REPORT TO THE COMMISSIONER:
ACTIVITIES OF
THE VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2020

Submitted by

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Chair
Virginia Department of Health Institutional Review Board

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Regulations for the conduct of human research, developed and approved by the Virginia Board of Health, became effective on July 1, 1993 and were most recently updated on January 14, 2016. The regulations apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants. According to those regulations, prior to the initiation of a human research project, a description of the proposed project shall be submitted to a research review committee for review and approval. The Virginia Department of Health (VDH) subsequently appointed an Institutional Review Board (IRB). In addition, a guidance document, *Virginia Department of Health Institutional Review Guidelines and Procedures,* was developed and updated in March 2016.

The Office for Human Research Protections (OHRP), within the U.S. Department of Health and Human Services (DHHS), is responsible for ensuring the safety and welfare of people who participate in HHS-sponsored research. VDH has voluntarily registered and has applied for and received Federalwide Assurance for its IRB from OHRP. Registration with OHRP facilitates DHHS's effort to establish effective communication with IRBs. In addition, receiving an assurance from OHRP formalizes an institution's commitment to protect human subjects.

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either 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 study does indeed meet the criteria for exemption before the research study may commence. This type of review is called an "exempt review." If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights. If the risks to human subjects appear questionable or the project does not fit into the federally defined categories for exemption, the IRB will notify the investigator that he/she must submit the study as a new protocol for either full or expedited review.

Under the Code of Federal Regulations 45 CFR 46.110, certain categories of human subject research involving no more than minimal risk, as well as minor changes to approved research, qualify for what is called "expedited review." In these instances, a designated IRB member (or group of members) reviews the proposed research rather than the entire IRB, with final review and approval by the IRB chair.

When full board review is necessary (e.g., based on level of risk or the inclusion of vulnerable subjects), 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 2020: March 16, May 18, July 13, and October 19. 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 2020.

Review Type	Approved	Not Approved
Full Review	0	0
Expedited Review	20	0
Exempt Review	11	0

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED:

A. Full Reviews **None**

B. Expedited Reviews

Study #: **70016**
Title: Catchment Area Analysis for Massey Cancer Center II (MCC)
Principal Investigator: David Wheeler, PhD, Virginia Commonwealth University (VCU)
Approved: January 15, 2020 (previously approved by the VCU IRB)
Study Purpose: The aims of this study are to estimate the Massey Cancer Center catchment area with more current cancer diagnosis data and to characterize the areas in terms of important demographic variables. Information gained about the MCC catchment area and its population will be used to better serve the population and increase cancer control and prevention efforts.

Study #: **70017**
Title: A Secondary Analysis of State Cancer Registries to Understand the Epidemiology of Liver Cancer in the Washington DC Area
Principal Investigator: Lorien Abroms, Sc, MA, George Washington University (GWU)
Approved: February 28, 2020 (previously approved by the GWU Clinical Trials Office)
Study Purpose: The purpose of this study is to examine liver cancer mortality and risk factors in Washington DC area through an examination of state cancer registries. Demographic and behavioral data will be analyzed to determine which populations are at greatest risk to develop liver cancer.

Study #: **70018**
Title: In Vitro Fertilization Outcomes after Cancer
Principal Investigator: Hazel Nichols, PhD, University of North Carolina (UNC)
Approved: April 2, 2020 (previously approved by the UNC IRB)
Study Purpose: The purpose of this research is to enhance cancer care for the ~75,000 women diagnosed with cancer at reproductive ages each year by providing contemporary evidence on fertility preservation outcomes

Study #: **70019**
Title: Unresolved Issues in Newborn Screening (NBS): Quantifying the Harms of a False Positive Result
Principal Investigator: Beth Tarini MD, MS, Children's National Research Institute
Approved: May 4, 2020 (previously approved by the Children's National Research Institute IRB). The Children's National Research Institute IRB will serve as the designated IRB.
Study Purpose: To comprehensively examine the scope, magnitude, and risk factors for harms to children and parents/guardians of a false positive newborn screening (NBS) result.

Study #: **70020**
Title: Identifying Strategies to Increase the Recruitment and Retention of Minority Males in the Public Health Workforce: A Two-State Comparative Case Study Approach
Principal Investigator: Melicent R. Miller, MSPH, Virginia Department of Health (VDH) (doctoral dissertation project)
Approved: May 4, 2020 (previously approved by the Georgia Southern University IRB)
Study Purpose: The purpose of this study is to examine the characteristics of the local health departments that are associated with employee recruitment and retention strategies and employee perceived organizational support.

Study #: **70021**
Title: Evaluation of the Process of Referring and Linking Clients to Key Community Services in HIV Status Neutral Service Navigation
Principal Investigator: Mary Beth Cox, MSW, MPH, Virginia Department of Health (VDH)
Approved: June 22, 2020 (previously approved by the George Washington University (GWU) Clinical Trials Office)
Study Purpose: The purpose of this study is to better describe and understand the pathway of clients who were referred for the priority services identified as part of Bridges 757 (a program for men who have sex with men and Trans women of color in the Hampton Virginia area), with a focus on what helped and hindered the referral process from the clients' and providers' perspectives.

Study #: **70022**
Title: COVID-19 Specimen Procurement for Quidel Bank
Principal Investigator: Noelle Bissell, MD, VDH (New River Health District)
Approved: August 3, 2020
Study Purpose: To collect left-over, de-identified, unlinked nasal/nares swabs and/or nasopharyngeal swabs from subject being tested for COVID-19 disease. The specimens will be added to the Quidel Biobank and used for further development of the Sofia 2 SARS Antigen FIA assay.

Study #: **70023**
Title: Evaluation of Antibody Response to SARS COV2 Virus in Subjects Subjected to COVID-19
Principal Investigator: Noelle Bissell, MD, VDH (New River Health District)
Approved: August 3, 2020
Study Purpose: To assist with development of further testing for SARS COV2. New River Health District will partner with TechLab to provide swab and saliva samples of known positive clients and clients seeking testing to assist with development of antigen and antibody tests.

Study #: **70024**
Title: An Updated Study of Mortality among North American Synthetic Rubber Industry Workers
Principal Investigator: Nalini Sathiakumar, MD, DrPH, University of Alabama (UAB)
Approved: August 10, 2020 (previously approved by the UAB IRB)
Study Purpose: This is a study of synthetic rubber industry workers to further assess the impact of a known carcinogenic on bladder cancer. Previous studies have shown excess cancers in Lymphohematopoietic cancers and bladder cancers in this cohort.

Study #: **70025**
Title: Juvenile Delinquency and Adult Gun Sales: Comparative Effectiveness of Different Minimum Age Standards for Firearm Purchase
Principal Investigator: Jeffrey Swanson, Duke University (DU)
Approved: August 24, 2020 (previously approved by the University of Virginia IRB)
Study Purpose: The project will test the hypothesis that a higher minimum age for legal firearm possession by young adults with a juvenile crime history is protective in terms of significantly reducing gun-related suicide and violent crime in this high-risk population. (North Carolina, Delaware and Virginia were chosen because they have differing laws regarding juvenile delinquency records and minimum age standards for adult gun sales.)

Study #: **70026**
Title: Incidence and Management of Breast Cancer and Post-mastectomy Breast Reconstruction in Virginia: A Regional Study
Principal Investigator: John T. Stranix, MD, University of Virginia (UVA)
Approved: August 27, 2020 (previously approved by the UVA IRB)
Study Purpose: The goal of this project is to provide a more comprehensive knowledge of access to breast reconstruction services in Virginia and determine if access is indicative of a broader snapshot of total breast cancer care and how it varies geographically and by socioeconomic status, age, race, insurance status and distance to facilities.

Study #: **70027**
Title: A Retrospective Network Analysis of Syphilis Cases and Contact Investigations in Henrico and Richmond City to Identify Potential Contact Prioritization Factors
Principal Investigator: Jonathan Newman, William and Mary (W&M)
Faculty Supervisor: Dr. Greg Conradi Smith, (W&M)
Approved: August 27, 2020 (previously approved by W&M IRB)
Study Purpose: This is a retrospective study to analyze the structure of sexual contact networks of individuals with syphilis derived from public health records aggregated over the past five years. The network measures will be used to identify and characterize strategies for improved public health outcomes such as decreased syphilis incidence.

Study #: **70028**
Title: Comprehensive Sexual Education Initiative
Principal Investigator: Meagan Robinson, PhD, Virginia Department of Health (VDH)
VDH Collaborator: Maddie Kapur
Approved: September 16, 2020
Study Purpose: The goal of the study is to determine fidelity to the education program, *Get Real: Comprehensive Sexual Education Curriculum*. The program goal is to increase access to comprehensive, evidence based education programs for teens.

Study #: **70029**
Title: National Diabetes Prevention Program (DPP) Value-based Performance (VPB) Pilot
Principal Investigator: Melicent Miller, MSPH, Virginia Department of Health (VDH)
Approved: October 5, 2020
Study Purpose: The purpose of this research is to assess the effectiveness of alternative approaches aimed at increasing enrollment and retention in the National DPP. From the study results, best practices can be developed to increase retention in the program workshops and improve health outcomes by reducing one's risk for developing diabetes.

Study #: **70030**
Title: Clinical Course and Outcomes of People with Coronavirus Disease and Tuberculosis: A Multi-center Cohort Study
Principal Investigator: Scott K. Heysell, MD, MPH, University of Virginia (UVA)
Approved: October10, 2020 (previously approved by the UVA IRB)
Study Purpose: The purpose of the study is to review extant medical records around the world of patients with TB who have also reported to be COVID-19 positive in order to describe patient outcome and determine the feasibility of creating an international data repository.

Study #: **70031**
Title: VDH Cancer Registry Data to Describe UVA's Cancer Center Catchment Area
Principal Investigator: Roger Anderson, PhD, University of Virginia (UVA)
Approved: October 10, 2020 (previously approved by the UVA IRB)
Study Purpose: The study will use Virginia Cancer Registry data, in conjunction with West Virginia's state health department data, to draw a full cancer profile of patients in the UVA Cancer Center's catchment area. The overall aim is to identify cancer trends within the UVA catchment area and to describe how parts of the catchment area might differ in relation to availability of cancer resources and services.

Study #: **70032**
Title: Richmond Gun Violence Data Base
Principal Investigator: Dr. Michael Aboutanos, Virginia Commonwealth University (VCU)
Approved: November 2, 2020 (previously approved by the VCU IRB)
Study Purpose: The purpose of this study is to create a comprehensive database regarding gun violence by merging data from 8 different registries/databases already in existence in order to determine demographic risk factors for firearm injury; determine the morbidity and mortality of firearm injury based on location of injury; and determine the risk of firearm re-injury.

Study #: **70033**
Title: Comparison of Translation Methodology for an Autism Spectrum Disorder (ASD) Screening Tool
Principal Investigator: Michaela DuBay, PhD, CCC-SLP, University of Virginia (UVA)
Approved: November 2, 2020 (previously approved by the UVA IRB)
Study Purpose: The study aims to examine the impact of translation methodology on the accuracy of screening tools in detecting risk of ASD in early childhood.

Study #: **70034**
Title: Validation Studies for SARS CoV-2 Detection in Breath Samples
Principal Investigator: Carla Finkielstein, PhD, Virginia Tech (VT)
Approved: November 12, 2020 (previously approved by VT IRB)
Study Purpose: The study will determine if the breath sample analysis on the Tera breath analysis spectroscopic resonance system is equally accurate to the standard RT-qPCR test that is done on nasopharyngeal and mid-nasal swab samples obtained from the same person as part of surveillance testing to identify negative cases.

Study #: **70035**
Title: The Great New Community Survey Investigating the Health and Wellness of the Transgender and Gender Non-conforming Population Residing or Receiving Care in Virginia
Principal Investigator: Dr. Karen Ingersoll, University of Virginia (UVA)
VDH Collaborators: Kate Gilmore and Chelsea Canan, VDH
Approved: December 21, 2020 (previously approved by the UVA IRB)
Study Purpose: The goal of this study is to learn more about the health and wellness of the transgender and gender non-conforming population residing in Virginia including health status and social determinates of health for this population.

C. Exempt

Study #: **50225**
Title: Investigating the Determinate of Poor Maternal Birth Experiences and Outcomes in Virginia
Principal Investigator: Chioma Amadi, MPH, Virginia Department of Health (Richmond City and Henrico Health Districts)
Approved: February 3, 2020
Study Purpose: The purpose of the study is to analyze racial disparities in maternal birth experiences and outcomes in Virginia.

Study #: **50226**
Title: VA PRAMS Analysis: The Association of Maternal Health Insurance Status and Maternal Health Outcomes
Principal Investigator: Alexandra Atkeson (MPH student), University of North Carolina (UNC)
Approved: February 6, 2020 (previously approved by UNC IRB
Study Purpose: The purpose of this study is to examine the insurance status during the perinatal period in relation to pre-pregnancy and post-pregnancy depression.

Study #: **50227**
Title: The Relationship between Mother's Insurance Status during Prenatal Care and Compliance with the Back-to-Sleep Campaign Between 2016-2017 in Virginia: A Cross-sectional Study using Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) Data.
Principal Investigator: Katherine Hellmann (MPH Student), New York University (NYU) Dr. Andrea Deierlein, Faculty Supervisor

Approved: February 20, 2020 (previously approved by NYU IRB)
Study Purpose: The purpose of the study is to determine whether maternal prenatal health insurance status is associated with compliance with the back-to-sleep campaign, which educated women to place their infants on their backs when sleeping.

Study #: **50228**
Title: Geography 280 Mapping Health and Wellness Course
Principal Investigator: Wendy Stout, University of Richmond (U of R)
Approved: February 28, 2020
Study Purpose: The purpose of this project is to analyze Geo-coded opioid and cancer related incidents in order to help students become aware of major health concerns in Richmond and throughout the state. Data will be analyzed by students in the GEOG 280 Mapping Health and Wellness course at the University of Richmond.

Study #: **50229**
Title: Transplant Cancer Match Study (TCM)
Principal Investigator: Eric Engels, MD, MPH, National Cancer Institute (NIH)
Approved: May 4, 2020 (previously approved by NIH IRB)
Study Purpose: The purpose of this study is to determine cancer risk in transplant recipients. The project will provide population-based estimates of cancer risk for the United States transplant population, quantify cancer incidence and mortality in the population, and inform research and public health efforts to address the cancer burden.

Study #: **50230**
Title: Chevron Mortality Studies
Principal Investigator: Heidi s. Erickson, PhD, MS, Chevron Services Company
Approved: August 3, 2020 (previously approved by the Ethical & Independent Certification Services IRB)
Study Purpose: The purpose of this project is to examine patterns of mortality of Chevron employees and compare them to the US General population.

Study #: **50231**
Title: Estimate of COVID-9 Induced Excess Mortality at the County Level
Principal Investigator: Marie-Laure Charpignon, BSc, MSc, Massachusetts Institute of Technology (MIT)
Approved: August 10, 2020 (previously approved by MIT IRB)
Study Purpose: This is a multi-state study to calculate the “excess” deaths that happened outside of the healthcare system by comparing 2020 deaths at the county-level nationwide to an age-adjusted baseline mortality rate based on the past 5 years.

Study #: **50232**
Title: Sexual Risk Avoidance Education Program (SRAE)
Principal Investigator: Jewel Wright, Virginia Department of Health (VDH)
Approved: September 16, 2020
Collaborator: Madeline Kapur, VDH
Study Purpose: This is an evaluation of the Sexual Risk Avoidance Education (SRAE) program aimed at preventing negative outcomes that could have lasting effects on a young person's health, future career prospects, and economic stability.

Study #: **50233**
Title: Understanding the Relation between Zika Virus Infection during Pregnancy and Adverse Fetal, Infant and Child Outcomes: A Protocol for a Systematic Review and Individual Participant Data Meta-analysis of Longitudinal Studies of Pregnant Women and their Infants and Children
Principal Investigator: Nathalie Broutet, World Health Organization (WHO)
Approved: November 2, 2020
Collaborator: Katherine Crawford, Virginia Department of Health
Study Purpose: The study is a meta-analysis of Zika related studies to develop a systematic data base to estimate the relative and absolute risk of congenital Zika infections. The data base will be used to develop and validate a risk prediction model to identify pregnancies at the highest risk of Congenital Zika Syndrome (CZS) or adverse developmental outcomes.

Study #: **50234**
Title: COVID-19 Contact Tracing Linkages for William and Mary and Williamsburg
Principal Investigator: Iyabo Obasanjo, PhD, William and Mary (W&M)
Approved: October 27, 2020
Collaborator: Dr. Natasha Dwamena, Virginia Department of Health (VDH)
Study Purpose: The purpose in this study is to determine the contact points for COVID-19 spread among college campus community and its neighboring community, in order to build more effective control measures.

Study #: **50235**
Title: Effect of Concealed Carry Policies on Gun Injury
Principal Investigator: Susan Parker, University of Michigan (U of M) (faculty advisor: Edward C. Norton, PhD
Approved: December 21, 2020 (previously approved by U of M IRB (VDH)
Study Purpose: The purpose of the study is to assess the effects of concealed carry policy changes on types of firearm related injuries and the related morbidity and mortality among children, and disparities based on race/ethnicity, and rural/urban.

II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:

None

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

VDH IRB 2020 Membership		
Committee Members	**Qualifications for Service**	**Institutional Affiliation**
IRB CHAIR		
Bethany Geldmaker	PhD in Nursing	Office of Family Health Services, Division of Child and Family Health, Virginia Department of Health
VOTING MEMBERS		
Denise Bonds	MD, MPH District Health Director	Blue Ridge 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	Division of Child and Family Health, Virginia Department of Health
Dr. Maceo Freeman	Doctor of Divinity	St. Paul's Baptist Church
Blythe Balestrieri	PhD in Criminal Justice	Virginia Commonwealth University
ALTERNATE MEMBERS		
Cecilia Barbosa	PhD in Public Health	Community (non-VDH Representative)