

May 4, 2016  
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:**

Ovidiu Cotea (Present by phone)

Bob Eadie (non-scientist)

Daphne Holden

Keshia Reid (Expertise in Subpart B: Pregnant women)

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

### **Absent:**

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

Nina McGrew (non-affiliated)

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**Other Attendees:** Karen Card, M.P.H., Bonnie Gaughan-Bailey, M.P.A., Juanita Chalmers, and Rotanya Bryan, M.P.A.

### **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.

Members present by phone received all pertinent materials prior to the meeting to allow adequate time for review and request of additional information, if needed. Members present by phone actively and equally participated in the discussion of all protocols.

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

Minutes from the **April 20, 2016** 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:** Falls Reported Among Minority and non-minority Employees (FRAME) in Residential Construction

**Submission:**  
(Initial)

**Principal Investigator:**  
Alberto Caban-Martinez, MD

**Presenters:**  
Daphne Holden  
Bob Eadie

**Meeting Discussion:** This is a 6 month pilot project designed to create a survey to elicit information on falls and near-misses in residential construction. 40 people recruited for focus groups. The survey will be administered to 240 construction workers. One hour of time and \$20 compensation. Recruits will be 21 + in age, fluent in English. Focus group members will also answer an anonymous survey. No vulnerable populations will be enrolled in the study. Researchers will verbally consent subjects prior to starting the focus group and give them a consent sheet with contact information to take home. Audio recordings will be taken of focus group after verbal consent is given. Consent will be read aloud, a copy will be given to participants, including contact information.

Dr. Holden reviewed previous meeting's follow-up (reviewer's questions and researcher responses). Reviewers asked if experience in construction industry necessary? The researchers wants to recruit

participants, including workers with varied levels of experience, including those new to the industry. The one-page survey will collect information about length of experience. Responses will be coded, and the other information will be examined by these strata.

Reviewers asked why the team was seeking a waiver of written consent. Researchers want no link between participants and research; the consent would be the only link. In addition, she asked will the team get adequate numbers for this study. Researchers respond with the cooperation of a large employer; previously they have recruited 400+ persons in Miami.

Dr. Holden was satisfied that the researchers have addressed the issues. Mr. Eadie recounted Dr. Schoenfisch's comments and lack of approval, to date. Dr. Schoenfisch's outstanding complaint is the written consent, and the lack of experience requirement. The consent is written at 12-grade reading level. Dr. Schoenfisch defers to the rest of the panel. Mr. Eadie requested some way in which the team will assure that the participants understand the consent and document this, the exact way not specified. Despite "fluent" in study description, Mr. Eadie feels the chances of finding day laborers with true fluency is low.

Mr. Eadie was not concerned, enough to reject, with length of experience requirement. Hopes the researchers will use the length of experience to better understand the results.

Dr. Holden addressed questions to Dr. Caban-Martinez: protocol requires English language fluency, but all materials are also in Spanish. Can you clarify? Participants can read and write in \*either\* English and Spanish. Bob asks if Haitians, other Central Americans would be excluded? Dr. Caban-Martinez's experience with the community says that the employer recruits English-speakers, so the pool is heavy with English-speakers. \*\*Ask for revision of "read or write in English"\*\*

In the survey stage of the study, workers will fill out the survey at the worksite. Dr. Caban-Martinez notes that the consent is not developed for this yet; the team intends to return to the IRB.

Participants will be recruited through email/post, but protocol also says participants will be contacted at the worksite during breaks. Dr. Caban-Martinez allows that he might find out a better method in the focus groups, therefore both are still a possibility. Focus groups will be recruited at the worksites only.

At focus groups, participants will be given a one-page anonymous survey, including length of tenure in construction.

Focus group discussion script, which will be read aloud, as a verbal consenting process. Dr. Holden likes the script now, says is at appropriate level. (unlike the other "consent"). Dr. Holden asks if there can be an inserted part where the team pauses, asks for participant's understanding of the script. What is the "something" that participants will be given for contact? Dr. Caban-Martinez responds the verbal consent form, with contact info for team and research protection office. The contact info will not be included in the verbal reading. Dr. Caban-Martinez says the copy is at 8-th grade level. Dr. Holden asks why the participant can't receive a copy of the verbal script. Dr. Caban-Martinez says they can do that as well. Dr.

Holden recommended use the same words for script and consent, wants the take-home version to be in understandable language.

**Motion:** A motion of approval was made and seconded. Study approved for twelve months.

**Total votes for approval:** Affirmative: 5 Negative: 0 Recusal: 0 absent: 2

**(#2) Protocol Title:** Use of an Online Immunization Registry in the Pediatric Emergency Department to Confirm Tetanus Vaccination as up to date with Injuries requiring tetanus vaccination in children who present to the Emergency Department

**Submission:**  
(Initial)

**Principal Investigator:**  
Cristina Zeretzke

**Presenters:**  
Shamarial Roberson  
Keshia Reid

**Meeting Discussion:** This is a retrospective study that seeks to determine if the Florida SHOTS immunization registry offers an accurate means to confirm the vaccination status of children who present to the pediatric emergency department (ED) with injuries requiring a tetanus vaccination. The research design is sound and likely to yield the expected knowledge. Tetanus is a life-threatening disease caused by the bacterium *Clostridium tetani* which usually enters and infects an individual through an acute wound. The tetanus vaccine, a preventative measure to prevent tetanus, can be administered to pediatric patients presenting in the Emergency Department (ED) with a wound susceptible to tetanus. Use of an immunization registry can potentially help ED clinicians confirm vaccination status and avoid repeat vaccinations and unnecessary blood draws, as well as save time and resources. Researchers requested a waiver of consent because the study involves a secondary analysis of existing registry data and medical records with no attempt to contact participants, and no other interactions or interventions; however, private identifiable data elements are involved.

Ms. Roberson had some initial concerns about the amount of information requested from the medical records. Ms. Roberson also had concerns about the use of the primary provider's name in the study and her approval of the study was contingent upon the removal of that variable. Ms. Roberson recommended approval and Dr. Reid seconded.

**Motion:** A motion of approval was made and seconded. Study approved for twelve months.

**Total votes for approval:** Affirmative: 5 Negative: 0 Recusal: 0 absent: 2

**(#3) Protocol Title:** GS-1216 A Phase 3b, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed Dose Combination (FDC) in HIV-1 Positive Subjects who are Virologically Suppressed on Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF).

**Submission:**  
(Continuing)

**Principal Investigator:**  
Todd Wills, MD

**Presenters:**  
Ovidiu Cotea  
Daphne Holden

**Meeting Discussion:** The primary reviewer provided an overview of the study. A phase 3B randomized double blind study to compare two drugs. Complera and a new drug. Also to determine the safety on the two treatment arms as it relates to bone mineral density. Site is in Hillsborough. Dr. Wills is experienced and knowledgeable. Three participants are enrolled. No vulnerable populations. The study is progressing as expected, with no delays or problems. No reportable events in last year. The study is closed to enrollment. Secondary analysis continues. Dr. Cotea has no concerns. Risk is greater than minimal. Dr. Cotea recommends for approval. Dr. Holden concurs and adds no comments. She seconded. This study is approved for another twelve months.

**Motion:** A motion of approval was made and seconded. Study approved for another twelve months.

**Total votes for approval:** Affirmative: 5 Negative: 0 Recusal: 0 absent: 2

**(#2) Protocol Title:** Clofazimine in the long-term treatment of leprosy-Phase III

**Submission:**  
(Continuing)

**Principal Investigator:**  
Beata Casanas, DO

**Presenters:**  
Ovidiu Cotea  
Daphne Holden

**Meeting Discussion:** The primary reviewer provided an overview of the study. Clofazimine is a well-known and effective drug for leprosy, the standard of care per WHO and national Hansen's Disease org. Approved since 1986, but no longer available in US outside FDA through IND. This requires informed consent. This is a class C drug for use in pregnant women only if benefit outweighs risk. Site is in Hillsborough. PI is Beata Casanas, well-known and experienced. This site is a Hansen's disease treatment site. No study participants to date. This continuing review is to keep site ready to treat in future. Dr. Cotea has no concerns. Dr. Holden adds there is no COI, no changes to protocol. A possibility of children, protocol has child assent.

**Motion:** A motion of approval was made and seconded. Study approved for another twelve months.

**Total votes for approval:** Affirmative: 5 Negative: 0 Recusal: 0 absent: 2

Next Meeting: May 18, 2016

Other Business: None

Meeting Adjourned: 3:00 pm