# REPORT TO THE COMMISSIONER:
# ACTIVITIES OF
# THE VIRGINIA DEPARTMENT OF HEALTH
# INSTITUTIONAL REVIEW BOARD
# CALENDAR YEAR 2018

**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 2018

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 46.110, 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, 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 2018: January 8, April 9, July 9, and October 29. 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 2018.

| Review Type | Approved | Not Approved |
|---|---|---|
| Full Review | 0 | 0 |
| Expedited Review | 17 | 0 |
| Exempt Review | 5 | 0 |

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

### A. Full Board Reviews

None

### B. Expedited Reviews

**Study #:** **40259**
**Title:** Community Based Barriers to Care at the Emily Couric Clinical Cancer Center
**Principal Investigator:** Pam DeGuzman, PhD, University of Virginia (UVA)
**Approved:** January 31, 2018 (previously approved by UVA IRB)
**Study Purpose:** The purpose of this study is to assess community-based barriers to screening, prevention, and survivorship care in the community served by the Emily Couric Cancer Center in Charlottesville, Virginia.

**Study #:** **40260**
**Title:** A Qualitative Study of Decision-making in Public Health
**Principal Investigator:** Pam DeGuzman, PhD, University of Virginia (UVA)

**Approved:** January 31, 2018 (previously approved by Walden University IRB)

**Study Purpose:** The purpose of this study is to examine how local public health agencies make decisions after budget cuts. Research questions focus on decision-making processes and the factors that limit those decisions. Study is qualitative in nature by conducting interviews with Virginia Department of Health (VDH) public health officials, reviewing VDH documentation, and reviewing VDH funding.

**Study #:** **40261**
**Title:** Garrett Lee Smith (GLS) Youth Suicide Prevention Program Evaluation
**Principal Investigator:** Lisa Wooten, MPH, Virginia Department of Health (VDH)
**Approved:** February 16, 2018 (previously approved by ICF International IRB)

**Study Purpose:** The purpose of this study is to conduct a National Outcomes Evaluation of the GLS Suicide Prevention Program. The evaluation aims to expand the evidence base for suicide prevention; address factors contributing to suicide deaths and attempts; and establish standards for developing, implementing and evaluating suicide prevention programs.

**Study #:** **40262**
**Title:** Virginia Transgender Health Initiative 2017-2018 Survey Pilot Test
**Principal Investigator:** Dr. Karen Ingersoll, University of Virginia (UVA)
**VDH Contact:** Anne Rhodes, PhD, Virginia Department of Health (VDH) Division of Disease Prevention
**Approved:** March 5, 2018 (previously approved by UVA IRB)

**Study Purpose:** This is a pilot survey to gain perspective on the needs and health-related behaviors of the transgender population in Virginia. The survey is an update from a previous epidemiological study of transgender people conducted in 2005. A small group will pilot the draft survey prior to a full launch throughout the state. The feedback from this study will be used to refine and revise the survey instrument and implementation methodology prior to a statewide launch.

**Study #:** **40263**
**Title:** Zika Family Survey
**Principal Investigator:** Linda Squiers, PhD, Research Triangle Institute (RTI) International
**VDH Contact:** Shea Elizabeth Browne, Virginia Department of Health (VDH)

**Approved:** March 20, 2018 (previously approved by RTI Office of Research Protection)

**Study Purpose:** The purpose of this exploratory multi-state study is to assess the kinds of healthcare and support services that women who were exposed to the Zika virus during pregnancy are receiving and to identify challenges these mothers may encounter in obtaining appropriate services for their infant.

**Study #:** **40264**

**Title:** The Data to Care (D2C) Public Health Strategy: Successes, Challenges and Lessons Learned in Identifying, Linking and Re-engaging Persons Diagnosed with HIV to Medical Care

**Principal Investigator:** James W. Carey, PhD, MPH, Centers for Disease Control and Prevention (CDC)

**Approved:** April 13, 2018 (previously approved by Emory University IRB)

**Study Purpose:** The goal of this study is to identify approaches that have been effective in implementing the D2C program and how health departments use D2C strategies to link and re-engage persons living with HIV (PLWH) in care. D2C is a CDC public health program designed to locate and link PLWH to medical care.

**Study #:** **40265**

**Title:** Third National Survey of WIC Participants (NSWP-III)

**Principal Investigator:** Paul Ruggiere, PhD, 2M Research Services

**Approved:** May 3, 2018 (previously approved by Integ Review IRB)

**Study Purpose:** This is a series of studies designed to provide additional information regarding the characteristics of a nationally representative sample of WIC participants. The studies are designed to produce estimates of improper payments resulting from participant certification errors in the WIC program, document participants' program experiences and state and local policies and operations.

**Study #:** **40266**

**Title:** Using Smart Phone Technology to Support PrEP Uptake and Adherence in Virginia, Pilot Study

**Principal Investigator:** Karen Ingersoll, PhD, University of Virginia (UVA)

**Approved:** May 10, 2018 (previously approved by the UVA IRB)

**Study Purpose:** The purpose of this study is to test the feasibility and acceptability of integrating the PrEP app within local health departments to evaluate usability and satisfaction and measure initial effects of the app on medication adherence and PrEP uptake.

**Study #:** **40267**
**Title:** Understanding Patient and Provider Perceptions of Fruit and Vegetable Prescription Programs in the New River Valley
**Principal Investigator:** Maureen McGonagle, New River Health District
**Approved:** May 17, 2018
**Study Purpose:** The purpose of this study is to explore how patients, providers and administrators perceive and engage with the New River Health District Garden Prescription Program, specifically, what factors influence client and provider use of the Garden Prescription Program.

**Study #:** **40268**
**Title:** Vision 21: Linking Systems of Care for Children
**Principal Investigator:** Jared Keely, PhD, Virginia Commonwealth University (VCU)
**Approved:** May 23, 2018 (previously approved by VCU IRB)
**Study Purpose:** The goals of this study are 1) to document common forms of victimization, behaviors, feelings and symptoms by those who have experienced crime and/or trauma and 2) to determine the reliability and validity of the Virginia Victimization Screen (VVS).

**Study #:** **40269**
**Title:** Evaluation of Data Collected During Sexual Health Clinic
**Principal Investigator:** Clare Ruday, RN, MSN, Thomas Jefferson Health District
**Approved:** June 14, 2018
**Study Purpose:** The purpose of this study is to determine the demographics and behavioral choices that are associated with increased risk to sexual health.

**Study #:** **40270**
**Title:** The Great New Community Survey: Investigating the Health and Wellness of the Transgender and Gender Non-conforming (TGNC) Populations Residing in Virginia
**Principal Investigator:** Karen Ingersol, PhD, University of Virginia (UVA)
**Approved:** August 15, 2018 (previously approved by UVA IRB)
**Study Purpose:** The purpose of the study is to learn more about the health and wellness of the transgender/gender non-conforming population residing in Virginia. The study aims to do the following: learn about the health status and social determinants of health for the TGNC population; evaluate access to quality health care; and assess psychological and behavioral factors associated with increased HIV risk.

**Study #:** **40271**
**Title:** Comparison of DNA Methylation Profiles in Leukocytes, Prostate Cancer Tissues and Adjacent Normal Prostate Tissues among Vegans and Non-vegetarians
**Principal Investigator:** Gary Fraser, MD, Loma Linda University (LLU)
**Approved:** September 12, 2018 (previously approved by LLU IRB)
**Study Purpose:** To determine if diet-specific DNA methylation pattern in tissues, already found in blood cells, are present in both normal tissue and cancer tissue. A finding of consistent differences in epigenetic patterns in biologic material from subjects with different dietary patterns could open wide perspectives for further research including the development of anti-cancer therapies, starting from prevention to more effective and person-specific approaches to treatment.

**Study #:** **40272**
**Title:** Thomas Jefferson Health Department (TJHD) Community Health Survey
**Principal Investigator:** Denise E. Bonds, MD, MPH, Thomas Jefferson Health District
**Approved:** September 15, 2018
**Study Purpose:** The purpose of this study is to better understand the general health of residents within the Thomas Jefferson Health District by specific geographic groupings. The researchers are interested in learning about physical activity, diet, food security, body mass index (BMI), use of and access to various types of health care, and perceptions of and experiences in the community.

**Study #:** **40273**
**Title:** IUD Expulsions in Adolescent Patients
**Principal Investigator:** Kim Luk, MD, MPH, Alexandria Health Department
**Approved:** November 7, 2018
**Study Purpose:** The purpose of this study is to assess the frequency of intrauterine device (IUD) expulsions in adolescent patients and the potential factors that may predispose youth to expulsions.

**Study #:** **40274**
**Title:** Influences on Human Papillomavirus Vaccination among Adolescents in Rural Populations
**Principal Investigator:** Heather Childress, RN, Bluefield College
**Approved:** November 7, 2018 (previously approved by Bluefield College IRB)

**Study Purpose:** The purpose of this study is to determine parental beliefs about vaccines and document how the beliefs influence the initiation of HPV vaccine.

**Study #:** **40275**
**Title:** Understanding User Characteristics, Preferences and Experiences to Develop an mHealth Recovery Aid for Active Suboxone Clients
**Principal Investigator:** Chelsea Canan, PhD, MPH, University of Virginia
**Approved:** November 20, 2018 (previously approved by UVA IRB)
**Study Purpose:** The goal of this study is to conduct research into the adaption of an existing smartphone app currently used by HIV patients for individuals in opioid use disorder recovery. The information will be used to understand what types of mobile app features these patients believe would benefit them in their recovery.

**C. Exempt**

**Study #:** **50215**
**Title:** Emergency Room Visits Related to Poor Ambient Air Quality
**Principal Investigator:** Dwight Flammia, PhD, Virginia Department of Health (VDH)
**Approved:** April 25, 2018
**Study Purpose:** The purpose of this study is to examine whether poor ambient air quality has an impact on public health in the form of increased emergency room visits or hospital admissions.

**Study #:** **50216**
**Title:** Evaluation of Sexual Health Education Sessions at the New River Valley Regional Jail
**Principal Investigator:** Sophie Wenzel, MPH, (DrPH Candidate) VA Tech
**Approved:** June 5, 2018 (previously approved by VA Tech IRB)
**Study Purpose:** The purpose of the study is to understand whether sex education classes provided at a regional jail are effective in improving sexual health among recently released inmates.

**Study #:** **50217**
**Title:** To Evaluate the Timeliness and Completeness of Reporting of Salmonella Surveillance in the US State Health Departments, 2011-2016
**Principal Investigator:** Palak Panchal, MPH, University of Illinois at Chicago

(UIC)

**Approved:** June 22, 2018 (previously approved by the UIC IRB)

**Study Purpose:** The purpose of this study is to evaluate the timeliness and completeness of reporting of Salmonella surveillance in US state health departments, 2011-2016. The objectives are to determine the time involved in the critical steps in case identification, reporting process, and completeness of reporting. The study may provide a framework for developing best practices across the states for Salmonella disease surveillance.

**Study #:** **50218**

**Title:** Presumptive and Follow-up Treatment for Gonorrhea and Chlamydia among Patients Attending Public Health Department Clinics in Virginia, 2016

**Principal Investigator:** River Pugsley, PhD, Centers for Disease Control and Prevention/Virginia Department of Health

**Approved:** September 12, 2018

**Study Purpose:** The purpose of this study is to describe the prevalence and appropriateness of presumptive treatment for Chlamydia and Gonorrhea in sexually transmitted disease and family planning clinics in Virginia. The study will examine both patient and clinic characteristics and document the variations in treatment outcomes in patients who were not presumptively treated.

**Study #:** **50219**

**Title:** The Effects of Land Cover Change on the Spatial Distribution of Lyme Disease in Northern Virginia Since 2001

**Principal Investigator:** Megan Stevenson, Virginia Tech (VA Tech)

**VDH Collaborator:** David Gaines

**Approved:** September 12, 2018 (previously approved by VA Tech IRB)

**Study Purpose:** The purpose of the study is to determine if the geographic distribution of Lyme disease in Northern Virginia has increased in spatial extent and density since 2001 in correlation to the increasing suburbanization of the counties and to determine if forest fragmentation results in increased risk for Lyme disease.

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

None

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

| VDH IRB 2018 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<br>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 (resigned effective July 2018; currently serve as alternate) | PhD in Public Health | Community (non-VDH) Representative |
| Blythe Balestrieri | PhD in Criminal Justice | Virginia Commonwealth University |
| **ALTERNATE MEMBERS** | | |
| Cecilia Barbosa | PhD in Public Health | Community (non-VDH Representative) |