



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

Meeting Details

Date: 9/15/2025	Time of Meeting Called to Order: 1:33 PM Time of Meeting End: 2:51 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 1:35 PM	Scientific	Y	Teams	
Prince Danso-Odei, MD, DrPH, MPH	Scientific	N	Teams	

Gladys Liehr, Dr. rer. Nat., joined at 2:00 PM	Scientific	Y	Teams	
Bridgette Morton	Deputy Director, Public Health Research		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. Committee combination into one – all members are now on IRB 1. The two chairs are still the same.
3. Training – we are working on creating training for members. Please reach out if there is a specific topic you would like included that was not mentioned on the IRB member survey.
4. CITI certifications – please review certifications and make sure they are up to date. If renewal is needed, please send completed certification to Victoria Creel.
5. Outstanding reviews – Victoria Creel will send out an email to all committee members with the list of their assigned outstanding reviews.
6. Next meeting date – Victoria Creel will send out a survey to committee members to pick a date.

Submissions for Convened Board Review

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 Sandra Schoenfisch		
Effective Date of Approval:	Contingent Approval on 9/15/2025					
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:	<p>Experienced researchers conducting study. Written informed consent is in multiple languages, data security is robust, and participant protections are in place. The study is scientifically rigorous, ethically sound, and appropriately protective of participants.</p> <p>The questions below in the Controverted issues section will be sent to the researchers and the board moved to approve contingently. Motion for contingent approval made by Dr. Schoenfisch, seconded by Dr. Cooksey, all members present (7 members) voted 'aye'. No abstentions or substitutions.</p>					
Controverted Issues, if applicable:	<p>-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.</p> <p>-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?</p>					
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 type="checkbox"/>	<input checked="" 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:		Childhood Cancer Survivor Study Linkage, VPR Phase 2 (2024-004)				
Submission:		Principal Investigator:		Presenters:		
Initial		Gregory Armstrong		Prince Danso-Odei Nina Mattei		
Effective Date of Approval:		9/15/2025				
Approval Period:		12 months				
Level of Risk:		Not greater than minimal risk				
Funding Source, if applicable:		NCI				
Grant Name, if applicable:						
IND or IDE, if applicable:		N/A				
Documents Reviewed and Notes:		Waiver of consent requested, as the study only uses existing data, involves no participant contact, and would be infeasible without a waiver. The study is methodologically sound, ethically appropriate, and poses minimal risk. Motion for approval made by Dr. Danso-Odei, seconded by Ms. Mattei, all members present (7 members) voted 'aye'. No abstentions or substitutions.				
Controverted Issues, if applicable:		N/A				
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:	The Florida Cohort to Monitor and Improve Health Outcomes – Wave 4					
Submission:		Principal Investigator:		Presenters:		
Initial		Robert Cook		Sandra Schoenfisch Prince Danso-Odei		
Effective Date of Approval:	9/15/2025					
Approval Period:	12 months					
Level of Risk:	Not greater than minimal risk					
Funding Source, if applicable:	NIH NIAAA					
Grant Name, if applicable:						
IND or IDE, if applicable:	N/A					
Documents Reviewed and Notes:	Original questions about Creole consent were answered in the previous meeting. Dr. Danso-Odei has no issue with approving the study at this time. The study is scientifically valuable, ethically sound, and protective of participants' rights. Motion for approval made by Dr. Danso-Odei, seconded by Dr. Schoenfisch, all members present (8 members; Dr. Liehr joined the meeting at 2:00 PM) voted 'aye'. No abstentions or substitutions.					
Controverted Issues, if applicable:	N/A					
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:		
8	0	0	0	N/A		

Protocol Title:	Five Point Initiative: A Cluster Randomized Trial of a Bundled Implementation Strategy to Address the HIV Epidemic in Black Communities					
Submission:		Principal Investigator:		Presenters:		
Initial		Sannisha Dale		Susan Bulecza Julia Fashner		
Effective Date of Approval:	9/15/2025					
Approval Period:	12 months					
Level of Risk:	Not greater than minimal risk					
Funding Source, if applicable:	NIMH					
Grant Name, if applicable:						
IND or IDE, if applicable:	N/A					
Documents Reviewed and Notes:	All security measures are in place for the data. The DUA is approved. Several pilot studies have been completed by the researchers. Original reviewers suggested approval. Motion for approval made by Dr. Schoenfisch, seconded by Dr. Danso-Odei, all members present (8 members) voted 'aye'. No abstentions or substitutions.					
Controverted Issues, if applicable:	N/A					
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:		
8	0	0	0	N/A		

Protocol Title:	Disparities in maternal care access, quality, and outcomes, before, during, and after the COVID-19 pandemic					
Submission:		Principal Investigator:		Presenters:		
Initial		Peiyin Hung		Prince Danso-Odei Nina Mattei		
Effective Date of Approval:	9/15/2025					
Approval Period:	12 months					
Level of Risk:	Not greater than minimal risk					
Funding Source, if applicable:	NIMH					
Grant Name, if applicable:						
IND or IDE, if applicable:	N/A					
Documents Reviewed and Notes:	Secondary data analysis with no patient interaction. No anticipated risks. Waiver of consent requested due to no participant contact. Motion for approval made by Dr. Schoenfisch, seconded by Dr. Cooksey, all members present (8 members) voted 'aye'. No abstentions or substitutions.					
Controverted Issues, if applicable:	N/A					
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:		
8	0	0	0	N/A		

Protocol Title:	Big data approaches for Safe Therapeutics in Healthy Pregnancies (BOOST-HP)					
Submission:		Principal Investigator:		Presenters:		
Initial		Almut Winterstein		Prince Danso-Odei Nina Mattei		
Effective Date of Approval:	9/15/2025					
Approval Period:	12 months					
Level of Risk:	Not greater than minimal risk					
Funding Source, if applicable:	NIMH					
Grant Name, if applicable:						
IND or IDE, if applicable:	N/A					
Documents Reviewed and Notes:	Secondary data analysis with no direct participant interaction. Researchers seeking a waiver or alteration of consent. Data will be housed in secure system. Motion for approval made by Dr. Bulecza, seconded by Dr. Schoenfisch, all members present (8 members) voted 'aye'. No abstentions or substitutions.					
Controverted Issues, if applicable:	N/A					
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:		
8	0	0	0	N/A		

Expedited Reviews

For informational purposes only

Protocol Title:	Development of Intermodal Perception of Social Events: Infancy to Childhood (Florida International University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Bahrack, Lorraine	Macdonald, Megan MPH

Protocol Title:	Development of Intermodal Perception of Social Events: Infancy to Childhood (Florida International University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Bahrack, Lorraine	Schoenfisch, Sandra PhD, MS, BSN, RN

Protocol Title:	Variations in Needs after Colorectal Cancer Diagnosis (#170013BU) (Boston University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Boehmer, Ulrike PhD	Holden, Daphne Ph.D, MS

Protocol Title:	Environmental Risk Factors and Adverse Birth Outcomes in Florida (Emory University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Chang, Howard PhD	Martinasek, Mary PhD

Protocol Title:	MAPLE: Health outcomes and cognitive effects of marijuana use among persons living with HIV/AIDS (University of Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Cook, Robert MD, MPH	Card, Karen DrPH

Protocol Title:	(#170025U13) The Wellness Outreach for Mothers and Babies (WOMB) Program (University of Miami)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Hernandez, Julieta	Macdonald, Megan MPH

Protocol Title:	Disparities in Cancer Outcomes in Florida (University of Central Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Hines, Robert	Macdonald, Megan MPH

Protocol Title:	Population-Based Assessment of Treatment Patterns and Outcomes among Women with Newly Diagnosed Ductal Carcinoma in Situ (Georgetown University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Mitchell, Jean	Holden, Daphne Ph.D, MS

Protocol Title:	(160043U13) Mapping the effects of wider neighborhood disorganization on health behaviors and pregnancy outcomes. (University of Miami)	
Submission:	Principal Investigator:	Presenters:

(Continuing Review)	Moise, Imelda PhD., MPH	Card, Karen DrPH
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Protocol Title:	Black Women: Etiology and Survival of Triple-negative Breast Cancers (Best) Study (Vanderbilt University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Pal, Tuya MD	Frentzen, Barbara MSN, ARNP

Protocol Title:	Young breast cancer survivors- Genetic Risk services Access and Delivery Evaluation (YOU-GRADE) (Vanderbilt University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Pal, Tuya MD	Card, Karen DrPH

Protocol Title:	(#160030MOFF) Biobank for African American Prostate Cancer Research in Florida (Moffitt)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Park, Jong	Card, Karen DrPH

Protocol Title:	Perinatal Quality Indicator Project (Maternal and Infant Health Care Quality Improvement) (University of South Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Sappenfield, William MD, MPH	None

Protocol Title:	(#170039U9) Postpartum Contraceptive Use, Repeat Pregnancy, and Birth Intervals among Women in Florida (University of South Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Sayi, Takudzwa	Eadie, Robert JD

Protocol Title:	Assessing Needs by Enhancing Resiliency Among Vulnerable Populations Through the "Lean on Me" Program (Florida Department of Health)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Selph, Jasmine MPH-pending	Eadie, Robert JD

Protocol Title:	Anti-tuberculosis drug pharmacokinetics: the role of the gut microbiome (University of Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Seraphin, Nancy	Macdonald, Megan MPH

Protocol Title:	(A5332) Randomized Trial to Prevent Vascular Events in HIV REPRIEVE-Hillsborough CHD (Florida Department of Health)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Somboonwit, Charurut MD	Macdonald, Megan MPH

Protocol Title:	(#160050HDD) Positive Health Check Evaluation Trial (Florida Department of Health)	
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Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Somboonwit, Charurut MD	Card, Karen DrPH

Protocol Title:	The Effects of Neighborhood Change on Geographic Mobility, Socioeconomic Status, and Health Outcomes of Low-Income Women (Hunter College)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Van Parys, Jessica PhD	Card, Karen DrPH

Protocol Title:	SAFETY OF GADOLINIUM-ENHANCED MRI EXPOSURE DURING PREGNANCY ON ADVERSE FETAL OUTCOMES (University of Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Winterstein, Almut PhD	Schoenfisch, Sandra PhD, MS, BSN, RN

Protocol Title:	Cancer Incidence in PFOS Exposed Workers (University of Miami)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Alexander, Bruce	Ramnon, Merlene PhD, MPH, MSN, BSN

Protocol Title:	Study of Cause-Specific Mortality and Cancer Incidence in a Combined Cohort of Uranium Enrichment Workers (National Institute for Occupational Safety and Health)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Anderson, Jeri PhD	Forrest, Jamie MS

Protocol Title:	Racial Differences in BRCA1/2 Testing: Patients or Providers? (University of Pennsylvania)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Armstrong, Katrina MD	Forrest, Jamie MS

Protocol Title:	Exploring barriers and facilitators to prenatal care among Caucasian/White and African American/Black women in Leon County (Florida State University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Blackburn, Claudia RN, MPH	Reid, Keshia PhD

Protocol Title:	The NYU Women's Health Study (New York University)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Zeleniuch-Jacquotte, Anne M.D.	Ichite, Nkechi PharmD, PhD

Protocol Title:	Cancer Incidence and Cancer Mortality in the World Trade Center Health Registry (New York City Department of Health and Mental Hygiene)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Cone, James	Cui, Dongming MD, MPH, DrPH

Protocol Title:	Foreto Patient Registry (RTI Health Solutions)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Gilsenan, Alicia	Arango, Jaime EdD	

Protocol Title:	Outcome Evaluation of Palm Beach County Healthy Beginnings Program (Children's Services Council of Palm Beach County)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Goodman, Jeff	Reid, Keshia PhD	

Protocol Title:	Disparities in Cancer Outcomes in Florida (University of Central Florida)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Hines, Robert	Arango, Jaime EdD	

Protocol Title:	Cancer Risk among Firefighters and Emergency Service Rescuers and Officers Exposed to the World Trade Center Disaster (WTC Health program)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Prezant, David MD	DeWalt, Robin	

Protocol Title:	Mapping of Premature Births in all Florida Counties (March of Dimes)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Reeves, Lori	Reid, Keshia PhD	

Protocol Title:	Improving Public Health Practice: A Pilot Study of High Risk Infant Referrals in Three Florida Counties (Florida State University)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Rowan, Alan Rowan DRPh	Reid, Keshia PhD	

Protocol Title:	Associations of Obesity with Severe Maternal Morbidity (#160038U9) (University of South Florida)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Sappenfield, William MD, MPH	DeWalt, Robin	

Protocol Title:	(#160044U9) Why a Decrease in Florida's Preterm Birth Rate, 2005 to 2014? (University of South Florida)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Sappenfield, William MD, MPH	Forrest, Jamie MS	

Protocol Title:	Newborn Auditory Brainstem Response and Sudden Infant Death Syndrome (University of Miami)		
Submission:	Principal Investigator:	Presenters:	
(Continuing Review)	Simpson, Elizabeth Ph.D.	Ramnon, Merlene PhD, MPH, MSN, BSN	

Protocol Title:	(A5332) Randomized Trial to Prevent Vascular Events in HIV REPRIEVE-Hillsborough CHD (Florida Department of Health)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Somboonwit, Charurut MD	None

Protocol Title:	Characterizing the Burden of Cancer among Adults from the Hispanic Community Health Study/Study of Latinos (Default Site)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Sotres-Alvarez, Daniela DrPH	Ramnon, Merlene PhD, MPH, MSN, BSN Liehr, Gladys PhD, CSM, FCCM, PMP

Protocol Title:	The Health-Smart Behavior Program™ at the Alachua County Health Department (University of Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Tucker, Carolyn	Forrest, Jamie MS

Protocol Title:	Views of Staff Performing HIV Testing and Counseling (University of South Florida)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Turner, DeAnne MPH	Arango, Jaime EdD

Protocol Title:	Maintenance and Extension of a Cohort of Career Firefighters as a Non- WTC Exposed Comparison for the FDNY Firefighter Cohort. (Fire Dept of the City of New York)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Webber, Mayris DrPH	Forrest, Jamie MS

Protocol Title:	Maintenance and Extension of a Cohort of Career Firefighters as a Non- WTC Exposed Comparison for the FDNY Firefighter Cohort. (Fire Dept of the City of New York)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Webber, Mayris DrPH	Forrest, Jamie MS

Protocol Title:	Maintenance and Extension of a Cohort of Career Firefighters as a Non- WTC Exposed Comparison for the FDNY Firefighter Cohort. (Fire Dept of the City of New York)	
Submission:	Principal Investigator:	Presenters:
(Continuing Review)	Webber, Mayris DrPH	Forrest, Jamie MS

Acknowledgement for Closure

For informational purposes only

Protocol Title:	Disparities in Cancer Outcomes in Florida (University of Central Florida)	
Submission:	Principal Investigator:	Presenters:

Place on agenda for acknowledgement of Closure	Hines, Robert	None
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Protocol Title:	Registry Linkage and Cohort Study of Cancer Risks in U.S. Radiologic Technologists (National Institutes of Health)	
Submission:	Principal Investigator:	Presenters:
Place on agenda for acknowledgement of Closure	Linnet, Martha	None

Protocol Title:	Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer (#160026RTI) (RTI Health Solutions)	
Submission:	Principal Investigator:	Presenters:
Place on agenda for acknowledgement of Closure	Subramanian, Sujha	None

Protocol Title:	Laboratory and Epidemiological Characteristics of Zika Virus Infections in Florida (Florida International University)	
Submission:	Principal Investigator:	Presenters:
Place on agenda for acknowledgement of Closure	Trepka, Mary Jo MD, MSPH	None