

**REPORT TO THE COMMISSIONER:  
ACTIVITIES OF  
THE VIRGINIA DEPARTMENT OF HEALTH  
INSTITUTIONAL REVIEW BOARD  
CALENDAR YEAR 2019**

**Submitted by**

**Bethany Geldmaker, PhD  
Chair  
Virginia Department of Health Institutional Review Board**

**REPORT TO THE COMMISSIONER:  
ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH  
INSTITUTIONAL REVIEW BOARD FOR CALENDAR YEAR 2019**

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 46.104 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 46.110, 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 (based on level of risk, the inclusion of vulnerable subjects, e.g.), 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 VDH IRB chair. Dr. Geldmaker has been an active member of the IRB since 2001.

VDH IRB meetings were held quarterly during 2019: January 14, April 22, July 15, and November 4. 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 2019.

<b>Review Type</b>	<b>Approved</b>	<b>Not Approved</b>
Full Review	1	1
Expedited Review	18	0
Exempt Review	5	0

**I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED:**

**A. Full Reviews**

**Study #:** 70003 -C  
**Title:** Urine Colorimetry for tuberculosis Pharmacokinetics Evaluation in Children and Adults  
**Principal Investigator:** Scott Heysell, MD, MPH, University of Virginia (UVA)  
**Approved:** March 19, 2019 (Previously approved by Rutgers/UVA)  
**Study Purpose:** The purpose of this study is to determine if urine colorimetry during active TB can provide insight comparable to the gold standard blood-based therapeutic drug monitoring and would improve the current “one-size-fits-all” approach to TB around the world

**Study #:** 1-2019  
**Title:** Exposure to Violence as a Precursor to Incarceration for Women  
**Principal Investigator:** Sophie Wenzel, MPH, DrPH, Virginia Tech

**Not Approved:** July 15, 2019 The project, as submitted, does not adequately address the risks for vulnerable participants (prisoners) as required by Federal Regulation 45 CFR 46 subpart C

**Study Purpose:** The purpose of this study is to better understand incarcerated women's exposure to violence prior to incarceration.

## **B. Expedited Reviews**

**Study #:** 40276  
**Title:** Prevalence and Effects of Racial Discrimination among Women Who Recently Gave Birth  
**Principal Investigator:** Jasmine Zapata, MD, MPH, University of Wisconsin-Madison  
**Approved:** January 11, 2019  
**Study Purpose:** The purpose of this study is to describe the prevalence of racial discrimination among non-white childbearing women in the United States, and to explore whether associations exist between experiences of racial discrimination and maternal and infant health outcomes.

**Study #:** 40277  
**Title:** Listeria Knowledge among Pregnant WIC Clients in the Lord Fairfax Health District  
**Principal Investigator:** Meredith Davis, MPH, Virginia Department of Health (VDH), Lord Fairfax Health District  
**Approved:** January 11, 2019  
**Study Purpose:** The purpose of this study is to describe listeria-related knowledge and behaviors among pregnant WIC clients in the Lord Fairfax Health District.

**Study #:** 40278  
**Title:** Investigating the Relationship of Maternal Perceptions, Psychosocial and Sociodemographic Characteristics with Complementary Infant Feeding Practices  
**Principal Investigator:** Michelle Dorsey Graf, RN, MSN, CFNP, Vanderbilt University  
**Approved:** January 18, 2019 (previously approved by Vanderbilt IRB)  
**Study Purpose:** The purpose of this pilot study is to describe maternal perceptions (i.e., risks, benefits, and priorities) of complementary feeding practices and to

investigate the relationships of maternal perceptions, psychosocial, and sociodemographic variables with complementary feeding practices.

**Study #:** 70000  
**Title:** Opioid Pharmacy Qualitative Studies - Fairfax  
**Principal Investigator:** Julia Painter, PhD, MPH and Benjamin Schwartz, MD  
Virginia Department of Health (VDH) Fairfax County  
Health Department  
**Approved:** February 14, 2019  
**Study Purpose:** The purpose of this qualitative study is to gain insights into 1) pharmacists' experiences and observations with counseling and educating around opioids, 2) opportunities and barriers to routinely provide counseling and education, and 3) thoughts about changes that could be made by pharmacists and pharmacies to improve opioid-related outcomes for patients.

**Study #:** 70001  
**Title:** Using Smart Phone Technology to support HIV Medication Refill Adherence in Virginia – Pilot Study  
**Principal Investigator:** Rebecca Dillingham, MD, MPH Virginia Department of Health (VDH) Fairfax County Health Department  
**Approved:** February 28, 2019  
**Study Purpose:** The purpose of this study is to test a smartphone application (app), adapted from a HIV engagement and retention in care app, that aims to aid the process of medication refills.

**Study #:** 70002  
**Title:** Micro-Elimination of Hepatitis C in Rural Appalachian Community; Understanding Patient Treatment Experiences  
**Principal Investigator:** Rebecca Dillingham, MD, MPH University of Virginia (UVA)  
**Approved:** March 27, 2019 (previously approved by the UVA IRB)  
**Study Purpose:** The purpose of this study is to better understand Southwest Virginia patients' experiences with hep C treatment via surveys, case studies, and interviews.

**Study #:** 70004  
**Title:** HIV Pre-Exposure Prophylaxis (PrEP)  
**Principal Investigator:** Mary Beth Cox, MSW, MPH, Virginia Department of Health (VDH)

**Approved:** March 29, 2019  
**Study Purpose:** The purpose of this study is to gain a better understanding of client adherence practices to PrEP and to evaluate the influence of social media and marketing on clients' PrEP decisions.

**Study #:** 70005-C  
**Title:** Implementation Interventions for Pre-Exposure Prophylaxis in Public Health Sexually transmitted Infectious Clinics and Related PrEP Minority Trends  
**Principal Investigator:** Allison Webel, PhD, RN Case Western Reserve University

**Approved:** April 16, 2019 (previously approved as by the Case Western Reserve IRB)

**Study Purpose:** The purpose of this study is to explore interventions used in the implementation of HIV pre-exposure prophylaxis (PrEP) programs in public health sexually transmitted infections (STI) clinics and associated equity in PrEP outcomes by race/ethnicity and other demographic factors. The research aims include:

- 1) Describe barriers and facilitators to minority PrEP services delivery in public health sexually transmitted infections (STI) clinics.
- 2) Examine trends in PrEP care continuum outcomes overall and by STI clinic with respect to patient race/ethnicity, age, sex, gender identity, income, insurance status, and HIV risk factors.
- 3) Characterize implementation interventions that distinguish PrEP services penetration in racial/ethnic minorities.

**Study #:** 70006  
**Title:** Factors Associated with Treatment Disparities among Virginia Cutaneous Melanoma Patients

**Principal Investigator:** Edward Prodanovic, MD, Eastern Virginia Medical School (EVMS)

**Approved:** April 16, 2019 (previously approved by the EVMS IRB)

**Study Purpose:** The purpose of this retrospective study is to identify if there is delay in diagnosis and treatment of patients in Virginia with melanoma, reasons for delay, and cost of treatment.

**Study #:** 70007  
**Title:** Access to Allogeneic Transplant for Patients with Acute Myelogenous Leukemia (AML) in the State of Virginia  
**Principal Investigator:** Karen Ballen, MD, University of Virginia (UVA)

**Approved:** April 16, 2019 (previously approved by the National Marrow Donor Program IRB and by the UVA IRB)

**Study Purpose:** The primary objective of this study is to describe geographic and socioeconomic differences in the rate of hematocrit (HCT) and estimated unmet need among adults diagnosed with AML in Virginia in 2013-2017.

**Study #:** 70008

**Title:** Individuals with Special Health Care Needs (ISHCN)

**Principal Investigator:** Monalisa Mbaitisi, MPH, Virginia Department of Health (VDH)

**Approved:** May 30, 2019

**Study Purpose:** The purpose of this survey is to assess the level of oral health knowledge and current oral health status of Individuals with Special Health Care Needs (ISHCN).

**Study #:** 70009

**Title:** Determining Knowledge and the Uptake of the HPV Vaccine

**Principal Investigator:** Emma Mitchell, PhD, MSN, RN, University of Virginia (UVA)

**Approved:** May 8, 2019 (Previously approved by UVA IRB)

**Study Purpose:** The purpose of this study is to determine knowledge regarding cervical cancer and its connection to the HPV vaccination, as well as determining how much is known about the protection the HPV vaccine provides.

**Study #:** 70010

**Title:** An Examination of Preconception Health and Health Behaviors among Low Socioeconomic Status Women

**Principal Investigator:** Audra Gollenberg, PhD, Shenandoah University

**Approved:** June 3, 2019 (Previously approved by Shenandoah University IRB)

**Study Purpose:** The purpose of this study is to assess the preconception health status among high-risk, low socioeconomic diverse reproductive-aged women using established preconception health indicators; to determine barriers to accessing preconception care among high-risk reproductive age women; and to identify opportunities for engaging health department clients in preconception/inter-conception care.

**Study #:** 70011  
**Title:** Elucidating Multi-Level Factors Related to Cancer Incidence and Morality in Virginia: Insights Gained from the Mid-Atlantic Twin Registry  
**Principal Investigator:** Bernard F. Fuemmeler, PhD, MPH, Virginia Commonwealth University (VCU)  
**Approved:** June 20, 2019 (Previously approved by VCU IRB)  
**Study Purpose:** The study purpose is to create a database that merges data from the Virginia Cancer Registry (VCR) with data from the Mid-Atlantic Twin Registry (MATR) to be used for research purposes. Merging both databases can yield information regarding the following questions: 1) What is the heritability for the most common cancers among those represented in the linked database? 2) To what degree is the influence of genes on cancer risk modified by environmental pollutants and/or aspects of neighborhood deprivation? 3) What are the risk/protective factors associated with cancer?

**Study #:** 70012  
**Title:** Clinical Characteristics and Laboratory Testing of Psittacosis  
**Principal Investigator:** Kelly Shaw, PhD, Virginia Department of Health (VDH)  
**Approved:** July 24, 2019  
**Study Purpose:** The purpose is to study the characteristics of this rare disease in a large group of people and increase awareness of psittacosis among clinical and public health professionals.

**Study #:** 70013  
**Title:** Communicating with Parents about their Child's Sickle Cell Trait Result  
**Principal Investigator:** Beth Tarini, MD, MS, Children's National Health System  
**VDH Collaborator:** Shamaree Cromartie  
**Approved:** August 7, 2019 (previously approved by the Children's National Medical Center IRB)  
**Study Purpose:** The purpose of this study is to explore the counseling experiences of parents after they received their child's sickle cell trait (SCT) results from the Newborn screening and to identify parent's preferences about sickle cell trait disclosure and counseling.

**Study #:** 70014  
**Title:** Quantifying Cancer Morbidity Risks for Users of Smokeless and Combustible Tobacco Products



**Principal Investigator:** Thomas M. Dubinin, PhD, William E. Wecker Associates  
**Approved:** October 3, 2019  
**Study Purpose:** The purposed of this study is to quantify the morbidity and mortality risks of oral cancer (along with cancers of the esophagus, larynx, stomach and pancreas) based on the route of exposure to tobacco products.

**Study #:** 70015  
**Title:** Assessing Factors that Influence Flu Vaccine Uptake in a Point of Dispensing (POD) Setting  
**Principal Investigator:** Laura P. Kornegay, MD, MPH, Virginia Department of Health, Central Shenandoah Health District  
**Approved:** October 18, 2019  
**Study Purpose:** The purposes of this study is to 1) determine how persons found out about the POD; 2) determine motivators for persons to obtain a flu shot in the POD setting; 3) determine the source of information about flu vaccines in correlation with the targeted population groups for pandemic vaccination.

### C. Exempt

**Study #** 50220  
**Title:** Epidemiological Study of Land Applied Biosolids  
**Principal Investigator:** Dwight Flammia, PhD Virginia Department of Health (VDH)  
**Approved:** January 18, 2019  
**Study Purpose:** The purpose of the study is to determine if the application of biosolids to land in Virginia poses a human health risk due to the presence of pathogens in the biosolids.

**Study #:** 50221  
**Title:** Finding Commonalities among Inactive Enrolled Virginia WIC Participants in Order to Provide Suggestions for Outreach and Retention  
**Principal Investigator:** Megan Williams, Virginia Department of Health (VDH)  
**Approved:** July 2, 2019  
**Study Purpose:** The purpose of this project is to determine if enrolled, inactive Virginia WIC participants have common traits that would allow intervention to increase participation.

**Study #:** 50222  
**Title:** Improving Care Giver Adherence to Recommended Infant Care Practices  
**Principal Investigator:** Anne Kellams, MD University of Virginia (UVA)  
**Approved:** August 28, 2019 (previously approved by the UVA IRB)  
**Study Purpose:** The purpose of this pilot qualitative study is to develop and test strategies to improve caregiver adherence to the American Academy of Pediatrics recommended infant care practices related to safe sleep, and to enhance the reach by adding a culturally sensitive prenatal education component targeting low-income populations who are most at risk for sleep-related infant deaths.

**Study #:** 50223  
**Title:** Small Area Estimation of Disability Prevalence  
**Principal Investigator:** Derek A. Chapman, PhD, Virginia Commonwealth University (VCU)  
**Approved:** October 3, 2019 (Previously approved by the VCU IRB)  
**Study Purpose:** The purpose of this project is to determine which neighborhoods within Virginia have high disability prevalence and how neighborhood characteristics impact disability prevalence rates.

**Study #:** 50224  
**Title:** Postpartum Health Care Receipt among Immigrant Women in the United States  
**Principal Investigator:** Maria W. Steenland, ScD, Brown University  
**VDH Contact:** Kenesha Smith Barber, PhD  
**Approved:** November 1, 2019 (Previously approved by the Brown University IRB)  
**Study Purpose:** The purpose of this project is to examine whether state policies for public health care coverage of immigrant women during pregnancy are associated with postpartum health care, health behaviors and health outcomes in this population.

**II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:**

None

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

<b>VDH IRB 2019 Membership</b>		
<b>Committee Members</b>	<b>Qualifications for Service</b>	<b>Institutional Affiliation</b>
<b>IRB CHAIR</b>		
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
<b>VOTING MEMBERS</b>		
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
Blythe Balestrieri	PhD in Criminal Justice	Virginia Commonwealth University
<b>ALTERNATE MEMBERS</b>		
Cecilia Barbosa	PhD in Public Health	Community (non-VDH Representative)