June 19, 2019
1:30-3:00 PM

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) (non-affiliated)
Bob Eadie (non-scientist) (Present by phone)
Barbara Frentzen (Present by phone) (non-affiliated)
Ovidiu Cotea (Present by phone)
Megan Macdonald (Expertise in Subpart D: Children)
Karen Card (Co – Chair) (Present by phone)

Absent:
Katisa Donaldson (non-affiliated) (non-scientist) (Expertise in Subpart D: Children) (Expertise in adults unable to consent)
Daphne Holden

Other Attendees: Rotanya Bryan, MPA 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 May 15, 2019 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

Continuing Review

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

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Alonso, Jorge	Cotea, Ovidiu MD, MPH Schoenfisch, Sandra PhD, MS, BSN, RN

Meeting Discussion: This is a previously approved treatment protocol to provide the Stamaril vaccine for Yellow Fever in place of the YF-vaccine. Dr. Cotea (primary presenter) a general overview of the study. Yellow fever is a disease that is prevalent in many parts of Africa and South America. In partnership with the drug manufacturer Sanofi, the Health Department in Miami/Dade will be providing

the Stamaril vaccine, which is not currently available in the United States. Since 2017 the treatment protocol has been ongoing. No major events have been reported. No adverse events have been reported. 3,270 patients have been enrolled since the protocol was approved. Vulnerable populations are still allowed to enroll. The investigative team qualifications remain satisfactory. The consent is still applicable and adequate. Risks remain the same in the treatment protocol.

The secondary presenter (Dr. Schoenfisch) agreed with the Dr. Cotea's review. However, she recommended conditional approval of the application due to the fact that the application does not have the most current points of contact within the for the Immunization program and lists employees no longer at DOH. Ms. Frentzen also noted that CITI training was not updated for several staff and a consent with a signature had been submitted for review. Rotanya Bryan informed the Board that the CITI certifications had been sent in last minute and were now up-to-date, minus one researcher. Ms. Bryan will follow-up to assure we receive the updated CITI info. She, Ms. Bryan was also in the process of redacting the name on the consent. Ms. Bryan will follow-up on that point when she contacts the site re current DOH staff names. The primary presenter recommended approval, and secondary presenter recommended conditional approval.

Motion for approval: Approval was made and seconded.

Total votes to approve for 12 months: (Total members voting: 6) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 2

Next Meeting: July 17, 2019

Other Business: None

Meeting Adjourned: 1:50 pm