

**REPORT TO THE COMMISSIONER:
ACTIVITIES OF
THE VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2017**

Submitted by

**Bethany Geldmaker, PhD
Chair**

Virginia Department of Health Institutional Review Board

**REPORT TO THE COMMISSIONER:
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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 the Code of 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 the 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 a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights. 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.

Under the Code of Federal Regulations 45 CFR 46.101 (b), certain categories of human subject 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 July 2017, Dr. Bethany Geldmaker was elected by the IRB members to serve as the chair following the resignation of Dr. Adrienne McFadden, former Director of the Office of Health Equity, who was serving as the interim chair.

VDH IRB meetings were held quarterly during 2017: February 13, April 10, July 10, and October 16. 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 2017.

Review Type	Approved	Not Approved
Full Review	0	0
Expedited Review	17	0
Exempt Review	12	0

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

A. Full Board Reviews

None

B. Expedited Reviews

Study #: 40242
Title: National Healthy Start Program Evaluation
Principal Investigator: Janelle Banks, MPH, Maternal and Child Health Bureau, HRSA
Approved: January 27, 2017
Study Purpose: The goal of the National Healthy Start evaluation is to determine the effect of the transformed federal healthy start program on changes in participant-level characteristics. The national evaluation includes three components: 1) implementation; 2) utilization; and 3) outcome. The implementation evaluation will describe Healthy Start programs and strategies and identify program factors that are associated with effective implementation. The utilization evaluation will examine the characteristics of participants and non-participants and factors that help explain differential penetration or service rates. The outcome evaluation will assess the overall effectiveness of the program with regard to producing

expected outcomes among the target populations and factors that help explain variation in the program's impact on individual level outcomes.

Study #: 40243
Title: Assessing the Effectiveness of Richmond Family and Fatherhood Initiative Parenting Programs Among Incarcerated Fathers and Mothers in the Richmond City Justice Center
Principal Investigator: Anthony J. Mingo Sr., Richmond City Health Department
Approved: January 31, 2017
Study Purpose: To assess the effectiveness of the Richmond Family and Fatherhood Initiative Parenting Programs among incarcerated fathers and mothers in the Richmond City Justice Center.

Study #: 40244
Title: Prevalence of Microcephaly Over Ten Years
Principal Investigator: Colin Benusa, MPH candidate, Virginia Commonwealth University
Approved: January 31, 2017
Study Purpose: This is a student capstone project. The purpose of the research is to better understand the prevalence of microcephaly and the various characteristics including maternal, infant and prenatal characteristics associated with microcephaly.

Study #: 40245
Title: Validation of a New Abuse Assessment Tool
Principal Investigator: Joanna Hemmat, Fairfax County Health Department
Approved: February 13, 2017
Study Purpose: The purpose of this study is to validate a new tool to assess intimate partner violence against pregnant women.

Study #: 40246
Title: The Effect of Maternal Education on Infant and Maternal Health: New Causal Evidence
Principal Investigator: Ji Yan, PhD, Appalachian State University
Lisa Schulkind, PhD, University of NC- Charlotte
Approved: March 3, 2017
Study Purpose: The purpose of this study is to compare education and health outcomes for women with birthdates just before their state's school entry date to those who are born just after the entry date. General hypothesis is that maternal education, which is

affected by school entry policies, will impact the health of mothers and infants through one of several causal channels including health knowledge, income, fertility, marriage, etc.

Study #: 40247
Title: Cancer Case Comparisons
Principal Investigator: Susan Modesitt, MD, University of Virginia
Approved: March 17, 2017
Study Purpose: This study will compare low and high-grade ovarian epithelial cancers with regards to demographic characteristics and treating hospital descriptors, and assess factors correlating with missing grade. The hypothesis is that demographic characteristics and disease descriptors may vary depending on the grade of the ovarian cancer.

Study #: 40248
Title: 2017 Statewide Oral Health Needs Assessment of Head Start Children
Principal Investigator: Shahid M. Hafidh, MPH, Virginia Department of Health
Approved: April 17, 2017
Study Purpose: The purpose of the 2017 Oral Health Assessment of Head Start Children is to collect data regarding the oral health status of this population, as well as other factors influencing access to care. Based on studies of other low socioeconomic populations, it is anticipated that low-income pre-school children will have more disease and a lack of access to care than their higher income counterparts.

Study #: 40249
Title: A Descriptive Analysis of Chlamydia and Gonorrhea Incidence in Portsmouth, Norfolk and Accomack Virginia (Years 2009-2016)
Principal Investigator: Dan G. Robison, PhD, CPT, Eastern Virginia Medical School
Approved: July 24, 2017
Study Purpose: The purpose of the study is to describe the current state of gonorrhea and chlamydia in Portsmouth, Norfolk, Franklin, and Accomack, Virginia in terms of treatment facility, age, gender, race, ethnicity, and diagnosis.

Study #: 40250
Title: Add Health Biology of Chronic Disease Emergence and Medical Outcome Surveillance
Principal Investigator: Eric A Whitsel, MD, MPH, University of North Carolina
Approved: August 1, 2017

Study Purpose: The purpose of this study is to establish a scalable infrastructure for monitoring chronic disease events among men and women who have been tracked from adolescence into adulthood as part of the National Longitudinal Study of Adolescent to Adult Health (Add Health).

Study #: 40251
Title: Using Vital Statistics Natality Data to Assess the Impact of Stressful Events on Birth Outcomes
Principal Investigator: Erdal Tekin, PhD, American University
Approved: August 1, 2017
Study Purpose: The broad goal of this project is to examine the impact of exposure to stressful life events during pregnancy on infant health using geocoded Vital Statistics natality data from birth certificates. To accomplish this broad goal, the researcher proposes to use the beltway sniper attacks that took place during September and October of 2002 in the District of Columbia, Maryland, and Virginia as a source of an extreme level of stress.

Study#: 40252
Title: Registry Linkage and Cohort Study of Cancer Risks in the U.S. for Radiologic Technologists
Principal Investigator: Martha S. Linet, MD, MPH, National Cancer Institute
Approved: September 14, 2017
Study Purpose: The purpose of this study is to follow up with approximately 150K radiologic technologists across the country who have been tracked since the 1980s to study cancer incidence.

Study #: 40253
Title: Neighborhood Deprivation and Preterm Birth: The Mediating Influence of Neighborhood Violence
Principal Investigator: Timothy Ihongbe, Student, Virginia Commonwealth University (VCU)
Dr. Saba W. Masho, VCU faculty.
Approved: September 21, 2017
Study Purpose: The study aims to examine the mediating influence of neighborhood violence on the association between neighborhood deprivation and preterm birth using a sample of women who gave birth between 2006 and 2015 in Richmond City, Virginia.

Study #: 40254
Title: Tick and Lyme Disease Knowledge, Attitudes and Practices in the New River Health District
Principal Investigator: Monica Goyanko, Virginia Tech

Approved: September 22, 2017
Study Purpose: The purpose of this study is to 1) measure the current knowledge in the community of the causes, treatment and prognosis of Lyme disease and 2) to determine if an individual changes their behavior upon receiving information about Lyme disease.

Study #: 40255
Title: Incidence, Latency and Survival of Cancer Following World Trade Center (WTC) Exposure

Principal Investigator: Charles Hall, PhD, Albert Einstein College of Medicine
Approved: September 25, 2017

Study Purpose: This is a long-term follow-up project to study cancer latency. The study combines data from three cohorts of rescue/recovery workers exposed to the WTC site with cancer data to examine which types of cancers have elevated post-exposure risk. The research study will address if cancer incidence is increased after exposure to WTC rescue/recovery effort and which cancers are increased. It will also help to determine how long the post-exposure period is before there is an increased incidence of cancer.

Study #: 40256
Title: Community-wide Study of Cancer Care, Palliative Care and Hospice

Principal Investigator: J. Brian Cassel, PhD, Virginia Commonwealth University
Approved: September 29 2017

Study Purpose: The purpose of this study is to demonstrate the feasibility and value of conducting a population-based study on palliative care for cancer patients by determining if cancer patients who received their care in the Richmond region received specialist palliative care services and, if so, where and when.

Study #: 40257
Title: Understanding User Characteristics, Preferences and Experience to Develop Retention in Care Program for Potential and Active Pre-Exposure Prophylaxis (PrEP) Patients

Principal Investigator: Karen Ingersoll, PhD, University of Virginia
Approved: November 3, 2017

Study Purpose: The purpose of this study is to conduct initial research on adapting a successful HIV retention in care program that was developed at the University of Virginia (Positive Links). The study aims to understand what actions, activities, and information a PrEP related phone app could provide or facilitate for users.

Study #: 40258
Title: Moving Forward Together 3 (Peer Promoting Exercise Adoption and Maintenance among Cancer Survivors)
Principal Investigator: Bernardine M. Pinto, PhD, University of South Carolina
Approved: November 8, 2017
Study Purpose: The study aims to extend the reach of interventions by training Reach to Recovery (RTR) volunteers at the American Cancer Society to deliver intervention and make exercise interventions more accessible to survivors. The data obtained from this study will be useful in guiding cancer care organizations that offer peer support in implementing peer-mentoring approach through exercise.

C. Exempt

Study #: 50201
Title: Exploring Preconception Health in a Diverse Population of Women Using Community Based Participatory Research
Principal Investigator: Audra Gollenberg, Ph.D., Shenandoah University
Approved: January 20, 2017
Study Purpose: The goal of this study is to better understand the thoughts and beliefs regarding health prior to pregnancy and the ways in which programs might assist persons wishing to improve their health in the future.

Study #: 50202
Title: Factors Affecting Farmer's Markets Nutrition Voucher Use among Participants in the Special Supplemental Nutrition Program for Women, Infants and Children
Principal Investigator: Jennifer Mayer, Oceana WIC, Virginia Beach
Approved: January 27, 2017
Study Purpose: The goal of this study is to explore shopping habits, attitudes, and barriers to the use of Farmers' Market Nutrition Program (FMNP) vouchers by the Virginia Beach WIC participants who received vouchers during the 2016 FMNP season.

Study #: 50203
Title: Assessment of Post-Operative Time and Post Discharge Wound Infection of Abdominal Hysterectomy
Principal Investigator: Jinni J. Amin, MPH, Walden University
Approved: February 10, 2017
Study Purpose: The purpose of the study is to examine the overall rate of abdominal hysterectomy surgical site infections following postoperative procedures through analysis of existing VDH data.

Study #: 50204
Title: Fine-Scale Analysis of Forest Fragmentation and Lyme Disease in the New River Health District
Principal Investigator: Korine N. Kolivras, PhD, Virginia Tech
Approved: February 17, 2017
Study Purpose: The purpose of the study is to examine the association between Lyme disease and forest fragmentation in the New River Health District in order to identify environmental risk factors that contribute to Lyme disease.

Study #: 50205
Title: Retrospective Review of Communicable Disease Control Measures
Principal Investigator: Meredith Davis, MPH, Lord Fairfax Health District
Approved: February 27, 2017
Study Purpose: The purpose of the study is to determine the proportion of communicable disease investigations that resulted in implementing one or more public health control measures, the frequency each control measure was used, and timeliness of control measures.

Study #: 50206
Title: Retrospective Analysis of Enteric Disease Exposures
Principal Investigator: Meredith Davis, MPH, Lord Fairfax Health District
Approved: February 27, 2017
Study Purpose: The purpose of the study is to determine the proportion of communicable disease investigations that resulted in the identification of a likely route of exposure and to describe the exposure routes for each disease.

Study #: 50207
Title: Social Determinants of First Live Births in the Peninsula and Hampton Health Districts
Principal Investigator: Kayla Jordan, MPH, Eastern Virginia Medical School
Approved: March 17, 2017
Study Purpose: The purpose of the study is to evaluate descriptive statistics on first live births on the Peninsula (including Newport News, York County, James City County, Williamsburg, Poquoson, and Hampton) over the last three (3) years to determine if there are any specific groups of women with adverse pregnancy outcomes.

Study #: 50208
Title: Effects of Collaboration between Hospitals and Health Departments around Assessments and Plans for Population Health Activities
Principal Investigator: David Chang, MD, DrPH, Portsmouth Health District
Approved: May 10, 2017
Study Purpose: The purpose of this dissertation research study is to better understand the effect that assessment processes have on population health activities, and specifically, what effect, if any, has collaborative assessment and planning processes between health departments and hospitals had in Virginia.

Study #: 50210
Title: Utilization of Dental Services among Pregnant Women
Principal Investigator: Shillpa Naavaal, BDS, MPH, MS, American Board of Dental Public Health, Virginia Commonwealth University
Approved: July 11, 2017
Study Purpose: This study will use the Pregnancy Risk Assessment Monitoring System (PRAMS) data to estimate dental utilization among pregnant women and determine associated factors with the use of dental care during pregnancy in Virginia during 2012-2014.

Study #: 50211
Title: Work-Related Opioid Exposure among Virginia's First Responders
Principal Investigator: Caroline E. Holsinger, PhD, MPH, Virginia Department of Health
Approved: August 1, 2017
Study Purpose: The purpose of this study is to assess Virginia's First Responders' extent of exposure, health effects and knowledge about protective measures to prevent exposure to opioid drugs.

Study # 50212
Title: How Does Post-Secondary Educational Opportunity Affect College and Life Outcomes? Evidence from College Openings in Virginia
Principal Investigator: Kevin Connolly, Harvard University
Approved: November 17, 2017
Study Purpose: The purpose of this study is to determine how educational opportunity affects college and life outcomes.

Study # 50213
Title: Hepatitis C Baseline Knowledge
Principal Investigator: Terry Knick, BSN, RN, University of Virginia Health System
Approved: December 21, 2017
Study Purpose: The purpose of this study is to assess the community's attitudes and knowledge of Hepatitis C in order to develop a plan for education and intervention.

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 2017 Membership		
Committee Members	Qualifications for Service	Institutional Affiliation
IRB CHAIR		
Bethany Geldmaker	PhD in Nursing and Child Health Care Consultant	Office of Family Health Services, Division of Child and Family Health, Virginia Department of Health
VOTING MEMBERS		
Denise Bonds	MD, MPH District Health Director	Thomas Jefferson Health District, Virginia Department of Health
Ana Lizzette Colón	MPH, Eastern Region Epidemiologist	Eastern Region Field Office, Virginia Department of Health
Bethany J. Geldmaker	PhD in Nursing and Child Health Care Consultant	Division of Child and Family Health, Virginia Department of Health
Pastor Maceo Freeman	Doctor of Divinity	St. Paul's Baptist Church
Cecilia Barbosa	PhD in Public Health	Community (non-VDH) Representative
Blythe Balestrieri	PhD in Criminal Justice	Virginia Commonwealth University
ALTERNATE MEMBERS		
Vacant		