COMMONWEALTH of VIRGINIA

Department of Health

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January 7, 2026

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: Activities of the Institutional Review Board Calendar Year 2024

This report is submitted in compliance with the Virginia Acts of the Assembly – 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/KB
Enclosure

Pc: The Honorable Janet V. Kelly, Secretary of Health and Human Resources

ACTIVITIES OF
THE INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2024

REPORT TO THE GOVERNOR AND THE
GENERAL ASSEMBLY

2025

VIRGINIA DEPARTMENT OF HEALTH

PREFACE

The regulations require 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 shall require the committee to report any significant deviations from the proposals as approved.

VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD MEMEBERS

Dr. Bethany Geldmaker, Chair
Virginia Department of Health

Dr. Kavita Imrit-Thomas
Portsmouth Health District

Dr. Antonio Payares
Virginia Commonwealth University

Ana Lizzette Colón
Eastern Region Field Office
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Dr. Maceo Freeman
St Paul's Baptist Church

Dr. Noelle Bissell
New River Health District

Dr. April Eikerenköetter
Richmond, Virginia

Dr. Janice M. Hicks
IRB Coordinator
Virginia Department of Health

TABLE OF CONTENTS

Preface **2**
Virginia Department of Health Institutional Review Board Memebers 2
Table of Contents **3**
Executive Summary **4**
Introduction **4**
Report Outline 6
A. Full ReviewsNone 6

EXECUTIVE SUMMARY

The Virginia Department of Health (VDH) is submitting this report in compliance with the Virginia Acts of the Assembly – the Code of Virginia § 32.1-12.1 which states:

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In 2024, the Board conducted 13 expedited reviews of research proposals and 11 exempt reviews. All projects were determined to present minimal risk to human subjects and approved by the Board. During the year the Board 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 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) to serve as the human research committee. In addition, a guidance document, *Virginia Department of Health Institutional Review Procedures,* was developed and 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, 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.

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 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 45 CFR 46.116.
- Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR46.117.
- 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 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.

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either an exempt 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 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 research 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 detailed in 45 CFR 46.104, researchers still have ethical responsibilities to protect participants' rights. If the risks to human subjects appear questionable or the research 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 Regulation 45 CFR 46.110, certain categories of human subject research involving no more than minimal risk, as well as minor changes to previously 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."

VDH IRB meetings were held quarterly during 2024: January 8th, April 8th, July 15th, and

October 7th. Minutes are available on request.

REPORT OUTLINE

The following is a description of the research studies reviewed and approved by the Virginia Department of Health Institutional Review Board during 2024.

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED:

A. FULL REVIEWS NONE

B. EXPEDITED REVIEWS

Study #: **70076**
Title: Using Vital Statistics Natality Data to Assess the Impact of Arsenic-based Legacy Pesticides on Fetal Deaths and Birth Outcomes
Principal investigator: Erdal Tekin, PhD, American University (AU)
Study Purpose: The goal of the proposed project is to investigate the impact of in-utero exposure to legacy pesticides containing arsenic and lead on fetal deaths as well as birth and infant health outcomes.
Approved: January 9, 2024

Study #: **70077**
Title: Human Relationships as Infrastructure for Epidemic Preparedness
Principal investigator: John Aggrey, PhD, Virginia Tech (VT)
Study Purpose: The study's goal is to examine how human relationships impact epidemic response and how it can be utilized for effective epidemic preparedness.
Approved: February 7, 2024

Study #: **70078**
Title: Support via Online Social Network to Promote Safe Infant Care Practices toward Reducing Racial Disparities in Infant Mortality (SUPERSONIC)
Principal investigator: Rachel Moon, MD, University of Virginia (UVA)
Study Purpose: This project is designed to assess the effectiveness of a video-based infant care education program called Today'sBaby, developed specifically for WIC eligible clients, to promote adherence to American Academy of Pediatrics recommendations around safe sleep practices and breastfeeding.
Approved: February 7, 2024

Study #: **70079**
Title: Social Media and Risk Reduction Enhanced Reach (SMARTER)
Principal investigator: Anne Kellams, MD, IBCLC, FAAP, FABM, University of Virginia (UVA)

Study Purpose: SMARTER is a randomized controlled trial (RCT) to assess newly developed mobile health (text-messaging) prenatal interventions to promote best practices in infant sleep and feeding practices developed specifically for WIC eligible clients.
Approved: February 14, 2024

Study #: **70080**
Title: AARP Diet and Health Study
Principal investigator: Rashmi Sinha, PhD, National Cancer Institute (NCI)
Study Purpose: The purpose of this study is to examine the relationship between diet, lifestyle, chronic disease and cancers especially breast, large bowel and prostate.
Approved: March 19, 2024

Study #: **70081**
Title: Study of Cancer, Mortality and Other Health Outcomes after Occupational/Environmental Exposure
Principal investigator: David J. Prezant, MD, Fire Department of New York (FDNY)
Study Purpose: This project aims to identify the cancer incidence, latency and survival among firefighters and other emergency service rescuers exposed at the World Trade Center during the September 11 disaster.
Approved: May 2, 2024

Study #: **70082**
Title: Virginia Immunization Plan
Principal investigator: Rebecca Epstein, MSW, Institute for Public Health Innovation (IPHI)
Study Purpose: This project aims to identify the barriers and assets that shape beliefs, attitudes, and practices related to immunizations for various subgroups across Virginia and the extent to which variables and influences impact vaccination decisions and practices.
Approved: May 16, 2024

Study #: **70083**
Title: Virginia Beach Health District Long COVID Surveillance Project
Pr**incipal investigator:** Betty Rouse, BS, Virginia Department of Health (VDH)
Study Purpose: The objective is to determine the incidence of Long COVID among 2023 COVID infections and enumerate service needs for those experiencing Long COVID.
Approved: June 13, 2024

Study #: **70084**
Title: Epidemiology and Amyotrophic Lateral Sclerosis (ALS) Mortality in Virginia and North Carolina
Principal investigator: Katie Kurkjian, DVM, MPH, Virginia Department of Health (VDH)

Study Purpose: The study includes an epidemiological investigation into statewide trends of ALS (Amyotrophic Lateral Sclerosis) morbidity and mortality, looking for random versus clustered distribution as well as trends in person, place or time.
Approved: August 14, 2024

Study #: **70085**
Title: The Influence of Residing in Maternity Care Deserts on Maternal and Birthing Outcomes in Virginia
Principal investigator: Michelle Rockwell, PhD and David Gregory, MD, Carilion Clinic
Study Purpose: The goal of this research is to improve the understanding of disparities in the experience of maternity care and pregnancy outcomes in Virginia in areas where a maternity desert exists.
Approved: November 7, 2024

Study #: **70086**
Title: A Study of Association Between Health Insurance, Antiretroviral Treatment and HIV Pre-exposure Prophylaxis in Men Aged 20-85 in Virginia
Principal investigator: Lauren Maxwell, MPH, Walden University Student
Study Purpose: The study will evaluate whether there is an association between age, ethnicity, county/region or health insurance (employer, Medicaid/Medicare, state funded) and prescribing oral HIV medication (PrEP and ART).
Approved: November 8, 2024

Study #: **70087**
Title: Database Linkage Study to Evaluate the Risk of Medullary Thyroid Carcinoma (MTC)
Principal investigator: Sara Irvin, PhD, IQVIA
Study Purpose: This research study seeks to add to the scientific information generated to date about the risk of MTC in adult patients who received treatment with LA GLP-1 RA therapies.
Approved: November 21, 2024

Study #: **70088**
Title: Examining the Relationship Between the Social Determinants of Health (SDOH) and Latent Tuberculosis Infection (LTBI)Treatment Success in Virginia
Principal investigator: Amber Harmon, Duquesne University Student
Study Purpose: The purpose of this study is to analyze the possible effects of both individual factors and the SDOH on the treatment of LTBI.
Approved: December 18, 2024

C. EXEMPT REVIEWS

Study #: **50321**

Title: Investigating Factors Associated with Disparities in Severe Maternal Morbidity and Pregnancy-related Hypertension: A novel population based multi-state analysis of linked PRAMS data
Principal Investigator: Jared Parrish, PhD, Association of State and Territorial Health Office (ASTHO)
Study Purpose: This study will investigate both pre-pregnancy and pregnancy factors that may contribute to the racial disparities observed among those experiencing Severe Maternal Morbidity (SMM) and Pregnancy-Related Hypertension (PRH)
Approved: March 25, 2024

Study #: **50322**
Title: Perinatal Predictors of Postpartum Depression: Findings from Pregnancy Risk Assessment Monitoring System (PRAMS) Data in Virginia
Principal Investigator: Reem Sharaf-Alddin, MD, MSc, CPH, Old Dominion University (ODU)
Study Purpose: This study aims to identify the perinatal predictors of Postpartum Depression (PPD) among pregnant women in Virginia by determining if there is an association between pre-pregnancy BMI, exposure to tobacco smoke during pregnancy, or low breastfeeding indicators and a postpartum depression.
Approved: January 24, 2024

Study #: **50323**
Title: Tick Surveillance and Control Program of the Southeastern Center for Excellence in Vector Borne Disease
Principal Investigator: Rhoel Dinglasan, PhD, MPH, MPhil**,** University of Florida (UF)
Study Purpose: The study will match the tick and tickborne pathogen data collected by the Virginia Department of Health, Division of Surveillance and Investigation with reported tickborne disease cases in Southern Virginia.
Approved: February 14, 2024

Study #: **50324**
Title: Exploration of the Spatial Variability of Asthma Attacks, Cardiac Arrest and Stroke in Virginia using Syndromic Surveillance Data
Principal Investigator: Loren Hopkins, PhD, Rice University
Study Purpose: The purpose of this study is to examine the rates of asthma attacks, cardiac arrest and stroke by zip code level in Virginia to understand the spatial variability.
Approved: May 9, 2024

Study #: **50325**
Title: The Impact of Criminal Sentencing in Virginia
Principal Investigator: Megan Stevenson, PhD, University of Virginia (UVA)
Study Purpose: The purpose of this project is to evaluate the impact of sentencing policies in Virginia on recidivism, economic well-being and decisions related to marriage and divorce.

Approved: May 16, 2024

Study #: **50326**
Title: Implementation of Low-Cost, Locally Sourced Negative Pressure Units in a Long-Term Care Setting in Central Virginia and their Effect on COVID-19 Transmission.
Principal Investigator: Cali Anderson, MPH, Virginia Department of Health (VDH)
Study Purpose: The purpose of this study is to examine the effect of low-cost negative pressure unit implementation on respiratory illness health outcomes throughout long term care facilities in the Central Virginia Health District. The investigation will also study patterns of COVID-19 within these long-term care facilities.
Approved: May 16, 2024

Study #: **50327**
Title: Postpartum Coverage Extension Evaluation
Principal Investigator: Andrew Barnes, PhD, Virginia Commonwealth University (VCU)
Study Purpose: This is an evaluation of the Medicaid waiver that expands postpartum coverage to 12 months.
Approved: October 8, 2024

Study #: **50328**
Title: Addiction and Recovery Treatment Services Evaluation
Principal Investigator: Peter Cunningham, PhD, Virginia Commonwealth University (VCU)
Study Purpose: This is an evaluation of the Medicaid waiver that expands additional addiction and recovery treatment services for Medicaid patients.
Approved: October 21, 2024

Study #: **50329**
Title: Social Determinates Effects on Utilization of Sexual Health Clinics
Principal Investigator: Keia Spence, FNP-BC, Old Dominion University (ODU)
Study Purpose: The purpose of this study is to identify how Social Determinates of Health (SDOH) impact individual's use of public sexual health clinics.
Approved: October 25, 2024

Study #: **50330**
Title: The Association between Medicaid Pregnancy Dental Benefits and Dental Cleaning, Pregnancy Complications, and Infant Death
Principal Investigator: Brandy Lipton, PhD, University of California Irvine (UCI)
Study Purpose: This study will analyze Pregnancy Risk Assessment Monitoring System (PRAMS) data to explore the impact of Medicaid dental benefits for pregnant women on dental cleanings and maternal and infant health outcomes.

Approved: December 18, 2024

Study #: **50331**
Title: A Secondary Analysis of PRAMS Respondent Data
Principal Investigator: Brittney Tennyson, BS, Virginia State University (VSU) Student
Study Purpose: The purpose of this study is to examine Pregnancy Risk Assessment Monitoring System (PRAMS) data to identify the factors/correlations between experiencing racism, SES, adverse birth outcomes, and PPD symptoms.
Approved: November 20, 2024