COMMONWEALTH of VIRGINIA
Department of Health
Karen Shelton, MD
State Health Commissioner
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

May 15, 2024

MEMORANDUM

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable L. Louise Lucas
Chair, Senate Finance and Appropriations Committee

The Honorable Luke E. Torian
Chair, House Appropriations Committee

FROM: Karen Shelton, MD
State Health Commissioner, Virginia Department of Health

SUBJECT: Institutional Review Board Annual Report 2022

This report is submitted in compliance with the Code of Virginia – § 32.1-12.1 , which states:

> *The Board shall promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of this title for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Commissioner or his designee at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved.*

Should you have any questions or need additional information, please feel free to contact me at (804) 864-7002.

KS/AJ
Enclosure

Pc: The Honorable John Littel, Secretary of Health and Human Resources

ACTIVITIES OF
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2022

Submitted by

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

VDH VIRGINIA DEPARTMENT OF HEALTH

ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD FOR CALENDAR YEAR 2022

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 Federal wide 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.

The primary responsibility of the VDH IRB is to protect the rights and wellbeing of human subjects who participate in research. The federal regulations (45 CFR 46.111) provides that the IRB may only approve research after it has determined that all the following requirements are met:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by §46.116.
- Informed consent will be appropriately documented or appropriately waived in accordance with §46,117.
- When appropriate, the research plan makes adequate provision of monitoring the data collected to ensure the safety of subjects.
- VDH IRB requires that investigators and other key project staff are trained in the rights and protection of human subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- Additionally, when some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either an 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 board 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 2022: January 10, April 11, and October 17. 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 2022.

Review Type	Approved	Not Approved
Full Review	*0*	0
Expedited Review	9	0
Exempt Review	27	0

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED:

A. Full Reviews None

B. Expedited Reviews

Study #: **70050**
Title: Mortality Data for the Translational Data Warehouse
Principal investigator: Brian Wells, Wake Forest Health Services
Study Purpose: The purpose of this project is to expand the translational data warehouse at Wake Forest University to include routine patient care data on North Carolina residents who died in Virginia.
Approved: January 18, 2022 (previously approved by the Wake Forest Health Services IRB)

Study #: **70051**
Title: Firearm Injuries in Virginia - Focusing on Community Impact
Principal investigator: Lauren Yerkes, MPH Virginia Department of Health
Study Purpose: The purpose of this study is to better understand how firearm injuries affect Virginians through the conduct of focus groups.
Approved: April 28, 2022

Study #: **70052**
Title: Implementation of Low-Cost Solutions to Help Facilitate Linkage to Care for Persons with Hepatitis C Virus (HVC) Infection
Principal investigator: Cynthia Morrow, MD, MPH, Virginia Department of Health and Marrieth Rubio, MD, Carilion
Study Purpose: The purpose of the study is to determine if an intervention will lead to a greater likelihood of an individual identified as having HCV attending their first treatment appointment. This is a qualitative/quantitative study, informed by current literature, asking patients with a new diagnosis of HCV infection, patients with a history of HCV infection, and providers who specialize in HCV treatment about their perceptions of barriers and facilitators to treatment.
Approved: April 28, 2022 (previously approved by the Carilion IRB)

Study #: **70053**
Title: The Effects of LARC- A Focused Initiative
Principal investigator: Analisa Packham, Ph.D. Vanderbilt University
Study Purpose: The purpose of this study is to determine the effects of contraceptive access on health outcomes such as unintended pregnancy rates and abortion rates. VDH and Vanderbilt are interested in noting any impacts of these programs related to geography, race, ethnicity, age, and any other patient trends that are presented in the data.
Approved: July 5, 2022 (previously approved as exempt by Vanderbilt University IRB).

Study #: **70054**
Title: Integrated Plan Focus Groups
Principal investigator: Ashley Yokum, Virginia Department of Health
Study Purpose: The purpose of this study is to conduct focus groups to assess service needs and gaps in accessing HIV prevention and care services, and to identify potential barriers to the uptake of HIV testing, HIV prevention, and HIV care services.
Approved: July 26, 2022

Study #: **70055**
Title: Overdose Prevention Behavior and the Risk Environment among People Who Inject Drugs in Rural Appalachia
Principal investigator: Billy Brooks, Eastern Tennessee State University (ETSU)
Study Purpose: The purpose of this study is to identify overdose prevention behaviors reported by individuals who inject drugs and develop a theory based behavioral model of overdose prevention behaviors for rural Appalachian people who inject drugs.
Approved: July 26, 2022 (previously approved as exempt by ETSU)

Study #: **70056**
Title: People with Active Opioid Use Disorder as First Responders to Overdoses: Improving Implementation Intentions to Administer Naloxone
Principal investigator: Franklin Edwards, Virginia Tech
Study Purpose: The goal of this exploratory study is to test a low-cost and just-in-time adaptive planning intervention to increase Naloxone obtainment, carriage, discussion, and administration among people who use opioids.
Approved: October 12, 2022 (previously approved by Virginia Tech IRB)

Study #: **70057**
Title: The Decision-Making Process of Persons with Latent Tuberculosis for Preventative Treatment: A Grounded Theory Mini-study
Principal investigator: Amber Harmon, Duquesne University (VDH)
Study Purpose: This study aims to understand the decision-making process a person with latent tuberculosis infection uses when considering treatment to prevent tuberculosis (TB).
Approved: October 12, 2022 (previously approved by Duquesne University IRB)

Study #: **70058**
Title: Air Pollution, Heat, Cold, and Health: Disparities in the Rural South
Principal investigator: Michelle Bell, Yale University
Study Purpose: This research aims to investigate the hypothesis that higher exposure to environmental health risk factors (e.g., air pollution, weather variables, climate, land use) is associated with higher risks and burdens of health outcomes such as deaths and birth outcomes in rural populations in the US and such associations differ by individual-level and community-level health determinants.
Approved: November 15, 2022 (previously approved by Yale University IRB)

C. Exempt

Study #: **50260**
Title: Valuing Black Assets to Close Racial Health Disparities
Principal Investigator: Johnathan Rockwell, Gallup Institute
Study Purpose: The purpose of this study is to identify the social factors and characteristics of the physical environment that predict mortality at the zip code level, including exposure to pollution, green space, tree cover, and walkable communities. Brookings Metro proposes to develop a body of research that identifies and analyzes structures inherent in neighborhoods that predict positive outcomes: asset-based social determinants of health including infrastructure, education, housing, businesses, and other factors.
Approved: January 18, 2022

Study #: **50261**
Title: Viral Suppression for People with HIV with Low Incomes: Study of Disparities, Health Equity, and Cost-Effectiveness
Principal Investigator: Kathleen McManus, University of Virginia (UVA)
Study Purpose: The purpose of this study is to identify the modifiable aspects of healthcare delivery that optimize viral suppression in low-income people with HIV.
Approved: January 18, 2022 (previously approved by the UVA IRB)

Study #: **50262**
Title: Injectable PrEP Focus Group/Survey
Principal Investigator: Shahid Hafidh, Virginia Department of Health
Study Purpose: The purpose of the focus group/survey is to identify the knowledge that individuals have regarding the pre-exposure prophylaxis medication for the prevention of HIV (Injectable PrEP) and any barriers that may exist in the availability of obtaining the medication.
Approved: February 2, 2022

Study #: **50263**
Title: Virginia Department of Health: Building a Sustainable Data Commons to Support Strategic Planning
Principal Investigator: **A**aron Schroeder, PhD, University of Virginia (UVA)
Study Purpose: This study is a collaboration between the UVA Social and Decision Analytics Division and the Virginia Department of Health to design and build a common data set to support the dissemination of health information to policy makers, community leaders, health professionals, and the public as target audiences.
Approved: February 2, 2022 (previously approved by the UVA IRB)

Study #: **50264**
Title: A Multi-site Surveillance System to Characterize Prevalence, Natural History, Healthcare Service Use, Cost and Disparities in Access to Care; MD STARnet
Principal Investigator: Dr. Nicholas Johnson, Virginia Commonwealth University (VCU)
Study Purpose: The purpose of this study is to improve the care for those living with muscular dystrophy by expanding the MD STARnet system that collects critical information about muscular dystrophy by adding birth and death data for patients with muscular dystrophy.
Approved: February 8, 2022 (previously approved by VCU IRB)

Study #: **50265**
Title: Syphilis in the Valley: A Review of Current Screening Techniques of Primary Care Physicians in Frederick County/Winchester City, Virginia
Principal Investigator: Clarissa Bonnefond, Fredrick County Health Department
Study Purpose: The purpose of this survey of the primary care physicians (PCP) in Frederick County and Winchester City is to determine the number of patients screened and treated for Syphilis, how well the physicians feel they can identify syphilis, and what they feel needs to be improved.
Approved: February 15, 2022

Study #: **50266**
Title: Examining the Prevalence of SARS-CoV-2 Virus Infection and Variant Cases between International and Domestic Travelers and Non-Travelers in Virginia.
Principal Investigator: Stephen Duong, Virginia Commonwealth University (VCU) Student
Study Purpose: The study aims to examine the prevalence of SARS-CoV-2 cases and variant data between Virginians who have a history of international traveling and non-international traveling. The type of variants sequenced from the patients' specimens will also be examined.
Approved: February 16, 2022

Study #: **50267**
Title: Prevalence of Lyme Disease and Illness Onset Dates in Southwest Virginia
Principal Investigator: Tara Keen, Virginia Commonwealth University (VCU) Student

Study Purpose: The study will investigate the prevalence of Lyme disease over time by Virginia health region and average Lyme disease illness onset dates of all health regions in Virginia by year, between 2017- 2021. A descriptive epidemiologic analysis will be conducted to determine the demographics of individuals in the Southwest region with Lyme disease relative to those in the rest of the state without Lyme disease.
Approved: February 22, 2022 (previously approved by VCU IRB)

Study #: **50268**
Title: Emergency Medical Services (EMS) Provider Suicide Analysis
Principal Investigator: Jessica Rosner, VDH Office of Emergency Medical Services
Study Purpose: The purpose of this study is to identify demographic and work-related characteristics (e.g., marital status, years of service, volunteer status) associated with Emergency Medical Services (EMS) provider suicide.
Approved: February 22, 2022

Study #: **50269**
Title: 2022 Virginia EMS Provider Mental Health Survey
Principal Investigator: Vincent Valeriano, VDH Office of Emergency Medical Services
Study Purpose: The aim of this cross-sectional study using a voluntary anonymous survey is to evaluate the mental health status of Virginia's EMS providers and assess the perceived mental health cultures, services, and barriers to seeking help within providers' agencies.

Study #: **50270**
Title: A Comparison of Health Outcomes for SARS-CoV-2 Variant Infections in Virginia
Principal Investigator: Brandy Darby, DVM, MPH, Virginia Department of Health
Study Purpose: The purpose of this study is to compare health outcomes for patients infected with different lineages of SARS-CoV-2 identified in Virginia. The rate of symptomatic illness, hospitalization and death will be examined for the different lineages of SARS-CoV-2.
Approved: March 23, 2022

Study #: **50271**
Title: EMS Provider Death Analysis
Principal Investigator: Jessica Rosner, Virginia Department of Health
Study Purpose: The purpose of this study is to identify work-related characteristics (e.g., overexertion, line of duty injuries) associated with Emergency Medical Services (EMS) provider mortality.
Approved: March 29, 2022

Study #: **50272**
Title: State of Viral Hepatitis in Virginia, 2022 Assessment
Principal Investigator: Nicole Barron, Virginia Department of Health
Study Purpose: The purpose of this study is to assess viral hepatitis services and care in Virginia by establishing a baseline of exiting hepatitis services, service gaps, and barriers to providing/accessing services across all areas of Virginia.

Approved: April 28, 2022

Study #: **50273**
Title: Evaluating the Level of Care Provided to EMS Patients in Virginia When a Paramedic was On-scene
Principal Investigator: Adam Harrell, Virginia Department of Health
Study Purpose: This study will compare the level of care required to treat EMS patients with the level of certification on-scene EMS providers are able to deliver to determine the appropriate level of care provided.
Approved: June 6, 2022

Study #: **50274**
Title: PrEP Retention Awareness Survey
Principal Investigator: Christian Ryan, Virginia Department of Health
Study Purpose: The purpose of this study is to determine barriers to obtaining HIV pre-exposure prophylaxis medication (PrEP) for current clients, unenrolled clients and those not offered the medication.
Approved: June 6, 2022

Study #: **50275**
Title: Enteric Illness in Lord Fairfax District: Campground Owners' Knowledge of Waterborne enteric illness
Principal Investigator: Clarissa Bonnefond, Virginia Department of Health
Study Purpose: The purpose of this project is to gain an understanding of Lord Fairfax campground owners' level of knowledge regarding waterborne enteric illnesses.

Study #: **50276**
Title: Health Risk Behavior among Pregnant Women in Virginia
Principal Investigator: Melissa Little, PhD, MPH, University of Virginia (UVA)
Study Purpose: This is a retrospective study using Pregnancy Risk Assessment Monitoring System (PRAMS) de-identified data to examine health risk behaviors among pregnant women in Virginia.
Approved: July 26, 2022 (previously approved by UVA IRB)

Study #: **50277**
Title: Community Health Worker Assistance in Emotional Wellbeing
Principal Investigator: Carter Hall, College of William and Mary
Study Purpose: The purpose of this study is to determine the effectiveness of Community Health Workers in gaining client access to mental health, substance use, and domestic violence resources.
Approved: July 26, 2022 (previously approved by the College of William and Mary)

Study #: **50278**
Title: Health Disparities in Pancreatic Cancer
Principal Investigator: Dr. Jose Trevino, Virginia Commonwealth University (VCU)
Study Purpose: This is a retrospective analysis of Virginia Cancer Registry data to explore the existence of potential health disparities such as age, race, ethnicity, geography, food availability, etc. in pancreatic cancer patient outcomes. **f**
Approved: September 6, 2022 (previously approved by VCU IRB)

Study #: **50279**
Title: PrEP Uptake at Syringe Exchange Sites Study
Principal Investigator: Shahid Hafidh, Virginia Department of Health
Study Purpose: The purpose of this study is to access VDH clients' willingness to try HIV pre-exposure prophylaxis medication (PrEP).
Approved: September 14, 2022

Study #: **50280**
Title: Factors Associated with Substance Use Disorder in Virginia
Principal Investigator: Theresa J. McCann, PhD, MPH, CHSE, Virginia Tech
Study Purpose: This research project aims to better understand the relationships between various risk factors, in particular adverse childhood experiences (ACE) and social determinants of health (SDOH) and use of alcohol, tobacco, marijuana, and intravenous drugs among young adults.
Approved: October 12, 2022 (previously approved by Virginia Tech IRB)

Study #: **50281**
Title: Diversifying Cancer Registries to Include the Southwest Asian North African (SWANA) Community
Principal Investigator: Guleer Shahab, MPH, Virginia Commonwealth University (VCU)
Study Purpose: This study aims to examine the extent and impact of racial misclassification experienced by the Southwest Asian North African community within the context of cancer burden and to determine the differences in cancer incidence for the SWANA community as compared to the White community
Approved: October 18, 2022 (previously approved by the VCU IRB)

Study #: **50282**
Title: COVID-19 Lockdown Effects on Domestic Violence (DV) Among Virginians
Principal Investigator: Kenneth Gordon, Virginia Department of Health (Walden University)
Study Purpose: The study aims to determine the effects of the COVID-19 containment measures on the prevalence of Domestic Violence among Virginians. The data will provide information on the association between the pandemic's containment measures (lock-downs, shelter in place) and DV prevalence, the perpetrators' characteristics and hospitalization.
Approved: November 17, 2022 (previously approved by the Walden University IRB)

Study #: **50283**
Title: Pregnancy Outcomes in Relation to Maternal Oral Health during Pregnancy: Data from Pregnancy Risk Assessment Monitoring System (PRAMS)
Principal Investigator: May Salama, Old Dominion University (ODU)
Study Purpose: This study will analyze PRAMS data to test for the association between maternal self-reported oral health practices, and pregnancy outcomes, specifically low birth weight and preterm birth.
Approved: November 17, 2022 (previously approved by ODU IRB)

Study #: **50284**
Title: Characterizing Monkeypox Disease Risk from Contact Monitoring Data— Virginia, May 1–November 1, 2022
Principal Investigator: Eleanor Field, Virginia Department of Health
Study Purpose: The purpose of this study is to analyze existing data on persons with known exposures to monkeypox to understand factors such as sexual activity and underlying health conditions that may be associated with case outcomes.
Approved: December 1, 2022

Study #: **50285**
Title: Determining Heat Attributable Healthcare Visits in Virginia
Principal Investigator: Meredith Davis, Virginia Department of Health
Study Purpose: The purpose of this study is to explore the relationship between emergency department (ED) visits and heat index (temperature and humidity). The study will explore heat attributable ED visits by VDH health region and by rural/urban classification. Ultimately, the goal is to identify heat event thresholds to inform timely implementation of mitigation measures by public health to prevent heat-related illness.
Approved: December 1, 2022

Study #: **50286**
Title: Address COVID-19 Health Disparities Among Population at High-Risk and Underserved
Principal Investigator: Caitlin S. Pedati, MD, MPH, FAAP, Virginia Beach Health Department (partnering with EVMS)
Study Purpose: The purpose of this study is to determine ways to address COVID-19 health disparities among populations at high risk and underserved.
Approved: December 1, 2022

II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:

Study #: **40222**
Title: National HIV Behavioral Surveillance (NHBS)
Adverse Event: During the HIV test portion of the project, the participant stated to a member of the NHBS Field Staff that if they tested positive for HIV, they know who may have

infected them. The participant then started making threats toward the person who may have exposed them. The NHBS Field Staff then declined to tell the participant their HIV test result. Not presenting the test results to the participant is technically a protocol violation. A Field Incident Report form was completed and forwarded to the Centers for Disease Prevention and Control (CDC) and the VDH IRB was notified of the adverse event. CDC responded that the NHBS Field Staff member took the correct action by declining to give the test result.

VDH IRB Action: The IRB reviewed the adverse event and forwarded a letter to the Principal Investigator (PI) stating that the VDH IRB agreed with the action taken by the interviewer. The letter also suggested that the PI may consider updating the protocol to address this type of situation and/or address in future interviewer trainings.

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

VDH IRB 2022 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
Nicole Bissell	MD, MPH	New River Health District, Virginia Department of Health
ALTERNATE MEMBERS		
Janice Hicks	PhD in Social Policy and Social Work	Virginia Department of Health