



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

Meeting Details

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	

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

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:		

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		

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		

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

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: (Continuing Review)	Principal Investigator: Ashkin, David MD	Presenters: Bulecza, Susan DNP

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: (Continuing Review)	Principal Investigator: Bryant, Isaiah Completing PhD in Economics	Presenters: Danso-Odei, Prince MD, PhD

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

Acknowledgement for Closure

For informational purposes only

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

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

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

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

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'.