

**REPORT TO THE COMMISSIONER:
ACTIVITIES OF
THE VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2015**

Submitted by

**Adrienne McFadden, MD, JD
Interim Chair**

Virginia Department of Health Institutional Review Board

REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2015

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 policy document, *The Institutional Review Board (IRB) of the Virginia Department of Health (VDH): Guidelines and Procedures for Obtaining Review*, was developed and approved by the Commissioner in January 2001, updated in March 2005 and then again in December 2010.

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 exemption review, expedited review or full board review.

Under Federal regulations 45 CFR 46.101 (b), 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 an IRB chair, must make the determination that the study does indeed meet the criteria for exemption before the research study may commence. This type of review is called "exempt review". If 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. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

Under Federal regulations 45 CFR 46.101 (b), certain categories of 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, 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".

During 2015 Dev Nair, PhD, MPH, former Director of the Division of Policy and Evaluation in the Office of Family Health Services continued to serve as the chair of the VDH IRB following his appointment by the State Health Commissioner in 2012.

VDH IRB meetings were held quarterly during 2015; January 12, April 13, July 13, and October 26. 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 2015.

Review Type	Approved	Not Approved
Full Review	None	None
Expedited Review	15	None
Exempt Review	13	None

I. A DESCRIPTION OF EACH HUMAN RESEARCH PROJECT REVIEWED AND APPROVED OR DISAPPROVED:

A. Full Board Reviews

None

B. Expedited Reviews:

Study #: 40204
Title of Study: Joining Circles
Principal Investigator: Cornelia Deagle, PhD, MSPH, Virginia Department of Health
Action: Approved January 7, 2015
Description of Study: The purpose of this study is to enhance existing partnerships and expand linkages among American Indian intertribal communities, academic and public health organizations; and to identify health concerns and reduce health disparities, specifically obesity, in the indigenous population of Virginia.

Study #: 40205
Title of Study: Cohort Mortality Study of Workers Exposed to Tungsten Carbide
Principal Investigator: Gary M. Marsh, PhD, F.A.C.E
Action: Approved March 10, 2015
Description of Study: The purpose of the study is to determine the relationship between the level and duration of WCCo (Tungsten, Carbon, Cobalt) exposure and mortality from malignant lung neoplasms with analytic adjustment to the extent possible for potential co-exposures, including tobacco smoking habits among current and former workers potentially exposed at multiple US and EU industrial sites that produce(d) WCCo and/or manufacture(d) WCCo products.

Study #: 40206
Title of Study: VA Biomedical Monitoring Program
Principal Investigator: Christopher Retarides, PhD, Virginia Division of

Action: Consolidated Laboratory Services
Approved February 11, 2015
Description of Study: This study is being conducted by the Virginia Division of Consolidated Laboratory Services (DCLS) in partnership with the Virginia Department of Health (VDH) to address concern regarding First Responder personnel's environmental exposure to perchlorates and uranium and other toxic metals. The study data will be used to enable DCLS and the Biomonitoring Advisory Committee (BMAC) to establish the scientific and administrative framework necessary to provide an effective biomonitoring program in the Commonwealth of Virginia.

Study #: 40207
Title of Study: Study of Cause-Specific Mortality and Cause Incidence in a Combined Cohort of Uranium Enrichment Workers
Principal Investigator: Jeri L. Anderson, PhD
Action: Approved March 2, 2015
Description of Study: The project, a collaborative effort between the National Institute for Occupational Safety and Health and researchers at the University of Louisville, will examine the patterns of cause-specific mortality and cancer incidence in a pooled cohort of workers employed at three former U.S. uranium enrichment plants. This research may help clarify the relationship between internal exposure to uranium and low-dose protracted ionizing radiation exposure and certain health outcomes, and lead to interventions that reduce morbidity and mortality among nuclear workers.

Study #: 40208
Title of Study: Using Videoconferencing for Lactation Consultation: A Cross-Sectional Survey of Acceptance Among Independent Samples of Mothers and Fathers/Maternal Partners
Principal Investigator: Mona F. Habibi, MS
Action: Approved March 6, 2015
Description of Study: The purpose of this study is to learn more about ways to help mothers successfully breastfeed their babies; to know their thoughts and opinions about using webcam technology to receive breastfeeding consultation and about how they prefer to learn about breastfeeding.

Study #: 40209
Title: Food Safety Risk Assessment – Montgomery County, VA
Principal Investigator: Margaret Lee O'Dell, MD, MFA, Virginia Department of Health, New River Health District
Action: Approved April 8, 2015
Summary: The goals of the study are: 1) to identify gaps in knowledge among restaurant owners/managers that may impact the number of violations a restaurant could potentially receive during scheduled health department inspections to ultimately find more effective approaches to reduce those violations; 2) to determine how knowledgeable the general public is about food safety and protective food safety measures; and 3) to assess the perceptions of restaurant owners/managers and the public regarding food inspection scoring systems.

Study # 40210
Title: Perchlorate and Toxic Metals Study
Principal Investigator: Christopher J. Retarides, PhD, Virginia Division of Consolidated Laboratory Services
Action: Approved April 28, 2015
Summary: The purpose of this study is to determine levels of exposure of Virginia residents to certain metals and perchlorate, a naturally occurring chemical, present in the environment by measuring the concentration of these chemicals in urine. The study will provide for the initiation of a biomonitoring program and provide background data and a basis for comparison among different geographical and socioeconomic divisions.

Study #: 40211
Title: Urban-Rural Differences in Prescribing Habits and Attitudes Toward Long-Acting Reversible Contraceptives among Family Planning Clinicians in Virginia
Principal Investigator: Sarah D. Hakkenberg, University of Virginia
Action: Approved June 16, 2015
Summary: The purpose of this study is to examine the Virginia Department of Health family planning providers' contraceptive prescribing patterns and the factors that affect their decisions. Additionally, the study will focus on differences in prescribing habits between rural and urban Virginia and investigate why these differences exist.

Study #: 40212
Title: Sudden Death in the Young (SDY) Registry
Principal Investigator: Virginia Powell, PhD, Office of the Chief Medical Examiner, VDH
Action: Approved July 10, 2015
Summary: The purpose of the study is to establish a Sudden Death in the Young (ages 0 -17) Registry in four communities in the eastern area of the state to provide insight into the demography of these deaths, as well as risk factors, medical conditions, social and behavioral health factors, and other circumstances of injury and death in a cluster of high risk communities. The establishment of a SDY Registry in 4 communities will be used to develop summary reports to support public health prevention and intervention strategies.

Study #: 40213
Title: Oral Health Assessment of Virginia's Elders
Principal Investigator: Karen C. Day, DDS, MS, MPH
Action: Approved July 28, 2015 (based on 45 CFR 46.110-111)
Summary: The purpose of the 2015 Oral Health Assessment of Virginia Elders is to determine the oral health status of specific elder populations across the state (age 65 and older) among nursing home and assisted living residents, and well elders who attend senior congregate meetings.

Study #: 40214
Title: Comparing Delivery Models for a Tobacco Cessation Intervention in Southwest Virginia
Principal Investigator: Roger Anderson, PhD, University of Virginia, Cancer Center
Action: Approved August 3, 2015
Summary: The primary purpose of this pilot study is to examine the smoking cessation rates of participants enrolled in three delivery models for smoking cessation using the American Lung Associations “Freedom from Smoking” program in order to understand what is the most effective delivery model in rural southwest Virginia. The study results will be used to plan a full-scale study. The 3 delivery models include 1) clinical office based model utilizing physicians and nurses; 2) community based model utilizing community lay navigators with nurse consultation; and 3) community pharmacy based utilizing pharmacists and pharmacy students.

Study #: 40215
Title: Centering Pregnancy Care + Yoga (CPC+Y) for Diverse Pregnant Women
Principal Investigator: Patricia Anne Kinser, PhD, VCU School of Nursing
Action: Approved August 6, 2015 (based on 45 CFR 46.110-111)
Summary: The purpose of the study is to conduct a pilot longitudinal mixed-methods study of predominantly black and Hispanic overweight/obese pregnant women (n=20) who participate in the CPC+Y program at the Richmond District Health Department’s prenatal clinic during their pregnancies. The plan is to evaluate the feasibility, acceptability and potential effects of a unique approach for addressing overweight/obesity during pregnancy in a high-risk group within a multifaceted bio-behavioral context.

Study #: 40216
Title: Virginia Youth Survey
Principal Investigator: Dev Nair, PhD, Virginia Department of Health
Action: Approved September 9, 2015
Summary: The purpose of this survey is to monitor six categories of priority health behaviors among youth, including behaviors that contribute to unintentional injuries and violence; tobacco use; alcohol and other drug use; unhealthy dietary behaviors and physical inactivity. VDH will partner with the Department of Education and the Virginia Foundation for Health Youth to conduct the survey during the fall 2015 in 54 randomly selected middle schools and 92 randomly selected high schools in Virginia. The data will be used to facilitate planning and implementation of effective programs for the prevention of adverse health behaviors.

Study #: 40217
Title: Virginia Home Visitation Study
Principal Investigator: William Merritt Shobe, PhD, University of Virginia
Approved: October 15, 2015
Summary: The purpose of this study is to examine the effect that specific nonprofit home visitation providers have on medical outcomes and Medicaid costs in Virginia. This retrospective study will connect datasets from home visitation

providers (CHIP of Virginia and Prevent Child Abuse Virginia), the Virginia Department of Health (VDH) and the Department of Medical Assistance Services (DMAS).

Study #: 40219
Title: Promoting Informed Decisions about Lung Cancer Screening
Principal Investigator: Mona Deprey, MS, Alere Wellbeing
Approved: December 11, 2015
Summary: The purpose of the study is to test a video decision aid titled “Lung Cancer Screening – Is it Right for Me?” in a randomized controlled trial where multi-state (including Virginia) Quitline patients will receive either the decision aid video or the standard educational materials regarding screening from the National Cancer Institute. The study will determine if the video helped patients prepare to make a screening decision and if they decided to be screened.

C. Exempted Reviews

Study #: 50178
Title of Study: Development of a Proton Therapy Treatment Registry
Principal Investigator: Luisel J. Ricks-Santi, PhD
Action: Correspondence forwarded to PI indicating that the proposal is not considered research and IRB review is not applicable on February 11, 2015.
Description of Study: The purpose of the submission was to request Virginia Cancer Registry data in order to develop a registry which in the future would be available to evaluate patient outcomes, quality of life, provide follow –up information, calculate survival rates, analyze referral pattern, allocate resources at regional or state level, and evaluate efficacy of treatment modalities. This registry will be initiated with data from the Virginia Cancer Registry. This project is not human subjects research but supports the development of a patient cancer registry for future use.

Study #: 50180
Title of Study: Understanding the Role of Violence as a Social Determinate of Preterm Birth
Principal Investigator: Saba Masho, MD, DrPH
Action: Approved January 15, 2015
Description of Study: The study will assess the interaction between established individual-level risk factors and under-investigated community level social determinants in order to examine the association between neighborhood violence rate and poor birth outcomes. The hypothesis is that preterm birth rates will be correlated with crime rates after adjustment for community and individual level confounding variables. The study will also explore the extent to which violence contributes to the higher risk of preterm births among African Americans.

Study #: 50181
Title of Study: Lyme Disease Distribution and Risk Factors in the New River Valley
Principal Investigator: Margaret O’Dell, MD, New River Health District,

Action: Virginia Department of Health
Approved February 4, 2015
Description of Study: The purpose of this study is to determine the local burden of Lyme disease in the New River Valley using ArcGIS mapping software in order to inform the healthcare community and to determine what type of education and/or intervention would be best to address the problem of Lyme disease in that area.

Study #: 50182
Title of Study: Rappahannock Community Health Survey
Principal Investigator: Faika Zanjani, PhD
Action: Approved February 18, 2015
Description of Study: The purpose of this study is to conduct a randomized community survey in Rappahannock County, Virginia and surrounding counties. The objective of the survey is to assess rural medication safety behaviors and beliefs in older adults (50 + years).

Study #: 50183
Title of Study: The Effect of Maternal Pre-Pregnancy BMI on Preterm Birth in Virginia 2013
Principal Investigator: Lindsey Hall
Action: Approved February 18, 2015
Description of Study: This project aims to explore the effect of pre-pregnancy BMI on preterm birth using vital records data from the Virginia Department of Health for the year 2013. The results of this study may help inform future guidelines on proper weight loss (or gain) prior to pregnancy in order to ensure a healthy pregnancy and delivery for both mom and baby.

Study #: 50184
Title of Study: The Role of Maternal Low Birth Weight on her Infants' Fetal Growth in Virginia
Principal Investigator: Sylvia Rozario
Action: Approved March 17, 2015
Description of Study: The purpose of this study is to assess the association between maternal low birth weight and her infants' fetal growth (as measured by weight for gestational age) and birth outcomes among births to Virginia residents. This study will examine the role of intergenerational effects of parental low birth weight/gestational growth after controlling for factors in the current pregnancy.

Study #: 50185
Title: Canine Lyme Exposure Cases in the New River Valley
Principal Investigator: Margaret Lee O'Dell, MD, New River Health District
Virginia Department of Health
Approved: June 25, 2015
Summary: The purpose of this study is to determine the possibility of using canine Lyme exposure rates as a surveillance method for potential future human infection risk. Past medical records for canine Lyme exposure snap tests results along with other Lyme diagnostics that may have been done from 2004-2015 will be mapped. These results will be compared to human records of exposure and infection in the New

River Valley in order to search for potential correlations and make inferences based on the data.

Study #: 50186
Title: Factors that Influence Breast Cancer Diagnoses Among Virginia Women 40-64 Years Old Who Utilized the Every Women's Life Program (EWL) 1998-2012
Principal Investigator: Melanie Dempsey, Virginia Commonwealth University
Action: Approved July 9, 2015
Summary: The purpose of this study is to determine if there are difference in socio-demographic characteristics between women diagnosed with breast cancer and those not diagnosed; if self-reported preventive health behaviors are related to early detection and if there are differences in participants' source of information regarding the Every Women's Life program based on race, geographic locale, language, or education.

Study #: 50187
Title: Multilevel Analysis of Gestational Age at Time of Abortion
Principal Investigator: Jenny O'Donnell, MSc, Harvard, T.H. Chan School of Public Health
Action: Approved July 17, 2015
Summary: This is a multi-state study to measure the impact of geography, specifically county of residence, on gestational age at time of abortion, taking into account individual characteristics that are known to influence the outcome of interest. The study will provide additional understanding of the patterns of abortion access in previously understudied regions and may lead to new interventions to facilitate women's access to abortion services.

Study #: 50189
Title: Cancer Perceptions and Health Behaviors in Tazewell County, VA
Principal Investigator: Sarah Waddle (Student) James Madison University
Action: Approved September 10, 2015
Summary: The purpose of this study is to assess Tazewell County citizens' perceptions of cancer rates and how that is affecting their health behaviors. The research questions to be evaluated are: 1) what effect does the perception of cancer (leukemia) rates in Tazewell County have on the health behaviors of community members? 2) What effect does religious fatalism have on the health behaviors of community members? 3) What effect does preventative knowledge have on the health behaviors of community members? 4) What effect does health care access/resources have on the health behaviors of community members?

Study #: 50190
Title: Eco-epidemiology of Lyme Disease in Virginia
Principal Investigator: Paul M. Lantos, MD, Duke University Medical Center
Action: Conditionally approved August 26, 2015 contingent on receiving Duke's IRB approval (Duke IRB approval received 11/13/15)

Summary: The purpose of the study is to identify environmental predictors of human Lyme disease risk in Virginia such as elevation, forest fragmentation, land cover, and vegetation indices where the geographic range of the disease is rapidly expanding.

Study #: 50192

Title: Identifying Risk and Protective Factors for Developing Fungal Meningitis in the New River Valley-Phase II

Principal Investigator: Stephanie Nagy-Agren, MD, Virginia Tech Carilion School of Medicine

Approved: December 11, 2015

Summary: The purpose of this study is to identify risk and protective factors for developing fungal meningitis after receiving a contaminated epidural spinal injection from a fungal-contaminated lot of steroid solution in summer 2012. The study will evaluate the variations in the procedure to administer the injection to determine how they may have contributed to the development of fungal meningitis. The study outcome may result in improving procedures and standards of care for administering the injections in the future.

Study#: 50193

Title: Hospitalizations Attributable to Drugs with Potential for Abuse and Dependence Indicator Project

Principal Investigator: Thomas Largo, Michigan Department of Health and Human Services, Bureau of Disease Control, Prevention and Epidemiology

Approved: December 11, 2015

Summary: The purpose of this multi-state study is to determine the frequency and rate of hospitalizations attributable to drugs with the potential for abuse and dependence. The methodology for calculating cases and case rates was recently developed by the Alcohol and Other Drugs Indicator workgroup of the CSTE. This study is intended as a pilot to test the new methodology.

II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:

None

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

VDH IRB 2015		
Committee Members	Qualifications for Service	Institutional Affiliation
IRB CHAIR		
Dev Nair	PhD, MPH, Director of Policy & Evaluation Clinical Psychology	Virginia Department of Health
VOTING MEMBERS		
Ana Lizzette Colon	MPH. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Bethany J. Geldmaker	PhD in Nursing & Child Health Care Consultant	Virginia Department of Health
Ronnette Langhorne	RN, MS, Nurse Manger	Norfolk Virginia Department of Health
Janice Hicks	PhD in Social Policy and Social Work	Virginia Department of Health
Cecilia Barbosa	PhD	Community Representative
ALTERNATE MEMBERS		
Vacant		