September 16 , 2020
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)

Karen Card (CO-CHAIR)

Ovidiu Cotea

Robert Eadie

Robin DeWalt

Gina Larsen

**Absent:**

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**Other Attendees:** 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:**

**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 Title:** Advancing New Computer-based Health Outreach Regarding Sexual behavior (ANCHORS) Study: UH3 Project (University of Florida)

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Initial Submission) | Leeman, Robert PhD | Schoenfisch, Sandra PhD, M BSN, RN<br>Cotea, Ovidiu MD, MPH |

**Sandra:**

**Dr. Cotea:** Initial review - adds they are planning to recruit 80 participants that engage in heavy drinking and are at risk for HIV. They are recruiting younger generations. No objections to the study, no vulnerable populations and recommends approval

Sandra: motion

Dr. Cotea: Second

All approved

Total votes for approval: (Total members voting: ) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

**Protocol Title:** The Positively Quit Trial: Addressing disproportionate smoking rates among peo living with HIV (University of South Florida)

| **Submission:** | **Principal Investigator:** | **Presenters:** |
|---|---|---|
| (Initial Submission) | Marhefka, Stephanie | Card, Karen DrPH<br>Cotea, Ovidiu MD, MPH |

Positively quick trial assessing disproportion smoking rates among people living with HIV

**Karen Card:** This is out of the county health departments in Hillsborough from USF research team. Familiar with PI. Her team has a five-year study with a lot of people. Purpose: enroll smokers who are living with HIV. Strong protocol and study design. The investigator wants to recruit 428 people over five years. Randomize each person to control (demonstrated counseling for protection) treatment group (that plus specific not smoking behavioral components)

Testing by saliva and then again after that with a 365-day total follow-up.

There is no clinical treatment whatsoever. If a person decides not to participate this is separate from the clinical experience. Low risk behavioral counseling and has a positive risk benefit with participants. You cannot credit a benefit that may only be available to treatment groups, but you can say they are all getting counseling.

They have decided to do a long form consent and do not require signature. She thinks this is fine. They omitted specific FDOH IRB language, but is all inclusive (consent for screening and for the rest of the study)

Karen approves the long form consent with the inclusion of the FDOH language for the consent.

Payments of $5-40 for testing and treatment. The advertisement materials do not specify if this is for people with HIV positivity. This is the purpose of the first screening (smokers vs smokers with HIV).

You can receive up to $340 for the course of the study. She didn't feel this was a problem because it was not related to screening.

In summary, she would like to approve this study.

UF study so she wants the spelling error to be corrected. - we need to at least let them know of the spelling error.

**Second Reviewer:** Dr. Cotea does not have anything to add. This is a good study and it's well designed, and he recommends approval with minor modification

Bob Eadie to second the conditional approval

All in favor of the study approval with minor consideration

Total votes for approval: (Total members voting:) Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

## Educational discussion:

MIT article - DIY covid vaccine and no one knows if it works.

MIT Technology Review

Biotechnology

# Some scientists are taking a DIY coronavirus vaccine, and nobody knows if it's legal or if it works