REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD CALENDAR YEAR 2016

Submitted by

Adrienne McFadden, MD, JD
Interim Chair
Virginia Department of Health Institutional Review Board

REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2016

Regulations for the conduct of human research, developed and approved by the Virginia Board of Health, became effective on July 1, 1993 and were most recently updated on January 14, 2016. The regulations apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants. According to those regulations, prior to the initiation of a human research project a description of the proposed project shall be submitted to a research review committee for review and approval. The Virginia Department of Health (VDH) subsequently appointed an Institutional Review Board (IRB). In addition, a guidance document, Virginia *Department of Health Institutional Review Guidelines and Procedures* was developed and updated in March 2016.

The Office for Human Research Protections (OHRP), within the U.S. Department of Health and Human Services (DHHS), is responsible for ensuring the safety and welfare of people who participate in HHS-sponsored research. VDH has voluntarily registered and has applied for and received Federalwide Assurance for its IRB from OHRP. Registration with OHRP facilitates DHHS's effort to establish effective communication with IRBs. In addition, receiving an assurance from OHRP formalizes an institution's commitment to protect human subjects.

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either exemption review, expedited review or full board review.

Under Federal regulations 45 CFR 46.101 (b), certain categories of research that present little or no risk to human subjects (non-vulnerable subjects) do not require ongoing monitoring and review by an IRB. However, IRB staff, in consultation with an IRB chair, must make the determination that the study does indeed meet the criteria for exemption before the research study may commence. This type of review is called "exempt review". If the risks to human subjects appear questionable or the project does not fit into the federally defined categories for exemption, the IRB will notify the investigator that he/she must submit the study as a new protocol for either full or expedited review. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

Under Federal regulations 45 CFR 46.101 (b), certain categories of research involving no more than minimal risk as well as minor changes to approved research, qualify for what is called "expedited review". In these instances a designated IRB member or group of members reviews the proposed research rather than the entire IRB with final review and approval by the IRB Chair.

When full board review is necessary, the research proposal is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. This is considered "full board review".

In March 2016, Dr. Adrienne McFadden, Director of the Office of Health Equity was appointed to serve as Interim VDH IRB chair following the resignation of Dr. Dev Nair.

VDH IRB meetings were held quarterly during 2016; January 12, April 13, July 13, and October 26. Minutes are available on request. The following is a summary of the activities and actions of the VDH IRB as per state "Regulations for the Conduct of Human Research," 12VAC5-20-50, during calendar year 2016.

Review Type	Approved	Not Approved
Full Review	None	None
Expedited Review	22	None
Exempt Review	8	None

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED AND APPROVED OR DISAPPROVED:

A. Full Board Reviews

None

B. Expedited Reviews

Study # **40220**
Title: 2016 Virginia Adult Tobacco Survey
Principal Investigator: Lauren Evans, DrPH, Virginia Department of Health
Approved: February 25, 2016
Summary: The purpose of this study is to assess tobacco use, smoking cessation, secondhand smoke exposure, risk perception and social influences, and tobacco-related policy issues in Virginia. This will be the first statewide tobacco use survey in Virginia.

Study # **40221**
Title: How Does Environmental Landscape Change Shape Community Health in Virginia
Principal Investigator: Julia M. Gohlke, PhD, Virginia Tech
Approved: February 25, 2016
Summary: The goal of the proposed project is to use geographic and epidemiological tools to identify critical times and locations of changes in land use that may impact public health. The proposed study will focus on evaluating land use change in southwestern Virginia, with comparisons to other regions of Virginia, accounting for covariates such as income, smoking/substance abuse, education, marital status, and race/ethnicity.

Study #: **40222**
Title: National HIV Behavioral Surveillance (NHBS)
Principal Investigator: Celestine Buyu, MPH, MHSA, Virginia Department of Health
Approved: February 29, 2016
Summary: The purpose of this study is to utilize the National HIV Behavioral Surveillance (NHBS) to monitor selected behaviors and prevention services among groups at the

highest risks for HIV infection. The findings of this study will be utilized to enhance the understanding of HIV risk and testing behaviors of the groups and to develop and evaluated HIV prevention programs that provide services to them.

Study #: **40223**
Title: Fidelity Monitoring of Patient Navigators to Enhance Linkage and Retention in Medical Care
Principal Investigator: Danny Avula, MD, MPH, Richmond City Health Department
Approved: March 10, 2016
Summary: The purpose of this study is to evaluate how Motivational Interviewing is used by Patient Navigators to help People living with HIV (PLHIV) patients work through challenges and help them get and stay in medical care. The hypothesis is that conducting Fidelity Monitoring will increase MI-adherent behavior and improve service quality delivery to clients.

Study #: **40224**
Title: Association of Morphologic Cancer Type with Tobacco Use
Principal Investigator: Nathan M. Holt, PhD, William E. Wecker Associates, Inc.
Approved: March 10, 2016
Summary: The purpose of this study is to investigate the association between tobacco use and the incidence of cancer by type, site, and birth cohort. Researchers will study the relationship between age, gender, ethnicity, geographic location, rural or urban lifestyle, occupation, family history of cancer, tobacco history, and 5 year birth cohort (as independent variables) with counts of cancer diagnoses as the dependent variable.

Study #: **40225**
Title: Is SW Virginia a Good Candidate for Needle-syringe Program Implementation as a Means to Reduce HCV Incidence?
Principal Investigator: Margaret Lee O'Dell, MD, MFA, Virginia Department of Health
Approved: March 23, 2016
Summary: The purpose of this cross sectional study is to determine the feasibility and acceptability of a Needle-Syringe Program (NSP), as well as better characterize the endemic drug cases that are currently arising in SW Virginia. All individuals (age 18+ and English speaking) that test positive for HCV in SW Virginia Region, and whose cases are reported to the VDH, will be approached for participation in the study. They will be asked about their drug use and the acceptability of NSP. Local health care and law enforcement agencies will also be surveyed to assess the feasibility and acceptability of NSP.

Study #: **40226**
Title: Improving Health Literacy within the VDH Dissemination and Implementation of SIPsmartER in SW Virginia
Principal Investigator: Jamie Zoellner, PhD, RD, Virginia Tech
Reviewer: Ronnette Langhorne
Approved: March 23, 2016
Summary: The purposes of this study are to (1) assess the organizational health literacy practices within the 4 identified districts (Cumberland Plateau, Lenowisco, Mt.

Rogers, and New River) at the staff and customer levels using the instruments adapted from the Agency for Healthcare Research Quality; (2) develop and evaluate an intervention to enhance health literacy skills among VDH staff within the districts; and (3) assess the collaborative development of an implementation strategy with (professional development and technical assistance) for the SIPsmartER within the VDH system.

Study #:	**40227**
Title:	Evaluating the Clinical and Microbiologic Impact of discordant Results for Rifampin Resistance in Patients with Tuberculosis
Principal Investigator:	Eghosa Ivy Oyegun, MPH, Centers for Disease Control and Prevention
Approved:	April 15, 2016
Summary:	This is a retrospective impact evaluation that will focus on discordance between molecular and growth-based RMP-resistance results, when both are available, to evaluate the impact of disagreement between these two types of results on clinical decision making and subsequently on microbiological and clinical outcomes for the Tuberculosis patient. The hypothesis is that when patients in the discordant study group are treated as RMP-susceptible, they will have worse treatment outcomes than patients in the concordant study groups whose treatment regimen aligns with their DST test results. Through this study, CDC can add to scientific knowledge on the clinical significance of disputed mutations, understand clinical and programmatic approaches to treatment when discordant results are reported, identify areas to target educational and training efforts, and perhaps revise laboratory testing algorithms or reporting language to aid results interpretation.

Study #:	**40228**
Title:	Intervention and Outcomes in Duarte Galactosemia
Principal Investigator:	Judith L. Fridovich-Kell, PhD; Emory University School of Medicine Jennifer MacDonald, VDH contact
Approved:	April 15, 2016
Summary:	The goals of this project are to assess whether children with Duarte galactosemia, ages 6-12 years old, experience developmental disorders relative to controls, and if so, whether dietary exposure to milk in infancy or early childhood is associated with developmental outcomes. The specific aims of the study are to 1) determine whether school-age children with DG are at increased risk for disorders in cognitive development, auditory process, communication, socio-emotional development, and physical development and 2) determine whether dietary restriction of galactose (milk) in infancy or early childhood is associated with developmental outcomes of school-age children with DG.

Study #:	**40229**
Title:	Determining the Impact of Pregnancy of QFT Indeterminate Results
Principal Investigator:	Katherine Brewer, MSN, RN, Fairfax County Health Department
Approved:	May 3, 2016
Summary:	This study seeks to provide evidence towards optimal timing for testing for tuberculosis using an Interferon Gamma Release Assay (IGRA) in pregnant women.

The aim of this study is to answer the research question *"Among pregnant women, are there differences in IGRA indeterminate results and trimester at time of testing?"*

Study #: **40230**
Title: National Food Study Pilot
Principal Investigator: Janice Machado, MBA, Senior Study Director, Westat
Approved: May 19, 2016
Study Purpose: The purpose of this USDA funded study is to test an alternative method of collecting data on the foods acquired by American households that leads to more complete and accurate information about patterns of food acquisitions. Secondary objectives are to explore the feasibility of expanding the population of interest to include households receiving benefits from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and to collect more complete and accurate information on income.

Study #: **40231**
Title: MIECHV Reflective Supervision Survey
Principal Investigator: Mary Moore, Ph.D., VCU Survey and Evaluation Research Lab
Approved: June 10, 2016
Study Purpose: This is an evaluation of the Reflective Supervision training and coaching for Home Visiting Program Supervisors and Trainers that was implemented in 2015 and an evaluation of job satisfaction among home visitors and supervisors in Virginia. This project fulfills evaluation requirements set by HRSA in the funding of the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV). The central question of the evaluation is, "Has professional quality of life increased through the implementation of Reflective Supervision into the home visitor – supervisor relationship?"

Study #: **40232**
Title: WIC Family Health and Nutrition Survey
Principal Investigator: Sina Gallo, PhD MSc, RD, George Mason University
VDH Collaborator: Loudoun County Health Department
Approved: June 16, 2016
Study Purpose: To provide data to develop and target effective education and the improvement of community resources and programs for vulnerable subgroups in Loudoun County Virginia. Infant feeding, supplementation practices as well as access to community resources will be assessed in mothers who are currently enrolled in the federal Supplemental Nutrition Program for Women, Infants and Children (WIC). The secondary objective of this study is to determine whether current vitamin D recommendations are being adequately implemented and followed by mothers of newborns. Predictors for non-compliance will be explored. Maternal supplementation habits as well as knowledge and beliefs about vitamin D will also be explored.

Study #: **40233**
Title: Evaluation of Youth Health Equity Leadership Institute
Principal Investigator: Dr. Kathy Hosig, Virginia Tech
Approved: June 16, 2016

Study Purpose: This research will evaluate the Youth Health Equity Leadership Institute (YHELI). The purpose of the evaluation is to assess the effectiveness of YHELI. Anticipated findings are an increase in healthy behaviors, self- efficacy, self- identified leadership skills and intent to graduate high school.

Study #: **40234**
Title: Oral Health Assessment of Pregnant Women Enrolled in VDH WIC Clinics
Principal Investigator: Karen Day, DDS, MPH, Virginia Department of Health
Approved: June 30, 2016
Study Purpose: The purpose of the Oral Health Assessment of Pregnant Women Enrolled in WIC Clinics is to document the oral health status of this population, as well as their access to care and knowledge regarding oral health.

Study #: **40235**
Title: Cancer Incidence Study of Marines/Navy Personnel and Civilian Employees Exposed to Contaminated Drinking Water at USMC Base Camp Lejeune
Principal Investigator: Frank J. Bove, ScD, Division of Toxicology and Human Health Sciences, US Department of HHS
Approved: August 12, 2016 (previously approved by CDC IRB)
Study Purpose: The purpose of this retrospective cohort study of Marines/Navy personnel is to determine whether residential exposures to the drinking water contaminants at Camp Lejeune are associated with increased risks of specific cancers.

Study #: **40236**
Title: SIPsmartER Southwest Virginia: Main Participant Effectiveness Trial
Principal Investigator: Jamie Zoellner, PhD, RD, Virginia Tech
Approved: July 28, 2016
Study Purpose: This is an evaluation of the implementation of the SIPsmartER, a 6-month theory-based, health literacy focused intervention intended to help adults reduce sugar sweetened beverages (SSB) intake in the health districts of Cumberland Plateau, Lenowisco, Mount Rogers and New River.

Study # **40237**
Title: Systemic Immunosuppressive Therapy for Eye Diseases Cohort Study
Principal Investigator: John Kempen, MD, MPH, MHS, PhD, University of Pennsylvania
Approved: July 28, 2016
Study Purpose: This is a multi-center retrospective cohort study to evaluate the possible long-term adverse effects including mortality and cancer incidence related to immunosuppressive agents in ocular inflammation. The specific aims of the study are to 1) evaluate the safety or lack of safety of immunosuppressive therapy and overall cancer mortality; and 2) evaluate the safety or lack of safety of immunosuppressive therapy and cancer incidence.

Study #: **40238**
Title: Clinical Profiles and Treatment Utilization Patterns Associated with Suicide among Youth in Medicaid
Principal Investigator: Cynthia Fontanella, PhD, Ohio State University
Approved: August 26, 2016
Study Purpose: The goal of this study is to obtain a better understanding of the clinical and demographic characteristics and patterns of care that differentiate suicide decedents from non-decedents which will contribute to the development of targeted approaches to assist clinicians in effectively identifying and treating child and adolescent Medicaid beneficiaries at risk for suicide.

Study #: **40239**
Title: Performance Measures Before and After Introductions of Breast Tomosynthesis into Screening Environment
Principal Investigator: Stephen L. Rose, MD, Washington Radiology Associates, A Solis Mammography Center, Fairfax, Virginia
Approved: September 7, 2016
Study Purpose: This is a retrospective review of screening mammography patients and linkage with the cancer registry data comparing conventional 2D to tomosynthesis 3D+2D mammography. Patients will be linked to cancer registry data to analysis type and interval after a negative screening mammography. Study is seeking to determine if the interval cancers with 3D+2D are lower than with 2D screenings.

Study #: **40240**
Title: Assessing the Incidence of Osteosarcoma among Teriparatide Users Using Medicare Part D and State Cancer Registry Data
Principal Investigator: Alicia Gilsenan, PhD, RTI Health Solutions
Approved: November 21, 2016
Study Purpose: The purpose of this study is to determine if patients aged 65 years and older being treated with Forteo (an osteoporosis medication) are more likely to develop osteosarcoma, a rare bone cancer, compared to patients matched on demographic and co-morbidity indicators who do not use Forteo.

Study #: **40241**
Title: Observational Study Assessing Incidence of Osteosarcoma among Forteo (teriparatide) Users by Linking State Cancer Registry Data to Large National Pharmacy Database Data.
Principal Investigator: Susan Oliveria, ScD, MPH, IMS Health
Approved: December 7, 2016
Study Purpose: The primary purpose is to estimate the incidence of osteosarcoma in patients who have received treatment with Forteo over time as compared to a general population comparator cohort and an osteoporosis comparator group using an incidence rate ratio (IRR) and 95% confidence interval (CI).

C. Exempt

Study #: **50191**
Title: Connecting Health Care and Transportation Access through Analysis of Prenatal Care
Principal Investigator: Christina Galardi, MPH, University of North Carolina
Approved: February 19, 2016
Summary: The goal of this study is to determine the impact of transportation factors on access to health care and the impact on pregnancy outcomes. The study questions include: 1) What transportation factors pose barriers to patient access to medical care, especially prenatal visits; 2) What transportation policies can modify these factors; 3) What are the implications of missed perinatal care due to transportation on health throughout the life course?

Study #: **50194**
Title: Virginia Community Pharmacists Survey (VCPS)
Principal Investigator: Shahid M. Hafidh, MPH, Virginia Department of Health
Approved: January 29, 2016
Summary: The purpose is to measure the number of community pharmacists engaged in medication therapy management (MTM) services within the Commonwealth, their perceptions and identified barriers. The project is funded under a National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, cooperative agreement and fulfills the CDC annual report requirements.

Study #: **50195**
Title: Virginia Healthy Start Evaluation
Principal Investigator: Saba Masho, MD, DrPH, VCU
Approved: February 1, 2016
Summary: The purpose of this evaluation project is to determine the effectiveness of the Virginia Healthy Start Initiative's Loving Steps Program in preventing adverse perinatal outcomes. The study will examine the impact of the program on: Infant mortality; preterm birth; LBW; breastfeeding initiation; prenatal care entry; cause of infant death and whether the infant was in NICU.

Study #: **50196**
Title: Racial and Socioeconomic Disparities in Emergency Department Visits for Influenza like Illness in Virginia for the 2010-2011 Flu Season
Principal Investigator: Sean D. Cleary, PhD, George Washington University
Approved: March 10, 2016
Summary: The purpose of this study is to evaluate the association between socio-demographic factors of race, ethnicity, economic status, insurance status, household composition of a zip code, county or health district and an increase in influenza-like illness (ILI) emergency department visits seen within specific geographical areas.

Study #: **50197**
Title: Exploring Early Childhood Home Visitors Perspective of their Training and Impact on Families in Northern Virginia
Principal Investigator: Tori Kristi VanDer Merwe (MPH Candidate) University of Liverpool
Approved: March 10, 2016
Summary: This is a process evaluation of the HV training developed and offered live and online by the Virginia Home Visiting Consortium (HVC). Focus will be on the efficacy of the training, how the training affected job performance, and how the training might have led to behavior change (as it relates to public health) for participating families.

Study #: **50198**
Title: Virginia's Planning District Ten-Community Themes and Strengths Assessment
Principal Investigator: Aaron Pannone, PhD, University of Virginia
Approved: April 22, 2016
Summary: This study will utilize the Mobilizing for Action through Planning and Partnerships (MAPP) strategic framework to determine the community members' perception of the areas of health and how health can be improved.

Study #: **50199**
Title: Factors Associated with Pregnancy and Birth Related Behavioral and Health outcomes among Young Women in Virginia
Principal Investigator: Hongyun Tracy Fu, PhD, Eastern Virginia Medical School
Approved: July 21, 2016
Study Purpose: The study will analyze existing VA PRAMS data to explore factors associated with pregnancy and birth related behavioral and health outcomes among young women in Virginia.

Study #: **50200**
Title: Examining Access to Healthy Food Retail in Hampton Roads, Virginia
Principal Investigator: Bill McKinney, PhD, The Food Trust, Philadelphia, PA
Approved: October 3, 2016
Study Purpose: This study seeks to better understand the relationship between diet-related death and access to food stores in Virginia by analyzing diet-related death data from the most recent years for which data is available, at the census tract level and compare the info to existing datasets on food retail throughout Virginia.

II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:

None

III. COMMITTEE MEMBERS, THEIR QUALIFICATIONS FOR SERVICE ON THE COMMITTEE, AND THEIR INSTITUTIONAL AFFILIATION:

VDH IRB 2016 Membership		
Committee Members	**Qualifications for Service**	**Institutional Affiliation**
IRB CHAIR		
Adrienne McFadden (interim chair)	MD, JD Director Office of Health Equity	Office of Health Equity, Virginia Department of Health
VOTING MEMBERS		
Denise Bonds	MD, MPH District Health Director	Thomas Jefferson Health District, Virginia Department of Health
Ana Lizzette Colon	MPH, in Epidemiology & Regional Surveillance Coordinator	Eastern Region Field Office, Virginia Department of Health
Bethany J. Geldmaker	PhD in Nursing & Child Health Care Consultant	Division of Child and Family Health, Virginia Department of Health
Pastor Maceo Freeman	Master of Divinity	St. Paul's Baptist Church
Janice Hicks	PhD in Social Policy and Social Work	Office of Family Health Services, Virginia Department of Health
Cecilia Barbosa	PhD in Public Health	Community Representative
Blythe Balestrieri	PhD in Criminal Justice	Virginia Commonwealth University
ALTERNATE MEMBERS		
Vacant		