



COMMONWEALTH of VIRGINIA

B. Cameron Webb, MD, JD
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

10/20/2026

MEMORANDUM

TO: The Honorable Abigail D. Spanberger
Governor of Virginia

The Honorable L. Louise Lucas
President Pro-Tempore, Senate of Virginia

The Honorable Don Scott
Speaker, House of Representatives

FROM: Dr. Cameron Webb
State Health Commissioner, Virginia Department of Health

SUBJECT: 2025 Annual Institutional Review Board (IRB) Report on Human
Subjects Research

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.

CW/KB
Enclosure

Pc: The Honorable Marvin B. Figueroa, Secretary of Health and Human Resources

2025 ANNUAL INSTITUTIONAL REVIEW BOARD (IRB) REPORT ON HUMAN SUBJECTS RESEARCH

CALENDAR YEAR 2025

REPORT TO THE GOVERNOR AND THE
GENERAL ASSEMBLY

CY2025

VIRGINIA DEPARTMENT OF HEALTH



PREFACE

The Virginia Department of Health (VDH) is submitting this report in compliance with the Code of Virginia § 32.1-12.1. The mandate requires the Virginia Department of Health 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 any significant deviations from the proposals as approved.

VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD MEMBERS

Virginia Commonwealth University

Dr. Antonio Payares, Adjunct Professor, Department of Kinesiology

Dr. Kristi Mincey, Director, Undergraduate Public Health Education and Training

St. Paul's Baptist Church

Dr. Maceo Freeman, Jr., Prime Time Life Stage Pastor

Virginia Department of Health

Dr. Bethany Geldmaker, Chair, Child Health Consultant, Office of Family Health Services

Dr. Kavita Imrit-Thomas, Director, Portsmouth Health District

Ana Lizzette Colón, Epidemiologist, Eastern Region Field Office

Dr. Noelle Bissell, Director, New River Health District

Henrico County Public Schools

Dr. April Eikerenköetter, Educator

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EXECUTIVE SUMMARY

During 2025 the Board reviewed five (5) non-exempt research studies and twenty (20) exempt research studies. All studies were determined to present minimal risk to human subjects and were approved by the IRB. During the year, the IRB did not identify any significant deviations from the approved research proposals.

INTRODUCTION

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 any facility operated, funded or licensed by the department, that conducts or 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) to serve as the human research committee. In addition, a guidance document, *Virginia Department of Health Institutional Review Procedures*, was updated in May 2025.

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 (FWA) for its IRB from the 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 Code of Federal Regulations (45 CFR § 46.111) provides that the IRB may only approve research after it has been 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.

- 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 confidentiality of data.
- Additionally, when some or all 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.

Research classified as *exempt* involves minimal or no risk to participants and is exempt from certain requirements of the Federal Policy for the Protection of Human Subjects (45 CFR § 46). Although exempt, it is still considered human subjects research and must be reviewed by the IRB to verify that it meets the criteria for exemption. Researchers remain responsible for protecting participants' rights. Common types of exempt research include normal educational practices, surveys, interviews, observations of public behavior, benign behavioral interventions with adults, secondary use of publicly available or de-identified data, and taste or food quality studies.

Non-exempt research does not meet the exemption criteria under 45 CFR § 46.104 and may involve more than minimal risk, vulnerable populations, sensitive topics, or invasive procedures. These studies require IRB review through either an expedited or full-board process. Expedited review is allowed only for studies involving no more than minimal risk and that fall within specific procedural categories established by DHHS, such as certain clinical studies of drugs or devices, blood sample collection, prospective biological specimen collection, non-invasive data collection procedures, use of existing non-research data, and voice or image recording. Expedited reviews are conducted by designated IRB members, with final approval by the IRB chair. Full-board review is required when studies involve higher risk or vulnerable populations. In these cases, the proposal is reviewed at a convened meeting with a quorum of IRB members, and approval requires a majority vote.

VDH IRB meetings were held quarterly during 2025: February 3, April 7, July 14, and October 6. Minutes are available on request.

DESCRIPTION OF IRB REVIEWED STUDIES

The following is a description of the research studies reviewed and approved by the Virginia Department of Health Institutional Review Board during 2025.

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED:

A. NON-EXEMPT

Study #: 70089
Title: Crater Health District Long COVID Surveillance Project

Principal investigator: Katrina Saphrey, MPH, CIC, Virginia Department of Health (VDH)

Study Purpose: The purpose of this project is to determine the prevalence of Long COVID cases among reported confirmed and probable cases in Crater Health District residents, adopt a Long COVID definition, and determine the impacts of Long COVID on activities of daily living.

Approved: January 17, 2025

Study #: 70090

Title: Evaluation of Medication for Opioid Use Disorder in Fairfax County Adult Detention Center, funded by Opioid Abatement Authority

Principal investigator: Dr. Evan Lowder, Ph.D., and Dr. Chelsea Foudray, George Mason University (GMU)

Study Purpose: This study aims to examine fatal and non-fatal overdoses as well as behavioral health and criminal justice outcomes in the Fairfax County Adult Detention Center population following the initiation of buprenorphine while incarcerated and referral to community resources upon release.

Approved: February 4, 2025

Study #: 70091

Title: Prince William Health District Community Health Assessment (CHA) Youth Input from Focus Group

Principal investigator: Diane Anderson, DrPH, Virginia Department of Health (VDH)

Study Purpose: The purpose of this study is to identify the health concerns, behaviors and needs of youth residing in the Greater Prince William Region.

Approved: February 18, 2025

Study #: 70092

Title: Risk of Cancer Among Firefighters: A Registry-Based Case-Control Study

Principal investigator: Toby Egan, Ph.D., University of Maryland (UMD)

Study Purpose: This study compares cancer rates between those with an occupation listed as firefighter and non-firefighter to determine if the rates differ and if firefighters are predisposed to certain types of cancer.

Approved: June 19, 2025

Study #: 70093

Title: The Impact of Virginia's Medicaid Expansion on Breast Cancer Diagnosis, Treatment, and Surgical Intervention

Principal investigator: Rebecca Britt, MD, FACS, Eastern Virginia Medical School (EVMS)

Study Purpose: The purpose of this study is to determine whether Virginia's Medicaid expansion impacts breast cancer diagnosis, treatment, and surgical intervention.

Approved: July 15, 2025

B. EXEMPT

Study #: 50332
Title: Emergency Medical Services (EMS) Prehospital Needle Decompression for Tension Pneumothorax
Principal Investigator: Daisy Banta, MPH, Virginia Department of Health (VDH)
Study Purpose: The purpose of this study is to identify the necessity of needle decompression procedures performed in cases of suspected tension pneumothorax during patient care in the pre-hospital setting.
Approved: February 19, 2025

Study #: 50333
Title: Emergency Medical Services (EMS) Prehospital Blood Administration
Principal Investigator: Jessica Rosner, DrPH, Virginia Department of Health (VDH)
Study Purpose: The purpose of this study is to determine if patients who receive blood products in the pre-hospital setting experience increased rates of survival and lower rates of medical complications than patients who do not receive pre-hospital blood products.
Approved: February 19, 2025

Study #: 50334
Title: Alexandria Youth Risk Behavior Survey (YRBS) Data Analysis Practicum Project
Principal Investigator: Danait Tzeggai, MPH, Virginia Department of Health (VDH)
Study Purpose: This study will assess data from the 2023 Youth Risk Behavior Survey from Alexandria students to analyze associations between specific behaviors and academic performance at the local level, allowing for development of tailored public health interventions.
Approved: March 18, 2025

Study #: 50335
Title: Perinatal Mental Health Analysis from Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) and the Postpartum Assessment Health Survey (PAHS)
Principal Investigator: Marie Thoma, Ph.D., University of Maryland (UMD)
Study Purpose: This study aims to assess the prevalence of perinatal depression, anxiety, and other perinatal mood and anxiety disorders (PMADs) and the utilization of associated health care services among WIC-eligible populations in Virginia.

Approved: March 18, 2025

Study #: 50336

Title: Analysis of Enteric Disease and Gastrointestinal Illness Outbreak

Principal Investigator: Taylor Bullard, Virginia Department of Health (VDH) and Old Dominion University (ODU)

Study Purpose: This purpose of this study is to better understand gastrointestinal illness outbreaks in Virginia's Northwest Region. The study will analyze data from two of VDH's surveillance systems.

Approved: April 2, 2025

Study #: 50337

Title: Rare Disease Survey

Principal Investigator: Lauren Staley, MPH, Virginia Department of Health (VDH) and the Rare Disease Council (RDC)

Study Purpose: The purpose of this survey is to identify the needs of individuals affected by rare diseases in the Commonwealth, to determine the challenges and barriers experienced.

Approved: April 15, 2025

Study #: 50338

Title: Buprenorphine Dispenses and HCV/HIV Infection in Virginia

Principal Investigator: Elham Erfanian, Ph.D., Black Hills State University (BHSU)

Study Purpose: The purpose of this study is to examine the association between the use of buprenorphine and HCV/HIV infection in Virginia.

Approved: April 15, 2025

Study #: 50339

Title: The Impact of Commercial Accountable Care Organizations (ACO) in Improving Adolescent Vaccinations and Reducing Associated Disparities in Virginia

Principal Investigator: Shillpa Naavaal, Ph.D. and Askar Chujmaitow, MD Virginia Commonwealth University (VCU)

Study Purpose: The purpose of this study is to evaluate whether primary care clinics in ACOs achieve higher Human papillomavirus (HPV), Meningococcal, Tdap, and Influenza (Flu) vaccination rates among adolescents aged 9-17 relative to non-participating providers.

Approved: April 16, 2025

Study #: 50340

Title: Bridging Recovery: Evaluating Clinical and Community Impact Across Four Public Health Pathways for Substance Use Response

Principal Investigator: Arushi Arora, HPH.D., Virginia Department of Health (VDH) Internship Academy

Study Purpose: The purpose of this study is to evaluate the Peninsula Health District Comprehensive Harm Reduction program's response to

substance use to determine the impact on clinical and community outcomes.

Approved: June 3, 2025

Study #: 50341

Title: Flood Attributable Visits in Virginia Using ESSENCE and Weather Data

Principal Investigator: Julia Gohlke, Ph.D., Virginia Tech (VT)

Study Purpose: The purpose of this study is to explore the relationship between flood attributable healthcare visits and flooding within the patient's home zip code to determine variations by rural/urban classification and healthcare professional shortage areas.

Approved: June 3, 2025

Study #: 50342

Title: Data Matching – Exploring Cognitive Spectrums through Twins (aka the Twin Spectrum Study)

Principal Investigator: Elizabeth Prom-Wormley, Ph.D., MPH, Mid-Atlantic Twin Registry (MATR), Virginia Commonwealth University (VCU)

Study Purpose: The primary objective of this study is to utilize a large twin registry, the Mid-Atlantic Twin Registry, to measure both autism and comorbid symptom levels along a continuum in the twin population.

Approved: July 29, 2025

Study #: 50343

Title: Retrospective Epidemiological Review of Tuberculosis (TB) Program Indicators and Demographics in Low-Incidence Region

Principal Investigator: Megan Allgauer, SCs, Virginia Department of Health (VDH)

Study Purpose: This project is a retrospective epidemiological review of active Tuberculosis (TB) cases in the low-incidence region of Southwest Virginia to identify potential signals of delayed diagnosis or poorer outcomes.

Approved: August 21, 2025

Study #: 50344

Title: Impact of Cash Value Benefits (CVB) Increase on Perinatal Health and Child's Dietary Intake: A quasi-experimental study

Principal Investigator: Namrata Sanjeevi, Ph.D., Washington State University (WSU)

Study Purpose: Overall objective is to evaluate the impact of Cash Value Benefits (CVB) on improving WIC clients' perinatal health.

Approved: October 10, 2025

Study #: 50345

Title: School Nurses and Human Papillomavirus (HPV) Vaccination in Virginia

Principal Investigator: Emma Mitchell, Ph.D., RN and Kathleen Porter, Ph.D.-University of Virginia (UVA)

Study Purpose: The goal of this study is to understand the role that Virginia school nurses (grade 7 and up) serve in Sexual Transmitted Disease (STD) education and the administration of the Human Papillomavirus (HPV) vaccine.

Approved: October 22, 2025

Study #: 50346

Title: Cross-state Comparisons of Postpartum Contraception and Pregnancy Intendedness

Principal Investigator: Michael S. Rendall, Ph.D., University of Maryland (UMD)

Study Purpose: The purpose of this study is to examine the intendedness and planned status of pregnancies and postpartum contraceptive use with method type across states using Pregnancy Risk Assessment Monitoring System (PRAMS) data.

Approved: October 23, 2025

Study #: 50347

Title: Bridging the Gap: Connecting the Pediatric Healthcare System with the WIC Program through Third-Party Referral

Principal Investigator: Dr. Harry Zhang, Old Dominion University, (ODU)

Study Purpose: The study aims to develop, implement, and evaluate a new approach to address pediatric healthcare for WIC clients using a third-party referral platform, Unite Us (UU), to connect pediatric clients and WIC in the Hampton Roads area.

Approved: October 25, 2025

Study #: 50348

Title: Blood Pressure Care Before, During, and After a Hypertensive Disorder of Pregnancy

Principal Investigator: Megan McLaughlin, MD, University of California San Francisco (UCSF)

Study Purpose: This is a retrospective, cross-sectional analysis using existing Pregnancy Risk Assessment Monitoring System (PRAMS) Phase 9 surveillance data to analyze patterns of blood pressure care across the pregnancy continuum.

Approved: November 13, 2025

Study #: 50349

Title: The Effects of 2022's Infant Formula Shortage on Infant Health and Parental Decision-Making

Principal Investigator: Parker Sonnenberg, Florida State University (FSU)

Study Purpose: This project investigates the causal relationship between the 2022 large-scale infant formula shortage on infant feeding practices and subsequent changes in maternal mental health and infant health.

Approved: November 18, 2025

Study #: 50350

Title: Dental Related Emergency Room Visits in Virginia

Principal Investigator: Mengxi Zhang, Ph.D., Virginia Tech (VT)

Study Purpose: The purpose of this study is to evaluate the impact of two statewide Medicaid dental policy changes implemented in 2021 and 2022 on emergency dental care utilization.

Approved: December 16, 2025

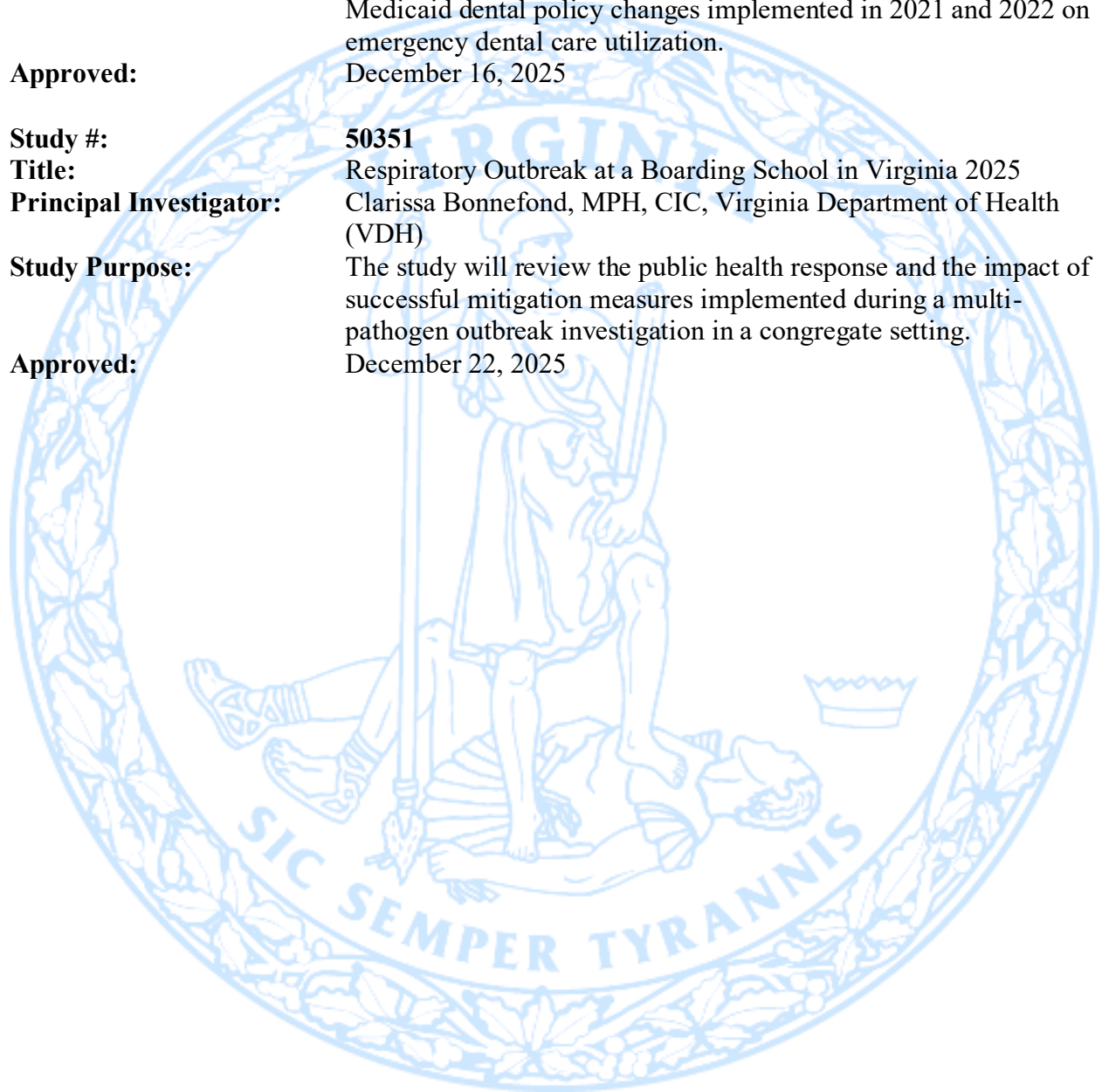
Study #: 50351

Title: Respiratory Outbreak at a Boarding School in Virginia 2025

Principal Investigator: Clarissa Bonnefond, MPH, CIC, Virginia Department of Health (VDH)

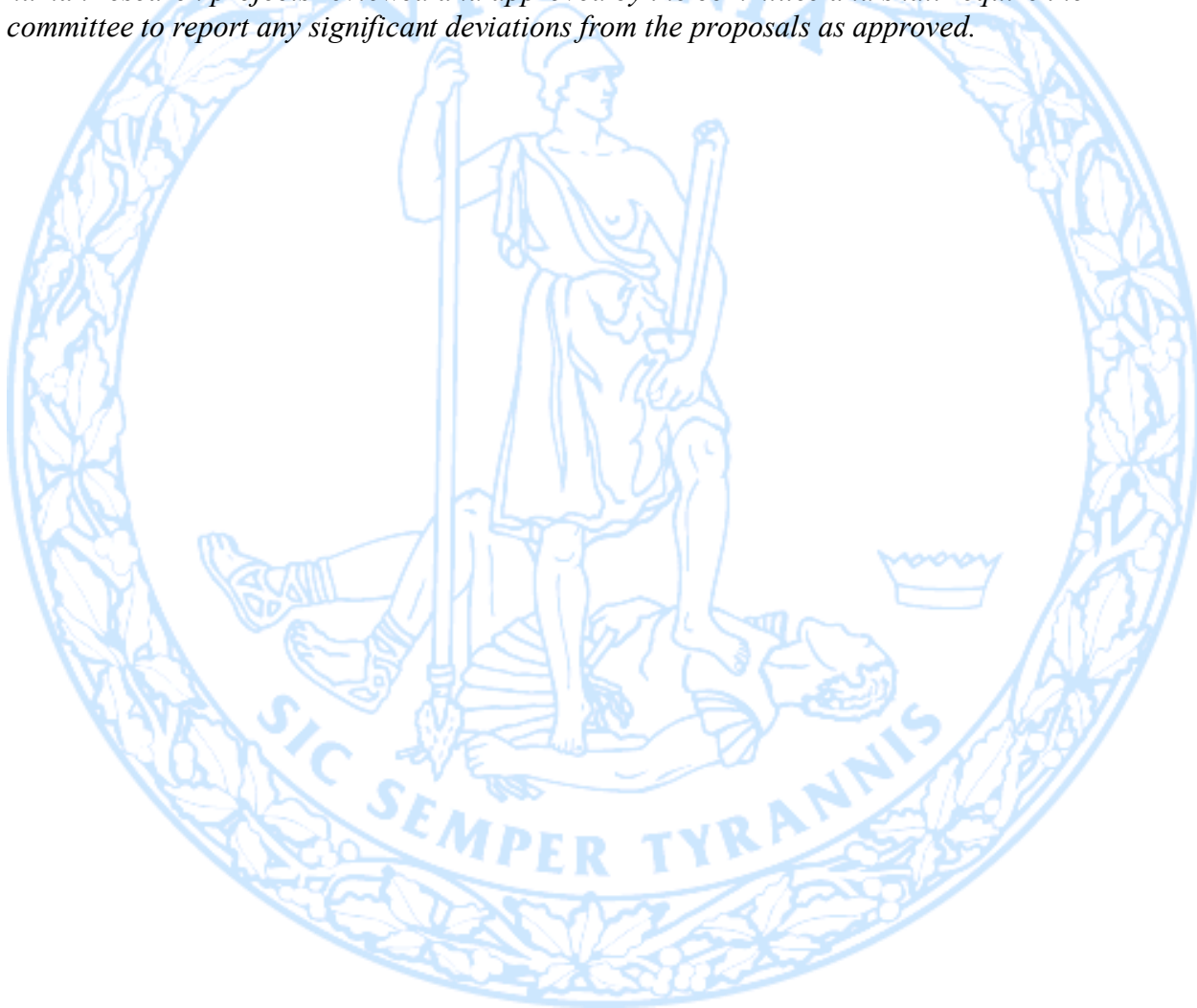
Study Purpose: The study will review the public health response and the impact of successful mitigation measures implemented during a multi-pathogen outbreak investigation in a congregate setting.

Approved: December 22, 2025



APPENDIX A CODE OF VIRGINIA § 32.1-12.1

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.



APPENDIX B ACRONYMS AND ABBREVIATIONS

DHHS/HHS – U.S. Department of Health and Human Services

IRB – Institutional Review Board

FWA – Federal-wide Assurance

OHRP – Office for Human Research Protections

VDH – Virginia Department of Health

