



Florida Department of Health
Public Health Statistics and Performance Management
Institutional Review Board

Meeting Details

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| Date: 10/20/2025 | Time of Meeting Called to Order: 1:31 PM Time of Meeting End: 2:13 PM | Location: Microsoft Teams |
| Purpose: To conduct & review new research studies involving human participants, modifications to existing studies, and continuing review of ongoing research to ensure research studies comply with regulations per the Department's ethical standards. | | Meeting Summary by: Victoria Creel, IRB Coordinator |

| IRB Member Attendees | Status | Affiliated (Y/N) | Method of Attendance | If alternate, name of regular member substituted; reason for substitution |
|--|---|------------------|----------------------|---|
| Sandra Schoenfisch, PhD, MS, BSN, RN | Chair, Subpart D: Children Representative, Scientific | N | Teams | |
| Merlene Ramnon, PhD, MPH, MSN, BSN | Chair, Scientific | Y | Teams | |
| Adrian Cooksey, DrPH, MPH | Scientific | Y | Teams | |
| Susan Bulecza, DNP | Scientific | N | Teams | |
| Vincent Edwards | Non-Scientific | Y | Teams | |
| Nina Mattei, MS, joined at 1:38 PM | Scientific | Y | Teams | |
| Prince Danso-Odei, MD, DrPH, MPH joined at 1:34 PM | Scientific | N | Teams | |

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| Gladys Liehr, Dr. rer. Nat., left at 1:48 PM | Scientific | Y | Teams | |
| Victoria Creel | IRB Coordinator | | Teams | |

| Number of Members on Roster | Number of Members Required for Quorum | Is Quorum Met? |
|-----------------------------|---------------------------------------|----------------|
| 10 | 6 | Yes |

Conflict of Interest Attestation

IRB Members were asked if there were any conflicts of interest and, if so, to recuse themselves from the meeting, or from voting on the applicable study.

Business Items

The following business items were discussed during the IRB Committee Meeting.

1. Introductions
2. Outstanding reviews – committee members were reminded to complete their assigned reviews.
3. CITI certifications – please review certifications and make sure they are up to date. If renewal is needed, please send completed certification to Victoria Creel.
4. Meeting minutes – one adjustment to Dr. Liehr's credentials requested. At 1:41 PM, Dr. Bulecza made a motion to approve, which was seconded by Dr. Schoenfisch. Minutes are approved by the committee with eight ayes.
5. Next meeting date – Victoria Creel will send out a survey to committee members to pick a date.

Submissions for Convened Board Review

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| Protocol Title: | | Characterizing the Burden of Cancer among Adults from the Hispanic Community Health Study/Study of Latinos (2022-076) | |
| Submission: | | Principal Investigator: | Presenters: |
| Continuing Review | | Daniela Stores-Alvarez | Gladys Liehr, Dr. rer. Nat. Nina Mattei |
| Effective Date of Approval: | Approval on 10/20/2025 | | |
| Approval Period: | 12 months | | |
| Level of Risk: | Greater than minimal risk | | |
| Funding Source, if applicable: | DHHS | | |
| Grant Name, if applicable: | | | |

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| IND or IDE, if applicable: | N/A | | | | | |
| Documents Reviewed and Notes: | <p>Continuing review. Originally a contingent approval from Dr. Liehr because identified data is being used and Dr. Liehr wanted to identify how they would protect the data. The research team sent a detailed response, which was shared with Dr. Liehr and approved. Study is data analysis, no interaction with subjects. The study aims to identify definitive cancer outcomes to mitigate cancer health disparities. A PI change and an addition of IT personnel to the study team was submitted for modification. The changes do not affect the risk to participants. Ms. Mattei agrees and approved the study.</p> <p>Dr. Liehr left the meeting at 1:48 PM. Quorum was still maintained. Motion to approve made by Dr. Schoenfisch, seconded by Dr. Bulecza, all members present (7 members) voted 'aye'. No abstentions or substitutions.</p> | | | | | |
| Controverted Issues, if applicable: | | | | | | |
| Informed Consent Forms Reviewed? | | | Informed Consent Forms Meet Regulatory Requirements? | | | |
| <input checked="" type="checkbox"/> | | | <input checked="" type="checkbox"/> | | | |
| Motion: | | | | | | |
| Approved | Approved with Stipulations | Conditions Pending for Approval | Disapproved | Tabled | Tabled Assistance | Terminated |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Voting: | | | | | | |
| For: | Against: | Abstain: | Recused: | Substitutions: | | |
| 7 | 0 | 0 | 0 | N/A | | |

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| Protocol Title: | MWCCS – MULTICENTER AIDS COHORT STUDY (MACS)/WOMEN'S INTERAGENCY HIV STUDY (WIHS) COMBINED COHORT STUDY (2025-002) | | |
| Submission: | Principal Investigator: | Presenters: | |
| Initial | Maria Alcaide | Prince Danso-Odei Nina Mattei | |
| Effective Date of Approval: | Contingent Approval on 9/15/2025 – meant to finalize on 10/20/2025 | | |
| Approval Period: | Dependent on satisfaction of contingencies 12 months | | |
| Level of Risk: | Greater than minimal risk | | |
| Funding Source, if applicable: | NIH | | |
| Grant Name, if applicable: | | | |
| IND or IDE, if applicable: | N/A | | |

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| Documents Reviewed and Notes: | No vote – still awaiting responses from research team, regarding controverted issues below. | | | | | |
| Controverted Issues, if applicable: | From previous meeting: -Does Creole need to be part of the consent languages? Ask the researchers if Creole needs to be a language option for the consent forms. -What measures are researchers putting in place for the more than minimal risk? Researchers have consultants on hand in case the participant becomes uncomfortable with the questionnaire. Counselors are also on standby. For use of albuterol, we will ask how they are dealing with the informed consent regarding that. What emergency measures are in place in the event someone has an adverse reaction to the albuterol? | | | | | |
| Informed Consent Forms Reviewed? | | | Informed Consent Forms Meet Regulatory Requirements? | | | |
| <input type="checkbox"/> | | | <input type="checkbox"/> | | | |
| Motion: | | | | | | |
| Approved | Approved with Stipulations | Conditions Pending for Approval | Disapproved | Tabled | Tabled Assistance | Terminated |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Voting: | | | | | | |
| For: | Against: | Abstain: | Recused: | Substitutions: | | |
| 0 | 0 | 0 | 0 | N/A | | |

Expedited Reviews

For informational purposes only

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| Protocol Title: | Compassionate Use of Delamanid for the treatment of Multidrug-Resistant (MDR) Tuberculosis in Patients with Limited Therapeutic Options. (Florida Department of Health) | |
| Submission: | Principal Investigator: | Presenters: |
| (Continuing Review) | Ashkin, David MD | Bulecza, Susan DNP |

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| Protocol Title: | A study of the ways in which in-utero exposure to contaminated water caused by flooding affects early childhood health. (University of Kentucky) | |
| Submission: | Principal Investigator: | Presenters: |
| (Continuing Review) | Bryant, Isaiah Completing PhD in Economics | Danso-Odei, Prince MD, PhD |

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|------------------------|--|------------------------|
| Protocol Title: | The Florida Cohort to Monitor and Improve Health Outcomes - Wave 4 (University of Florida) | |
| Submission: | Principal Investigator: | Presenters: |
| (Continuing Review) | Cook, Robert MD, MPH | Fashner, Julia MD, MPH |

Acknowledgement for Closure

For informational purposes only

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| Protocol Title: | Cancer Incidence in PFOS Exposed Workers (University of Miami) | |
| Submission: | Principal Investigator: | Presenters: |
| Place on agenda for acknowledgement of Closure | Alexander, Bruce | None |

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| Protocol Title: | Variations in Needs after Colorectal Cancer Diagnosis (#170013BU) (Boston Univeristy) | |
| Submission: | Principal Investigator: | Presenters: |
| Place on agenda for acknowledgement of Closure | Boehmer, Ulrike PhD | None |

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| Protocol Title: | Implementing a Healthcare Provider Education Intervention in Rural Communities to Reduce Morbidity (University of Florida) | |
| Submission: | Principal Investigator: | Presenters: |
| Place on agenda for acknowledgement of Closure | Llau, Anthoni PhD | None |

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|--|--|--------------------|
| Protocol Title: | Adverse Coronavirus Disease 2019 (COVID-19)-related outcomes among persons living with HIV in Miami-Dade County (Florida Department of Health) | |
| Submission: | Principal Investigator: | Presenters: |
| Place on agenda for acknowledgement of Closure | Trepka, Mary Jo MD, MSPH | None |

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| Protocol Title: | (#160044U9) Why a Decrease in Florida's Preterm Birth Rate, 2005 to 2014? (University of South Florida) | | |
| Submission: | Principal Investigator: | Presenters: | |
| Place on agenda for acknowledgement of Closure | Sappenfield, William MD, MPH | None | |

At 2:12 PM, motion to adjourn made by Dr. Bulecza, seconded by Dr. Schoenfisch and Dr. Cooksey, all members present (7 members) voted 'aye'.