

COMMONWEALTH of VIRGINIA

Karen Shelton, MD State Health Commissioner Department of Health P O BOX 2448 RICHMOND, VA 23218

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

March 13, 2025

### MEMORANDUM

| TO:      | The Honorable Glenn Youngkin<br>Governor of Virginia                                |
|----------|---|
|          | The Honorable L. Louise Lucas<br>Chair, Senate Finance and Appropriations Committee |
|          | The Honorable Luke E. Torian<br>Chair, House Appropriations Committee               |
| FROM:    | Karen Shelton, MD<br>State Health Commissioner, Virginia Department of Health       |
| SUBJECT: | Activities of the Institutional Review Board Calendar Year 2023                     |

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) 864-7006.

KS/JH Enclosure

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



# ACTIVITIES OF THE INSTITUTIONAL REVIEW BOARD CALENDAR YEAR 2023

## REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY

2023

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 Virginia Department of Health

Dr. Maceo Freeman St Paul's Baptist Church

Dr. Nicole Bissell New River Health District

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### 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:

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.

During 2023 the Board conducted 17 expedited reviews of research proposals and 34 exempt reviews. All projects were determined as posing minimal risk to human subjects and approved by the Board. 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 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. 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) provide 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 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 (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 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 that 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 2023: January 9<sup>th</sup>, April 17<sup>th</sup>, July 17<sup>th</sup>, and October 2<sup>nd</sup>. 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 2023.

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

### **B.** Expedited Reviews

| Study #:  | 70059  |
|---|--|
| Title:  | Study on the Incidence of Cancer Diagnosis and Mortality   |
| Among Military Aviators and Aviat   | tion Support Personnel   |
| Principal investigator:   | Natalie Wells, MD, MPH Defense Health Agency, Armed  |
| Forces Health   |  |
| Study Purpose:  | The purpose of this study is to determine if there is a  |
| •   | rtain site-specific cancers among military aviators and  |
|   | to similar age, sex, and race groups in the U.S. general   |
| population.   |  |
| Approved:   | January 18, 2023 (Previously approved by the Defense   |
| Health Agency IRB)  |  |
|   |  |
|   |  |
| Study #:  | 70060  |
| Title:  | Increasing Overdoses in Richmond, VA – A Community   |
| <b>Title:</b><br>Conversation to Understand the Fac   | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)  |
| Title:<br>Conversation to Understand the Fact<br>Principal investigator:  | Increasing Overdoses in Richmond, VA – A Community   |
| <b>Title:</b><br>Conversation to Understand the Fact<br><b>Principal investigator:</b><br>Health Department   | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County   |
| Title:<br>Conversation to Understand the Fac<br>Principal investigator:<br>Health Department<br>Study Purpose:  | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County<br>The purpose of this study is to identify the most important  |
| Title:<br>Conversation to Understand the Fact<br>Principal investigator:<br>Health Department<br>Study Purpose:<br>issues contributing to the significant   | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County<br>The purpose of this study is to identify the most important<br>increase in both fatal/non-fatal overdoses in the community                                       |
| Title:<br>Conversation to Understand the Fac<br>Principal investigator:<br>Health Department<br>Study Purpose:  | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County<br>The purpose of this study is to identify the most important<br>increase in both fatal/non-fatal overdoses in the community                                       |
| Title:<br>Conversation to Understand the Fact<br>Principal investigator:<br>Health Department<br>Study Purpose:<br>issues contributing to the significant   | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County<br>The purpose of this study is to identify the most important<br>increase in both fatal/non-fatal overdoses in the community                                       |
| Title:<br>Conversation to Understand the Fact<br>Principal investigator:<br>Health Department<br>Study Purpose:<br>issues contributing to the significant<br>and the actions that may help slow/p | Increasing Overdoses in Richmond, VA – A Community<br>tors Driving Substance Use (IORV Study)<br>Jennifer Shepheard, MSc, Richmond City Henrico County<br>The purpose of this study is to identify the most important<br>increase in both fatal/non-fatal overdoses in the community<br>prevent fatal/non-fatal overdoses. |

| Study #:                             | /0001   |
|--------------------------------------|---|
| Title:                               | University of Virginia HPV Research Project           |
| Principal investigator:              | Emma McKim Mitchell, Ph.D., MSN, RN, University of    |
| Virginia (UVA)                       |   |
| Study Purpose:                       | The purpose of this study is to explore the impact of |
| changing policies in Virginia on HPV | / vaccine uptake.                                     |
| Approved:                            | April 14, 2023 (Previously approved by UVA IRB)       |
|                                      |   |

| Study #:                           | 70062  |
|------------------------------------|--|
| Title:                             | Spatial Analysis of COVID-19 Incidence During the            |
| Delta and Omicron Waves, in the Ce | entral Virginia Health District                              |
| Principal investigator:            | Cali Anderson, MPH, Lynchburg Health Department              |
| Study Purpose:                     | The purpose of the study is to conduct spatial analysis of   |
| COVID-19 incidence during the Del  | ta and Omicron waves in the Central Virginia health district |

to document the demographics and factors that may have influenced health outcomes and identify high burden areas and the differences between each COVID-19 wave. **Approved:** April 14, 2023

| Study #:   | 70063   |  |
|--|---|--|
| Title:   | Cancer Incidence and Cancer Mortality in the World Trade  |  |
| Center Health Registry   |   |  |
| Principal investigator:  | James E. Cone, MD, MPH, New York City Health  |  |
| Department   |   |  |
| Study Purpose:   | The purpose of this study is to systematically evaluate the   |  |
| <b>e</b> 1 <b>.</b>  | th consequences of the 9/11 disaster in a selection of those<br>orm those at risk and improve preparedness for future |  |
| Approved:  | April 28, 2023  |  |
| Study #:   | 70064   |  |
| Title:   | Health Equity in Fertility Specialty Care among Cancer  |  |
| Survivors  |   |  |
| Principal investigator:  | J. Alejandro Rauh-Hain, MD, MPH, MD Anderson Cancer   |  |
| Center   |   |  |
| Study Purpose:   | The purpose of this study is to determine factors impacting   |  |
| health equity in fertility specialty care among cancer survivors |   |  |
| Approved:  | May 11, 2023 (previously approved by the MD Anderson  |  |
| Cancer Center IRB)   |   |  |
| Study #:   | 70065   |  |
| Title:   | Community-Based Cohort Study of Disease Incidence in  |  |
| Ohio and West Virginia   | · · ·   |  |

| Ohio and West Virginia  |  |  |
|---|--|--|
| Principal investigator:   | Nelson Kyle Steenland, Ph.D., Emory University         |  |
| Study Purpose:  | The purpose of this study is to conduct a record-based |  |
| follow-up of subjects exposed to Perfluorooctanoic acid (PFOA), a product used in the |  |  |
| manufacturing of Teflon, to determine the incidence of cancer.                        |  |  |

# Approved:May 17, 2023 (original study approved by New YorkUniversity IRB, the follow-up study approved by BRANY IRB)Study #:70066Title:The NYU Women's Health Study (NYUWHS)Principal investigator:Yu Chen, MPH, Ph.D., New York University (NYU)Study Purpose:The overall objective of the NYUWHS is the investigationof risk factors, including circulating biomarkers, in relation to risk of cancer and other diseases.Approved:May 23, 2023 (previously approve by BRANY IRB)

| Study #:                | 70067  |
|-------------------------|--|
| Title:                  | The Impact of Housing Instability on Breastfeeding |
| Behavior in             | Hampton Roads, Virginia                            |
| Principal investigator: | DaShaunda D. Taylor, Ph.D., MPH, Old Dominion      |
| University (ODU)        |  |

### **Study Purpose:**

The goal of this project is to assess the relationship between breastfeeding and housing instability in the Hampton Roads region of Virginia, evaluate this relationship by race/ethnicity, and identify and coordinate with community stakeholders to determine how to increase breastfeeding initiation and continuance for the recommended duration.

### **Approved:**

June 9, 2023 (previously approved by the ODU IRB)

|   | <b>70068</b><br>Vaccine Safety Datalink (VSD)<br>Michael Horberg, MD, Mid-Atlantic Permanente Medical<br>The primary objective of the VSD infrastructure task is to<br>a common data model within the KPMAS that allows for<br>examine the association between vaccines, health status and<br>across the patient population.<br>June 14, 2023 (previously approved as exempt by the |
|---|---|
|   | <b>70069</b><br>University of Virginia Mortality Data<br>Glenn Wasson, Ph.D., University of Virginia (UVA)<br>The purpose of this protocol is to develop a cancer research<br>cal data for research purposes. The database will contain<br>al data sources, existing research databases and biorepository<br>August 24, 2023 (previously approved by UVA IRB)                       |
| Study #:<br>Title:<br>Understanding Community Factors #<br>Principal investigator:<br>District<br>Study Purpose:<br>informant interviews with communi<br>resources related to opioid use and a<br>Approved: | Andrea Young, RN, BSN, MPH, Prince William Health<br>The needs assessment includes listening sessions and key<br>ty leaders to assess the current needs, challenges, and  |
| Study #:<br>Title:<br>Symptomatology and Post-COVID (<br>Principal investigator:<br>Study Purpose:<br>long-term symptoms and newly diag<br>a COVID-19 infection.<br>Approved:                               | <b>70071</b><br>A Descriptive Analysis of Self-Reported Long COVID<br>Conditions in Central Virginia<br>Cali Anderson, MPH, Central VA Health District<br>The purpose of this study is to identify the most common<br>gnosed medical conditions that participants experienced after<br>September 29, 2023   |

| Principal investigator<br>Study Purpose: | <ul> <li>70072         <ul> <li>Emerging Challenges in Newborn Screening: Benefits and neertain Prognoses After Newborn Screening (NBS)</li> <li>Beth Tarini, MD Children's National Hospital The project's overall objective is to examine the scope and and harms to parents and their children who receive an uncertain prognosis November 1, 2023 (previously approved by the Children's</li> </ul> </li> </ul> |
|--|---|
| Study #:                                 | 70073   |
| Title:                                   | Statewide Listening Sessions on Healthcare Access and   |
| Health Needs of Transg                   |   |
| Principal investigator<br>Study Purpose: | Ted Heck, MS, Virginia Department of Health (VDH)<br>The purpose of this study is to determine how VDH can  |
| v i                                      | ender community regarding quality-of-life risk factors and outcomes, by   |
|  | standing of cultural, and linguistic characteristics regarding social   |
|  | and how demographics and geographics differ from region to region.  |
| Approved:                                | October 25, 2023  |
| Study #:                                 | 70074   |
| Title:                                   | Assessing Residential Neighborhood Exposome Exposures   |
| and the Associations w                   | ith Cancer Incidences   |
| Principal investigator                   | : David Wheeler, Ph.D. Virginia Commonwealth University   |
| (VCU)<br>Study Purpose:                  | The overall goal of this case-control project is to assess  |
| • •                                      | perience of residing in disadvantaged neighborhoods over time   |
| contributes to disparitie                |   |
| Approved:                                | November 16, 2023 (previously approved by the VCU   |
| IRB)                                     |   |
| S4 J #.                                  | 70075   |
| Study #:<br>Title:                       | <b>70075</b><br>Pathogen Genomic Center of Excellence VCU   |
| Principal investigator                   |   |
| University (VCU)                         | • DI. Gregory Duck, Th.D., Virginia Commonwealth  |
| Study Purpose:                           | The purpose of the study is to build infrastructure to  |
| quickly sequence the g                   | enome of pathogens in outbreak situations and use the data for genetic  |
| epidemiology to prepar                   | e for next epidemic or pandemic event.  |
| Approved:                                | December 7, 2023 (previously approved by VCU IRB)   |
| C. Exempt                                |   |
| Study #:                                 | 50287   |

Title:Expanded Second Tier Dried Bloodspot ScreeningThrough Next Generation Sequencing Assay Targeting CFTR2 Variants

| <b>Principal Investigator:</b><br>Consolidated Laboratory Services (D<br><b>Study Purpose:</b><br>for the detection of additional mutati                            | The purpose of this study is to evaluate a new test method  |
|---|---|
| Approved:   | January 11, 2023  |
| for gestational age (SGA) in Virginia   | Ksenia Primich, MPH, Virginia Department of Health<br>The purpose of this study is to examine the association<br>dverse birth outcomes – low birth weight (LBW) and small   |
| Approved:<br>Study #:   | January 11, 2023 <b>50289</b>   |
| Title:<br>A Population-based Analysis Using<br>Principal Investigator:<br>Study Purpose:<br>cancer research database that integra                                   | Predicting Outcomes Among Cancer Patients in Virginia:  |
| Approved:   | January 18, 2023 (Previously approved by the ODU IRB)   |
| Study #:<br>Title:<br>in Emergencies: The Case of COVI<br>Principal Investigator:<br>Study Purpose:<br>of COVID-19 and the national formuparticipants.<br>Approved: | <b>50290</b><br>Understanding WIC Women's Infant Feeding Decision<br>D-19 and the Formula Shortage<br>Davida Mensah, MS, Rappahannock Health District<br>The proposed study's purpose is to understand the effects<br>ala shortage on breastfeeding rate among Virginia WIC<br>January 23, 2023 |
|   |   |
| Study #:<br>Title:<br>during the Post-vaccination Timefran<br>Principal Investigator:   | <b>50291</b><br>Predictors of COVID Hospitalization in Loudoun County<br>ne (2021/2022)<br>Catherine Visintainer, MD, George Washington University  |
|   | The purpose of this study is to determine if demographic<br>k for COVID-19 hospitalization have changed among<br>availability of the COVID-19 vaccines and the emergence<br>ARS CoV-2 in Virginia.<br>February 3, 2023 (previously approved by GWU IRB)   |

50292 Study #: **Title:** Association Between Historical Redlining and Birth Outcomes in Virginia, 2016-2020. **Principal Investigator:** Ksenia Primich, MPH and Meagan Robinson Maynor, Dr.PH, Virginia Department of Health **Study Purpose:** This study will examine the association between historical redlining and preterm birth (PTB), low birth weight (LBW), and small for gestational age (SGA) over a five-year period (2015-2019) in the following areas of Virginia: Richmond, Newport News-Norfolk-Virginia Beach, Lynchburg, and Roanoke. **Approved:** February 14, 2023 Study #: 50293 Title: Urban Heat Exposure in Richmond, VA **Principal Investigator:** Todd Lookingbill, Ph.D., University of Richmond (U of R) **Study Purpose:** This study will test the hypothesis that urban heat islands pose a serious threat to human health through exposure to extreme heat. **Approved:** March 14, 2023 (previously approved by the U of R IRB) Study #: 50294 Title: Secondary Data Analysis of Virginia Youth Survey Data Melissa Little, Ph.D., MPH, University of Virginia (UVA) **Principal Investigator: Study Purpose:** This study will use a secondary data analysis to gain a better understanding of the role of social determinants in adolescent tobacco use. **Approved:** March 14, 2023 (previously approved by UVA IRB) Study #: 50295 Persons with Lived Experience (PWLE) Review of Viral Title: Hepatitis Elimination Plan **Principal Investigator:** Emily Schreer, BA, Virginia Department of Health The purpose of this study is survey PWLE to gain feedback **Study Purpose:** on the draft of Hep Free VA: Virginia's Viral Hepatitis Elimination Plan. March 9, 2023 **Approved:** 50296 Study #: Title: Use of Spatial Epidemiology and Hotspot Analysis to Examine Disparities in Low Birthweight and Premature Birth in Virginia **Principal Investigator:** Abdullah Al-Taiar, MD, Old Dominion University (ODU) **Study Purpose:** This study will examine hotspots of low birth weight/prematurity in Virginia to determine the individual and community associated factors. March 13, 2023 (previously approved by ODU IRB) **Approved:** Study #: 50297 Title: Application of Wastewater-Based Epidemiology for Forecasting COVID-19 Future Trends Using Copula **Principal Investigator:** Anna Jeng, ScD, Old Dominion University (ODU) 11

Study Purpose:The study aims to develop practical tools for forecasting<br/>COVID-19 distribution for pandemic management and prevention using the analysis of<br/>wastewater SARS-CoV-2 viral load and demographic variables.<br/>Approved:March 16, 2023 (previously approved by the ODU IRB)Study #:50298

Study m.Every<br/>EveryTitle:Emergency Medical Services (EMS) Trigger-Tool AnalysisPrincipal Investigator:Jessica Rosner, MPH, Virginia Department of HealthStudy Purpose:The purpose of this study to identify the frequency oftriggers (e.g., clinical events that may result in adverse events or harm) occurring during patientcare in the pre-hospital setting.March 31, 2023

| Study #:                            | 50299  |
|-------------------------------------|--|
| Title:                              | Examining Postpartum Depression Screening Factors in         |
| Virginia by Race                    |  |
| Principal Investigator:             | Darrian Thomas, BSW, Virginia Commonwealth                   |
| University (VCU)                    |  |
| Study Purpose:                      | The purpose of this study is to better understand the        |
| relationship between race and postr | partum depression and identify gans in postpartum depression |

relationship between race and postpartum depression and identify gaps in postpartum depression screening practices as it relates to differences in race.

Approved: April 28, 2023 (previously approved by VCU IRB)

| Study #:   | 50300   |
|--|---|
| Title:   | National WIC Association Multistate Participant Survey      |
| Principal Investigator:                              | Lorrene D. Ritchie, Ph.D., MS, RD, University of            |
| California Davis (UC Davis)                          |   |
| Study Purpose:                                       | The purpose of this study is to determine WIC participants' |
| satisfaction and how to increase the benefits of WIC |   |
| Approved:  | May 11, 2023 (Previously approved by the UC Davis IRB)      |
|  |   |

Study #:50301Title:Gap Analysis of Intimate Partner Violence (IPV) andPostpartum Depression/Anxiety (PPD/A) Screenings.Principal Investigator:Natasha Sriraman, MD, VA Chapter, American Academyof Pediatrics (AAP)Study Purpose:The proposed study will investigate facilitators andbarriers for conducting intimate partner violence (IPV) and postpartum depression and anxiety(PPD/PPA) screenings among physicians within their respective clinics.Approved:May 17, 2023

Study #:50302Title:Secondary data from VDH for the Virginia PopulationEstimates and School Enrollment ProjectionsPrincipal Investigator:Principal Investigator:Qian Cai, Ph.D., University of Virginia, Weldon CooperCenterCenter

Study Purpose:The purpose of this request is to produce more accurate<br/>data regarding Virginia population estimates required for state funding formulas and used in<br/>the development of school enrollment projections which are required by the General<br/>Assembly.Approved:June 14, 2023 (previously approved by the UVA IRB)

| Approved.  | June 14, 2023 (previously approved by the 0 VA IKD)                           |  |
|--|---|--|
| Study #:   | 50303   |  |
| Title:   | Community Health Workers (CHWs) for a Healthy                                 |  |
| Virginia Project Evaluation  |   |  |
| Principal Investigator:  | Michelle White, MS, Health Quality Innovators                                 |  |
| Study Purpose:   | The purpose of this study is to identify system,                              |  |
| -  | characteristics that can contribute to the successful                         |  |
| implementation of community health worker programs to address future pandemics and to ameliorate the health and social needs that are exacerbated by health emergencies. |   |  |
| Approved:  | June 27, 2023   |  |
|  |   |  |
| Study #:   | 50304   |  |
| Title:   | Assessing Trauma Triage in Virginia Emergency Medical                         |  |
| Services (EMS)   |   |  |
| Principal Investigator:  | Daisy Banta, MPH, Virginia Department of Health                               |  |
| Study Purpose:   | The purpose of this study is to identify risk factors and                     |  |
| Approved:  | ver- triaging of trauma patients in the prehospital setting.<br>July 28, 2023 |  |
| Approved.  | July 20, 2025   |  |
| Study #:   | 50305   |  |
| Title:   | Virginia COVID-19 After Action Study Interviews                               |  |
| Principal Investigator:  | Stephen Eubank, Ph.D., University of Virginia (UVA)                           |  |
| Study Purpose:   | The purpose of this project is to conduct a COVID-19 after                    |  |
| action study in order to improve the   | quality of modeling analysis by identifying the information                   |  |
| needed and the current information   | supplied during the COVID-19.   |  |
| Approved:  | July 26, 2023 (previously approved by the UVA IRB)                            |  |
| Study #:   | 50306   |  |
| Title:   | Quantitative Analysis of Virginia Domestic                                    |  |
| Travelers Exposed to COVID-19 fro  |   |  |
| Principal Investigator:  | Tessa DeWalt, MS, Virginia Department of Health                               |  |
| Study Purpose:   | The purpose of the study is to assess COVID-19 disease                        |  |
| development after an airline exposure, in order to better understand disease exposure risk   |   |  |
| attributable to airplane travel.   |   |  |
| Approved:  | August 9, 2023  |  |
| Study #:   | 50307   |  |
| Title:   | Acute Care Utilization Among Sickle Cell Patients in Eight                    |  |
| States, 2018.  | -   |  |
| Principal Investigator:  | Parker Parks, MPH, Virginia Department of Health                              |  |
|  |   |  |

Study Purpose:The purpose of this study is to determine how hospitalutilization among Sickle Cell Disease patients vary by age, sex, and payer source.Approved:August 9, 2023

| Study #:<br>Title:<br>(PRAMS) Linkage Project  | <b>50308</b><br>Virginia Pregnancy Risk Assessment Monitoring System  |  |
|--|---|--|
| Principal Investigator:<br>Health  | Kenesha Smith Barber, Ph.D., Virginia Department of   |  |
| <b>Study Purpose:</b> between experiences or behaviors su                                | The purpose of this study is to examine the relationships<br>ich as use of alcohol/substance use, access to insurance and<br>naternal morbidity in different race/ethnic groups.<br>August 24, 2023 |  |
| Study #:   | 50309   |  |
| Title:   | Biocomplexity Institute COVID-19 Response:  |  |
| Surveillance, Modeling and Operational Support   |   |  |
| Principal Investigator:  | Bryan Lewis Ph.D., MPH, University of Virginia  |  |
| <b>Study Purpose:</b><br>what-if scenarios and forecasts) of C<br>state and local level. | The study will conduct analysis and modeling (including COVID-19 data to assist in decision and policy making at the  |  |
| Approved:  | August 24, 2023 (previously approved by UVA IRB)  |  |
| Study #:   | 50310   |  |
| Title:   | Neighborhood, Home- and Community-Based Services,   |  |
| and Older Adults' Health in Virginia   |   |  |
| Principal Investigator:  | Seon Kim, Virginia Commonwealth University (VCU)  |  |
| Study Purpose:   | This research will explore the relationship between   |  |
| neighborhood characteristics, Home health in Virginia.                                   | and Community Based Services (HCBS), and older adults'  |  |
| Approved:  | August 30, 2023   |  |
| Study #:   | 50311   |  |

| Study #:   | 50311   |
|--|---|
| Title:   | Impact of Rice Diet on Hypertension and Metabolic             |
| Disease  |   |
| Principal Investigator:                          | Pao-Hwa Lin, Ph.D., Duke University                           |
| Study Purpose:                                   | The purpose of this study is to investigate the impact of the |
| Rice Diet on hypertension and metabolic disease. |   |
| Approved:  | September 29, 2023 (previously approved by the Duke           |
| University IRB)                                  |   |
|  |   |

| Study #:                                | 50312  |
|---|--|
| Title:                                  | Sickle Cell Disease and Social Vulnerability           |
| <b>Principal Investigator:</b><br>(VDH) | Shamaree Cromartie, MPH, Virginia Department of Health |

**Study Purpose:** The purpose of this study is to determine the incidence of Sickle Cell Disease births and their associated characteristics. **Approved:** September 29, 2023 Study #: 50313 Title: VCU Health Psychology Analysis of VA Youth and Adult Survey Data **Principal Investigator:** Caroline Cobb, Ph.D., Virginia Commonwealth University (VCU) **Study Purpose:** The purpose of this project is to explore electronic nicotine delivery use and weight management intentions among Virginia youth including how family ties in the Latino/Hispanic community influence smoking in middle and high school youth. September 29, 2023 **Approved:** Study #: 50314 Title: Targeted Community Outreach (TCO) Focus Groups (FGs) & Key Informant Interviews (KIIs) **Principal Investigator:** Katherine Schroeder, MPH, Lord Fairfax Health District **Study Purpose:** The aim of this study is to better understand the community's concerns, goals, and health needs of residents from Lord Fairfax Health District which serves Clarke, Frederick, Page, Shenandoah, and Warren counties and Winchester City. **Approved:** October 3, 2023 Study #: 50315 Title: Comprehensive Harm Reduction Survey **Principal Investigator:** Bruce Taylor, MS, ED, Virginia Department of Health The purpose of this survey is to gain insight into the needs **Study Purpose:** of the population served and evaluate the Harm Reduction program. **Approved:** November 6, 2023 Study #: 50316 Title: Secondary Analysis of Virginia Emergency Medical Services (EMS) Clinicians 2019 Mental Health Survey **Principal Investigator:** Jessica Rosner, MPH, Virginia Department of Health (VDH) **Study Purpose:** The purpose of the analysis is to determine if demographic and occupational characteristics are associated with self-reported suicidal symptoms among Virginia EMS clinicians. **Approved:** October 25, 2023 Study #: 50317 Title: Secondary Analysis of Virginia Emergency Medical Services (EMS) Clinicians 2022 Mental Health Survey **Principal Investigator:** Jessica Rosner, MPH, Virginia Department of Health

**Study Purpose:** 

**Approved:** 

The purpose of this study is to determine if demographic and occupational characteristics are associated with self-reported substance use and the presence of self-reported mental health conditions.

| Approved:  | October 25, 2023   |  |
|--|--|--|
| Study #:   | 50318  |  |
| Title:   | The Effects of Locally Based Cooling Centers on Heat-        |  |
| Related Illness in Virginia  |  |  |
| Principal Investigator:  | Dr. Daniel J. Vecellio, Ph.D., George Mason University       |  |
| (GMU)  |  |  |
| Study Purpose:   | The purpose of this study is to determine if counties or ZIP |  |
| codes with official cooling centers e  | experience reductions in heat-related illness during extreme |  |
| heat events as compared to those counties or ZIP codes without official cooling centers. |  |  |
| Approved:  | November 29, 2023, (previously reviewed by GMU IRB)          |  |
|  |  |  |
| Study #:   | 50319  |  |
| Title:   | Determining Factors Associated with Hepatitis C (HCV) in     |  |
| Virginia from 2018-2022: Explorin  | g Target Areas for Future Surveillance                       |  |
| Principal Investigator:  | Joylynn Tilley, Eastern Virginia Medical School (EVMS)       |  |
| Study Purpose:   | This project will examine the factors associated with Hep    |  |
| C (HCV) in Virginia.   |  |  |
| Approved:  | December 19, 2023  |  |
|  |  |  |
| Study #:   | 50320  |  |
| Title:   | The Other Ehrlichiosis: First Reported Human Fatality by     |  |
| Ehrlichia Ewingii Infection  |  |  |
| Principal Investigator:  | James Broyhill, Virginia Department of Health (VDH)          |  |
| Study Purpose:   | This study will provide data about a relatively newly        |  |
|  | 1 4 1 4 11 11  |  |

identified uncommon and generally non-lethal tickborne illness.

December 19, 2023