PharmD, PhD

Jaime Arango, EdD

Meeting Discussion: Clofazimine use in the long-term treatment of leprosy is a previously approved compassionate use protocol. The presenter (Dr. Ichite) provided a general overview of the study. Clofazimine is used in the treatment of Hansen's disease along with other leprosy drugs. The drug was approved in the 1980's when other agents were ineffective, but is no longer available in the United States. Dr. Ashkin currently holds the IND and ships the drug to physicians when it is needed.

There have been no changes or amendments to the research since the last review period. Study is still open for enrollment. No patients have enrolled during the approval period. Dr. Arango concurred with Dr. Ichite's review and seconded Dr. Ichite's approval.

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

Total votes for approval: Affirmative: 7 Negative: 0 Recusal:0 Absent:1

Protocol Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida (Florida Department of Health)

Submission:
(Continuing Review)

Principal Investigator:
Smith, Angela BS, MHA

Presenters:
Ichite, Nkechi PharmD, PhD
Roberson, Shamarial DrPH

Meeting Discussion: Stamaril Vaccine for Yellow Fever Immunization is a previously approved treatment protocol. The presenter (Dr. Ichite) provided a general overview of the study. Yellow Fever is mosquito borne illness caused by a virus. The disease is prevalent in countries with large mosquito populations such as Sub-Saharan Africa and South America. Travelers take Stamaril as a prophylaxis. This drug is manufactured by Sanofi in France and is available in the U.S.A as an Expanded Access Program.

This treatment protocol is being administered at the Lee County Health Department. Patients receive the vaccination through an IND. Participants are from 9 months to 71 years old. Pregnant women are also allowed to receive the vaccination. Program is ongoing. Lee County CHD requested that a change in Principal Investigator from Yvonne McConnell to Angela Smith. No changes in the standard clinical care. Dr. Roberson agreed with review and seconded Dr. Ichite's recommendation for 12 month approval

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

Total votes for approval: Affirmative: 7 Negative: 0 Recusal:0 Absent:1

Protocol Title: Use of Stamaril Vaccine for Yellow Fever Immunization in Florida (Florida Department of Health)

Submission:
(Continuing Review)

Principal Investigator:
Alonso, Jorge

Presenters:
Ichite, Nkechi PharmD, PhD
Roberson, Shamarial DrPH

Meeting Discussion: Stamaril Vaccine for Yellow Fever Immunization is a previously approved treatment protocol. The presenter (Dr. Ichite) provided a general overview of the study. Yellow Fever is mosquito borne illness caused by a virus. The disease is prevalent in countries with large mosquito populations such as Sub-Saharan Africa and South America. Travelers take Stamaril as a prophylaxis. This drug is manufactured by Sanofi in France and is available in the U.S.A as an Expanded Access Program.

This treatment protocol is being administered at the Miami/Dade County Health Department. Patients receive the vaccination through an IND. Participants are from 9 months to 71 years old. Pregnant women are also allowed to receive the vaccination. Program is ongoing. No changes in the standard

clinical care. Dr. Roberson agreed with review and seconded Dr. Ichite's recommendation for 12 month approval

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

Total votes for approval: Affirmative: 7 Negative: 0 Recusal:0 Absent:1

Next Meeting: August 1, 2018

Other Business: none

Meeting Adjourned: 10:15 am