4/21/21
1:30-3:00pm
TEAMS Meeting: Video recording archived and available upon request

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) (scientist) (affiliated)
Karen Card (scientist) (affiliated)
Ovidiu Cotea (scientist) (affiliated)
Megan Macdonald (Expertise in Subpart D: Children) (scientist) (affiliated)
Robin DeWalt (scientist) (affiliated)
Gina Larsen (non-scientist) (non-affiliated)
Bob Eadie JD

Absent: Andrew Wentzell

Other Attendees: Robin DeWalt, Gavin Grigg, and Bonnie Gaughan-Bailey

Announcements: Andy Wentzell on extended medical leave. Please contact Bonnie, Robin or Gavin as needed.

Calendar Invites: Delete old IRB appointments that Roytona and Andy to remove them from your calendar. Th new meetings will be from Robin DeWalt and are reoccurring meetings utilizing TEAMS.

Questions for announcements: None

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.

Conflict of Interest:

Conflict of Interest: None declared

Members did not report any:

Submissions for Convened Board Review

Initial review

Meeting Discussion: scientific description of the protocol – address rationale, background, general overview, researcher qualifications, e.g.,

Protocol Title: Developing the evidence base for overdose policies: a multilevel analysis of NHBS (Default Site)

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Cooper, Hannah PhD	Card, Karen DrPH
		Megan Macdonald, MPH

Karen Card is the primary reviewer:

(1) Reviewers determined the application not-greater than minimal risk study and is consistent with sound research design and does not unnecessarily expose subjects to risk because this study examines secondary data only, with no contact to participants.

(2) Risks are reasonable in relation to anticipated benefits because the study Data source is national HIV behavioral survey which is conducted every three years with the options of adding questions.

They are using this survey for the outcome and the population being considered was the population who inject drugs and not necessarily related to HIV and asks them their experience with overdose. This, therefore, is a self-reported overdose experience and outcomes. Research protocol was very well designed, and the investigators are well qualified.

(3) Selection of subjects is equitable because subjects are selected based on inclusion criteria which is based on a population who inject drugs and not necessarily related to HIV and asks them their experience with overdose that are self-reporting. Advertising and recruitment does not involve coercion or undue influence to participate. This, therefore, is a self-reported overdose experience and outcomes

(4) The researcher has chosen a waiver of consent as this is a secondary data analysis study.

Staff: if there is a waiver of consent documentation, use reviewer worksheet to document in minutes.

(5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. The study is using very few identifiers with a unique survey ID and zip codes to drill down to the locations of some of these determinants.

(6) Committee members discussed the provisions protecting privacy interests and determined that

adequate provisions were in place due to the lack of contact with subjects.

(7) Committee members discussed the provisions protecting confidentiality and determined that adequate provisions were made to protect the confidentiality of data there is no contact with study participants.

(8) No vulnerable populations are enrolled in the study.

Staff if there are vulnerable populations, ensure the IRB provides protocol specific findings and discusses these at the convened meeting.

Motion to approve #1: Karen moves to approve this study

Motion to approve #2:

Secondary reviewer Megan MacDonald:

Secondary data analysis using multilevel modeling procedures to look at opioid misuse and overdose. Researchers state there is an established database but there is evidence lacking from those who use these drugs.

Researchers are qualified and they are using very few identifiers (unique survey ID and zip codes to drill down to the locations of some of these determinants. No vulnerable populations, no contact with subjects, and not greater than minimal risk)

Motion to approve #2: Megan moves to approve this study

Sandra: Any questions or concerns/comments to add: None

All in favor: Yes

No Nays or abstentions

Pass unanimously.

Total votes to approve for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Submission:	**Principal Investigator:**	**Presenters:**
(Initial Submission)	Shariff-Marco, Salma PhD	Card, Karen DrPH
		Cotea, Ovidiu MD, MPH

Karen Card: Primary reviewer

(1) Reviewers determined the application was not-greater than minimal risk study and is consistent with sound research design and does not unnecessarily expose subjects to risk because the study uses secondary data analysis with no contact with participants with a waiver of consent.

(2) Risks are reasonable in relation to anticipated benefits because the study utilizes the Department and Cancer registry and is considering three cancers (breast, cervical, and colon cancers). They are looking at specific ethnicities, a number of nine ethnicities listed (membership of ethnicity, where they were born, and residents in the neighborhood where others share similar ethnicity). The researchers want to determine the independent impacts of the ethnicity, nativity, and those associated neighborhoods. Data comes from 5 states with the highest number of ethnic enclaves within those listed ethnicities (FL, CA, NY, NJ, & TX). If you can quantify the effect of those three relationships, they can then target those groups appropriately. No questions about the data security, study is minimal risk, disclosures are minimal risk.

(3) Selection of subjects is equitable because subjects are selected based on inclusion criteria which is based on Data comes from 5 states with the highest number of ethnic enclaves within those listed ethnicities (FL, CA, NY, NJ, & TX) and subjects prescreening for ethnicity, nativity, and location of enclave and recruitment does not involve coercion or undue influence to participate.

(4) The researcher has requested a waiver for consent which is appropriate for this study given the scope and geographic reach.

Staff: if there is a waiver of consent documentation, use reviewer worksheet to document in minutes.

(5) Committee members discussed the safety monitoring plan in the application and determined that adequate provisions were made for safety monitoring. The use of secondary data will be deidentified and will pose minimal risk to the participants.

(6) Committee members discussed the provisions protecting privacy interests and determined that adequate provisions were in place due to the statement that there will be no contact of study participants.

(7) Committee members discussed the provisions protecting confidentiality and determined that adequate provisions were made to protect the confidentiality of data because there is no contact with study participants.

(8) No vulnerable populations are enrolled in the study.

Motion to approve #1: Karen voted to approve this study

Dr. Cotea: second reviewer

Karen summarized it well. She agrees with everything that Karen stated and also proposed approval of this study.

Minimal risk, waiver of consent, secondary data analysis, looking for ethnic populations in five states

Motion to approve #2: Dr. Cotea made a second motion for approval

All in favor: Yes

No Nay and no Abstention

Unanimously approved by all committee members in attendance

Total votes to approve for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Modification

Protocol Title: CARLA vs. Biktarvy in treatment-experienced, suppressed participants SOLAR (Switch Onto Long Acting Regimen) (University of South Florida)

Submission:	**Principal Investigator:**	**Presenters:**
(Modification)	Casanas, Beata D.O.	Schoenfisch, Sandra PhD, MS, BSN, RN Cotea, Ovidiu MD, MPH

Sandra Schoenfisch is the primary reviewer:

(1) Reviewers determined the modifications to this not-greater than minimal risk study did not change the research design or exposure to risks because well designed study, the study includes a long form consent, individuals are screened thoroughly before they are enrolled and follow-up care is provided.

. (2) The modifications do not add new risks or change the probability or magnitude of existing risks, which were previously determined to be reasonable. (3) The modification to participant selection continues to be equitable because subjects are selected inclusion criteria. (4) The modification does not

change the consent procedures, which continue to be appropriate and clear. (5) The modification did not change plans for safety monitoring. (6-7) There were no modifications to protections for privacy interests or confidentiality protections. (8) The modification did not change inclusion criteria; there are no vulnerable populations are enrolled in the study.

Additional information from Sandra:

This is a Phase IIIb randomized multicenter study including multiple states including Florida.

The study is looking at the evaluation, efficacy, and safety to switch to the distribution to injection vs oral over time.

Well-designed study, long form consent is present and clear, individuals are screened thoroughly before they are enrolled and follow-up care is provided.

Researchers are qualified to do this research.

Modification they needed to add additional info from USF and make changes on the clarity. Using home test kits to look at their viral levels.

This study is important and has the opportunity to improve the lives of the patients and the management and the status of the HIV.

Motion to approve #1: Sandra Schoenfisch

Dr. Cotea is a second reviewer

If successful may revolutionize the treatment for HIV.

Modification was for the addition and removal of research staff.

Researchers are qualified and the consent form is very well written.

No subjects at Tampa site, currently.

No concern and no objection.

Motion to approve #2: Dr. Cotea recommends approval

Sandra: some of the delays have had to do with COVID and how they are seeing clients and the frequency. These modifications have been made as a result.

Questions? None

All in favor: Yes

No Nays or abstentions

Unanimously reviewed

Total votes to approve for 12 months: Affirmative: 6 Negative: 0 Recusal: 0 Absent: 0

Thanks to all who spent time reviewing and their attention to detail

Bonnie: We did achieve reaccreditation status from AAHRPP - Thanks to ALL!!!

Questions or comments from any of the reviewers: None

Next Meeting: May 19th

Adjournment